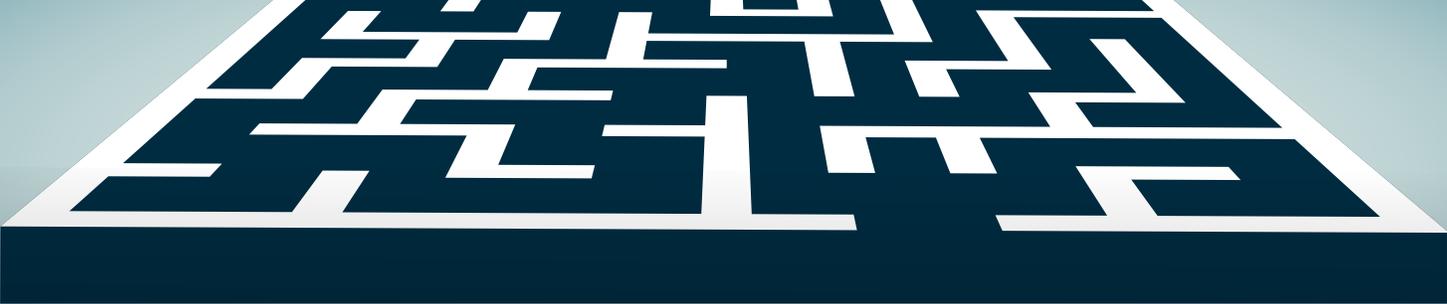


# The Strategic Role of the Regulatory Professional





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## Introduction: The Strategic Role of the Regulatory Professional



By Gloria Hall

Welcome to the Q1 2020 *Regulatory Focus* Article Series. It is my pleasure to bring together some of the top regulatory influencers from around the world—all with diverse experience—to offer their perspectives on how the shifting landscape and evolving regulatory approaches are impacting the regulatory profession today. With the need of regulatory science to keep pace with the changing global landscape, technological advancements, increased innovation and the complexity of the drug and device development process, the role of the regulatory professional has become ever more strategic. This insightful collection of articles illustrates the expanding strategic role of regulatory professionals and demonstrates the vital role regulatory plays within organizations and throughout the product lifecycle.

### Global Responsibility and Critical Skills

Regulatory expert, **Adriana Becker**, discusses the widening range of responsibility for regulatory professionals and the increasing importance of their role to an organization's bottom line. In "[The Changing Role of the Regulatory Professional](#)," Becker covers the value of continuously developing

new skills in addition to regulatory and scientific knowledge to more effectively interface with colleagues with varying expertise. She highlights the effects of increased regulatory scrutiny, such as through compliance with the European Union's new *Medical Devices Regulation (MDR)* and *In Vitro Diagnostic Regulation (IVDR)* and emphasizes the benefit of developing good writing skills.

Regulatory operations professionals face a much different world from the one they did 10 years ago. As novel therapy development increases, regulatory standards are evolving and technology is starting to play a more prominent role in the management of regulatory information. In "[How the Role of Regulatory Operations Professionals Will Evolve in the new Decade](#)," **Rachel Belani** introduces forward-looking trends that may affect how the role of regulatory operations professionals will progress over the next decade. Belani, a leading regulatory strategist, brings together three regulatory operations professionals who share their perspectives on the changing regulatory landscape and emerging challenges.

The life science industry is one of the most heavily regulated industries. Executives, senior managers and in-

vestors must understand how different decisions about a product can impact its regulatory path and how this affects commercialization. Regulatory affairs consultant, **Isabella Schmitt**, discusses the reasons why continuous evaluation of the regulatory framework is important for company decision makers and how companies making efforts to understand the regulatory landscape for their product benefit in [“Why Understanding Regulatory Affairs is Important to key Company Decision Makers.”](#)

Scientific and medical writer, **Viji Ramesh**, describes the best practices for developing informed consent documents, including skillful writing to communicate objectives, benefits, implications, risks and the inconveniences of participating in the clinical trial, as well as communicating the rights extended to clinical trial participants. [“Writing Informed Consent Documents: A Balancing Act”](#) covers important aspects a medical writer can contribute to developing a strong yet easily understandable informed consent, including paying particular attention to using plain language, making the document readable, being aware of potential social and cultural issues, avoiding scientific, legal or medical jargon and information overload.

### Regulatory Strategy

Today’s smaller, virtual, venture-backed start-up companies have created an environment where lean staffing has become the norm rather than the exception, and many companies are opting in favor of an individual regulatory and/or quality compliance person. As a result, companies are outsourcing and relying on external consultants to be the “masters” of a specific regulatory or scientific area. Senior regulatory professionals, **Steven J. Knapp** and **Andrew S. Verderame**, explore employing regulatory affairs consultants in [“Regulatory Affairs Consultants: Who Needs Them and Why.”](#) The authors offer advice on

who needs consultants and why, the “dos and don’ts” of finding, managing and maintaining consultants, how to choose the right consultant with the right background and expertise for the needed tasks and consultant service and pricing models.

In the regulated industry, consultants are engaged for a variety of activities ranging from manufacturing, to testing, to quality control and quality assurance, to regulatory affairs. [“How to Hire and Engage Consultants for Success”](#) debates the reasons companies are hiring consultants and how companies can ensure success in executing the relationship. Principal consultant, **David W. Husman**, emphasizes points to consider, including hiring the right consultant for a specific task, onboarding a consultant, clarifying and communicating expectations regarding specific projects, getting updates from consultants and having a structured project ending to ensure all deliverables have been received.

Over recent years, there has been a steady decline in the number of FDA enforcement letters pertaining to the advertising and promotion activities for prescription drug products. At the same time, the Office of Prescription Drug Promotion (OPDP) have issued guidance documents to provide a framework for industry to address current issues facing today’s regulatory professionals. Regulatory enthusiast, **Kate Morris Jurcik**, discusses how regulatory professionals can make benefit-risk decisions with limited agency guidance materials or enforcement examples in [“Assessing Risk and Strategic Business Decision-Making Without Consistent FDA Enforcement.”](#) She concludes that, given a scarcity of enforcement letters from FDA in recent years, regulatory professionals must turn to other tools to understand FDA

and other government agency issues related to drug promotional activities.

### Professional Development and Growth Strategies

In the pharmaceutical industry, working in the regulatory field offers many possibilities for horizontal career changes. Depending on one's experience and goals, a regulatory professional may be able to fit into any number of niches with many opportunities to move between different areas of focus, even without specific experience in the area you may be interested in entering. Senior regulatory affairs associate, **Kate Forte**, shares her personal experience in "[Transitioning Between Medical Writing and Regulatory Affairs in a Contract Research Organization](#)." She summarizes both roles and presents the similarities and differences between these two areas.

Many national governments today have policies in place to foster growth of the medical technology and biopharmaceutical industry to contribute to the new knowledge economy. As the industry grows, organizations continue to face increasing pressure to find and retain talented and suitably qualified staff across a range of functions involved in the discovery and development of new therapeutics. In "[Professional Development: Benefits of Obtaining Professional Qualifications](#)," associate professor **Orin Chisholm** discusses the advantages of formal qualifications for a regulatory career and highlights some of the English-language Master's-level courses offered globally.

### Leadership Skills

Quality assurance and regulatory affairs professional, **Amaris Ajamil**, positions the governance and implementation infrastructure as critical factors in cultivating a 'culture of quality' and building the necessary trust employees may need to help achieve it. In her thought provoking article, "[Regulatory](#)

[Leadership for a Culture of Quality in the US Medical Device Industry](#)," Ajamil outlines the critical attributes of a culture of quality, explains how such a culture can be built, the benefits it offers and touches on the roles played by regulatory/quality professionals in leading the effort to build quality.

The past few decades have seen an exciting evolution in the regulatory profession. Increasingly complex products, corporate structures and regulatory environment have created a demand for highly skilled regulatory leaders. Their roles have enhanced in importance and stature over the years and have now been recognized as a key strategic role. Many are now represented at the C-suite levels in their organizations. In "[Critical Thinking and Leadership Skills for Regulatory Professionals](#)," retired regulatory executive **Robert Yocher** presents various sets of often underemphasized skills required for a successful regulatory professional career. Every person, at every level can, use them every day.

While these short summaries were meant to pique your interest, I hope you spend some time reading the complete articles and benefit from the shared experiences of the authors. This collection was meant to give you the information needed to enhance the skills necessary for a satisfying, successful career in regulatory as well as provide strategies for continual professional development. Your feedback is always welcome.

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**Cite as:** Hall G. "The Strategic Role of the Regulatory Professional." *Regulatory Focus*. March 2020. Regulatory Affairs Professionals Society.



## The Changing Role of the Regulatory Professional



By Adriana Becker

This article discusses the widening range of responsibility for regulatory professionals and the increasing importance of their role to an organization's bottom line. The author covers the value of continuously developing new skills in addition to regulatory and scientific knowledge to more effectively interface with colleagues with a variety of expertise. She highlights the effects of increased regulatory scrutiny, such as through compliance with the European Union's new *Medical Devices Regulation (MDR)* and *In Vitro Diagnostic Regulation (IVDR)* and emphasizes the benefit of developing good writing skills.

### What do you do for a living?

Regulatory professionals know how difficult it can be to answer the question: "What do you do for a living?" It is a difficult to answer because we do a little bit of everything. Working within an industry whose main output

is a biotechnological product—whether a device, drug or somewhere in-between—to be successful, a regulatory professional must be involved at every phase of developing, marketing and selling a product. Additionally, in a constantly changing global regulatory environment, the specialist is constantly responsible for and involved in ensuring the consistent quality of products on the market. Increased regulatory body scrutiny, combined with a high demand for newer and better healthcare products and technologies, requires even more highly trained regulatory professionals who are quickly becoming integral to an organization's "bottom line."

### Regulatory's Role in the Product Lifecycle

A medical device manufacturer (regardless of company size) will employ many professionals with various kinds of expertise, such as medical doctors, engineers and scientists, quality, risk

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and clinical specialists, sales and marketing team members, legal advisors and more. Developing a medical device from bench-to-bedside requires the integration of various specializations at every level of the product lifecycle, from initial development to the global regulatory submission/registration and postmarket phase. The regulatory professional's responsibility is to continuously monitor and integrate the expertise of these professionals to align with regulatory requirements during all phases of product development. Through all phases, meeting objectives and deliverables, both strategic and tactical, is paramount. In the design phase, this can mean providing a team with the regulatory framework for shaping design inputs and outputs, strategically communicating potential market approval "go and no-go" situations based on product design decisions and working intimately with a core design team to process all the possible impacts of product changes as the device is developed and, often, incrementally innovated.

Once a device is on the market, the product vigilance (postmarket surveillance) process begins and continues until the product is removed from market. Thus, a regulatory professional's responsibility for a device lasts until product "sunset." This over-arching responsibility makes the regulatory professional's role a crucial component of the product's lifecycle, an expertise and function upon which companies are increasingly dependent to ensure safety and longevity of their medical device.

### **A Changing Landscape**

As 2020 begins, reviewing the remarkably increased role of regulatory professionals throughout the industry over the past two decades reveals big changes. In the past, regulatory duties within a company did not necessarily unify within a specialized role; regulatory affairs may have been handled by employees from various functions

within the company. The regulatory professional often arrived at his or her position from a variety of backgrounds, and not all backgrounds were strictly scientific. Currently, specialized formal degrees, certificate programs and trainings are available with increasing frequency, allowing for developing or honing specific regulatory skills for both new as well as continuing professionals.<sup>1</sup> Some of these programs include Masters in Regulatory Affairs, such as those offered at, for example, George Washington University, Northeastern University, Johns Hopkins University and the University of Southern California. Available as well are Regulatory Affairs Certification (RAC) through RAPS. Regardless of the path toward learning the profession, a certain set of skills and skill characteristics, as well as the timing of regulatory changes (for example the implementation of the EU *Medical Devices Regulation (MDR)*), have demanded the regulatory professional to move from a transitory role within a company to occupying a clearly defined professional role, one now indispensable within organizations.

In the premarket Product Development Phase (PDP), global regulatory requirements, along with product standards and clinical guidelines, affect everything from design inputs to verification and validation testing. It is becoming increasingly both evident and imperative that regulatory professionals who are well-versed in both US and outside US (OUS) requirements should be involved in any core team for product design. They are necessary to provide guidance and input at the earliest phase, possibly forestalling any major issues down the line, such as special regulatory considerations for medicinal or animal tissue components, or the need to make a late design change to a product due to inherent safety requirements prescribed by a particular region's regulatory requirements.

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To think many steps ahead while simultaneously considering previous experience, such a specialist must be a highest-caliber systems thinker, able to synthesize information from many different sources and experts (for example, engineering and clinical) to be able to determine how decisions made in the PDP are to be shaped and adjusted to fulfill the regulatory requirements of placing products on the market. This type of thinking, across multiple domains, requires not only the general understanding of decisions and how they shape the product, such as what type of engineering testing is required to produce a viable physical product, but also requires the creative problem-solving capabilities for integrating the output of various expertise into clear, logical and sufficient technical documentation for a finished device, one intended to pass all regulatory checks and balances with “flying colors.”

#### **New and Better Skills Needed**

During the regulatory workflow, project management and organizational skills are also important for keeping open the channels of communication leading to evaluating the pros and cons of potential device changes before they enter the change control process. This can be accomplished by working with engineering, supply chain and sterilization departments to ensure required testing is being performed to appropriate regulatory specifications and standards. These tasks require a certain level of influence, although one may not be in a position of authority. Therefore, the regulatory professional needs to be able to develop trustworthy relationships with various experts, working diplomatically, while remaining firm on ethics and regulatory requirements. In other words, the rigidity of regulations must be balanced with flexibility, well developed people skills, patient-focused thinking and respect for others’ expertise. Additionally, demonstrating a willingness to step up into a leadership role, making decisions that

would need to be justified to regulatory agencies, or having the “pushback” for having to say the difficult “no” within an organization, while working on compromise and alternative solutions, is a daily challenge. Conflict resolution is paramount. While none of these skills are easy to develop, they are all key to success. Thus, it is important to work on developing relationships, learning how to speak persuasively and how to interact face-to-face versus relying on e-mail to solve problems. These skills require a very proactive and engaged, scientifically and technically minded individual.

#### **Cross-Functional Communication**

Today, the regulatory professional must be able to fully integrate and adapt to the knowledge held by a variety of individuals with technical and business expertise who work outside of the regulatory world. Excellent communication is the primary way of efficiently obtaining new and disparate pieces of information from various departments within the organization and connecting them in new ways to achieve the desired outcome—which is an effective final device, safe for the patient and marketable across multiple regions. This type of knowledge transfer to the regulatory department is crucial to device development and impossible without efficient cross-functional communication, as the medical device regulatory world is increasing in complexity and requires an increased need for deriving new patterns of problem solving rather than relying on familiar ones.

While experience in the regulatory workings of small and large companies is still the best teacher, a regulatory professional can work on ramping up regulatory skills by interacting with as many individuals as possible in various departments. First-hand experience, gained by visiting the manufacturing floor, observing or getting involved in device testing and updates, while continuously asking questions, helps foster a deeper understanding and a

*Formal training in scientific and technical writing also helps regulatory professionals develop a sense of theme and narration while focusing on formulating and presenting logical arguments to demonstrate scientific concepts, carry out template work or provide concise written responses to technically complex questions via enhanced critical thinking.*

curiosity beneficial for one's ability to process device changes quickly, to think creatively and to be able to answer questions from regulatory agencies.

Combining skills from the development phase while moving into the registration phase also necessitates a regulatory professional to apply scientific and technical knowledge together with writing skills to build narratives into regulatory submissions. As the requirements for these submissions differ from region to region, a specialist must acutely tailor any submission to a specific country's requirements while, at the same time, translate complex technical terminology and scientific concepts related to the device into more simplified terms

### **Good Writing: More Important Than Ever**

In addition to solid technical and scientific skills, writing global submissions requires medical writing skills. Beyond on-the-job experience, organizations, such as the European or American Medical Writers Association (EMWA/AMWA), offer networking and training programs to develop this skillset. There are also formally developed regulatory affairs programs and medical writing certificates/degrees offered by various universities, including the University of Southern California, the University of California, Irvine, the University of California, Santa Cruz as west coast examples, or the University of Georgia, the Johns Hopkins University and Northwestern University on the east coast. Formal training in scientific and technical writing also helps regulatory professionals develop a sense of theme and narration while focusing on formulating and presenting logical arguments to demonstrate scientific concepts, carry out template work or provide concise written responses to technically complex questions via enhanced critical thinking. A regulatory-centric program can tailor these medical writing skills specifically to global clinical and regulatory requirements, familiarizing the regulatory professional with both simultaneously.

Often, each regulatory submission will be different. Too, having multiple device types can provide additional challenges. A specialist must combine conceptual reasoning with technical writing skills to connect new ideas and work across contexts—essentially asking questions such as: Can what worked well in this submission also be applied to the next? What parallels exist between these two regions' regulatory requirements, where the same effort can be applied unilaterally to shorten the time from submission to approval? Where are these devices similar and where are they different? With this kind of information, the specialist can spend less time on problems already seen in previous submissions while tackling any novel problems using analogous experience. These types of questions will lead the regulatory professional to interface at a yet deeper level with various departments across the organization. It is as important to know upfront the fundamental questions to ask of these highly skilled experts as it is to know the answers to those questions, which can then be efficiently transferred and applied by the specialist to the regulatory context. Very specific product knowledge and technical details are thus synthesized by the regulatory professional into submissions or responses in a manner that answers any query, saves time and fulfills the spirit of the regulations, and effectively shortens the time to market, simplifies the implementation of product changes within the organization and, all the while, maintains good relationships with regulatory agencies.

### **Interfacing With Regulatory Agencies**

The latter aspect is where the regulatory professional balances another important role—interfacing with regulatory agencies, via not only submissions, but also during audits, answering questions and participating in various meetings. His or her skills are utilized in parallel, while also being bidirectional within the organization and without dealing

*With the advent of the European Union's 2020 revision the Medical Devices Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR), the inter-organizational aspects of device design, submission and market maintenance are now more clearly highlighted in the legislation.*

directly with regulatory agencies. At any given time, depending on the size of the regulatory department and the organization itself, specialists handle this bidirectional flow of information for an entire product portfolio while also sustaining and maintaining ongoing changes to products on the market and handling postmarketing vigilance.

### MDR/IVDR Impact

The variety of regulatory activities have led to an increased role for the regulatory professional in an organization, one which is continuously “ramping up” with no signs of slowing down. With the advent of the European Union’s 2020 revision the *Medical Devices Regulation (MDR)* and *In Vitro Diagnostics Regulation (IVDR)*, the inter-organizational aspects of device design, submission and market maintenance are now more clearly highlighted in the legislation. Revisions put the regulatory professional’s responsibilities in the spotlight while providing opportunities to demonstrate new skills, but not without additional challenges. The added pressures of interoperability and the heightened requirements for technical documentation require a ramp-up in training as well as a change in company culture and mentality regarding regulatory issues. Especially in organizations where departmental “silos” may have sustained efforts previously, the specialist will now have to wear multiple hats and understand exactly how various changes across *MDR/IVDR* will impact the organization beyond its own functions and day-to-day activities. Many more documents are now required to be created and maintained, including clinical evaluation plans, PMS plans, periodic safety and update reports, implant cards and trending requirements for vigilance, to name a few. Regulatory will touch on these new processes and documents. Practically speaking, the everyday job requirements for the regulatory professional have increased at least two-fold or more. Changes in *MDR* will increase the number of required inter-departmental meetings,

the number of Standard Operating Procedures (SOPs) that require input and implementation, and the number of people who will require approvals from regulatory. Efficient organization will be the only way to keep up with the constant changes, along with appropriate delegation, better time management and concise problem solving.

Two areas where the *MDR* has especially expanded the expected responsibilities of the regulatory professional include the understanding of the clinical and postmarket surveillance/clinical follow-up (PMS/PMCF) requirements. The requirements for clinical and PMS/PMCF as they relate to Europe need to be considered at the very inception of the PDP of a device—considerations for bringing a device to market in the EU can no longer be secondary. Clinical requirements for *MDR*, as well as postmarket requirements for the device, need to be strategically discussed as early as design input for a device to meet its General Safety and Performance Requirements (GSPRs). Any regulatory department has a responsibility to not only drive the organization toward increased involvement in such early discussions, but also to provide tactical support and training for the clinical or postmarket group on the variety of new requirements about which they need to be aware. In smaller organizations, the regulatory and clinical/postmarket professional or group of professionals may be one and the same so getting “up to speed” on these new responsibilities is especially important.

### Closer Collaboration

Additionally, regulatory professionals must work much more closely with clinical and marketing specialists on the information provided in the Clinical Evaluation Report (CER) and the technical file and labeling/Instructions for Use (IFU) as there is an increased emphasis in *MDR* on consistency in technical documentation across departments. This means that the intended use, indications, clinical claims and benefits for any device on the market must be presented

unambiguously and consistently as well as fully supported by clinical data across all documentation. The company website or marketing brochures must not present claims different than those in the CER. Once more, the IFU cannot have an intended use different than what is presented in the technical documentation. As device engineering and innovation is a continuous process, the regulatory professional will need to be closely involved to ensure that compliance is maintained.

Device usability is another area where regulatory professionals will now have to apply extra attention. The connection between the GSPRs of a device and usability need to be established early on. In order to claim conformance in a device's GSPR checklist, the regulatory professional will need compliant usability documents. Usability requirements/human factors requirements should be built directly into user needs documents and translated to design inputs. Design inputs will then have to be verified and validated during performance testing; the regulatory professional will need to ensure this has indeed been done for the purpose of the GSPR checklist. If the device is already on the market, PMS data may provide signals regarding any additional needed usability aspects. This information will have to be fed through regulatory back to design and engineering, who will need to collaborate on any potential changes.

### Conclusion

As discussed above, the regulatory professional now holds a well-defined role within an organization. In the medical device sphere alone, a single, sweeping global regulation change, such as *MDR/IVDR*, has significant impact on the reliance of an organization's regulatory department. Once more, the global regulatory environment is not static. Skills, such as effective communication, conceptual reasoning, project management, creative problem solving, diplomacy, conflict resolution and clarity in scientific writing, are nonnegotiable for

navigating the environment at every device design step. It is also important for both new and veteran regulatory professionals to continuously develop these skills in addition to their regulatory and scientific knowledge. In a world where daily interactions across time zones and cultures, together with easy access to information, has become the *status quo*. The indispensable regulatory professional has to be more than just a scientific expert; he or she must be a people and communications expert with a keen sense of organizational culture and the ability to connect and manage "threads" from all sides in order to propel ethical, safe medical device innovation to patients in need.

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### About the Author

**Adriana Becker** is a senior consultant at Qserve Group with more than a decade's worth of medical devices/biotech industry experience. As part of the regulatory affairs group, Becker's domain of expertise is primarily in EU medical device regulation, currently focused on compliance to the new *Medical Devices Regulation (MDR)* and *In Vitro Diagnostics Regulation (IVDR)* for medical devices marketed in the European Union. Becker holds a regulatory science MSc from the University of Southern California. She can be contacted at [adriana.becker@Qservegroup.com](mailto:adriana.becker@Qservegroup.com).

**Cite as:** Becker A. "The Changing Role of the Regulatory Professional." *Regulatory Focus*. February 2020. Regulatory Affairs Professionals Society.



# How the Role of Regulatory Operations Professionals Will Evolve in the new Decade



By Rachel Belani

This article introduces forward-looking trends that may affect how the role of regulatory operations professionals will progress over the next 10 years. Regulatory operations professionals from three biopharmaceutical companies also share their perspectives on the changing regulatory landscape and emerging challenges.

### Introduction

Regulatory operations professionals face a much different world from the one they did 10 years ago, as novel therapy development increases, regulatory standards are evolving and technology is starting to play a more prominent role in the management of regulatory information.

The industry is shifting its focus from developing blockbuster therapies that treat various diseases, to developing precision medicine, specialty drugs and targeted gene therapies that focus on treating, or even curing, specific diseases and disorders. In some areas

of medicine, these products are being paired with medical devices to improve the quality of delivery, monitoring or adherence; adding another layer of complexity when it comes to defining the overarching regulatory strategy and pathway to market.

This volume and pace of innovation is adding to the complexity that regulatory professionals have grown accustomed to managing on a daily basis. They must now figure out how to collect, aggregate, manage, analyze and intelligently act upon an ever increasing volume of data coming from health authorities and other competent authorities around the world. Many recognize that the existing processes and technology, e.g., spreadsheets, file sharing applications and business systems, are no longer sufficient.

Modern regulatory professionals are prioritizing solutions and strategies that will help them keep pace with three industry trends expected to impact their role in getting medicines to market over the next decade. These include:

1. more drugs and therapies entering new markets
2. the deployment of cloud capabilities
3. the maturation of new industry standards and requirements

### More Drugs and Therapies in New Markets

FDA's [New Drug Therapy Approvals 2019 Annual Report](#) highlighted the steady increase of novel drug approvals over the last 10 years, reporting that an average of 37 drugs were approved per year from 2009-2019.<sup>1</sup> In the last three years, this average has increased to 51 approvals per year; an almost 40% increase. Of the 48 novel drugs approved in 2019, 33 (almost 70%) were approved in the US before receiving approval in another country. Growth in approvals also was observed for new and expanded use of already FDA-approved drugs, biosimilars and other emerging therapy classes. Lastly, the rate of expedited development and review pathway designations also has been increasing, allowing regulatory reviews/approvals to happen more frequently and with greater speed. Many expect this trend to continue, and the overall impact on the regulatory operations role could vary, depending on the sponsor's focus and geographic reach.

With the rise of specialty medicines and precision treatments, the volume of ongoing clinical trials requiring regulatory oversight has increased significantly. In December 2019, for example, there were 325,352 registered studies in 209 countries—[nearly four times the volume of 2010](#), when there were 82,867 active studies.<sup>2</sup>

This increase in activity means sponsors and Contract Research Organizations (CROs) must now handle an enormous amount of project-critical data coming from multiple sources. It is not uncommon, for instance, to receive information from genomic sequencing, medical imaging and mobile health systems—and for that to be

generated and delivered by thousands of different devices.

More often these days, regulatory professionals are expected to be experts on the changing regulatory climate globally. Today, they need to know almost as much about the inner workings of the National Medical Products Administration (NMPA) in China as they do about the US Food and Drug Administration (FDA). Similarly, they must be well-versed in the requirements and implications of all new and emerging privacy regulations in every country in which they operate, whether it is the *General Data Protection Regulation (GDPR)* in Europe or the *Health Information Portability and Accountability Act (HIPAA)* in the US.

Between the data related to their daily jobs and information coming from various regions or countries in which they operate, regulatory operations professionals have their hands full.

“The biggest challenge for us is absolutely the amount of information coming our way that must be processed, understood and considered each day,” said Mark De Rosch PhD, FRAPS, chief regulatory officer for [Epizyme](#), Inc., a late-stage biopharmaceutical company developing epigenetic therapies. “Nearly all of that information is originating from regulatory agencies around the world, which was not the case five or 10 years ago. Trying to manage and process the sheer volume of information from so many locations is incredibly difficult.”

Most organizations recognize the need to get their arms around data. However, many still depend upon a mesh of manually intensive and business software tools for Regulatory Information Management (RIM). In fact, depending on company size, regulatory processes can involve anywhere from a dozen to more than 100 different systems and spreadsheets to securely manage correspondence, commitments, submission documents and archived dossiers.<sup>3</sup>

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This reliance on fragmented technology and manual processes can cause delays, hamper visibility and access to key data, and lead to unnecessary inefficiencies. This is why 86% of pharmaceutical organizations surveyed by Gens and Associates are embarking on digital transformational journeys in one or more regulatory areas. The goals of such efforts are clear. Most organizations want to improve visibility and oversight of the constantly growing volume of information about their products, programs and in the end, insights about the market response and the patients. They seek a single source of truth for relevant information that can be stored in a secure, unified, and globally accessible hub.<sup>4</sup>

### Deploying RIM Capabilities

A major benefit of adopting a modern RIM system is that it does more than just store documents related to a drug application. Modern RIM systems connect regulatory content and data to give companies of all sizes an authoritative source for submission documents, published dossiers, product registration information and health authority interactions in one platform. This platform approach aides global regulatory teams, giving them better visibility and control into upcoming priorities and other critical regulatory obligations or initiatives. Technology is an enabler for regulatory; however, the timing and development stage of the company is important as these factors impact the regulatory team's ability to gain efficiencies by implementing a modern RIM system.

Startups tend to start out with uncontrolled systems or outsource regulatory functions because they do not have the activity and submission volume to justify the need for managing their own RIM system. In some cases, it's not part of their strategy in the first place—especially if funded by or sharing resources with a larger pharmaceutical company. Startups and

small pharmaceutical companies are incredibly busy, accounting for 63% of all new prescription drug approvals the past five years, but few have large regulatory teams. More commonly, they will have individuals doing the work of several people, which is why many augment or outsource regulatory capabilities to partners or consultants and defer on bringing capabilities in-house.<sup>5</sup>

Many smaller companies think this approach is their only choice. However, others find that implementing modern, cloud-based RIM system is easier than implementing the RIM systems of the past—and is something they can accomplish in a reasonable amount of time. A single platform also makes it easier to trust the integrity of the information since it resides in a validated, controlled system.

“Bringing our first regulatory publishing system in-house was very costly and took a long time to accomplish, but replacing it with a modern, cloud-based solution only took about six weeks and cost significantly less from an implementation and licensing perspective,” acknowledged Mike Epstein, senior director of regulatory operations for [ACADIA Pharmaceuticals](#), a biopharmaceutical firm focused on central nervous system (CNS) disorders. “In the cloud, we are now able to centralize many of our regulatory activities, including preparing submissions and tracking health authority interactions, in a single, unified system. This allows us to easily and quickly generate reports, analyses, and other data that can be shared more broadly across research and development.”

One other advantage of modern RIM systems is that some—not all—have been specifically optimized for use by regulatory teams. They are built to support end-to-end regulatory processes for drug development; as opposed to some solutions that started outside of life sciences and then were customized to meet the needs of global pharmaceutical companies.

*... 86% of pharmaceutical organizations surveyed by Gens and Associates are embarking on digital transformational journeys in one or more regulatory areas.*

*Formal training in scientific and technical writing also helps regulatory professionals develop a sense of theme and narration while focusing on formulating and presenting logical arguments to demonstrate scientific concepts, carry out template work or provide concise written responses to technically complex questions via enhanced critical thinking.*

RIM systems are also adding capabilities that allow for the capture and aggregation of business intelligence—in this case regulatory intelligence—into the technology used by global regulatory teams.

The Organization for Professionals in Regulatory Affairs (TOPRA) defines regulatory intelligence as the act of processing targeted information and data from multiple sources, analyzing the data in its relevant context and generating a meaningful output. The industry's focus is shifting to improving their regulatory intelligence capabilities.

This involves reducing the number of repositories, connecting internal and external intelligence in meaningful ways, and ultimately making intelligence more accessible and actionable to better support decision-making. The aim is to apply regulatory intelligence throughout the entire lifecycle of a product—from pre-clinical development through commercialization. Some regulatory teams are even extending their regulatory intelligence efforts by investing in Real World Evidence (RWE) and predictive analytics to mine existing information for valuable insights, augment planning efforts and mitigate risk.

“We are always looking to measure how and what we are doing more accurately to advise business decisions,” said Scott Cleve, vice president of regulatory operations and compliance at [bluebird bio](#), which is developing gene therapies for severe genetic diseases and cancers. “From a regulatory perspective, we are researching how predictive analytics might suggest new ways of approaching regulatory authorities to increase the probability of approval.”

Some firms are also considering the value Artificial Intelligence (AI) and Machine Learning (ML) for automating manually intensive and time-consuming processes, said Analyst Steve Gens, founder of Gens and Associates, who believes most will be in “experimentation” phases in 2020 and 2021, but that AI could become common in three to four years.

Bluebird bio is among a growing number of companies exploring how AI can facilitate regulatory processes.

“We are starting to look at AI and build use cases to see what it could do for us,” Cleve said. “There is a lot of work that must happen first, though, to cleanse our data and ensure that it is correctly labeled and identified so we can feed it into the (AI) algorithm and retrieve something useful from it.”

### Contending With Data

For decades regulatory submissions have taken the form of document dossiers. Over the last several years, regulators have taken an interest in data feeds to complement the dossier. In 2012, the European Medicines Agency (EMA) mandated the submission product details via the [Extended EudraVigilance Medicinal Product Dictionary \(XEVMPPD\)](#). EMA will soon mandate the submission of far greater volumes of product information through the [Identification of Medicinal Products \(IDMP\)](#) initiative.<sup>6</sup>

While organizations could get away with manually curating and entering XEVMPPD data, IDMP's scope is far greater and reaches well outside the regulatory organization. One key IDMP objective is to standardize data commonly referred to as Substance, Product, Organization and Referential (SPOR) data. To comply efficiently, companies must master their SPOR data, and many are embracing IDMP as the impetus to make the necessary changes.

SPOR data is generated from within safety, regulatory, manufacturing and other departments. The variation in data definitions and terminology across these systems and across regions makes it challenging to aggregate it all. While a challenge, IDMP also presents an opportunity. The process of establishing a consistent nomenclature, adopting coded values and controlled vocabularies, and identifying the authoritative source for each data point will naturally produce significant process improvements.

The expected arrival of IDMP is compelling organizations to harmonize their data, with most teams preparing to modernize their regulatory information management capabilities, said Gens.

“Many companies completed their IDMP gap analysis and were alarmed by the size and complexity of the necessary IDMP compliance project,” he said. “They are subsequently focused on how to keep all this mission-critical data clean and updated over the long term.”

### The Industry Prepares for Change

This article discussed some of the trends that will change or expand the role of regulatory operations professionals in the coming years. Emerging therapies and markets will play a big part in changing the face of the regulatory landscape, while technology will serve as an important enabler and less of a commodity, in getting drugs to market. Looking ahead, regulatory operations professionals’ role will continue to broaden and evolve significantly. They will need to adjust to the constant change around them by transforming their processes and technology—ultimately helping to improve the speed and chances of regulatory approval worldwide.

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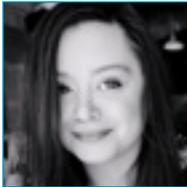
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**Cite as:** Belani R. “How the Role of Regulatory Operations Professionals Will Evolve in the new Decade.” *Regulatory Focus*. February 2020. Regulatory Affairs Professionals Society.



# Why Understanding Regulatory Affairs is Important to key Company Decision Makers



By Isabella Schmitt, RAC

This article discusses the reasons why continuous evaluation of the regulatory framework is important for company decision makers and how companies that make efforts to understand the regulatory landscape for their product benefit.

### Introduction

The life science industry is one of the most heavily regulated industries. Executives, senior managers and investors must understand how different decisions about a product can impact its regulatory path and how this affects commercialization. Also, the decision framework may change depending on where the product is within the lifecycle of development. This article discusses the reasons why continuous evaluation of the regulatory framework is important for company decision makers and how companies that make efforts to understand the regulatory landscape for their product benefit. The author emphasizes pivotal decisions

such as target indications, intended use claims and different marketplaces and how an understanding of the regulatory requirements of these items can facilitate decision making.

In bringing a medical product to market, there are a variety of key players responsible for the overall development. From Chief Executive Officers (CEOs), senior managers and scientists to board members and investors, the product is subject to much oversight during its evolution. While these stakeholders may have differing perspectives on how to reach the finish line, the ultimate goal of creating a successful product is shared. Arguably, the product milestone most indicative of success is regulatory approval or clearance, a milestone without which, a product cannot move on to commercialization. While this milestone occurs later in the lifecycle of the product, regulatory considerations must be addressed early on, as the ultimate approval (or clearance) is dependent on the decisions, actions and results obtained throughout the

*As regulatory outcomes can energize or extinguish the life of a company, successfully navigating and understanding the regulatory paths can provide competitive advantages to companies, leading to higher valuations.*

development lifecycle. Thus, it is necessary for entrepreneurs, inventors and investors to fully comprehend the regulatory pathway, its implementation and how decisions and assessments made along the product development pathway can alter the regulatory requirements, not only prior to commercialization, but after the device is available in the marketplace as well.

Since regulatory oversight exists throughout the entire product lifecycle, regulatory considerations and strategy are an integral part of the overall business plan and may ultimately help in defining the initial indications, desired labeling claims and target markets. As regulatory outcomes can energize or extinguish the life of a company, successfully navigating and understanding the regulatory paths can provide competitive advantages to companies, leading to higher valuations. On the other hand, failing to comprehensively assess and paint a full picture of these items will affect the success in commercializing a product, not only due to the inability to meet agency requirements, but also because investors are unlikely to (and should not) invest in a company that cannot provide a clear projection of timelines, costs and required testing for bringing a product to market.

### **Pre-Approval/Clearance (Early Stage)**

Even in the earliest stages of strategizing, regulatory considerations play a fundamental role in determining the labeling claims and targeted indications. Many emerging entrepreneurs start their journey with a technology (perhaps this was a product they worked on in graduate school or perhaps they obtained the technology from a prior failed venture) but not with a clear indication of how they want to use it, putting the company at risk due to indecisiveness that leads to unclear product development and disjointed commercialization plans. Without a

clear problem-solving mindset, the company's decision-makers may find themselves perpetually perfecting the technology without really understanding what it is for, what it needs to do, how it needs to perform, how to commercialize it and its marketability. Companies that get stuck in this stage for long periods of time regularly have difficulties inspiring their employees and convincing external stakeholders to invest time, money and resources into the company and product.

In some cases, even when senior management begins to consider the application of the technology, the technology may have multiple potential markets and indications that the company can target and claims that the company can make, effectively resulting in the following:

- the company trying to broaden the claims to encompass multiple indications
- the company developing one technology that generates multiple products

All too often, these situations result in a lack of focus, one in which senior management begins attempting to develop these multiple products at once or starts holding conversations about the array of potentialities for the product. An inability to concentrate on one product hinders the progress of all potential products, and rightfully, raises red flags with investors and strategic partners.

Senior managers and executive teams who have difficulty selecting a single product to focus on initially may be trying to capture all possible value propositions because they erroneously think the company will be able to succeed in developing all of the products simultaneously. This situation is typical in the early stages of product development or company formation, stages that are often plagued with a phenomenon called optimism bias, a bias that leads individuals to believe that they are more likely to succeed

than fail. This does not mean that company decision makers are incapable of evaluation at these stages. Optimism propels individual to meet their goals; however, optimism unchecked may lead to lack of focus, at best, and poor decision making, at worst.

For example, an early-stage executive of a company in possession of an in vitro diagnostic technology that has the ability to detect multiple viral strains may have difficulty determining the following:

- Intended use: will it diagnose or monitor?
- Initial target indication: will it be specific to a certain illness? What indication will it be?
- Complexity: will it test for one illness or will it be a panel?

These types of questions must be evaluated and answered before a company can progress with design and testing, as the decisions will alter the regulatory pathway and the associated requirements. If this “example executive” tries to address multiple markets and value props at once, not only will product development efforts be multiplied, but various regulatory pathways will likely need to be navigated as well. In this particular example, claims of diagnosis are likely to increase the regulatory burden over claims of monitoring. A higher risk indication, such as HIV, will likely result in a higher risk classification than one associated with lower risk, such as influenza. And, devices that include multiple tests in a panel will necessarily increase the regulatory burden as greater evidence requirements will be necessary to address the expanded indication. Thus, if the executive does not properly evaluate these choices and choose an application to focus on, the company will quickly become spread too thin to move forward. Performing a market analysis of potential target indications, as well as the regulatory requirements for development and approval of these

various potential indications, facilitates the decision of the executive, allowing the project to advance, both financially and technologically in situations such as these.

Medical devices also may choose to exclude indication statements all together, making their claims general rather than specific. Many existing product codes are for general use devices, such as catheters. Senior management must determine the type of claims they wish to make for the device, as this may impact the overall development process. In situations in which the manufacturer wants a more specific indications claim than the FDA product code or Code of Federal Regulations (CFR) number specifies, early interaction with FDA is advisable as this will allow the company to avoid making any wrong assumptions about how the product will be regulated, as a premarket submission under a general product code may preclude the company from marketing toward a specific indication for use.

Claims also may go beyond indications to include patient outcomes. Outcomes claims will necessarily require additional evidence, may require longer timelines for clinical follow-up and may alter the regulatory pathway. Often, an executive whose device is targeting outcomes claims beyond the scope of predecessor devices is advised to obtain a Premarket Approval (PMA) or de novo, if not to meet regulatory requirements, then to obtain better reimbursement for the device.

In cases in which the targeted claims are still up for consideration, a market analysis may help, but the ways in which certain claims and technological aspects affect the regulatory pathway also must be assessed, as the total addressable market may not be sufficient to justify a large regulatory burden. If a company erroneously applies a simpler regulatory pathway, the company may find remediation of this error impossible, as the failure

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to successfully navigate the regulatory pathway initially will surely disrupt the faith investors had in the company, making additional raises, necessary to fund additional product development efforts, challenging.

Companies with a considerable number of options will necessarily have to develop a more substantive business plan, determining the hierarchy of the products to be generated and the markets to target. This business plan should take into account a global market analysis, global regulatory analysis and global sales and reimbursement considerations. However, given that the market, sales and reimbursement are irrelevant if regulatory approval or clearance is not obtained, a clear understanding and accurate assessment of regulatory must be generated in these early stages. Because the success of a medical products depends so heavily on regulatory outcomes, many transactions between companies, investors and strategic partners are dependent on well-defined regulatory milestones.

### Different Markets

Regulatory requirements also differ in different target marketplaces, so in choosing an initial market, the regulatory landscape must be well understood. For example, in the past, many medical device companies would first launch their venture in Europe and obtain [CE Mark](#) prior to FDA approval.<sup>1</sup> However, given the changes to regulation in Europe, with the introduction of the EU [Medical Devices Regulation \(MDR\)](#) and [In Vitro Diagnostic Regulation \(IVDR\)](#), companies are now holding off on obtaining European approval.<sup>2,3</sup> Moreover, companies are actually coming to the US FDA to obtain insight on product development and potential regulatory requirements that they then apply to their development and technical file for the EU. A company who made the decision to use the old playbook for global regulatory strategy would find themselves in a bind in this situation, as choosing the EU for

the target market may increase the overall timeline to commercialization.

Aligning the regulatory plan across multiple markets to the extent that this is possible is advisable. An understanding of the various regulatory requirements in each market is necessary for this. For instance, if a company understands that a product is regulated similarly in Health Canada and the EU, it can align its product development plan to easily address both markets. The company also may consider launching in Australia as well, as Australia's regulatory body, the Therapeutic Goods Agency (TGA), recognizes CE Mark approval. Thus, in one fell swoop, the product may obtain multiple clearances or approvals.

### Investor Assessment (Early-Stage)

Investors, particularly angel investors, should take a careful look at the detailed regulatory plan, including whether the company has an advisor, employee or consultant who understands the regulatory process, and whether the company has spoken to FDA about the pathway and plan. A company that understands its regulatory and development milestones, coordinates the milestones with fundraises and has identified inflection points that may allow for an exit, inspires greater confidence for investors while de-risking follow-on investments. Even having done a comprehensive analysis, companies with novel technologies for which there is little past precedent to rely on are associated with higher regulatory risks and for good reason. Products that have no pre-identified evaluation criteria and no comparable devices of which to gain a real-world understanding of risk profile often result in deeper analysis by and extra scrutiny from FDA. Acknowledging this, FDA has put programs, such as the Breakthrough Devices and Breakthrough Technology Programs, in place in an attempt to alleviate this issue. As these programs are intended to help novel products

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*Investors, particularly angel investors, should take a careful look at the detailed regulatory plan, including whether the company has an advisor, employee or consultant who understands the regulatory process, and whether the company has spoken to FDA about the pathway and plan.*

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with the potential for benefit to public health get through the regulatory process more smoothly, companies whose products have been designated under one of these categories show reduction in regulatory risk for investors, as FDA has essentially labeled the product one that the agency has an interest in approving. Other situations in which an expedited approval or higher probability of approval may be likely are those in which political factors may be at play within FDA. Public demands or patient advocacy groups may provide pressure on FDA to approve a drug or device. Companies that understand how to adequately measure the patient need for a product and utilize patient preference mechanism may enable a more rapid approval.

### Postapproval (Late Stage)

The chosen (or designated) regulatory pathway will have an impact on postapproval requirements. While, in many cases, exits will have occurred prior to the implementation of post-market requirements, limiting this concern for early investors, potential acquirers may be wary of products who have the potential for substantial post-market burdens. In particular, [PMA products](#) often require postapproval studies that incur significant additional costs, whereas [510\(k\)s](#) typically do not require clinical studies at all.<sup>4,5</sup> For products with small potential markets, such as pediatric products, considerable postapproval requirements may be a deterrent for many potential acquirers.

Even if the postmarket regulatory burden is low, executive teams and senior management should ensure that they have a robust method for capturing and evaluating data as well as maintaining compliance with regulations, as companies that lapse in compliance may be given warning letters, which, if ignored, can lead to action by the Department of Justice at FDA's request. Staying on top of the regulations not only encompasses complying with mandatory

reporting requirements and maintaining quality systems but also keeping up to date with changes in regulation, such as re-classifications. While rare, re-classifications may change the requirements for a product on the market. To give an example, in December 2019, a final decision was made by FDA to re-classify Cranial Electrotherapy Devices (CES) into two classifications.<sup>6</sup> CES devices indicated for treating insomnia and anxiety were classified as Class III devices subject to special controls, detailed in the new regulation, while CES devices indicated for treating depression were reclassified as Class III devices requiring a PMA. As such, companies marketing CES devices, regardless of indication, now must review their dossiers, along with their non-clinical and clinical evidence to ensure their data is sufficient to maintain compliance with the new requirements; if not, the companies will have to address any gaps with necessary testing and file a new premarket submission. Company leaders and personnel of CES companies that do not stay on top of regulatory issues may fall out of compliance due to ignorance with regard to the change of regulation, ultimately resulting in FDA regulatory action.

### Planning for Success

Ultimately, having a clear understanding of the product is necessary for management teams to effectively work with most stakeholders, including investors, consultants, advisors, strategists and regulatory bodies. (See **Table 1**)

While regulatory approval and oversight is often considered a large obstacle in a company's path to commercialization, an executive or investor's relationship with the regulatory agencies and/or the regulatory process need not be considered adversarial. In fact, the regulatory bodies share the same goal as the rest of the stakeholders—providing patients with a new and potentially better product. The goal of a regulatory body is not to thwart innovation. The regulatory bodies want to see successful

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*Ultimately, having a clear understanding of the product is necessary for management teams to effectively work with most stakeholders, including investors, consultants, advisors, strategists and regulatory bodies.*

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**Table 1. Key Decisions for Success**

Key Decisions for Success	Key Considerations in Decisions
What is the problem the technology is solving?	Is this actually a problem? What do potential users think?
What is the device's function?	N/A
Should the intended use statement be general to function or specific?	How does the level of specificity affect the pathway?
What are the pathway options?	Does a more complex pathway result in more market gains?
What are the major milestones in each pathway?	Will it be possible to raise funds at multiple milestones? How important are each of these milestones?
What are the various global markets to target?	How large are these markets? How difficult is it to get regulatory approval?
What are the postmarket requirements for different regulatory pathways and regulatory bodies?	How will this be viewed by potential acquirers? Does the Total Addressable Market (TAM) justify the postmarket regulatory burden?

products placed on the market. They are focused on the advancement of public health by promoting the creation of medical products that are more effective, safer and more affordable for patients and users. When one understands that the agencies require that all companies provide evidence-based documentation with regard to the safety and effectiveness of their products, prior to launching, and that all products

must provide follow-up surveillance and reporting after the product is available in the marketplace, one can start viewing these requirements as an aid in product development and ultimately as risk mitigation for their company, preventing bad press and customer feedback in the future and keeping low-bar competitors out of the marketplace.

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## About the Author

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**Cite as:** Schmitt I. “Why Understanding Regulatory Affairs is Important to key Company Decision Makers.” *Regulatory Focus*. February 2020. Regulatory Affairs Professionals Society.



## Writing Informed Consent Documents: a Balancing act



By Viji Ramesh, MSc

This article describes the best practices used to develop informed consent documents including skillful writing to communicate the objectives, benefits, implications, risks and inconveniences of participating in the clinical trial, as well as the rights as clinical trial participants. The author covers the important aspects a medical writer can contribute to developing a strong and easily understandable informed consent, including paying particular attention to using plain language, making the document readable, being aware of potential social and cultural issues, avoiding scientific, legal or medical jargon and information overload.

### Introduction

An informed consent document is required to help people decide whether to participate in a clinical trial. Providing them with a consent document clearly explaining everything they need to know about the trial, including the benefits and risks, helps with their deci-

sion making. A well-prepared informed consent document should be readable and simplified as compared to the protocol. However, it must cover all the study's essential elements and potential consequences, such as adverse events and ethical standards. A good medical writer can provide a consent document accomplishing all these items.

Clinical trial designs have become increasingly complex.<sup>1,2</sup> To ensure such complex science is well communicated to study participants and to ensure that appropriate decisions for a patient to participate are made, it is essential to have a robust informed consent process in place. This includes an interactive discussion between trial site staff and potential participants, supported by an informed consent document explaining relevant trial information in a simple, clear and meaningful way.<sup>3</sup>

According to the Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on

*... the US Code of Federal Regulations, 21 CFR 20.50 states that “the information that is given to the subject or the representative shall be in language understandable to the subject or the representative.”*

medicinal products for human use, such information needs to be kept “comprehensive, concise, clear, relevant and understandable to a lay person.”<sup>4</sup> Similarly, the US Code of Federal Regulations, 21 CFR 20.50 states that “the information that is given to the subject or the representative shall be in language understandable to the subject or the representative.”<sup>5</sup> Thus, it is important for potential participants to read, evaluate and consider the presented trial information to ensure they can make an informed decision to participate. Such information includes the objectives, benefits, implications, risks and inconveniences of participating in the clinical trial, and their rights as research participants.<sup>6</sup> Before the start of any clinical trial-related procedures to indicate voluntary consent, the informed consent document should be signed either by the participant or by his/her legally designated representative, making the informed consent document one of the most vital clinical trial elements.

A poor understanding of informed consent documents can lead to a reduced ability for participants to make appropriate health decisions, including:

- failure to communicate a particular symptom or condition to the trial investigator due to lack of understanding of the side effects of a trial treatment
- nonadherence to the lifestyle requirements stipulated by the protocol
- noncompliance with the treatment regimen or missed scheduled visits

These scenarios also may lead to poor trial outcomes and reduced sensitive data.<sup>7</sup>

Studies show that a lack of understanding of trial-related information and inadequately answered questions are among the reasons for non-participation in clinical trials.<sup>8</sup> Individuals who consider participating in clinical trials often have mental or physical conditions that cause pain or discom-

fort and participation in a clinical trial may be their only hope for alleviating such discomforts. Thus, an informed consent document not written to meet their understanding levels could lead to stress and refusal to participate. In other words, increased understanding of informed consent documents by individuals who do not have a medical or life sciences background is a direct indicator of the quality of informed consent documents. A well-written informed consent document, easily understandable and with relevant information can ease participant apprehensions. A clear understanding helps participants making their decision whether to participate in a research trial and may also improve compliance as participants are more likely to follow through until the end of the trial.

Informed consent, apart from the document itself, is the overall process involving a two-way communication between the investigator and the potential participant. First, the investigator explains the various aspects of the trial to the potential participant, including planned procedures and potential benefit and risk. Potential participants should be encouraged to ask questions to ensure they understand the trial and procedures so they can make an informed, voluntary decision. Hence, the investigator must not only know the trial protocol well, having reviewed the informed consent document thoroughly to be best prepared to answer questions.

### Preparing: the Medical Writer’s Role

Importantly, medical writers have strong role in the writing of the informed consent document as they must follow several best practices to develop an informed consent document balancing requirements of the study, participant, investigator and regulations, while explaining it simply, concisely and making it easy to understand. Of course, the medical writer must have a thorough understanding of the regulations. Then,

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*Plain language, language that is not scientific or jargon-filled, is the kind of communication the writer's audience can understand the first time they hear or read it. This means using short paragraphs, short sentences and short words while keeping the text clear and concise and at a sixth to eighth grade reading level.*

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using the protocol and investigator's brochure as the key source documents, the medical writer should obtain details, such as the trial design, potential benefits and risks of the Investigational Product (IP), trial procedures and type of samples and data to be collected from trial participants. The writer should understand the properties of the IP, dosage forms, methods of administration, the nonclinical and clinical studies that have already been conducted for this IP and the adverse events and other discomforts that may be related to the IP. It is also critical that the writer understands the local participant population as volunteer sex, literacy levels and population social practices and cultural norms may influence informed consent document content. For example, a medical writer needs to carefully consider how details regarding testing for pregnancy will be presented for a trial that enrolls adolescents. Another example is the unit used to present blood volume to be drawn from a participant; while the volume is often expressed in teaspoons or tablespoons in informed consent documents, such presentation is not considered appropriate in some countries where volume presented in milliliters.

Other important considerations while preparing the informed consent document include:

- Does the participant population include participants who are mentally incapacitated or in an unconscious state or pregnant women?
- Does the trial involve genetic tests, pharmacokinetic sampling, antibody testing or biomarker analysis?
- Does the trial involve photography or videography of the participants?
- Does the trial involve validation of any testing equipment?
- Does the informed consent use electronic consenting processes?

Further, consideration should consider possible problems if the informed consent documents are to be translated into several languages.

The medical writer also needs to have good planning and communication skills as they are also responsible for engaging several stakeholders including clinicians, medical experts, enrollment specialists and regulatory and legal experts to get their input, as applicable, and perspective while preparing to write the informed consent document.

### Writing the Informed Consent Using Plain Language

To develop an informed consent document for effectively communicating complex medical and scientific trial information to the participant, a medical writer also must be able to write in simple, plain language, understandable by those unfamiliar with medical or scientific terminology.

Plain language, language that is not scientific or jargon-filled, is the kind of communication the writer's audience can understand the first time they hear or read it.<sup>9</sup> This means using short paragraphs, short sentences and short words while keeping the text clear and concise and at a sixth to eighth grade reading level. The principles of plain language include:

- using common, everyday words
- using consistent terms throughout the document
- avoiding the use of medical, technical or scientific jargon
- defining technical terms at first instance
- avoiding the use of abbreviations
- using short, direct and simple sentences
- using conversational style addressing the participant
- avoiding information overload
- using figures, flowcharts and images to "drive" the message

It is advisable to repeat definitions of technical terms to avoid participants having to "flip" several pages to remind themselves of the definitions appearing at the beginning of the document.

A significant challenge faced by a

Table 1. Readability Scores

Reading Ease Score	Style Description	Estimated Reading Grade
0 to 30	Very Difficult	College graduate
30 to 50	Difficult	13th to 16th grade
50 to 60	Fairly Difficult	10th to 12th grade
60 to 70	Standard	8th and 9th grade
70 to 80	Fairly Easy	7th grade
80 to 90	Easy	6th grade
90 to 100	Very Easy	5th grade

medical writer while developing content for an informed consent document is avoiding the use of medical and technical terms used by those who write documents such as the protocol and investigator's brochure and who must use highly technical language. Further, a majority of other documents written by medical writers are for scientific or technical audiences. Terms such as benefit, experience, event, investigation, race or record, commonly used in regulatory documents, may have different meanings to individuals unfamiliar with medical or technical terms.

### Readability: a top Consideration

Enhanced readability is important to aid comprehension of informed consent documents. There are several formulas to gauge the readability of the language used in an informed consent document (Table 1). Most commonly used are Flesch-Kincaid Formula and Flesch Reading Ease. Microsoft Word has an inbuilt function to indicate the Flesch-Kincaid reading level and Flesch Reading Ease scores.<sup>10</sup>

Some methods to improve and achieve the desired readability scores involve:

- using active voice
- using conversational style
- using of first person
- breaking dense paragraphs with the use of bullets
- using adequate white spaces and margins

- using bold font or underlines, or sometimes both, for emphasis

Note: while readability contributes to the improved comprehension of the consent document, readability does not necessarily guarantee complete understanding of the document. Easy to read text might be difficult to understand unless the medical writer focuses on the sense and flow of the text.<sup>11</sup> Furthermore, in using plain language, one should not ignore the importance of presenting accurate information to the participant.

Explanation and definitions of technical and medical terms may lead to extensive “chunky” texts that fail to drive the point to the reader. Similarly, the use of white spaces and margins may increase the length of the document, leaving the reader impatient. In several countries, regulatory authorities insist on informed consent documents not longer than eight to 10 pages. Therefore, a medical writer needs to balance these two aspects well to ensure the participant receives an informed consent document with adequate information, but one not too lengthy.

A checklist capturing all the requirements to enhance comprehension and readability is important to be incorporated in the review process of the informed consent document to confirm these elements were considered during the development of the document.

Table 2 gives an illustration of how technical terms can be simplified for better understanding.

Table 2. Illustration of Technical Language Versus Simple Language

Column A: Technical Language	Column B: Revised Simple Language
<p>A fasting blood sample will be taken, using a needle to collect blood from a vein in your arm. A total of 20 ml of blood will be drawn for the routine clinical tests listed below to determine if you are eligible to participate in the study. The study doctor or study staff will explain this process to you and what will happen based on your test results.</p> <ul style="list-style-type: none"> <li>• full safety chemistry, hematology,</li> <li>• brief lipid profile</li> <li>• serum pregnancy test (for women of child-bearing potential)</li> </ul>	<p>After you have been on empty stomach for eight hours, the study staff will take blood samples from you to:</p> <ul style="list-style-type: none"> <li>• test the functioning of the internal organs like liver and kidney</li> <li>• check the health of blood and blood forming organs</li> <li>• check whether there is risk for developing heart diseases</li> <li>• if you are a woman who could get pregnant, check if you are pregnant</li> </ul> <p>The total amount of blood taken will be 20 mL (about four teaspoons). Based on the results of these tests, the study doctor will decide if you are fit to participate in this study.</p>

Table 3. Illustration to Improve Readability

Column A: Crowded Presentation	Column B: Spaced-out Presentation
<p>After signing this Informed Consent Form, some examinations, tests and/or procedures will be performed to confirm that you are eligible to participate in the study. Your study doctor or a member of the study staff will explain all of the study procedures to you and will answer any questions or concerns you may have regarding the study. You will be asked questions about your medical history and the other drugs that you are currently taking. Your performance status will be evaluated by a study doctor. You will undergo a physical examination, including measurements of height, weight and vital signs. An electrocardiogram and ocular examination will also be performed.</p>	<p>After you sign the Informed Consent Form, you will have some tests and procedures to find out if you are fit to participate in this study. The study doctor or the study staff will:</p> <ul style="list-style-type: none"> <li>• collect information about your medical history and any medicines that you are currently taking</li> <li>• check how well you are able to do your daily activities</li> <li>• do a physical examination, and check your height, weight, blood pressure, pulse, temperature and breathing,</li> <li>• do an electrocardiogram to check the functioning of your heart</li> <li>• do an eye examination to check your eyesight</li> </ul> <p>The study doctor or the study staff will explain these procedures to you. If you have any questions or concerns, please talk to the study doctor.</p>

Table 4. Illustration of Information Overload

Overloaded Information	To-the-Point Information
<p>Blood samples will be shipped to a central laboratory where test A and other mutation tests will be conducted. The test A and other mutation tests will be performed in batches by a central laboratory and therefore there is no defined timeframe for when the result will be available.</p>	<p>Blood samples will be shipped to a central laboratory for testing. The study doctor will call when the results come in.</p>

**Table 3** illustrates how a chunky text with technical terms (Column A) can be presented with use of bullets and white spaces to improve readability (Column B).

### Information Overload

Another challenge for the medical writer is the compulsion to include all information from clinical trial protocol into an informed consent document. While developing content, a medical

writer should be mindful that the audience for a protocol is different from the audience for an informed consent document. Not all information presented in the protocol is relevant to the participant. Compare the technical text presented in the two columns of **Table 4**, illustrating how relevant information can be presented in a clear, concise way.

Often, the medical writer includes additional information due to pressure from the clinical or medical reviewers

as the informed consent document may be viewed more as a legal document rather than a communication tool to the participant. Hence, it becomes the responsibility of the medical writer to carefully balance the regulatory requirements, requirements of the reviewing/approving bodies and the health literacy levels of the participant population while deciding on the content of the informed consent documents.

### Consistency in Terminology

While developing content for an informed consent document, a medical writer also needs to ensure consistency of terms across informed consents of different studies held in the same clinical trial program. Consistency of terminology is even more relevant while developing informed consents for participants who are enrolled from a previous trial into subsequent extension or compassionate use trials. Use of the interchangeable words across documents often leaves the participants confused, for example:

- study doctor and investigator
- research study and trial
- investigational and experimental
- patient and subject

### Presenting Risks in Informed Consent Documents

Communicating the risks of taking part in the trial, and the possible adverse events of the IP to a general audience, is a fair challenge for the medical writer. Even well-educated participants find it difficult to understand frequency and statistics of possible adverse events and discomforts. Further, the perception of some risks is also influenced by the participant's beliefs and values. Minor adverse events may be overestimated, whereas the impact of serious adverse events may not be fully understood. Participants may miss communicating certain events to the investigator unless they well understand the nature and the frequency of the possible adverse events.

The medical writer works closely with the clinical teams to develop the sections of the informed consent document presenting risks and discomforts. A balance between presenting accurate data on risks and discomforts and not causing alarm to the participant or discouraging their participation should be considered. Plain language equivalent to specific adverse events or medical assessments and procedures can be maintained as a compilation to facilitate future use, which improves efficiency by reducing the time when working on informed consent documents for similar indications. As the trial proceeds, the medical writer may be requested to update the informed consent with the latest available information on the possible adverse events and discomforts of the IP.

### Legal Language

Information regarding insurance provisions, compensation in the event of trial-related injury, method of storing and analyzing samples and data collected from participants and how confidentiality of participants' personal information is maintained are standardized text in most informed consent documents.

Essential for an informed decision is a basic participant understanding regarding their rights to data privacy as well as how data confidentiality will be managed by the parties who collect such data. If this information is too complex and contains legal terminology that is not explained in plain language, a potential participant may decline to enter the trial.

The medical writer works with legal experts to standardize the language explaining the participant's rights. Any attempt to alter text in these sections should not be made without consultation with legal experts and clinical teams. However, despite these efforts, participants usually find language in these sections difficult to comprehend.

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*The effort to ensure participant comprehension does not end with the approval of the informed consent document. The investigator, or the trial staff, employs methods such as teach-back, teach-to-goal or quizzes to evaluate if the participant has understood the content of the informed consent document.*

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### Informed Consent Aids

The medical writer can use pictographs, images and tables in the informed consent document to make the medical and scientific information easier to understand. Additional educational materials, such as Microsoft PowerPoint presentations, brochures, animation and other multimedia aids are developed in plain language and can enhance participant comprehension. These additional materials are linked to electronic consent documents or attached to paper consent documents. The transcripts for animation aids are developed in plain language and are also approved by the Independent Ethics Committee (IEC)/ Institutional Review Board (IRB) and regulatory bodies before being presented to the participants.

The use of informed consent aids ensures that only the essential information from the clinical trial protocol and investigator's brochure is included in the main informed consent document. If the participant is interested in additional information, they may refer to educational materials linked or attached to the main informed consent document. For example, describing all procedures that will be conducted in a multi-cohort trial or a trial that runs for several years in the main informed consent document makes the document lengthy and confusing to read. Instead, the details can be described in a separate document (as a Microsoft PowerPoint presentation or in a tabular presentation). This document can be referenced as a supplementary document in the appropriate section of the main informed consent document. This makes the main consent document short and easier to read while ensuring all details are available to the participants when needed.

### Child Assent Forms

Writing for audiences who are not familiar with medical or technical terminology is a difficult task. The challenge further intensifies when writing for

pediatric population. While a reading level of sixth to eighth grade is the requirement for an informed consent for adults, a medical writer aims to achieve a reading level of sixth grade or below for child assents.

The medical writer determines what is most relevant information that the child will need to know to participate information. For children, the writer also uses bigger font sizes, pictures, clipart images, animated drawings and colors to make the document easier for a child to understand. The assent document should not be more than two to three pages long. When using images and pictures, the medical writer checks with legal experts to ensure copyright-protected materials are not used.

Some trials require child assents to be written for different age groups of children due to different levels of maturity and understanding. The design, language and content of assents for children of age group six to 12 years is different from an is developed for children from 13 to 18 years of age.

### Evaluating Comprehension

The effort to ensure participant comprehension does not end with the approval of the informed consent document. The investigator, or the trial staff, employs methods such as teach-back, teach-to-goal or quizzes to evaluate if the participant has understood the content of the informed consent document.<sup>12</sup> They provide feedback to the medical writer based on their discussions with the participants on an ongoing basis, especially if some elements in the document need more clarity.

The informed consent document is periodically revised to ensure that participants remain updated on any change in the trial that may influence their decision to continue participation. When revisions are made to the protocol or to the investigator's brochure, the medical writer will determine if those changes impact the

informed consent document, including those potentially affecting a participant's rights or well-being.

### Conclusion

While there is little doubt that writing good quality informed consent requires skill, time and effort, a medical writer needs to have certain specific skills and experience to present technical terms in plain language.

Compilations of plain language alternatives and definitions of medical and research terms are available from various web resources to describe trial-related information. With experience, a writer becomes more efficient in writing plain language. Having

standardized templates for assents and informed consent documents goes a long way toward improving efficiency and reducing the effort and time spent. However, a writer should consider the application of the standard template texts on a case-by-case basis.

Medical writers liaise with clinical, medical and legal experts while developing informed consent documents. Although a medical writer must juggle regulatory requirements, cultural beliefs and reviewers' preferences, the objective of helping a trial participant make an informed decision and potentially improving the life of a patient in need makes it all worthwhile.

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**Cite as:** Ramesh V. “Writing Informed Consent Documents: a Balancing act.” *Regulatory Focus.* February 2020. Regulatory Affairs Professionals Society.



## Regulatory Affairs Consultants: Who Needs Them and Why



By Steven J. Knapp, MS, PharmD



Andrew S. Verderame, MBA, RAC

This article discusses employing regulatory affairs consultants and offers advice on who needs consultants and why, the “dos and don’ts” of finding, managing and maintaining consultants, how to choose the right consultant with the right background and expertise for the needed tasks and consultant service and pricing models. This article was adapted from a RAPS Convergence presentation held in Philadelphia 21-24 September 2019.

### Introduction

The advent of today’s smaller, virtual, venture-backed start-up companies has created an environment where lean staffing has become the norm rather than the exception. As a result, many companies are opting to have a single, individual regulatory and/or quality compliance person who must be a “Jack-of-all-trades.” As a result, the company often must outsource and rely on external consultants to be the

“masters” of a specific regulatory or scientific area.

Regulatory outsourcing is estimated to be growing at a 10 percent annual rate. It is further estimated that regulatory outsourcing will continue to grow, becoming a \$5.7 billion dollar industry by 2023, up from a \$2 billion dollar industry in 2014.<sup>1</sup> Large, multinationals will likely continue to find areas to outsource anything that is not considered one of the company’s strategically “core” functions. In that respect, smaller companies will look to outsource much of their regulatory tasks and functions by partnering with regulatory service providers.

However, managing consultants is challenging and it is useful to consider some of the recommended advantages and disadvantages of using them. A look at who needs consultants and why, as well as the “dos and don’ts” of finding, managing and maintaining consultants, from a company perspective, is a valuable exercise.

### Who needs consultants and why?

There are a variety of reasons for why a company may want to take on consultants and use them advantageously. The most common reason for hiring a consultant is when an assignment is temporary and there is a need for expertise from someone well-versed in a highly specialized discipline, especially if the company's therapeutic portfolio is dynamic and multi-dimensional. There also may be a need regarding health authority policy, possibly for Capitol Hill expertise or when there is a need for influential thought leaders. During periods of company change or for routine business cycles, there may be a need for routine strategy work or work on annual and periodic reports. On the other hand, there may be a need for drivers of a company's culture change or a need for someone to conduct confidential merger and acquisition due diligence.

Many internal resource constraints, usually based on staffing needs, may encourage companies to "on-board" a consultant. For example, budget issues, employee turnover, leaves of absence or peak workload periods may factor into the decision to seek a consultant. Too, the need for new or special skills sets or specific therapeutic or scientific areas expertise are often drivers for hiring consultants.

However, there are some disadvantages to using consultants. For example, consultants may have difficulty in maintaining relationships or difficulty in ensuring their availability when and where needed. Contracts are required, as is proper budgeting. Some company managers might not be convinced about the added value offered by consultants. Finally, because all companies are different, once a consultant is in place there may be start-up delays allowing for the consultant's "learning curve."

### Considerations for Choosing a Consultant

Regulatory expertise is, of course, at the top of the needs list, so the chosen

consultant should be fully versed in regulatory strategies, perhaps have country-specific knowledge, knowledge of Chemistry, Manufacturing and Controls (CMC), drug/device combinations and regulatory operations knowledge.

Depth of experience as well as specific experience, particularly in a therapeutic area, e.g., generics, biosimilars, orphan drugs or diagnostics, could be extremely valuable.

The reputation of the consultancy company or the reputation of the individual consultant should be carefully considered as well.

For issues of policy and high level strategy, consultants who have formerly been health authority employees probably top the list of useful backgrounds, along with heads of US Food and Drug Administration (FDA) advisory committees. Consultants who were formerly medical school top administrators or those who have worked on in specialized hospital units also may fill the bill, depending on the company's specific needs.

Consultants who have worked on European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) may be quite useful, especially for companies with European distribution. Finally, former FDA quality inspectors or former science Industry leaders, especially those who have research and development experience, can be quite useful.

The quality of communication with the consultancy company and/or the individual consultant is also high on the list for choosing the right firm and consultant. Asking several questions may clarify this issue. How responsive was the consultant or firm to the initial request for a consultant? How quickly was the confidentiality agreement negotiated? Has there already been direct communication with the consultant and does his/her personality seem to provide a good "fit" with the company's corporate culture? What other services does the consulting

firm offer if down-the-road contingencies call for unexpected needs? In other words, what consultancy service models are available from a candidate firm?

### Major Types of Consultancy Service Models

Consultancy service models can be divided into several types, including those for tactical support, preferred providers and strategic partnerships.

- **Tactical support:** used in case of sick leave, maternity leave, hiring freeze or resource shortage. Often used for specific projects, e.g., when the project ends, support ends. Flexible solutions are offered for peaks or when special expertise is required.
- **Preferred provider:** long-term tactical support, ongoing relationships for project-by project approach. Relatively easy to implement and used according to areas of expertise. Many companies have master service agreements and services can be added *ad hoc* when capacity or expertise does not exist in house or for a new project.
- **Strategic partnerships:** mutual collaborations, shared objectives and milestone outsourcing of functions, products, portfolios and regional responsibilities. Discounted pricing for large-volume work.

### Pricing Models

The costs of consultancy can be divided into two models: fixed price and fee-for-service. Fixed price models, which include a fixed price for a deliverable, agreed upon in advance, can provide predictable costs. Cost are generally higher because a “premium” is added as a “risk buffer” for the consultant group. Fee-for-service models will be hourly rates agreed upon for the various roles required for the project. Only actual working hours are charged and the costs are more difficult for the buyer to predict, but reflect the real-time use of resources and lower overall pricing.

## Types of Consultants

### Scientific Consultants

The most common reason for getting scientific consultants onboard is a specific need for a high level of scientific expertise. Some of the most common scientific areas for which consultants may be used are in toxicology, and likely for carrying out toxicokinetic and/or pharmacokinetic studies. A consultant also may be necessary for designing a clinical study and/or conducting one, research for Quality Assurance (QA) or research site initiation. Other scientific needs may be in areas of Chemistry, Manufacturing and Controls (CMC), regulatory affairs, e-submissions, medical and technical writing or regulatory exclusivity and/or for patent counsel.

### Clinical Studies

Clinical studies require unique skill sets the company's current staff may not possess. In order for a company to fully rely on Contract Research Organization (CRO) to handle tasks, it is incumbent on the consultancy company to ensure they can handle and have handled areas such as clinical trial design, which varies by drug treatment, site identification, selection and start-up, investigator training, conduct of actual studies, data-base creation and statistical analyses, safety reporting during study and study report writing.

### Quality Assurance

Quality Assurance (QA) needs within a company can vary widely, depending on the scope of company research. Some roles often carried out by consultants in this area include:

- site initiation and clinical trial monitoring
- internal departmental audits
- preparation for external health authority/notified body inspections
- Standard Operating Procedures (SOP) writing
- company-wide training programs
- vendor auditing/certification

*Consultancy service models can be divided into several types, including those for tactical support, preferred providers and strategic partnerships.*

- Quality Control (QC) analytical work, but not product release

### From the consultancy point-of-view, what makes a good client?

From the consultant's point-of-view, a company can be considered a good client when the company knows exactly what it is looking for when approaching consultants, and can effectively consider pricing estimates from multiple consulting groups. A good client also has a realistic budget, communicates well through a single point of contact, is clear regarding the company's expectations and can reach agreement on methods for dispute resolution should such action be called for. Also, from the consultant's point-of-view, a good client is one who participates in the consultancy process and "co-owns" the timelines and deliverables and, importantly, provides useful feedback. It is also important to remember the company is paying the consultant for the consultant's experience and advice so strongly consider taking the advice. Remember as well, good consultants don't just tell companies what companies want to hear, they tell the truth.

From the opposite view, companies should expect value from their consultants, just as they expect value from their regular employees. Value is much more than just math (e.g., 40 hours/week times 52 weeks/year). But, exactly what *kind* of value should companies expect from consultants? They should expect:

- quick start-ups
- experienced professionals
- timelines and deliverable agreement
- ease in terminating and/or modifying the agreement
- flexibility to add additional resources or meet aggressive deadlines
- possibly a different perspective, ideas for improvement

### When hiring a consultant, does size matter?

Companies looking to hire a consultant (for whatever function or need) must

ask: can this consultant offer what we need? Can they accommodate our requests? Some consultants might be a "one-man band" or "jack-of-all-trades." Such a consultant may come from a small group of consultants comprised or two to five people. Larger consultancy companies may have consultants with varied or specific expertise, as national-level constant groups may number from 10 to 70 individuals. Global consultancy groups may number from 100 to 1000 plus consultants. The size of the consultancy may make a difference depending on the variety of the hiring company's needs.

A general regulatory staff member within a small company is not expected to be a "master-of-all-trades," and neither are most regulatory consultants, who generally have specific niche expertise. As such, companies, especially smaller ones, often will need to rely on external regulatory consultants for expertise in specific or task-oriented areas. These task areas may include work on e-submissions, label development and Structured Product Labeling (SPL), combination products, ad promo review, running meetings with health authorities or writing the "summary/overview" segments of dossiers.

Regulatory strategy needs also vary widely depending on the areas and countries in which the company operates. Strategy roles often "farmed out" to specialty consults include:

- country expertise (for example, the European Union or Asia, such as Japan or China)
- those who have contacts with local health ministries
- those with contacts within specific US Food and Drug Administration divisions
- experience in negotiating "novel" clinical endpoints
- expertise in rare diseases, orphan drugs, fast-track designation or accelerated approval endpoints
- combination products expertise across centers

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*From the consultant's point-of-view, a company can be considered a good client when the company knows exactly what it is looking for when approaching consultants, and can effectively consider pricing estimates from multiple consulting groups.*

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- Center for Food Safety and Applied Nutrition CFSAN experience with natural supplements
- over-the-counter experience (switches or monographs)

### Task and Function Niche

Electronic publishing is a common area ripe for hiring outside consultants and one of the most common area of consultants because publishing is often too dynamic and expensive to keep in house for smaller companies. One advantage of hiring an electronic publishing consultant is not having to maintain trained publishing staff and the apparatus needed for publishing.

Legal counsel is another broad area often covered by a single person in a small company. This staff member may have to reach out to outside law firms to provide insights into a variety of specialized areas, including: patent defense and litigation, ad promo review and its legal liability perspective, Orange Book listing/Abbreviated New Drug Application (ANDA) suitability, exclusivity assessments, assisting with M&A activity, citizen petitions/dispute resolutions and regulation interpretation based on recent case law.

Pharmaceutical development, a broad area covering many disciplines, often requires onboarding a consultant, especially if the company only has one or two employees who are involved in development tasks. Consultants may need to be brought in for:

- stability program design
- resolution of packaging issues
- supply chain issues
- identification of GMP manufacturing sites
- technology transfer/production scale-up
- writing Chemistry, Manufacturing and Controls (CMC) sections of dossiers

CMC areas are complex and critical and, accordingly, are often the single most common source of FDA Com-

plete Response Letters (CRLs), particularly in the ANDA space. Consultants can offer stability when site and batch manufacturing negotiations may be required several years in advance of a submission. In addition, data requirements vary drastically depending of formulation type and delivery system and it may be difficult to find someone with organic chemistry, analytical chemistry and formulations backgrounds. Biologics and other cell-based products present unique challenges because of their three-dimensional structure and the development of bio-assays capable of predicting clinical activity.

### Conclusion and key “Take-Aways”

Using external consultants/resources in regulatory and quality areas is now commonplace in smaller companies and good consultants are an invaluable resource in today’s complex regulatory environment. Fortunately, there is no shortage of regulatory consulting groups from which to choose. However, in choosing the right consultancy group or individual consultant, it is important to make an informed decision, thinking first of value before thinking of cost.

There are advantages and disadvantages to initially and periodically weigh when considering bringing a consultant on board. Selecting the right consultant(s) for specific tasks is complex and there are many things to consider when selecting just the right one. Among the most important questions to ask before taking the final onboarding steps are: has a potential consultant been recommended and vetted? Are they a “known quantity?” Do they have a proven track record of success in the required tasks? Will they be needed “in-house” or will they work remotely? If they will be working on site, how might a consultancy candidate “mesh” with the company’s in-house team? Another consideration is whether a “full service” consulting company, one with consultants who

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*There are advantages and disadvantages to initially and periodically weigh when considering bringing a consultant on board. Selecting the right consultant(s) for specific tasks is complex and there are many things to consider when selecting just the right one.*

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can cover all the “bases” is needed. There are no right answers to who may be the right consultant when it comes time to decide.

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**Cite as:** Knapp S J and Verderame A S. “Regulatory Affairs Consultants: Who Needs Them and Why.” *Regulatory Focus*. January 2020. Regulatory Affairs Professionals Society.



## How to Hire and Engage Consultants for Success



By David W. Husman, PhD,  
ASQ CPGP, RAC

In the regulated industry, consultants are engaged for a variety of activities ranging from manufacturing, to testing, to quality control and quality assurance, to regulatory affairs. This article discusses the types of reasons for which consultants are engaged and how companies can ensure success in executing the engagement. The author emphasizes points such as hiring the right consultant for a specific task, onboarding a consultant, clarifying and communicating expectations regarding specific projects, getting updates from consultants and having a structured project ending to ensure all deliverables have been received.

### Introduction

In the regulated industry, depending on the size of the organization, between 50 and 90 percent of regulatory affairs operations were outsourced in 2019.<sup>1</sup> The Contract Manufacturing Organization (CMO) market alone represents more than \$3.5 billion annually.<sup>2</sup> In today's business climate, choosing the

right consultants for the right reasons can make the difference between positioning the company for success or setting the company up to spend a great deal of money to the frustration of everyone.

Communication within the organization is crucial to achieving success before considering reaching out to hire a consultant. It must be clearly understood what is trying to be achieved, how long it may take to achieve success and what success should look like. When choosing to bring in outside help, it is critical to understand the company will be spending a lot of money and, to achieve the goals, the appropriate time and other resources must be devoted to efficiently utilizing the consultants time.

The following are three primary reasons clients hire consultants:

1. knowledge augmentation
2. specific task execution
3. short term resource supplementation/replacement

## Knowledge Augmentation

When looking to augment the knowledge of an organization, it is critical to both select professionals who possess the requisite knowledge as well as have the ability to clearly and succinctly communicate the knowledge in a manner that members of the organization can receive and utilize it for the long term. The key in selecting the right consultant is to first have a clear concept of what knowledge the organization is lacking and whether there are one or more members of the organization who can both receive instruction and utilize the knowledge brought in from outside the organization. For example, take care to not ask for an advanced level presentation and implementation of a topic without having one or more employees who have a basic understanding of the given topic. This is not to say the company should plan for advanced implementation and not hire consultants with the ability to deliver advanced topics but, rather, recognize what might be more of a “phased” implementation to prepare the organization with the basics before moving on to more involved topics. Developing a comprehensive plan is critical at the onset of the project, one with clearly defined deliverables and timelines and with the assurance all parties understand their roles and the company’s expectations of them.

## Specific Task Execution

Typically, companies bring in outside help to execute specific tasks for one of three reasons:

1. Business need for timely execution of task while not compromising other business operations
2. One-time execution of a task without specific expertise on staff, e.g., construction project
3. Specialized knowledge necessary for compartmentalized task execution, e.g., specific equipment maintenance or calibration

While there may be other reasons than those listed above, companies need to recognize what they are bringing consultants (or temporary staff) in to accomplish, what knowledge and skills they need (specialized or not) and what the endpoint of the task(s) should look like. There must be a plan for how consultants are to be used while on site, what management/oversight will be necessary, what security concerns outside people raise, if any, and where they will be located for work while on site. Additionally, there should be a clear plan for when and how consultants will leave the site once the task is complete. Critical to plan development is a communication plan clearly delineating who needs to receive an overview and the details of the task execution project.

## Short Term Resource Supplementation/Replacement

The final major category for successfully using a consultant is for short-term resource supplementation, or short-term replacement of staff members. Although listed as short-term, these engagements are typically months long. Typical projects range from vacation coverage, to unexpected termination or loss of employees in key positions for which there was no succession plan. It is important for job descriptions and training programs to already be in place. Plans must clearly ensure that these resources receive the appropriate documented “onboarding” and similar training to what permanent employees would receive. While this training can be limited to the specific activities they will be executing, careful planning for activity execution will still determine the success or failure of this category of consultant.

As noted above, companies have a variety of reasons for bringing in consultants for specific task execution—from needing additional “hands,” to needing a specific knowledge set for the short-term or needing to minimize time to completion. While the desires and

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*When looking to augment the knowledge of an organization, it is critical to both select professionals who possess the requisite knowledge as well as have the ability to clearly and succinctly communicate the knowledge in a manner that members of the organization can receive and utilize it for the long term.*

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reasons for bringing in outside help may be good, too often these engagements do not achieve desired outcomes.

Too often, companies focus on the hiring process (typically with too great an emphasis on costs) but spend too little time focusing on the onboarding and engagement process with these new hires. There tends to be a mindset saying “the consultant has done this before, so they just know what to do” without full consideration and complete understanding regarding the uniqueness of each company and each engagement. When looking at typical challenges and failures, they tend to fall into the following categories:

- misalignment of consultant skills with required activities (too junior or too senior)
- unrealistic expectations, e.g., solve all our problems, but don't make any changes)
- inadequate or incomplete requirements, e.g., since you're here, can you also look at this?
- failure of communication both internally and between company and consultant, e.g., hiring authority is not the one managing the consultant and has not communicated what consultant is expected to do
- failure to understand time of commitments (at least initially) of current staff to fully achieve the benefits of the consultant interaction, e.g., if knowledge is to be transferred, time must be spent to achieve the transfer

### How can the likelihood of success be increased?

Before looking for consultants, determine what needs to be accomplished. Clarify and communicate goals and expectations to staff. Clearly communicate to the hiring group which specific needs require a consultant. Specifically, communicate to potential consultants what is to be accomplished.

## Hiring

There must be clear alignment between what is to be accomplished, what resources are required to meet that need and the ultimate consultant(s) engaged.

The US Food and Drug Administration (FDA) lays out some clear requirements for consultants in 21 CFR 211.34 Consultants<sup>3</sup> and 21 CFR 820.50 Purchasing Controls.<sup>4</sup>

### 21 CFR 211.34 Consultants

- Consultants advising on the manufacture, processing, packing or holding of drug products shall have sufficient education, training and experience or any combination thereof to advise on the subject for which they are retained.
- Records shall be maintained stating the name, address and qualifications of any consultants and the type of service they provide.

### 21 CFR 820.50 Purchasing Controls

- Evaluate and select potential suppliers, contractors and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation must be documented.
- Define the type and extent of control to be exercised over the product, services, suppliers, contractors and consultants, based on the evaluation of results.
- Establish and maintain records of acceptable suppliers, contractors and consultants.

Purchasing documents shall include, where possible, an agreement that the suppliers, contractors and consultants agree to notify the manufacture of changes in the product or service so that manufacturers may determine whether the changes affect the quality of a finished device.

To ensure consultants have appropriate education, training and experi-

*Too often, companies focus on the hiring process (typically with too great an emphasis on costs) but spend too little time focusing on the onboarding and engagement process with these new hires.*

*Absence of leadership from management leads to failure nearly 100 percent of the time, whereas fully engaged management throughout the consulting activities contributes to the success of all engagements.*

ence or any combination of those to advise on the subject for which they are retained, companies must know exactly for which subject they plan to retain consultants. This is typically accomplished by either a job description or a specific work order. Misalignment can lead to frustration company staff, failure to execute to achieve the desired outcome, as well as making the company vulnerable to regulatory action.

Records of consultant qualifications are required to be created, maintained and available for review during an inspection to demonstrate that consultants have the appropriate qualifications. These records should clearly demonstrate alignment between consultant's qualifications and the job at-hand.

Agreements should also ensure management is notified in a timely manner of any changes that could potentially impact the company's products. For clinical studies, additional documentation to ensure consultants do not have a financial interest, or other conflicts of interest, in the activities they are providing.

Assuming the right consultant has been engaged for the right activities, how can the company maximize its chances for success?

### Onboarding

Good consultants are going to arrive at the company facility on time and expecting to engage their client and getting up to speed on a client's systems and people as quickly as possible. They recognize the adage of "time is money" and are looking to maximize the client's return on investment by minimizing wasted time and non-value-added activities. They arrive with a "game plan" based on conversations held during the hiring process and will be checking to ensure they are in alignment with the site's expectations and timelines. Clients who have worked out basic logistics, such as making sure there are primary and secondary contacts

identified, established work spaces for the consultant, determined and scheduled any site required onboarding activities (security pass, system access, safety training, etc.) and have scheduled kick-off meetings with key players, are several steps ahead of those who wait to carry out these activities once the consultant is already on site. For engagements associated with regulatory submissions, expect consultants to request a large amount of information to be delivered in a manner that allows for editing—as necessary—to tailor to the submissions. Those who wait to plan typically find time quickly slipping away and the expected benefits are lost or delayed.

### The Engagement

In the experience of this author, the success or failure of the engagement typically comes down to the engagement of senior management. Absence of leadership from management leads to failure nearly 100 percent of the time, whereas fully engaged management throughout the consulting activities contributes to the success of all engagements. A key goal should always be learning what the consultant's "new eyes" and experience bring long-term to the organization. Consultants often hear "you have done this before, that's why I hired you, why do you need to talk to my people?" What many organizations fail to understand is every company is different; they are organized differently, have different systems and have various ways of engaging with employees—from instilling fear to building barricades to active participation. As noted above, good consultants work diligently to minimize their transition from outsider to insider, request a lot of information upfront, ask a lot of questions initially, spend time digesting the information, then propose solutions that will give the organization the best opportunity of success. A "one-size-fits-all" approach is very rarely successful in the long-term.

One should expect a combination of consultants working independently as well as requiring the valuable time of key players within the organization. Failure to allow for, and plan for, each step frequently contributes to delays and frustration for all involved.

### Milestones and Status Updates

Well-defined milestones and periodic updates ensure all parties continue to be aware of the consulting activity's progress and can alert the organization to any impediments to accomplishing the desired outcome. Companies must define the frequency of communication and the types of communication to balance the desire to continuously be aware of the progress of a project, but without causing consultants to spend a significant portion of their time creating non-value-added reports or sitting in endless meetings having little to no positive impact on the consulting activity. Having said that, it is also important to take opportunities to engage in both informal and formal updates. This allows management to determine their operation and the level of engagement or possible "push back" from employees. Updates also allow for changes, as necessary, to ensure success of the engagement.

### Final Deliverables

At the end of the engagement, it is important to have a structured project end to ensure all deliverables have been received, any security passes or system access has been returned/deactivated, as well as giving and receiving feedback. Too often this stage is where engagements go wrong, either from deliverables not providing the expected improvements or deliverables uncovering issues about which the company was either not aware or doesn't want to hear about. Remember, the consultant was hired for their expertise, honesty and assistance, so it is infinitely better to learn about issues while still able to make changes rather than wait until

a regulator uncovers them. If those responsible have been actively engaged with consultants throughout the project, there should be no surprises at the end.

With good engagements, it frequently tempting to extend projects to take on new tasks or initiate new projects. The keys here is to not lose the learnings from above. New tasks require updates to job descriptions or work orders, change in scopes in contracts and revised records to support the alignment of skills and tasks.

**Table 1. Key Success Factors**

- Senior Management engagement at all stages
- Timely and complete Communication – internal and external
- Defined Goals for Consultant
- Alignment between goals and consultant skill sets
- Defined Milestones and deliverables
- Identification of necessary timing including recognition of potentially significant impact on operations
- Detailed plan including process for hiring, onboarding, utilization, deliverables and conclusion

### Conclusion

Consultation, when well-planned, clearly communicated with specific follow-through, has a high probability for success. The adage "if you thought it was expensive to hire a professional, just look what happens when you hire an amateur," is always in play. Engaging the right partners for the right activities increases that probability for success. Choosing the wrong partners for the wrong tasks or failing to clearly communicate to all parties involved, leads to a high probability of failure and disappointment. There must be clear and complete internal communication along with a plan for engaging the consultant.

*Well-defined milestones and periodic updates ensure all parties continue to be aware of the consulting activity's progress and can alert the organization to any impediments to accomplishing the desired outcome.*

- This plan should clearly define an understanding of needs consultant is expected to fulfill.
- There must be a clear match between needs expected to fulfill and expertise and experience of consultant.
- Remember, consultants are not magicians, but also if they are expected to make massive changes, expect pushback from those being changed. If there was no integrity in the underlying data, consultants cannot suddenly transform it into reliable evidence of a quality product.
- Senior management must be actively engaged throughout the project.
- Take time to fully understand the final deliverables, key project learnings and update all records to reflect the end of the engagement.

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**Cite as:** Husman D W. “How to Hire and Engage Consultants for Success.” *Regulatory Focus*. January 2020. Regulatory Affairs Professionals Society.



## Assessing Risk and Strategic Business Decision-Making Without Consistent FDA Enforcement



By Kate Morris Jurcik

This article discusses how regulatory professionals can make benefit-risk decisions with limited Agency guidance materials or enforcement examples. The author concludes that with a scarcity of enforcement letters from FDA in recent years, regulatory professionals must turn to other tools to understand FDA and other government agency issues related to drug promotional activities.

### Introduction

Over the past seven years, there has been a steady decline in the number of FDA enforcement letters pertaining to the advertising and promotion activities for prescription drug products.<sup>1</sup> At the same time, the Office of Prescription Drug Promotion (OPDP) have issued guidance documents to provide a framework for industry to address many current issues we face in today's environment.<sup>2</sup> Some of these issues aligned with the rise of social media platforms, evolving technology and

recent case law which has prompted the government to document a position on data that is consistent with—but not found within—the approved prescribing information. Thus, it has become a clever 'game of chess' for industry as the 'heat' of the competitive landscape continues to intensify across various therapeutic areas. How should industry be thinking at a time like this? How should regulatory experts thoughtfully advise our business partners in such a way to keep public health at the forefront of each decision while balancing the need to get the right information to the right audience and, at the same time, ensure not "tipping the scale" into an area that may inadvertently trigger a violation?

### Setting the Scene

As of 9 December 2019, OPDP had issued nine enforcement letters located conveniently on their [website](#) for review.<sup>3</sup> Of those nine enforcement letters, seven were of the lesser of the two

Figure 1. In Review: OPDP Enforcement Letters



enforcement types, called an “Untitled Letter,” and two were the more severe type, called a “Warning Letter.” The major violations called out were what those in the industry may call “low hanging fruit,” meaning they seem, at least on the surface, to be obvious violations or “regulatory 101” violations. These included but are not limited to:

- omitting significant safety concerns
- unapproved uses
- unsubstantiated efficacy claims

With that analysis, it makes it fairly easy to inform business partners as to avoiding the “obvious” risks which are the easier things to identify. What makes these easier to identify is that they are either spelled out directly in the Code of Federal Regulations (21 CFR 202.1)<sup>4</sup> or there is a comprehensive FDA guidance document that addresses them with little room for interpretation.

For example, it is probably not the best idea to create a chart directly comparing the efficacy of “*drug x*” to the efficacy of “*drug y*” without a head-to-head comparative study. However, adding another layer of complexity, there are two relatively new guidance documents for industry outlining a pathway to provide data consistent with but not found within the prescribing in-

formation. What now? What about real-world data that looks at the outcomes of patients taking *drug x* vs. *drug y*? Can that be used? If so, what exactly can be claimed in promotion? If the study is sound, what type of disclosures would be required to ensure the data are not misleading? What type of audience is appropriate for this information? Could it be more appropriate for a formulary decision-maker vs. a prescriber? Or is this exactly the type of information prescribers need because the original comparator used in the clinical study is vastly outdated and no longer relevant to the current treatment landscape?

### Current Guidance

Currently, the most talked about FDA guidance to industry in the area of advertising and promotion of prescription products are *Medical Product Communications That are Consistent With the FDA-Required Labeling* (often called the CFL guidance) and *Drug and Device Manufacturer Communications with Payors, Formulary Committees and Similar Entities* (often called the payer guidance) both issued in June 2018.<sup>5,6</sup> Aside from setting the foundation for the type of data that can be provided if it meets the criteria laid out within the guidance, the documents expand

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*Regulatory professionals must invest by engaging with leadership to gain a firm understanding of top-level business goals. This will lead to a greater understanding of what key tactics and messages will 'ladder up' to meet those goals.*

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the possibilities for a host of data with varying sources. The company's marketing colleagues went to work immediately finding areas to strengthen the story of our respective products by providing additional information that is not found in product labeling. The evaluation of whether this data was consistent with labeling guidance falls not only on the trifecta of the medical, legal and regulatory review team, but necessitates additional team members who only see the review room a few times a year or never. These subject matter experts may include biostatistics, health outcomes research, clinical development and others depending on the type of data requested. Unfortunately, these subject matter experts are not as familiar with FDA regulations and guidance for the promotion and advertising of prescription products. This makes the leadership role of the regulatory reviewer even more pronounced and puts a spotlight on our ability to train, manage business expectations, problem solve and think more broadly than in the past.

### **Evolution of the Regulatory Reviewer**

The regulatory advertising and promotion role is evolving due to limited OPDP enforcement, an increasing crowded marketplace, an uptake in the Office of Inspector General (OIG) for the Department of Justice inquiries and enforcement and the issuing of the latest FDA guidance to industry. In order to be effective and add value to our organizations, regulatory professionals need to be viewed by colleagues as strategic leaders and shed the misperception that regulatory is a barrier. What we need is a seat at the table, and that seat is earned. By table, it is not only as a reviewer in the promotional review process but inclusion as a strategic business partner in other aspects of company planning and drug development activities. Regulatory professionals need to know a lot more

information at an earlier time point to make educated benefit-risk assessments when it comes to evaluating promotional messaging. This kind of input may be critical as the organization determines how to prioritize data within product labeling and a strategy for labeling negotiations. There also may be data that does not meet FDA standards for inclusion in the product label but would effectively align with the CFL guidance. This is yet another example of how the role is evolving.

Regulatory professionals must invest by engaging with leadership to gain a firm understanding of top-level business goals. This will lead to a greater understanding of what key tactics and messages will 'ladder up' to meet those goals. The information serves as a backdrop to dive into the current competitive landscape and develop a baseline of how industry colleagues have interpreted FDA guidance and the type of data that is being used in product differentiation. This also requires tracking the current enforcement landscape by FDA and other government agencies, reviewing content from labeling negotiations and maintaining a memory vault of previous FDA advisory comments if received. This collective of information is the foundation to becoming a strong business partner through a regulatory lens.

Equally important is understanding the risk threshold of the organization and who makes the ultimate decisions when it comes to advertising and promotional activities. This will level set the review team and provide accountability across the organization. In this capacity, regulatory experts serve as advisors providing multiple options with tiered approaches to minimize and mitigate risk. These discussions are not black and white (in this area they rarely are). There may be several ways to approach the situation at-hand and, therefore, securing a reliable network of other regulatory advertising and promotion experts can be affirming. Regu-

latory professionals have such a unique role, one often subjective in nature, it is okay to pause, pressure test and align on the topic (limiting detail to protect confidentiality) with colleagues in industry. In the end, regulatory professionals need to be confident that the advice they provide meets the standard of truthful (medically accurate) and not misleading advertising and promotion.

### Conclusion

With a scarcity of enforcement letters from FDA in recent years, regulatory professionals must turn to other tools to understand FDA and other government agency ‘hot buttons’ related to drug promotional activities. FDA guidance documents are useful tools for providing a window into FDA thinking on various topics, such as interactive social media platforms, communication of data not found within the US Prescribing Information and how to appropriately provide payor communications. FDA social science research also provides insight into topics FDA finds important (how different audiences interpret major risk statements; how consumers and HCPs interpret common terms and phrases in drug promotion and other aspects of consumer behavior<sup>7</sup> Tapping into a reliable regulatory network is a way of benchmarking how organizations approach and assess areas of potential risk. Thinking more broadly can help regulatory professionals who focus on advertising and promotion better navigate the day-to-day risk issues, even without the benefit of consistent FDA enforcement action, ultimately serving to provide informed guidance to our colleagues and business partners.

*Thinking more broadly can help regulatory professionals who focus on advertising and promotion better navigate the day-to-day risk issues, even without the benefit of consistent FDA enforcement action, ultimately serving to provide informed guidance to our colleagues and business partners.*

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**Cite as:** Jurcik K M. "Assessing Risk and Strategic Business Decision-Making Without Consistent FDA Enforcement." *Regulatory Focus*. December 2019. Regulatory Affairs Professionals Society.



## Transitioning Between Medical Writing and Regulatory Affairs in a Contract Research Organization



By Kate Forte, MSc

This article discusses transitioning from medical writing to regulatory affairs within a Contract Research Organization (CRO). Both roles are summarized and the similarities and differences between these two areas discussed. The author highlights why one might want to make the change in either direction and from her own transition experience, offers helpful hints for success.

### Introduction

In the pharmaceutical industry, working in the regulatory field offers many possibilities for horizontal career changes. Depending on one's experience and goals, one may be able to fit into any number of niches with many opportunities to move between different areas of focus, even without specific experience in the area you may be interested in entering. I made the transition from medical writing for individual studies to regulatory affairs, where I now look

after products worldwide. The move was a little scary, but it worked.

### The Beginning: Medical Writing

There are two main divisions within medical writing—regulatory medical writing, which is the subject of this article—and medical communications, which is more involved in “deliverables,” such as scientific articles and, accordingly, will not be discussed here.

On my first day as a medical writer, I was told medical writing is about three things: clarity, consistency and an “unhealthy obsession” with grammar rules. A medical writer can be involved at both pre and postmarketing stages and also may be involved at the study level, including the authoring clinical study protocols, Clinical Study Reports (CSRs) and safety narratives. The medical writer also may work at the product level, including the authoring of Development Safety Update Reports (DSURs)/annual reports, and Period Safety Update Reports (PSURs). There

Table 1. Key Skills

Writing Clarity and Thought	Expectation Management
Consistency	Mediation
Listening, Asking and Persuasion	Project Knowledge and Management

is great scope within medical writing, whether one wants to either specialize in one or two document types (such as CSRs or DSURs) or have a broader range of experience.

Clarity of writing and thought is important to the task. You need to be able to get your point across clearly and using plain language, even if the document you are writing is for a regulatory authority who might not be an expert in that specific therapeutic area or drug class you are writing about.

Consistency also is required. If you use inconsistent terms or phrases, you may confuse the reader and risk their misunderstanding. For example, switching between “subject” vs. “patient” may give the impression you are referring to two separate groups when you are not. It is also a much more pleasant experience to read a consistently worded document.

Listening and persuasion are key skills. The ability to listen to a client and understand what they want and “where they are coming from” is critical. Ask questions and persuade them to accept your viewpoint if you are suggesting a better or more effective way to perform a task. For example, you may have to convince a client that a 10-page, prior medications table may be better placed post-text with an in-text reference rather than in-text.

Become adept at “expectation management.” Clients often have very high expectations of what can be done in a certain allotted time period. Part of medical writing is knowing when timelines are too short or there is too much for one writer to handle. Being able to discuss this openly with clients is important. For example, honestly explaining why trying to turn around a

CSR within two weeks will negatively impact quality when a normal process takes 30 days plus. If you are reasonable in your objections, you can find middle ground.

Mediation is important. Client teams will have disputes and you may have to manage clients through them. For example, whether a particular series of figures belongs in-text in a CSR or in a post-text may be an issue. Allowing all parties to air their opinions or concerns is important, but you also have to be able to offer your own opinion and come to a mutually agreeable decision. In the previous example, the issue was resolved by explaining that a hyperlink would be placed in-text so that readers could immediately access the figures.

Project knowledge and management are critical. Organization and time management skills are necessary to get source documents and other support materials you need to get the work done accurately and within timelines. One also needs knowledge of the project, the therapeutic area, the client and internal teams, the contract and all relevant guidelines to be followed, which are usually the [International Council for Harmonisation \(ICH\)](#).

### The Change: Regulatory Affairs

I was not sure what to expect when I started working as a global regulatory affairs associate as I had no previous experience. Regulatory affairs supports the global lifecycle of a pharmaceutical product, preparing submission packages based on information provided internally by local regulatory affairs or by pharmaceutical clients. Coordination and information management is a large part of the job, with deliverable types ranging from the rollout of company

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core data sheet updates to relevant countries, to new marketing authorization applications. What I have learned is the position involves balancing a variety of different tasks. For example, to complete a variation submission requires authoring or requesting submission documents, creating the package, liaising with local RA and the client, making sure internal teams to get the required information, coordinating the final submission via the required pathway (specific country requirements or central such as the Central European Submission Portal), following up with stakeholders at all stages to track progress, meeting internal and external timelines and carrying out the maintenance of client/internal systems for tracking submissions.

Many of the skills are complimentary to medical writing, but the required knowledge is somewhat different. For regulatory affairs, one needs an in-depth knowledge of regulatory guidelines or at least a knowledge of where to find them. [ICH Guidance, Eudralex Volume 2: A, B and C](#), the [Quality Review of Documents Template](#), [Coordination Group for Mutual Recognition and Decentralized Procedures Guidances](#) are all available resources. They provide solid grounding in the basics of regulatory affairs and valuable source for new and seasoned regulatory affairs professionals.

### A Comparison

Within the CRO world, both roles are a contracted service. In my experience, medical writing and regulatory affairs interacted only situationally when requesting or delivering safety deliverables (DSURs, PSURs, risk management plans, etc.) for submission. But this may not always be the case.

While the two roles are similar, as they require meetings and interactions with clients and other internal or external parties, management of expectations, attention to detail, patience and strict adherence to guidelines and regu-

lations, there are some key differences. Medical writing generally consists of multiple individual deliverables. You can have a series of related documents (such as linked CSRs or a DSUR program), but they will be mostly self-contained with “lessons learned” between documents in a program. For example, a mistake in analysis in one CSR probably does not impact an upcoming CSR and, if it does, there is generally time to correct it prior to CSR drafting. Regulatory affairs is much more interconnected, where a change or the discovery of a mistake in one document, a summary of product characteristics/product information missing a contraindication, for example, can cause problems across all submissions for that product, resulting in the need for the submission multiple variations across multiple countries.

However, clarity of writing, consistency, listening, asking, persuasion, expectation management, mediation and project knowledge and management skills—all gained as a medical writer—will be of benefit in a transition to regulatory affairs because of the similarities between the roles as outlined above. Clarity and consistency will assist the client and the health authority assessors in reviewing and understanding the submitted documents. The ability to listen, ask questions and persuade will enable you to see your client’s point-of-view, but also to offer suggestions if, for example, you feel that the variation type selected for a submission is incorrect. In that instance, it would be your job to explain your position, using evidence from the variation guideline. Expectation management and mediation will help when there is disagreement within or across clients or internal teams (for example, on what variation type to choose for a submission). Project knowledge and management will give you confidence both to provide suggestions and assure the deliverable is on track. Once the regulatory affairs specific knowledge is

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in place ([EMA guidances](#), etc.), these skills could be highly transferable when interacting with clients, especially in the preparation of documents such as clinical overviews and in the actual variation submission process.

### Summary

The regulatory field is very open to movement within different areas. It allows a new entrant or even an “old hand” to either dive deeper and deeper into a specific area to become an expert or to move around and build a broad base of experience. I have found challenges moving from medical writing to regulatory affairs, but this change has given me a more holistic insight about where medical writing fits into the lifecycle of a product and how it and regulatory affairs complement one another.

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**Cite as:** Forte K. “Transitioning Between Medical Writing and Regulatory Affairs in a Contract Research Organization.” *Regulatory Focus*. August 2019. Regulatory Affairs Professionals Society.



# Professional Development: Benefits of Obtaining Professional Qualifications



By Orin Chisholm, GCULT,  
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This article discusses the benefits of formal qualifications for a regulatory career and highlights some of the English-language Master’s-level courses offered globally.

### Introduction

Many national governments today have policies in place to foster growth of the medical technology and biopharmaceutical industry to contribute to the new knowledge economy. As the industry grows, organizations continue to face increasing pressure to find and retain talented and suitably qualified staff across a range of functions involved in the discovery and development of new therapeutics. This is especially pertinent to the regulatory affairs function. The skills gap for suitably qualified staff can be addressed by graduate programs delivered by higher education providers.

### Benefits of Education and Professional Development for Organizations

Increasingly organizations in the therapeutics industry are developing

as “learning organizations” and as such they value creating, acquiring, interpreting, transferring and retaining knowledge, which leads to a competitive advantage for the organization.<sup>1</sup> As the learning organization evolves, higher education providers are increasingly partnering with industry to identify workforce needs and develop appropriate courses to meet these needs. As therapeutics become more complex, the clinical and regulatory environments become more complicated, pricing environments become more restrictive and demands from patients and healthcare providers for new therapeutics increase, universities can provide a unique environment where individuals with disparate backgrounds can come together to discuss new approaches to both the opportunities and risks facing the industry.

Organizations that measure the benefits of education, training and professional development of their staff find increases in productivity improve-

*Lifelong learning is an important aspect to employees maintaining currency and competitiveness in the business environment affecting the pharmaceutical industry today. A highly educated workforce is essential to being able to deliver agile, innovative thinking to develop new processes and frameworks around complex, novel therapeutic products coming through development.*

ment, organizational performance, sales or revenue, and overall profitability accruing from such activities, particularly when external education is supported and aligned with the company performance management system.<sup>2</sup> In addition, the organization's support of training, education and development can have an impact on its reputation as a favourable place to work.

Lifelong learning is an important aspect to employees maintaining currency and competitiveness in the business environment affecting the pharmaceutical industry today.<sup>3</sup> A highly educated workforce is essential to being able to deliver agile, innovative thinking to develop new processes and frameworks around complex, novel therapeutic products coming through development.<sup>4,5</sup>

Skilled regulatory professionals are in short supply in some regions and companies can no longer rely on just on-the-job training to meet their needs for professional development of regulatory staff with the increasing body of knowledge required to work effectively in this field.<sup>6,7</sup> Employers can create a supportive environment for staff wanting to pursue personal and career development by embedding a culture of learning in their workplace and encouraging staff to undertake further learning.<sup>8</sup>

The World Economic Forum suggests that the creation of relevant programs and courses developed in partnership with universities that have appropriately qualified teaching staff can facilitate the needs of industry for workforce reskilling.<sup>9</sup> Furthermore, the opportunity to learn in new and different ways and environments directly correlates to enthusiasm and inspiration of staff in the workplace. It improves staff morale, raises the bar for performance and pushes the organization to constantly improve.

Investing in professional development of employees helps them feel valued and that their employer is

willing to help them reach their full potential. It also allows employees to be more aware of changing trends and directions in their industry.<sup>10</sup>

### Benefits of Education and Professional Development for Individuals

As the industry grows, organizations continue to face increasing pressure to find and retain talented and suitably qualified staff. With tighter budgets and less time to develop in-house training resources, an optimum method companies can use for retaining talented staff is to provide access to external training by way of educational benefits such as paying for part of all of a relevant degree. With the emphasis on new ideas, futures thinking, research and development that occurs in universities and new approaches to educational pedagogy, they are in a unique place to deliver the cutting-edge training needed for staff involved in innovative approaches to therapeutic product development and regulation.

Training and development have a positive impact on the performance of individuals in an organization through acquisition of new knowledge and skills.<sup>11</sup> Declarative, procedural and strategic knowledge can all be enhanced by training. With an increase in PhD-qualified staff entering the industry, in-depth education and knowledge of the pharmaceutical industry and the regulatory function is required on top of the deep product and therapeutic area knowledge already obtained from postgraduate research degrees.<sup>12</sup> It is therefore beneficial for such incoming staff to undertake further formal education in regulatory affairs and pharmaceutical medicine. Graduate programs can be used to provide lifelong opportunities to support mid-career transitions. For example, staff wanting to transition into regulatory affairs from other internal functions such as clinical research, medical information or quality assurance.

Self-efficacy and self-management are enhanced as participants in academic programs learn to manage competing priorities of work, family and study. Cultural awareness can be enhanced by participating in formal education as participants need to interact with other students from varying backgrounds, who, as higher education becomes more global, are living in other countries. Indeed, many of these aspects are now emphasised in the learning outcomes (such as advanced disciplinary knowledge and skills and communication, adaptive and interactional skills) for academic programs.<sup>13</sup>

Different levels of competence are required at different levels of career progression in regulatory affairs and continual professional development can facilitate progression through these career levels.<sup>14</sup> For example, the RAPS Regulatory Competency Framework and Guide<sup>15</sup> has a hierarchy of knowledge and understanding of scientific and health concepts at different career stages, including:

- Level I—understands scientific and health principles related to healthcare product development and regulations
- Level II—keeps abreast of and assesses the scientific and/or clinical advances that impact healthcare product development and regulation
- Level III—remains up-to-date on scientific and clinical advances that impact healthcare product development and assesses the relationship to regulation and regulatory issues
- Level IV—serves as a thought leader in the understanding and application of evolving basic and translational science, regulatory science and public health to develop new approaches to improve the development, review and oversight of healthcare products and identifies and proactively responds to scientific and/or clinical advances that impact healthcare product development and regulation

Different levels of formal courses in regulatory affairs can address these levels; for example, an introduction to regulatory affairs course that provides a basic understanding of the development process for new therapeutic products, how a product navigates through clinical trials and regulatory approvals and how it is funded might be suitable for the development of skills and knowledge for the early levels of a regulatory affairs career. Courses covering more advanced topics such as regulatory intelligence, international regulatory affairs, leadership in regulatory affairs and how regulatory staff can strategically influence the regulatory landscape to ensure it is fit for purpose as new challenges to regulatory decision-making arise may be of more benefit to staff in the higher levels of their career progression.

At an individual level, university education provides an opportunity for individuals to gain personal fulfilment, challenge themselves and develop the self-confidence to advance their career. It can be difficult in the day-to-day busyness of work to stop and take time to consider big picture issues, where an individual's role fits into the whole therapeutic product development process, how the future of regulatory science is evolving and what one may need to ensure skills and knowledge are up to the task to meet future career requirements. Taking time for formal study can provide this opportunity.

Obtaining a relevant higher degree can differentiate the individual in the marketplace and show potential and current employers one's commitment to the field of expertise and openness to new ideas. Furthermore, participation in formal education expands the individual's network, which can lead to future career opportunities, invitations to join consultative committees

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*Different levels of competence are required at different levels of career progression in regulatory affairs and continual professional development can facilitate progression through these career levels.*

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and develop regulatory expertise by participating in high-level discussions and negotiations with government and other stakeholders regarding regulatory policy direction, in one's own country and internationally.

### Master's-Level Courses

There are many Master's-level coursework programs available through universities globally (Table 1). Some courses specifically cover just regulatory affairs and in other cases, there is a concentration of regulatory affairs subjects within the program. Some are offered fully online, others face-to-face or mostly online with residential periods as well. In addition, there are many other shorter programs, such as graduate certificates, available through both universities and private providers. University-level programs must comply with strict quality assurance requirements for their programs, undergo periodic academic reviews and meet relevant government standards for the courses they offer. This provides assurance of the quality of courses offered

by universities, whether they are fully online, face-to-face or a hybrid of these forms of education. International students may be able to take a full degree program from their home country. The mixture of courses and the emphasis of the subjects within each Master's program are often determined by the expertise of the faculty teaching into the program. In some cases, potential students apply for recognition of prior learning to be counted toward their degree or they may be able to undertake individual subjects without committing to a full Master's degree. They also may be able to take subjects from other providers and have them credited toward their degree. Universities also may offer research degrees in regulatory science including Master by research, professional doctorates (e.g., DRSc, DrPH) or PhD studies. Potential students should review programs on offer and determine their individual educational needs, often during discussions on professional development with their managers, before choosing the appropriate program for their needs.

Table 1. CMMI Development Model Version 2.0 Appraisal Practice Areas for FDA's Case for Quality Voluntary Pilot Program

Region	University	Name of Degree	Offering Mode	Website
Asia-Pacific	UNSW Sydney, Australia	Master of Pharmaceutical Medicine	online	<a href="https://med.unsw.edu.au/pharmaceutical-medicine">https://med.unsw.edu.au/pharmaceutical-medicine</a>
	University of Queensland, Australia	Master of Pharmaceutical Industry Practice	F2F	<a href="https://future-students.uq.edu.au/study/program/Master-of-Pharmaceutical-Industry-Practice-5703">https://future-students.uq.edu.au/study/program/Master-of-Pharmaceutical-Industry-Practice-5703</a>
	University of Sydney, Australia	Master of Medicine (Pharmaceutical and Medical Device Development)	F2F, online	<a href="http://sydney.edu.au/courses/master-of-medicine-pharmaceutical-and-medical-device-development">http://sydney.edu.au/courses/master-of-medicine-pharmaceutical-and-medical-device-development</a>
Europe	King's College London, UK	Master of Science in Drug Development Science	F2F	<a href="https://www.kcl.ac.uk/study/postgraduate/taught-courses/drug-development-science-msc-pg-dip-pg-cert">https://www.kcl.ac.uk/study/postgraduate/taught-courses/drug-development-science-msc-pg-dip-pg-cert</a>
	PME Institute, University of Duisburg-Essen, Germany	Master of Science in Pharmaceutical Medicine	F2F	<a href="http://www.pme-institute.com/index.php?id=112">http://www.pme-institute.com/index.php?id=112</a>
	TOPRA/ validated by University of Hertfordshire, UK	Master of Science in Regulatory Affairs	F2F	<a href="https://www.topra.org/TOPRA/TOPRA_Member/mscra/MSc_Regulatory_Affairs.aspx">https://www.topra.org/TOPRA/TOPRA_Member/mscra/MSc_Regulatory_Affairs.aspx</a>

Table 1. (continue)

Region	University	Name of Degree	Offering Mode	Website
Europe	Trinity College Dublin, Ireland	Master of Science in Pharmaceutical Medicine	F2F	<a href="https://www.tcd.ie/medicine/pharmacology-therapeutic/postgraduate/msc/">https://www.tcd.ie/medicine/pharmacology-therapeutic/postgraduate/msc/</a>
	University of Basel, Switzerland	Master of Science in Drug Sciences	F2F	<a href="https://www.unibas.ch/en/Studies/Degree-Programs/Degree-Programs/Drug-Sciences.html">https://www.unibas.ch/en/Studies/Degree-Programs/Degree-Programs/Drug-Sciences.html</a>
		Master of Advanced Studies in Medicines Development		<a href="http://web.ecpm.ch/master">http://web.ecpm.ch/master</a>
	University of Claude Bernard Lyon, Eudipharm, France	Master of Science in Pharmaceutical Medicine	F2F	<a href="https://www.pharmatrain.eu/diploma-master.php?id=8">https://www.pharmatrain.eu/diploma-master.php?id=8</a>
North America	Arizona State University	Master of Science in Clinical Research Management (Regulatory Science)	online	<a href="https://asuonline.asu.edu/online-degree-programs/graduate/master-science-clinical-research-management-regulatory-science/">https://asuonline.asu.edu/online-degree-programs/graduate/master-science-clinical-research-management-regulatory-science/</a>
	George Washington University	Master of Science in Health Sciences in Regulatory Affairs	online	<a href="https://healthsciencesprograms.gwu.edu/program/the-george-washington-university-regulatory-affairs-master-master-of-science-in-health-sciences-1527569596782">https://healthsciencesprograms.gwu.edu/program/the-george-washington-university-regulatory-affairs-master-master-of-science-in-health-sciences-1527569596782</a>
	Johns Hopkins University	Master of Science in Regulatory Science	F2F, online	<a href="https://advanced.jhu.edu/academics/graduate-degree-programs/regulatory-science/">https://advanced.jhu.edu/academics/graduate-degree-programs/regulatory-science/</a>
	Keck Graduate Institute	Master of Business and Science (Clinical and Regulatory Affairs)	F2F	<a href="https://www.kgi.edu/academics/henry-e-riggs-school-of-applied-life-sciences/academic-programs/master-of-business-and-science/concentrations/">https://www.kgi.edu/academics/henry-e-riggs-school-of-applied-life-sciences/academic-programs/master-of-business-and-science/concentrations/</a>
	Long Island University	Master of Science in Drug Regulatory Affairs	F2F	<a href="http://www.liu.edu/Pharmacy/Academic-Programs/Graduate/MS-Drug-Regulatory-Affairs">http://www.liu.edu/Pharmacy/Academic-Programs/Graduate/MS-Drug-Regulatory-Affairs</a>
	Massachusetts College of Pharmacy and Health Science	Master of Science in Regulatory Affairs and Health Policy	F2F, online	<a href="https://www.mcphs.edu/academics/school-of-pharmacy/regaff-pharmeco-healthpolicy/regulatory-affairs-and-health-policy-ms">https://www.mcphs.edu/academics/school-of-pharmacy/regaff-pharmeco-healthpolicy/regulatory-affairs-and-health-policy-ms</a>
	Northeastern University	Master of Science in Biotechnology (Regulatory Science concentration)	F2F, online	<a href="https://cos.northeastern.edu/biotech/academics/ms-biotechnology/concentrations/">https://cos.northeastern.edu/biotech/academics/ms-biotechnology/concentrations/</a>
		Master of Science in Biotechnology Innovation and Regulatory Science		<a href="https://sps.northwestern.edu/masters/regulatory-compliance/index.php#Regulatory%20Compliance%20Curriculum%20&amp;%20Program%20Tracks">https://sps.northwestern.edu/masters/regulatory-compliance/index.php#Regulatory%20Compliance%20Curriculum%20&amp;%20Program%20Tracks</a>
	Purdue University	Master of Science in Biotechnology Innovation and Regulatory Science	F2F, online	<a href="https://polytechnic.purdue.edu/degrees/ms-biotechnology-innovation-regulatory-science">https://polytechnic.purdue.edu/degrees/ms-biotechnology-innovation-regulatory-science</a>
	Rutgers, State University of New Jersey	Master of Business and Science (drug discovery and development)	F2F, online	<a href="https://mbs.rutgers.edu/program/drug-discovery-development-online">https://mbs.rutgers.edu/program/drug-discovery-development-online</a>
	San Diego State University	Master of Science in Regulatory Affairs	online	<a href="https://regsci.sdsu.edu/">https://regsci.sdsu.edu/</a>
St. Cloud State University	Master of Science in Regulatory Affairs and Services	F2F, online	<a href="https://www.stcloudstate.edu/graduate/regulatory-affairs/default.aspx?utm_source=website&amp;utm_medium=redirect">https://www.stcloudstate.edu/graduate/regulatory-affairs/default.aspx?utm_source=website&amp;utm_medium=redirect</a>	
St. John's University	Master of Science in Pharmacy Administration	F2F	<a href="https://www.stjohns.edu/academics/programs/pharmacy-administration-master-science">https://www.stjohns.edu/academics/programs/pharmacy-administration-master-science</a>	

Table 1. (continued)

Region	University	Name of Degree	Offering Mode	Website
North America	Temple University	Master of Science in Regulatory Affairs and Quality Assurance	online	<a href="https://www.temple.edu/pharmacy_qara/">https://www.temple.edu/pharmacy_qara/</a>
	University of Florida	Master of Science in Pharmaceutical Outcomes and Policy (Pharmaceutical Regulation speciality)	F2F, online	<a href="https://onlinepop.pharmacy.ufl.edu/programs/degrees-and-certificates/masters-degree/">https://onlinepop.pharmacy.ufl.edu/programs/degrees-and-certificates/masters-degree/</a>
	University of Maryland	Master of Science in Regulatory Science	online	<a href="https://www.pharmacy.umaryland.edu/academics/regulatoryscience/">https://www.pharmacy.umaryland.edu/academics/regulatoryscience/</a>
	University of Pennsylvania	Master of Regulatory Affairs, Master of Regulatory Science	F2F	<a href="http://www.itmat.upenn.edu/mra.html">http://www.itmat.upenn.edu/mra.html</a> , <a href="http://www.itmat.upenn.edu/msrs/">http://www.itmat.upenn.edu/msrs/</a>
	University of Southern California	Master of Science in Regulatory Science, Management of Drug Development, Medical Product Quality, or Regulatory Management	F2F, online	<a href="https://regulatory.usc.edu/programs/">https://regulatory.usc.edu/programs/</a>
		Doctor of Regulatory Science (DRSc)		
	University of Washington	Master of Science in Biomedical Regulatory Affairs	F2F	<a href="https://www.regulatoryaffairs.uw.edu/">https://www.regulatoryaffairs.uw.edu/</a>

For other courses, also see the RAPS website under Publications and Resources; [University Degrees and Certificates](#).

## Conclusion

There are many benefits to the individual and the organization from staff undertaking formal education, training and development in their field and many opportunities to increase the skills development of regulatory affairs personnel as therapeutic products increase in complexity.

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**Cite as:** Chisholm O. "Professional Development: Benefits of Obtaining Professional Qualifications." *Regulatory Focus*. August 2019. Regulatory Affairs Professionals Society.



By Amaris Ajamil, PhD, RAC

## Regulatory Leadership for a Culture of Quality in the US Medical Device Industry

This article discusses governance and implementation infrastructure as critical factors in cultivating a culture of quality and building the necessary trust employees may need to help achieve it. The author outlines the critical attributes of a culture of quality, explains how such a culture can be built, the benefits it offers and touches on the roles played by regulatory/quality professionals in leading the effort to build quality.

### The Case for Quality

In 2011, the US Food and Drug Administration (FDA), in partnership with the Medical Device Innovation Consortium (MDIC), launched the “Case for Quality Initiative.” This initiative sought to shift the mindset of the medical device manufacturer from mere regulatory compliance to true product quality.<sup>1</sup> True product quality dismisses the notion that quality activities are just “boxes” to check but, rather, focuses on continuous improvement

of processes to consistently yield safe and effective products. To demonstrate how an increased focus on true quality can benefit all stakeholders, including industry, patients, payers, providers and others, in 2018, FDA invited medical device manufacturers to participate in a voluntary pilot program. As part of the program, participants agreed to an appraisal of their organizational practices and committed themselves to further innovate their quality practices. In return, the participants experienced streamlined engagements with FDA and reduced surveillance and inspections (**Figure 1**).<sup>2</sup> The appraisal was conducted by a certified, third-party against an adapted Capability Maturity Model Integration (CMMI) model. The CMMI appraisal model used for this pilot focused on 11 practice areas which, together, provide a holistic view of an organization’s approach to true quality (**Table 1**).

In September 2019, FDA released a report detailing the successes of the

Figure 1. FDA's Case for Quality: CDRH Pilot Details

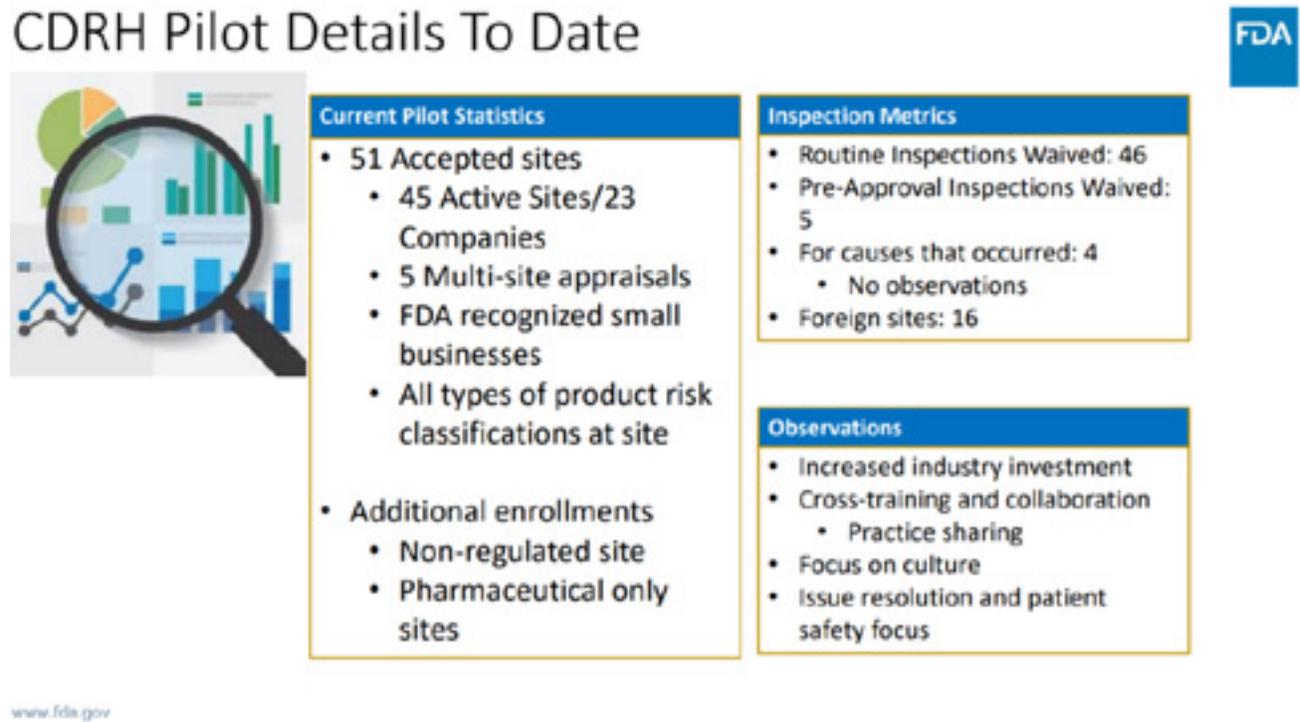


Table 1. CMMI Development Model Version 2.0 Appraisal Practice Areas for FDA's Case for Quality Voluntary Pilot Program

Practice Area	Description
Configuration Management	Manage the integrity of work products using configuration identification, version control, change control and audits.
Estimating	Estimate the size, effort, duration and cost of the work and resources needed to develop, acquire or deliver the solution.
Governance	Provides guidance to senior management on their role in the sponsorship and governance of process activities.
Implementation Infrastructure	Ensure the processes important to an organization are persistently and habitually used and improved.
Managing Performance and Measurement	Manage performance using measurement and analysis to achieve business goals.
Monitor and Control	Provide an understanding of the project progress so appropriate corrective actions can be taken when performance deviates significantly from plans.
Planning	Develop plans to describe what is needed to accomplish the work within the standards and constraints of the organization.
Process Quality Assurance	Verify and enable improvement of the quality of the performed processes and resulting work products.
Product Integration	Integrate and deliver the solution that addresses functionality and quality requirements.
Requirements Development and Management	Elicit requirements, ensure common by stakeholders and align requirements, plans and work products.
Technical Solution	Design and build solutions that meet customer requirements.

Figure 2. FDA's Case for Quality: Pilot Impact Metrics



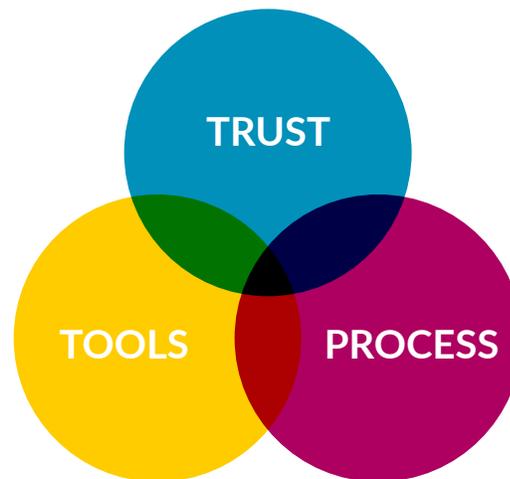
pilot program with the recommendation that the pilot be converted into a fully operational program for the US medical device industry.<sup>3</sup> Notable achievements, such as an 11 percent increase in production capacity, a 21-day reduction in change implementation and a reduction in defects were observed across pilot participants (Figure 2).<sup>4</sup> It is well known that, along with benefits, maturity and capability appraisal models have inherent cross-cultural, cross-industrial limitations which prevents any “one-size-fits-all” solution even within the same region.<sup>5</sup> Nevertheless, trends reported through FDA’s pilot program provide key insights into the operational practices of US medical device manufacturers. Across the board, pilot program participants reported an increase in the governance and implementation integration practice areas. Together, these practice areas describe the actions necessary to build a

culture of continuous improvement or a “culture of quality.” Pilot participants realized that success in the other nine practice areas would not be possible without a culture supporting and working to achieve true quality.

### What is a culture of quality?

There are many definitions of a “culture of quality” and what such a culture might look like across various industries. *Harvard Business Review* defines a culture of quality as “an environment in which employees not only follow quality guidelines, but also consistently see others taking quality-focused actions, hear others talking about quality, and feel quality all around them.”<sup>6</sup> The American Society for Quality (ASQ), in collaboration with *Forbes* in 2014, contrasts that definition with a description of an organization lacking such a culture, as one in which someone “put

Figure 3. Quality Management System Composition



some procedures in place and then, once a year, just before their audit, they clean up the factory.”<sup>7</sup> A true culture of quality has a strong foundation of compliance to notable industry standards, such as [ISO 9000](#) or [ISO 13485](#). However, a culture of quality is much more than simply demonstrating compliant processes. A culture of quality exists when employees understand the value of a process and work together to continually improve the process. It is the regulatory/quality professional’s responsibility to encourage a creative process of improvements from employees while maintaining a strong foundation for compliance.

#### Process, Tools and Trust

An organization’s quality management system is comprised of a set of processes and the tools to execute those processes. Processes and tools are constantly being created, instead, updated, made obsolete and then replaced, which is the very definition of “continuous improvement.” However, a system in constant flux can be thought to be disruptive to users (the employees). Changes and improvements also can be perceived as imposing, restricting or fleeting with little-to-no value and, therefore, unlikely to be executed.

Such a perception would undermine any progress made toward building a culture of quality. For continuous improvements to be welcomed, employees must trust how these process or tool improvements will allow them to better deliver safe, reliable and effective products without undue burden on employees. It is the role of the organization’s regulatory/quality professional to provide the framework (processes and tools) employees trust so they can produce high quality products and services (**Figure 3**).

What is trust? Trust can be defined as “a consistent experience of competence, integrity, honesty, transparency, commitment, purpose and familiarity.”<sup>8</sup> Users of a process may not need or have the capacity to understand the many details of “why” something is done in a particular way. But when they trust the process, there is greater peace-of-mind for the process resulting in a product of the highest quality. Users experience a reduced cognitive load since they are confident nothing is being missed. However, even in this definition of “trust” the juxtaposition of consistency and continuous improvement presents a challenge for the regulatory/quality professional. While the rate of change in the field of medical device regulation tries to catch

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up to the rate of technology advancement, the regulatory professional must work to maintain a stable and credible continuous improvement process through a well-defined governance and implementation infrastructure.

### The Role of Governance

Cultivating a culture of quality begins with a vision from executive leadership, but can only succeed with a unified, visible front championing the vision at all management levels. A quality culture with a strong governance clearly establishes the role and responsibility for management positions to both champion and enforce the culture of quality in the organization. Employees need to see that management prioritizes quality and safety, not only in words, but also in action. Actions following through on words builds trust. Examples where management can actively champion a culture of quality include:

- encouraging the identification of quality issues by team members
- being the first to dismiss any attempts of blame, shame or fault
- sharing accountability of a quality issue in the case of a product failure in the field
- openly and sincerely thanking and appreciating a team member for identifying a quality issue prior to release of a product
- giving the project team adequate time and budget to fully develop quality plans and other quality documentation
- ensuring the project team spends adequate time to develop quality plans and other quality documentation

While championing the culture of quality can be uplifting, the “flipside” of governance or enforcement is not regarded as something positive. Furthermore, it is typically the responsibility of the regulatory/quality professional to do the enforcing in the form of design reviews and Corrective and Preventive

Actions (CAPAs). When a quality issue arises or a potential issue looms on the horizon, it helps to approach the issue from a culture of quality perspective. Can the root cause of the issue be attributed to a failure in process, tools or trust? The regulatory/quality professional should first seek to understand motivations behind actions leading to the quality issue. Did a tool fail without the proper indicators? Did the process not clarify the value or purpose of the indicator? Did the user not trust the indicator and move ahead regardless? Whatever the root cause, users of the process should be involved in the improvement effort. Engagement in the process, especially with changes in process, builds trust.

### Implementation and Infrastructure

The notion of ‘disruptive change’ is exciting when it comes from a tech startup promising to revolutionize an industry with its new widget. In the world of medical device development and manufacturing, disruptive change threatens inconsistencies, unknowns and headaches for regulatory/quality professionals. The continuous improvement that supports a culture of quality has the potential to be disruptive without a proven implementation infrastructure. As the name implies, implementation infrastructure defines a consistent, stable and validated method for developing, testing, initiating, monitoring and improving process changes. Such infrastructure also must ensure that senior personnel will support, sponsor and enforce the process changes. An example of a mature implementation infrastructure may look like the following:

- Results of an internal audit or CAPA provides evidence-based rationale for a process change.
- The process change has objective criteria for improvement and has the potential to make a subtle yet impactful change (based on a metric or threshold).

- All employees or potentially effected groups are notified of an upcoming process change and are given opportunities to provide feedback.
- The process change is rolled out to low risk yet qualified production groups to verify effect on performance and to get workflow feedback. Senior personnel train selected production groups prior to verification and closely monitor these groups.
- If the change passes verification, it is then “rolled out” to all groups for implementation.
- Over a pre-determined time period, the process will be closely monitored and validated against the objective criteria for improvement.
- After the process change validation is complete, the process is still monitored as necessary and the cycle of improvement begins again.
- A continuous stream of planned improvements can achieve a level of consistency with a regular update schedule, like those of software update releases.

## Conclusion

The case for quality from a business perspective has been clearly defined and demonstrated for years.<sup>9,10</sup> Key drivers behind such investment include quality’s positive impact on effectiveness and profitability, quality’s ability to serve as a key competitive differentiator and the view that high quality represents a barrier to entry to competitors. Quality is also viewed as a vital tool in risk management and the drive for innovation.<sup>11</sup> To sustain return on investment, the organization needs to cultivate a culture of quality by continuously improving the organization’s processes, tools and sense of trust in those processes and tools. The practice areas of governance and implementation infrastructure highlighted by the CMMI Maturity Model are critical factors in cultivating a culture of quality and building trust. The paradigm

shift from compliance to true quality starts from the top and flows to each of the organization’s members, no matter their role or position.

Regulatory/quality professionals are responsible for the organization’s quality processes and tools. They should constantly question whether the processes and tools make sense regarding what the organization values and what the organization is trying to achieve. Regulatory/quality professionals should work to streamline processes, not with the goal of achieving compliance, but by reducing cognitive load on the users of the process so that they can make quality-driven decisions. They should be the collaborative partners in the improvement process, engaging process users to determine the least burdensome approach to solve quality issues and create value from a process. At the end of the day, the results of true quality should benefit patients and the organization, not the auditor.

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**Cite as:** Ajamil A. “Regulatory Leadership for a Culture of Quality in the US Medical Device Industry.” *Regulatory Focus*. January 2020. Regulatory Affairs Professionals Society.



# Critical Thinking and Leadership Skills for Regulatory Professionals



By Robert E. Yocher, MHSC, FRAPS

This article presents the opinions of a retired regulatory executive on the various sets of often underemphasized skills required for a successful regulatory professional career. Every person at every level can use them every day.

## Introduction

The past few decades has seen an exciting evolution of our profession. Increasingly complex products, corporate structures and regulatory environment have created a demand for highly skilled regulatory leaders. Their roles have enhanced in importance and stature over the years and have now been recognized as a key strategic role. Many are now represented at the C-suite levels in the organizations.

Most (but not all) people entering the regulatory field have a medical, science, engineering, math, computer or legal backgrounds. Scientific backgrounds are helpful to understand the products, their effects and intended uses. Legal backgrounds are helpful

to understand statutes, policies and regulations. Math and computer skills are very useful for the complex software and analytics, which are becoming increasingly vital to our industries.

However, with today's internet and instant information you can find regulations, medical terms and statistical help with a few keystrokes or specialized apps. Deep technical skills alone do not prepare you for growth within the organization. Reliance on more general skills take precedence the higher you go in an organization. These skills must be learned and practiced. Critical thinking and leadership skills may be more important to be successful today. These skills are often overlooked and must be learned and practiced from hiring to retirement. They are a foundation for the executive skills sought by a corporation. People who have these skills are readily recognized and rewarded at all levels.

*Whether complex regulations or abstract medical concepts, regulatory professionals are asked to interpret data constantly. The ability to connect pieces of information together to determine an accurate conclusion from the information available and clearly explain this so as to be understood by the various intended audiences is critical throughout your career.*

### What is critical thinking?

In a 1941, seminal study on critical thinking skills by an educator named Edward Glaser critical thinking skills became better known.<sup>1</sup> He stated, “Critical thinking generally requires ability to:

- recognize problems
- find workable means for meeting those problems
- gather and marshal pertinent information
- recognize unstated assumptions and values
- comprehend and use language with accuracy, clarity and discrimination
- interpret data
- appraise evidence and to evaluate arguments
- recognize the existence (or non-existence) of logical relationships between propositions
- draw warranted conclusions and generalizations
- test the conclusions and generalizations at which one arrives and
- reconstruct one’s patterns of beliefs on the basis of wider experience”

This is the essence of what a regulatory professional does. Glaser’s definition reads like a job description. They can be reduced to questioning, interpretation and communication.

### Basic Critical Thinking Skills

#### Questioning, Interpretation and Communication

Questioning is perhaps the quintessential act of critical thinking. Question everything. Do not take information on authority until you investigated it personally. Finding the answer is what critical thinking is all about. Use active open sentences and use sound investigative tools such as the five whys, the is/is not or other inductive or deductive tools. Check for objective evidence and evaluate the sources of information and its reliability. Questioning is fundamental to understanding he

problems, its solution, its implementation and its acceptance.

“Interpretation is the ability to analyze and understand the information you are being presented with and being able to communicate that to others.”<sup>2</sup> Whether complex regulations or abstract medical concepts, regulatory professionals are asked to interpret data constantly. The ability to connect pieces of information together to determine an accurate conclusion from the information available and clearly explain this so as to be understood by the various intended audiences is critical throughout your career.

Communication skills are key to achieve the two previous skills. Although under-emphasized by many educators, your interpersonal actions, presentation, writing and negotiating skills are needed from novice level through the executive level. These get better with practice but they are critical to advancing your career.

### Leadership Skills

Gene Wade once said “*Leadership is not what you do; it’s what others do in response to you.*”<sup>3</sup> Think of the difference between a boss and a leader. A boss is someone who orders you to follow and a leader is someone you want to follow.

A huge industry is devoted to leadership development with over 120,000 books on “leadership” appearing on Amazon. The academic research on leadership has coalesced around a few broad areas of vision creation, planning, networking, good decision-making, and influencing. Let’s examine these areas more closely.

### Leaders Often Share a Vision

Jesse Stoner Zemel once said, “*A vision is a clearly articulated, results oriented picture of a future you intend to create. It is a dream with direction.*”<sup>4</sup>

Leaders win followers by creating shared focused beliefs and in turn effect change. Commonality, synergy and alignment to accomplish goals lead to

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*Networking should start as early in your career as possible. Make your supervisor aware of your desire to network and why. Make it a point to eat lunch with a networked person at least once per week if possible. The networked resource is one of the most valuable tools in your toolbox and a strong indicator of your executive talent development.*

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success. Very few things are accomplished alone. This can be demonstrated at the team level in everyday work or in the boardroom. To help achieve this vision, you should understand what excites and energizes your teams or followers. Develop a well-articulated, compelling story. Visions should help people better understand how their jobs contribute to the success in reaching those shared goals.

### Good Leaders Build Plans

They ask others advice in their areas of expertise. They often create small but powerful teams. They clarify roles and responsibilities and identify behaviors critical to success. After meeting with the team and giving recognition to the people who strive for excellence, identify and fill any voids. Then they write and share the plan to effect the change to reach the vision. Clearly written plans with specific actions, agreed upon roles, responsibilities and behaviors are key to achieving success.

### Leaders use and Develop Networks

Networks are something vital throughout your career. Networks could be formal or informal. They could be co-workers (horizontal and vertical) colleagues or even customers. Networks are great resources and often help effect change management. They often help identify key stakeholders and the political landscape. They may aid in developing structure and systems, which may be needed to overcome concerns of negative skeptics avoiding potential escalation. Leaders often use their networks to provide intelligence or utilize them as promoters or sponsors. They often also are a resource to help create or promote community and culture.

As a professional grows within the organization, there will be less a less specific technical knowledge and more and more need for general management and business knowledge. Effective leaders are expected to know what is

going on in other parts of the company and the industry. They need to bring cross-functional knowledge to bear on issues and opportunities outside of just regulatory. Few issues at the executive level concern just one department but the company and all its stakeholders. Effective leaders make it their business to develop a wider view of the company, industry and the environment in which it must thrive. Leaders need to develop cross functional or cross disciplinary knowledge as well as maintaining good working relationships with peers who have expertise in other areas. To develop understanding other disciplines consider the following:

Learn the business from the perspective of the functional areas by asking:

- How they see the business and learn how that might be different from yours.
- What are their goals and strategies and learn their importance to the business.
- Who are their customers and what are their customers needs expectations and/or challenges.
- What are the metrics and why. Metrics typically point out critical variables that underlie important business processes.

Wherever possible seek out assignments in different functional areas or work on teams outside regulatory. Networking should start as early in your career as possible. Make your supervisor aware of your desire to network and why. Make it a point to eat lunch with a networked person at least once per week if possible. The networked resource is one of the most valuable tools in your toolbox and a strong indicator of your executive talent development.

### Influencing

The last part of leadership is influencing. Good leaders influence by fostering collaboration within their teams and their networks using mutual respect for others knowledge and

opinions. They build trust by being open to competing thoughts and expressing a desire to finding mutual solutions. They take time and effort to understand the other party's reality made up of personal characteristics past experiences, cultural and family influences, work environments, value systems, time constraints, motives, needs and goals. This understanding is a vehicle for helping us to determine what is important and unimportant to others. This allows for us to negotiate a solution and make better decisions. How do we do this? It goes back to our old friends discussed in critical thinking. Leaders who successfully facilitate the interactions of others ask questions that spark lively discussions, listen well, invite reactions, build on other people's ideas and navigate group discussions to agreement and shared decisions. They encourage the involvement of others. When group members interact, the resources of all members are used most fully and problem solving is promoted.

To influence others, it is best to spend some time get to know one another. Different things persuade different people. Knowing what feelings, values and perceptions your audience has is vital to understanding their agenda, needs and concerns about your message. Ask why they see things differently. Seek to understand the others point of view before you explain yours. Summarize what you hear until the other person agrees that you understand what he or she thinks and feel. Build on areas of agreement before addressing disagreements but clearly state your desire to find a solution mutually agreeable. Use open-ended questions and be willing to modify your position as you learn relevant information you may not have considered. Use shared values or common ground and try to connect to your proposals. Respect the roles of others and recognize and acknowledge the worth of all parties. Treat all parties with respect regardless of level or position, with dignity, civil-

ity and courtesy. Share what you know in a non-intimidating way. Deal with emotions. Do not ignore them. We all have them. Try to focus on the issues and not the personalities. Be tolerant of and encourage those who do not initially understand. Create a positive environment encouraging participation of all parties without embarrassment, ridicule or hurtful actions or inactions. Positive behaviors that build trust, openness and a sense of fairness are seen in every good leader.

Others may help support a leader (and at the same time possibly demonstrate their own leadership) by participating. If you do not know what to say, ask a question. By asking a clarification question, like please tell me more about X or could you please give me an example? you invite the other person to share more information, so that you can fully understand his/her message. Questions are powerful. Questions can convert resistance to acceptance or turn confusion into clarity. Questions could be used to determine underlying strategy. By asking questions about implications of actions, you are demonstrating that you are considering the big picture.

Some strategic questions might be:

- How does this fit within our stated mission?
- Will our actions have any untoward effects?
- Will our actions set a precedent?
- Have others used tried this and what was their outcome?
- What metrics are important?
- How do we measure success?

By asking questions others may feel more comfortable in participating and collaborating. To have the most effective problem solving, the most flexible workforce, the open sharing of thoughts and ideas is necessary. It helps develop the culture of collaboration. Peers will open up if they see frank discussions free of intimidation.

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If you are participating over the telephone, it is often disconcerting if there is a silent listener. Using fillers are a good way to support and signal that you are listening. The following are some examples:

- That makes sense.
- I understand.
- Okay.
- I agree.
- Interesting.
- Really?
- Am I a correct in that...? (Restating the key point).
- Paraphrase what you heard.

Active listening skills with the use of fillers help the leader and show your leadership at the same time. You may have seen the posters that say, “Listening is not the absence of talking but the presence of attention. Listening is not just simply hearing but understanding.” Without listening, leaders cannot effectively face the challenges in today’s complex business environment. Listening goes hand and hand with questioning.

In today’s environment of speed and complexity, a directive single strategic leader at the top of the organization may no longer be the most ef-

fective way to run a business. The truth is inspiring leaders are needed at every level of an organization. Corporate leaders must possess certain fundamental skills. Deep technical skills alone don’t prepare us for growth within the organization. Reliance on more general skills take precedence the higher you go in an organization. These skills must be learned and practiced. Just like an athlete daily exercise will bring “muscle memory.” They will give you a strong foundation in which to grow and likely be recognized by your peers and your superiors. Every person at every level can use them every day. You can exhibit these skills on a micro or macro level. You must go beyond being the subject matter expert. Create visions. Formulate plans. Network. Influence. Ask questions, listen more than you speak, seek advice from others. Observe the behavior of good leaders in and outside your organizations. You will most likely see the leaders you observe will draw their power not from their position or rank but from their ideas or behaviors. Most likely they will exhibit skills talked about here.

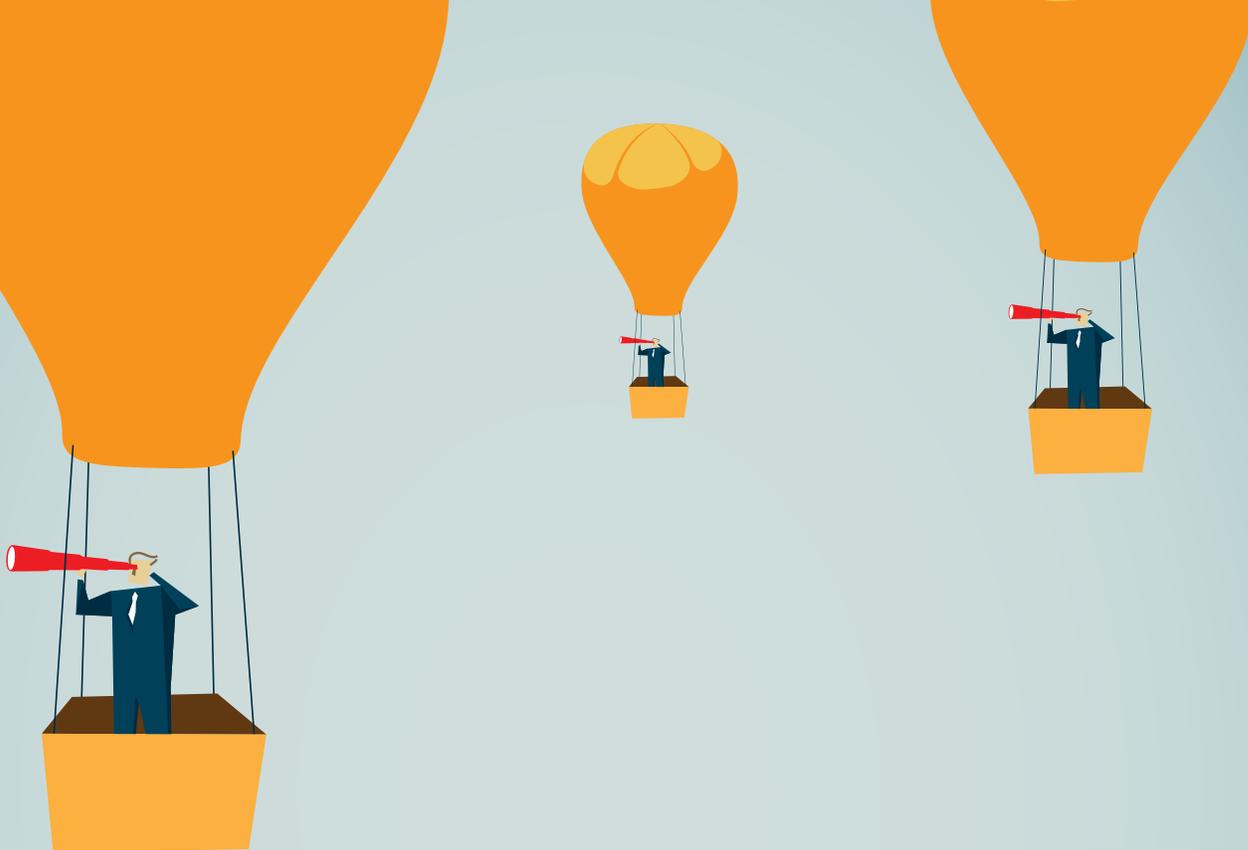
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**Cite as:** Yocher R. "Critical Thinking and Leadership Skills for Regulatory Professionals." *Regulatory Focus*. August 2019. Regulatory Affairs Professionals Society.



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