INTERNATIONAL CONSORTIUM *for*
INNOVATION & QUALITY
in PHARMACEUTICAL DEVELOPMENT

ANNUAL REPORT 2019

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INTERNATIONAL CONSORTIUM for INNOVATION & QUALITY in PHARMACEUTICAL DEVELOPMENT

ANNUAL REPORT 2019

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Foreword by the Consortium Chair

Carl L. McMillian, Ph.D.
Eli Lilly and Company
IQ Consortium Chair

As we take this opportunity to highlight the accomplishments of IQ during 2019 and prepare to recognize 10 years of the consortium's success, it is overwhelmingly clear that the engagement, participation and continued commitment of our members is the engine that drives us forward. Their remarkable contributions and dedication to the collaborative spirit of IQ reinforce — again and again — the power and benefits that accrue from industry-wide attention to solving our most challenging scientific and regulatory challenges. We continue to advance the innovation and quality of pharmaceutical development in ways only possible through our collective resolve.

IQ had an outstanding year in 2019. We have grown to nearly 40 member companies with over 1,700 scientists participating in our 10 leadership groups and 90+ working groups. Our leadership groups, working groups and IQ affiliates (IQ MPS and DILI, see page 23) continued to advance scientific inquiry and understanding on a range of issues, including drug toxicity, risk-based research strategies, biological sampling, and controlling impurities, all with the underlying goal of advancing science to benefit patients and the scientific and research communities dedicated to drug development. IQ continues to actively share the results of our collective research and gained knowledge with the broader pharma and biotech community through our 29 publications and 57 presentations, and through direct scientific exchange with global regulators via targeted workshops and meetings.

Consistent with our strategic objectives, IQ has advanced key regulatory relationships and expanded its global reach. We have had many years of ongoing dialogue with the U.S. Food and Drug Administration (FDA) through scientific roundtables, and in 2019 we featured FDA presentations at the IQ Symposium. In addition, we sponsored workshops that were co-organized or heavily attended by FDA colleagues. These constructive interactions and accomplishments underscore the strength of the relationship between IQ and the FDA, the healthy nature of our collaboration, and our science-based reputation in the federal regulatory space. On the international front in 2019, IQ members met for the first time with the Pharmaceuticals and Medical Devices Agency (PMDA) and pharmaceutical industry professionals in Japan, and continued to engage with industry professionals in China and Europe.

As a consortium, we have maintained continuity of membership and leadership so critical to our cumulative success. Our member companies have had active and sustained levels of participation across many leadership groups and the IQ Board of Directors continues to actively discuss how we can best identify, develop and engage the next generation of IQ leaders who will sustain and build on our record of innovation and scientific advancement. The Board remains committed to supporting the development of IQ's future leaders.

As we pursue activities in 2020 in support of our strategic objectives, we must continue to acknowledge, celebrate and learn from our accomplishments of the last decade. Our past achievements and publication record demonstrate that innovation and quality in pharmaceutical development remain the foundation of our consortium, a goal that will continue to drive us in the next decade.

Vision

The vision of the International Consortium for Innovation and Quality in Pharmaceutical Development (IQ Consortium, or IQ) is to be the **leading science-based organization** advancing innovative solutions to biomedical problems and enabling pharmaceutical companies to bring quality medicines to patients.

Mission

As a technically focused organization of pharmaceutical and biotechnology companies, **IQ advances science and technology** to augment the capability of member companies to bring transformational solutions that benefit patients, regulators, and the broader research and development (R&D) community.

Strategic Objectives

Collaborate across IQ member companies to create cross-functional data sets, scientific positions and conclusions with greater scope and impact than possible by any member company alone.

Advance relationships with global professional organizations, other consortia, academics and government research institutes to ensure scientific excellence and harmonization.

Proactively engage global regulators on issues and opportunities to advance science-based regulations in pharmaceutical development.

Share results of IQ's initiatives with international scientific and regulatory communities.

Ensure the continued value of IQ through committed leadership, focused and clear priority-setting, productive cross-disciplinary collaborations and active engagement by a diverse talent pool to plan for leadership succession.

2019

in Review

1,750

Participants

93 Working Groups

57 Conference Presentations and Posters

39 Member Companies

29 Publications

17 Surveys

16 Webinars

14 Comments on Regulatory Guidances and Standards

12 Meetings with Global Regulatory Bodies and Industry Associations

12 Data Sharing Projects since 2014

10 Leadership Groups

4 Workshops

The Power of Collaboration

With nearly 40 member companies — including some of the world's leading pharmaceutical and biotechnology companies — and over 90 scientifically driven working groups, IQ provides a science-focused forum for facilitating drug research and development. Our collaborative structure and culture foster powerful benefits.

Shared Technical Expertise

Members draw on the intellectual capital of more than 1,700 participating scientists in a pre-competitive space. Member company representatives engage collaboratively in a range of initiatives addressing timely and critical drug-development issues.

Professional Development

Members enter into project pilots and other work streams that might not be available through their individual companies. Industry leaders can harness the potential of IQ to build professional networks and hone "softer" team-building, emotional intelligence and communication skills.

Cost Efficiencies

Members enjoy substantial economies of scale. Annual fees are reasonable, administrative costs are well-controlled, resource redundancy is minimized and costly "dead ends" are often avoided.

Shared Research

IQ members leverage a unique database and data-sharing framework. Voluntarily contributed data are categorized and analyzed in formulating scientific positions, conclusions and recommendations. Survey results, white papers, conference proceedings, and other materials are shared consortium-wide.

Benchmarking and Analytics

IQ employs careful analysis of R&D data to assess performance, examine industry trends, answer critical business questions, establish best practices and identify opportunities for innovation and scientific development.

Regulatory Engagement

Consortium members enjoy a valuable platform from which they can engage with the FDA and with regulators in North America, Europe, South America and Asia.

Legal and Administrative Resources

The Consortium's Secretariat provides legal, compliance and technical support for IQ's activities, fostering compliance with antitrust laws and assisting with the combination of data sets across companies for use in defined research projects. The Secretariat also handles various administrative tasks, allowing IQ participants to maintain a scientific focus.

Affiliated Groups

As needs arise and members' interests warrant, IQ serves as an ideal forum to explore distinct pharmaceutical and biotechnological issues that are often launched into an affiliate initiative. These efforts seek to reduce redundancies and generate potential cost savings. Currently, scientists representing a cross-section of companies are focused on two IQ affiliates: the IQ Drug-Induced Liver Injury Initiative (IQ DILI) and the IQ Microphysiological Systems Affiliate (IQ MPS).

External Partnerships

IQ focuses on constructive scientific exchange through publications, conferences, workshops and roundtables. Our 90+ working groups frequently include representatives from government and academia, eliciting valuable and ongoing feedback from key opinion influencers and thought leaders.

Managed Risk

Two or more consortium members frequently sponsor cooperative research projects. This approach, even when it does not result in discovery, often provides data and insights that inform better decisions and further mitigate risk.

IQ Events

IQ provides a pre-competitive, science-focused forum to facilitate drug research and development. As a part of this mission, IQ hosts educational events to highlight technical expertise, to facilitate research and best-practice sharing, to encourage networking opportunities and to provide opportunities for meaningful engagement with regulators.

Symposium Organizing Committee 2019

Robyn Rourick • Genentech • Chair
William Marinaro • Merck • Vice Chair
Leslie Anthony • Eli Lilly and Company
Dave Christopher • Merck
Tycho Heimbach • Novartis
Chi (Anther) Keung • Cyclerion Therapeutics, Inc.
Ingrid Mergelsberg • Merck
Dennis O'Connor • Boehringer Ingelheim
Everett Perkins • Eli Lilly and Company
Maryam Rafie-Kolpin • AstraZeneca
Matt Schmidt • Merck
Raju Subramanian • Gilead
Jens Sydor • GlaxoSmithKline
Bo Wen • GlaxoSmithKline
Paul Wu • Bayer



IQ EVENT

IQ Symposium

IQ continued to leverage its growing ability to convene stakeholders with important perspectives on issues critical to members at its eighth IQ Symposium on March 26, 2019 in Rockville, MD. The symposium's focus was, "Rising to the Challenge: Developing Therapies for Underserved Populations." Patients, regulators, researchers, academics and clinicians participated in conversations about how to better respond to the unique problems of economically and geographically disadvantaged populations and individuals with rare or orphan diseases.

IQ Chair Carl L. McMillian, PhD (Eli Lilly and Company) and Robyn Rourick, PhD (Genentech, Inc.), chair of the IQ Symposium Organizing Committee (SOC), welcomed all participants. The audience first heard from Shamonica Wiggins and Jew-EL Darbone, who have lived with sickle cell disease since birth. Wiggins and Darbone founded Bold Lips for Sickle Cell, an organization that partners with pharmaceutical companies to advocate for patients and encourage individuals to enroll in clinical trials. Wiggins and Darbone believe it is essential to give patients a voice in all aspects of their disease, especially to encourage new therapies and treatments. They provided personal testimony of their challenges with obtaining appropriate treatment, informed the audience of patients' unique and sometimes under-recognized needs, and welcomed the collaboration between their organization and the pharmaceutical industry.

The IQ symposium also featured guest speakers from the U.S. Food and Drug Administration (FDA). Kellie Schoolar Reynolds, PharmD, from the FDA Center for Drug Evaluation and Research (CDER), described the Office of Clinical Pharmacology's (OCP) role in facilitating development of drugs for underserved populations. Denise Gavin, PhD from the FDA Center for Biologic Evaluation and Research (CBER) provided an overview of the regulatory considerations for cell and gene therapy products for rare or orphan diseases.

A broad conversation about pediatric needs and advances in the treatment of tuberculosis (TB) featured presentations from Sander Vinks, PharmD, PhD, FCP, of the University of Cincinnati, Sebastian Haertter, PhD of Boehringer Ingelheim and Nader Fotouhi, PhD of the TB Alliance. Dr. Vinks provided a clinical perspective and discussed how model-informed drug development may improve treatment outcomes by identifying optimal doses for individual patients, particularly neonates and children. Dr. Haertter emphasized the need to develop new paradigms in the pediatric space. He described how innovative statistical and modelling approaches may be applied to pediatric drug development to avoid unnecessary trials and reduce the overall burden on pediatric populations. Dr. Fotouhi discussed the TB Alliance's current strategies for evaluating drug regimens in TB patients and the challenges and progress towards a safe, short novel universal regimen for TB.

Partnership and collaboration was a recurring theme during the daylong symposium. Jakub Simon, MD, MS of Merck's Ebola Program spoke about the joint efforts of public health and defense agencies, non-profit organizations, universities and research centers to develop an Ebola vaccine. He noted the unique challenges of designing a clinical trial around vaccine efficacy for a disease that targets impoverished populations in remote areas and described how the collective action of various partners led to breakthroughs. Jorg Thommes, PhD of the Bill and Melinda Gates Medical Research Institute described how his organization takes an integrated multi-disciplinary approach to ensuring uninterrupted supply of products to low-middle income countries to prevent or treat TB, malaria, enteric infections and maternal and pediatric diseases.

All of the day's speakers gathered on stage for a question-and-answer session with the audience. Issues discussed ranged from harmonization in the review process, how to more effectively connect scientists to patients and new strategies to identify patients for clinical trials. The symposium was a unique convergence of individuals from industry, regulatory agencies, non-profit organizations, academia and patient advocacy groups who were connected by the common goal of improving patient-centered design and delivery. William Marinaro, PhD (Merck), vice chair of the SOC, concluded by saying the day reflected IQ's success in developing innovative collaboration and that he hoped everyone who participated felt inspired about future possibilities.

IQ EVENT

CMC Summit

IQ members gathered in Philadelphia on June 12, 2019 for the IQ Consortium's eighth annual Chemistry, Manufacturing and Controls (CMC) Summit, which brought together members of the IQ CMC Leadership and Working Groups for a day of valuable scientific and research updates, insightful discussions and a holistic review of the consortium's CMC portfolio. The Summit program featured two plenary talks, updates from each of the six CMC-focused leadership groups, presentations from four selected working groups, and an afternoon of breakout sessions on current topics selected by meeting organizers and participants.

In the first plenary session, Ganapathy Mohan, PhD (Merck) discussed the ongoing development of revised International Council for Harmonisation (ICH) guidelines on continuous manufacturing (CM) that in 2021 are expected to replace current guidelines of the ICH Technical Requirements for Pharmaceuticals for Human Use. Support is strong for updated, globally harmonized regulatory guidelines that will facilitate product implementation, regulatory approval and lifecycle management, particularly for CM products intended for sale in the international market. The proposed new guidelines would allow for flexible approaches to CM of small molecules and therapeutic proteins for new and existing products. They would also provide guidance to industry and regulatory agencies on regulatory expectations related to CM technologies.

The second plenary session was led by Derrick Smith, PhD (Merck) who presented cutting edge data on the use of 3D printing in the evaluation of active pharmaceutical ingredient (API) absorption in pre-clinical studies. Researchers are using 3D printing to expand the formulation-design space without modifying formulation composition, Smith said, noting that the earliest assessment of a new drug requires evaluation of the safety and clinical performance that include faster processes for gathering clinical data. A key gap in early assessment is the ability to evaluate modified-release drug products. Smith described how his team's use of polyvinyl alcohol capsule shells, produced with 3D printing, has demonstrated that API release can be delayed to allow for evaluation of regional absorption in pre-clinical studies.

In addition to the plenary talks, the Summit included presentations from four working groups that were chosen for their innovation and advancements in drug development. Ayman Allian, PhD (Amgen) presented the work of the Thermal Hazard and Process Safety Working Group, Brian Good, PhD (Eli Lilly and Company) presented the work of the Next Generation Documentation Working Group, Rubi Burlage, PhD (Merck) presented the work of the Patient Centric Product Design Working Group, and Mario Hubert, PhD (Bristol-Myers Squibb) presented the work of the Subvisible Particles Working Group.

Another highlight of the CMC Summit was the afternoon of breakout sessions. The CMC Coordinating Committee selected five contemporary topics, and all attendees were invited to participate in an open discussion on each topic to explore and establish collaborative relationships across the consortium. These discussions helped to launch new cross-functional initiatives as well as coordinate existing efforts. The CMC Summit continues to foster a collaborative dialogue that helps fulfill IQ's mission of advancing innovative solutions through pharmaceutical development.

IQ's Impact on Professional, Scientific and Regulatory Communities in 2019

In 2019, IQ Consortium participants contributed to numerous deliverables through benchmarking activities, information exchanges, data-sharing and other joint initiatives pursued across our membership. Following is a list of select key deliverables developed by IQ Consortium participants last year.

Publications

1. Abend, A., Curran, D., Kuiper, J., Lu, X., Li, H., Hermans, A., ... & Suarez-Sharp, S. (2019). Dissolution Testing in Drug Product Development: Workshop Summary Report. *The AAPS Journal, 21*(2). • Analytical LG

2. Adams, K., Clemons, D., Impelluso, L. C., Lee, D., Maguire, S., Myers, A., ... & Wright, M. (2019). An IQ Consortium Perspective on The Scientific Committee on Health, Environmental and Emerging Risks Final Opinion on the Need for Nonhuman Primates in Biomedical Research, Production and Testing of Products and Devices (Update 2017). *Toxicologic Pathology, 47*(5), 649-655. DOI:10.1177/0192623319857976. • 3Rs Translational and Predictive Sciences LG

3. Ainslie, G. R., Davis, M., Ewart, L., Lieberman, L. A., Rowlands, D. J., Thorley, A. J., ... & Ryan, A. M. (2019). Microphysiological Lung Models to Evaluate the Safety of New Pharmaceutical Modalities: A Biopharmaceutical Perspective. *Lab on a Chip, 9*(19), 3152-61. DOI: 10.1039/C9LC00492K. • MPS Affiliate

4. Andrews, P. A., McNerney, M. E., & DeGeorge, J. J. (2019). Exposure Assessments in Reproductive and Developmental Toxicity Testing: An IQ-DruSafe Industry Survey on Current Practices and Experiences in Support of Exposure-based High Dose Selection. *Regulatory Toxicology and Pharmacology, 107*, 104413. • DruSafe LG

5. Baudy, A.R., Otieno, M.A., Hewitt, P., Gan, J., Roth, A., Keller, D., Sura, R., Van Vleet, T.R., Proctor, W.R. (2019). Liver Microphysiological Systems Development Guidelines for Safety Risk Assessment in the Pharmaceutical Industry. *Lab on a Chip*. Epub 2019 Dec 4. DOI: 10.1039/C9LC00768G. • MPS Affiliate

6. Bradshaw, E. L., Spilker, M. E., Zang, R., Bansal, L., He, H., Jones, R. D. O., ... & Chan, J. R. (2019). Applications of Quantitative Systems Pharmacology in Model-Informed Drug Discovery: Perspective on Impact and Opportunities. *CPT: Pharmacometrics & Systems Pharmacology, 8*(11), 777-791. DOI:10.1002/psp4.12463. • Translational and ADME Sciences LG

7. Bransford, P., Cook, J., Gupta, M., Haertter, S., He, H., Ju, R., ... & Wenning, L. (2019). ICH M9 Guideline in Development on Biopharmaceutics Classification System-based Biowaivers: An Industrial Perspective from the IQ Consortium. *Molecular Pharmaceutics*. Epub. • Clinical Pharmacology LG • Translational and ADME Sciences LG • Drug Product LG

8. Burke, M. D., Keeney, M., Kleinberg, R., & Burlage, R. (2019). Challenges and Opportunities for Patient Centric Drug Product Design: Industry Perspectives. *Pharmaceutical Research, 36*(6), 85. DOI:10.1007/s11095-019-2616-5. • Drug Product LG

9. Chen, Y., Cabalu, T. D., Callegari, E., Einolf, H., Liu, L., Parrott, N., ... & Hall, S. D. (2019). Recommendations for the Design of Clinical Drug-Drug Interaction Studies with Itraconazole Using a Mechanistic Physiologically-Based Pharmacokinetic Model. *CPT: Pharmacometrics & Systems Pharmacology, 8*(9), 685-695. DOI:10.1002/psp4.12449. • Translational and ADME Sciences LG

10. Czeskis, B., Elmore, C. S., Haight, A., Hesk, D., Maxwell, B. D., Miller, S. A., ... & Wang, P. (2019). Deuterated Active Pharmaceutical Ingredients: A Science Based Proposal for Synthesis, Analysis, and Control. Part 1: Framing the Problem. *Journal of Labelled Compounds and Radiopharmaceuticals, 62*(11), 690-694. • Active Pharmaceutical Ingredient LG

11. Dahlgren, G., Tajarobi, P., Simone, E., Ricart, B., Melnick, J., Puri, V., ... & Bajwa, G. (2019). Continuous Twin Screw Wet Granulation and Drying -- Control Strategy for Drug Product Manufacturing. *Journal of Pharmaceutical Sciences, 108*(11), 3502-3514. DOI:10.1016/j.xphs.2019.06.023. • Drug Product LG

12. Dickmann, L. J. & Kothare, P. A. (2019). Can Digital Health Enable Higher Quality Real-World Evidence-Based Decisions? *Clinical Pharmacology & Therapeutics, 106*(1), 45-46. • Clinical Pharmacology LG

13. Haigney, S. (2019). Applying QbD to Upstream Processing: Using a QbD Approach from Early-stage Development through Commercialization Can Ensure that Upstream Processes are Efficient and Reliable. *BioPharm International, 32*(7):17-22. • Biologics CMC LG

14. Hardwick, R. N., Betts, C. J., Whritenour, J., Sura, R., Thamsen, M., Kaufman, E. H., & Fabre, K. (2019). Drug-induced Skin Toxicity: Gaps in Preclinical Testing Cascade as Opportunities for Complex in vitro Models and Assays. *Lab on a Chip*. Epub 2019 Oct 10. DOI: 10.1039/c9lc00519f. • MPS Affiliate

15. Hubert, M., Yang, D. T., Kwok, S. C., Rios, A., Das, T. K., Patel, A., ... & Cao, S. (2019). A Multicompany Assessment of Submicron Particle Levels by NTA and RMM in a Wide Range of Late-phase Clinical and Commercial Biotechnology-Derived Protein Products. *Journal of Pharmaceutical Sciences*. Epub 2019 Oct 21. • Biologics CMC LG

16. IQ CRO Outreach Working Group (2018). IQ 3Rs CRO Assessment Tool: A Risk-Based Approach to Assessments of Contracted Programs for Animal Studies. [Updated version released 2019 Sept 30]. Retrieved from https://iqconsortium.org. • 3Rs Translational and Predictive Sciences LG

17. Kretsinger, J., Frantz, N., Hart, S. A., Kelley, W. P., Kitchen, B., Novick, S., ... & Gastens, M. H. (2019). Expectations for Phase-appropriate Drug Substance and Drug Product Specifications for Early-stage Protein Therapeutics. *Journal of Pharmaceutical Sciences, 108(4)*, 1442-1452. • Biologics CMC LG

18. Liu, M., Fields, F. O., Prescott, J. S., Bello, A., Bower, N., Darakjy, S., ... & Derzi, M. (2019). Evaluation of Therapeutics for Severely Debilitating or Life-Threatening Diseases or Conditions: Defining Scope to Enable Global Guidance Development. *Clinical Pharmacology & Therapeutics*. Epub 2019 Oct 14. DOI:10.1002/cpt.1673. • DruSafe LG • Clinical Pharmacology LG

19. Palmer, M., Regev, A., Lindor, K., Avigan, M. I., Dimick-Santos, L., Treem, W., ... & Shneider, B. L. (2020). Consensus Guidelines: Best Practices for Detection, Assessment and Management of Suspected Acute Drug-induced Liver Injury Occurring during Clinical Trials in Adults with Chronic Cholestatic Liver Disease. *Alimentary Pharmacology & Therapeutics, 51*(1), 90-109. • IQ DILI Affiliate

20. Peterson, N., Mahalingaiah, P. K., Fullerton, A., Di Piazza, M. (2019). Application of Microphysiological Systems in Biopharmaceutical Research and Development. *Lab on a Chip*. Epub. DOI: https://doi.org/10.1039/C9LC00962K • MPS Affiliate

21. Ramanujan, S., Chan, J. R., Friedrich, C. M., & Thalhauser, C. J. (2019). A Flexible Approach for Context-Dependent Assessment of Quantitative Systems Pharmacology Models. *CPT: Pharmacometrics & Systems Pharmacology, 8*(6), 340-343. • Clinical Pharmacology LG • Translational and ADME Sciences LG

22. Ramsden, D., Fung, C., Hariparsad, N., Kenny, J. R., Mohutsky, M. A., Parrott, N., ... & Tweedie, D. J. (2019). Perspectives from the IQ Induction Working Group on Factors Impacting Clinical DDI Due to Induction: Focus on CYP3A Substrates. *Drug Metabolism and Disposition, 47*(10), 1206-1221. DOI: 10.1124/dmd.119.087270. • Translational and ADME Sciences LG

23. Roth, S. E., Avigan, M. I., Bourdet, D., Brott, D., Church, R., Dash, A., ... & Lentini, S. (2019). Next Generation DILI Biomarkers: Prioritization of Biomarkers for Qualification and Best Practices for Biospecimen Collection in Drug Development. *Clinical Pharmacology & Therapeutics*. Epub 2019 Sept 14. DOI: 10.1002/cpt.1571. • IQ DILI Affiiliate

24. Smith, S., Orr, R., Krisch, M., Scrivens, G., Bright, J., Fullerton, P., ... & Elder, D. (2019). Proceedings from Joint Pharmaceutical Analysis Group Meeting -- Stability IV: Developments in Stability Testing and Evaluation. *European Pharmaceutical Review*. • Analytical LG

25. Troth, S. P., Simutis, F., Friedman, G. S., Todd, S., & Sistare, F. D. (2019). Kidney Safety Assessment: Current Practices in Drug Development. *Seminars in Nephrology, 39*(2), 120-131. • DruSafe LG

26. Upreti, V. V., & Venkatakrishnan, K. (2019). Model-based Meta-analysis: Optimizing Research, Development, and Utilization of Therapeutics Using the Totality of Evidence. *Clinical Pharmacology & Therapeutics, 106*(5), 981-992. • Clinical Pharmacology LG

27. Valliere-Douglass, J., Marzilli, L., Deora, A., Du, Z., He, L., Kumar, S. R., ... & Wang, Y. (2019). Biopharmaceutical Industry Practices for Sequence Variant Analyses of Recombinant Protein Therapeutics. *PDA Journal of Pharmaceutical Science and Technology, 73*(6), 622-634. • Biologics CMC LG

28. Winiwarter, S., Chang, G., Desai, P., Menzel, K., Faller, B., Arimoto, R., ... & Broccatell, F. (2019). Prediction of Fraction Unbound in Microsomal and Hepatocyte Incubations: A Comparison of Methods across Industry Datasets. *Molecular Pharmaceutics, 16*(9), 4077-4085. • Translational and ADME Sciences LG

29. Wu, P., Hartman, T., Almond, L., Stevens, J., Thrift, J., Ojha, J., ... & Zhu, Y. (2019). Advancing Biologics Development Programs with Legacy Cell Lines: Advantages and Limitations of Genetic Testing for Addressing Clonality Concerns Prior to Availability of Late Stage Process and Product Consistency Data. *PDA Journal of Pharmaceutical Science and Technology*. Epub 2019 Sep 13. DOI: 10.5731/pdajpst.2018.009316. • Biologics CMC LG

Comments on Regulatory Guidances and Standards

1. IQ Analytical Quality by Design Working Group. (2019, August 30). Comments on the Medicines and Healthcare products Regulatory Agency Consultation, "The Application of Analytical Quality by Design Concepts to Pharmacopoeial Standards for Medicines."

2. IQ Clinical Pharmacology Leadership Group and Statistics Leadership Group Biostatistics Forum. (2019, September 5). IQ Consortium Comments on FDA-2019-D-2398, "Population Pharmacokinetics. Revised Draft Guidance for Industry." Retrieved from https://www.regulations.gov/document?D=FDA-2019-D-2398-0007.

3. IQ Clinical Pharmacology Leadership Group and Translational and ADME Sciences Leadership Group. (2019, April 24). IQ Consortium Comments on FDA-2018-D-4368, "Assessing the Effects of Food on Drugs in Investigational New Drug Applications and New Drug Applications - Clinical Pharmacology Considerations; Draft Guidance for Industry." Retrieved from https://www.regulations.gov/document?D=FDA-2018-D-4368-0006.

4. IQ Clinical Pharmacology Leadership Group, Translational and ADME Sciences Leadership Group, and Drug Product Leadership Group. (2019, May 22). IQ Consortium Comments on FDA-2018-D-4367, "Bioavailability Studies Submitted in New Drug Applications or Investigational New Drug Applications - General Considerations; Draft Guidance for Industry." Retrieved from https://www.regulations.gov/document?D=FDA-2018-D-4367-0006.

5. IQ CPLG Regulatory Guidance Review Working Group. (2019, February 8). IQ Consortium Comments on FDA-2018-D-4267, "Biomarker Qualification: Evidentiary Framework; Draft Guidance for Industry and Food and Drug Administration Staff." Retrieved from https://www.regulations.gov/document?D=FDA-2018-D-4267-0006.

6. IQ DruSafe Leadership Group and Quality Leadership Group. (2019, October 9). IQ Consortium Comments on FDA-2019-D-2330, "Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers; Guidance for Industry; Draft Guidance." Retrieved from https://www.regulations.gov/document?D=FDA-2019-D-2330-0024.

7. IQ DruSafe Leadership Group. (2019, April 19). IQ Response to Guideline 9301 - Request to Chinese Pharmacopeia Commission (CPC) to Delete the Abnormal Toxicity Test (Guideline 1141) from Pharmacopeia Chapter Manuscripts.

8. IQ DruSafe Leadership Group. (2019, April 2). IQ Consortium Comments on FDA-2018-D-4524, "S11 Nonclinical Safety Testing in Support of Development of Pediatric Medicines; International Council for Harmonisation; Draft Guidance for Industry." Retrieved from https://www.regulations.gov/document?D=FDA-2018-D-4524-0005.

9. IQ DruSafe Leadership Group. (2019, April 3). IQ Consortium Comments on FDA-2015-D-2818, "Rare Diseases: Common Issues in Drug Development; Draft Guidance for Industry." Retrieved from https://www.regulations.gov/document?D=FDA-2015-D-2818-0030.

10. IQ DruSafe Leadership Group. (2019, July 12). IQ Consortium Comments on FDA-2019-D-0621, "Bispecific Antibody Development Programs; Draft Guidance for Industry." Retrieved from https://www.regulations.gov/document?D=FDA-2019-D-0621-0017.

11. IQ ICH Q3D Implementation Working Group. (2019). Comments in response to USP Packaging Committee General Chapters <661.1>, <661.2>, and <1661>.

12. IQ ICH Q3D Implementation Working Group. (2019). USP Stimuli Article: Technical Guidance for the Preparation and Analysis of Pharmaceutical Materials for Compliance with USP <232>. *Pharmacopeial Forum 45*(5) Sept. - Oct. 2019.

13. IQ Impurities Safety Working Group. (2019). EFPIA/IQ Consortium Response to EMA Reflection Paper: "Qualification of Non-genotoxic Impurities (EMA/CHMP/SWP/545588/2017)."

14. IQ TALG ICH M10 Working Group. (2019, October 3). IQ Consortium Comments on FDA-2019-D-1469, "M10 Bioanalytical Method Validation; International Council for Harmonisation; Draft Guidance for Industry." Retrieved from https://www.regulations.gov/document?D=FDA-2019-D-1469-0011.

Presentations, Posters and Webinars

1. IQ 3RS SCHEER Report Response Working Group. (2019, October). *An IQ Consortium Perspective on the Scientific Committee on Health, Environmental and Emerging Risks Final Opinion on the Need for Non-human Primates in Biomedical Research, Production and Testing of Products and Devices (Update 2017)*. Poster presentation at American Association for Laboratory Animal Science Conference, Denver, CO.

2. IQ ALG Analytical QbD Working Group. (2019, September). Analytical Quality by Design (AQbD)/ *Analytical Method Lifecycle* [Podcast]. Retrieved from https://f.io/Ubrlms7O.

3. IQ ALG Dissolution Working Group. (2019, June). *Predictive Dissolution Modeling - When and How?* [Webinar]. Retrieved from https://register.gotowebinar.com/recording/2632594075073280771.

4. IQ ALG Dissolution Working Group. (2019, October). *Clinically Relevant Dissolution Specification (CRDS)* [Webinar]. Retrieved from https://register.gotowebinar.com/recording/63042000948185859.

5. IQ APILG Green Chemistry Working Group. (2019, April). *Useful Green Chemistry Metrics* [Webinar]. Retrieved from https://www.scientificupdate.com/webinar_events/useful-green-chemistry-metrics/20190904/.

6. IQ CPLG and TALG Quantitative Systems Pharmacology Working Groups. (2019, January). *Case Examples of Quantitative Systems Pharmacology (QSP) in Drug Discovery and Development: an IQ Consortium Perspective* [Webinar].

7. IQ CPLG and TALG Quantitative Systems Pharmacology Working Groups. (2019, May). *Introduction to Quantitative Systems Pharmacology (QSP) Modeling: Features and Applications* [Webinar].

8. IQ CPLG and TALG Quantitative Systems Pharmacology Working Groups. (2019, September). *Development of a Quantitative Systems Pharmacology (QSP) Model of Blood Coagulation and its Application in Clinical Development* [Webinar].

9. IQ CPLG Pediatric Working Group. (2019, March). *Innovation in Pediatric Drug Development: A Pragmatic View*. Presentation at the IQ Symposium -- Rising to the Challenge: Developing Therapies for Underserved Populations, Rockville, MD.

10. IQ CRO Outreach Working Group. (2019, March). *Supportive Care for Animals on Toxicology Studies: An Industrial Benchmark Survey.* Presentation at the Society of Toxicology meeting, Baltimore, MD.

11. IQ DILI Initiative. (2019). *Position Paper from IQ DILI Consortium: Best Practices for Detection, Assessment and Management of Suspected Acute Drug Induced Liver Injury During Clinical Trials in Adults with Chronic Cholestatic Liver Disease*. Poster presentation at the American Association for the Study of Liver Diseases - U.S. Food and Drug Administration DILI Conference, Hyattsville, MD.

12. IQ DILI Initiative. (2019, April). *An Overview of the IQ DILI Initiative*. Presentation at the World Drug Safety Congress, Philadelphia, PA.

13. IQ DILI Initiative. (2019, May). *Industry Perspectives and Initiatives to Fill Key Gaps in the Guidance*. Presentation at the American Association for the Study of Liver Diseases - U.S. Food and Drug Administration DILI Conference, Hyattsville, MD.

14. IQ DPLG Pediatric Working Group. (2019, April). *Development of Miniaturized Tablets as a Flexible Solid Dosage Form: Decoding the Small Size Challenge* [Webinar]. Retrieved from https://register.gotowebinar.com/recording/3050781226653484294.

15. IQ DPLG Pediatric Working Group. (2019, June). *Safety and Toxicity of Excipients for Pediatrics (STEP) Database* [Webinar]. Retrieved from https://register.gotowebinar.com/recording/6620485365598432769.

16. IQ DPLG Pediatric Working Group. (2019, May). *Neuroscience of Medicine Palatability* [Webinar]. Retrieved from https://register.gotowebinar.com/recording/5754412150253085451.

17. IQ DPLG Pediatric Working Group. (2019, November). *Challenges in Developing Age-appropriate Formulations for Neglected Tropical Diseases* [Webinar]. Retrieved from https://register.gotowebinar.com/recording/4437206020739278088.

18. IQ DPLG Pediatric Working Group. (2019, September). *Summary of Pediatric Formulation Development: Challenges of Today and Strategies for Tomorrow*. Poster presentation at the 11th European Paediatric Formulation Initiative Conference, Malmö, Sweden.

19. IQ DPLG Pediatric Working Group. (2019, September). *Summary of Pediatric Formulation Development: Challenges of Today and Strategies for Tomorrow*. Presentation at the 11th European Paediatric Formulation Initiative Conference, Malmö, Sweden.

20. IQ DruSafe Leadership Group. (2019, November). *Industry Perspective on Immune Tolerance*. Presentation at the 2019 American College of Toxicology meeting, Phoenix, AZ.

21. IQ DruSafe Leadership Group. (2019, October). *Industry Perspective on Immune Tolerance.* Presentation at the Boston Area Pharmaceutical Toxicology Group meeting, Cambridge, MA.

22. IQ Impurities Safety Working Group Q(SAR) Subteam. (2019, September). *Update on the DruSafe IQ Consortium on Mutagenic Impurities: QSAR Review of Impurities*. Presentation at the Environmental Mutagenesis and Genomics Society 50th Annual Meeting, Washington, DC.

23. IQ Impurities Safety Working Group. (2019, January). *DruSafe/IQ and EFPIA Non-mutagenic Impurities Initiatives*. Presentation at the Toxicology Forum 43rd Annual Winter Meeting, Crystal City, VA.

24. IQ Impurities Safety Working Group. (2019, November). *Pharmaceutical Impurities in the 21st Century: Scientific and Regulatory Developments*. Presentation at the 2019 American College of Toxicology Meeting, Phoenix, AZ.

25. IQ Impurities Safety Working Group. (2019, September). *Update of IQ Consortium — Non-Mutagenic Impurities*. Presentation at the Environmental Mutagenesis and Genomics Society 50th Annual Meeting, Washington, DC.

26. IQ Impurities Safety Working Group. (2019, September). *Considerations for Deriving Non-Mutagenic Impurity (NMI) Exposure Limits*. Presentation at the Environmental Mutagenesis and Genomics Society 50th Annual Meeting, Washington, DC.

27. IQ Lean Stability Working Group. (2019, March). *IQ Lean Stability Working Group Update*. Presentation at the Joint Pharmaceutical Analysis Group Meeting — Stability IV: Developments in Stability Testing and Evaluation, London, U.K.

28. IQ Lean Stability Working Group. (2019, October). *Lean Stability Case Studies*. Presentation at the Science of Stability meeting, Amsterdam, The Netherlands.

29. IQ Linkage of Critical Quality Attributes and Process Parameters Working Group. (2019, January). *CQA and Process Characterization. Are You Doing What Everyone Else is Doing? Output from an IQ Consortium Working Group*. Presentation at the CASSS Well Characterized BioPharmaceuticals Symposium, Washington, DC.

30. IQ Minimum Anticipated Biological Effect Level (MABEL) Working Group. (2019, April). *IQ Minimum Anticipated Biological Effect Level (MABEL) Working Group Survey Results and Recommendations*. Presentation at the 2019 U.S. Food and Drug Administration/DruSafe/BioSafe Annual Meeting, White Oak, MD.

31. IQ Minimum Anticipated Biological Effect Level (MABEL) Working Group. (2019, May). *A Science and Risk-Based Application of Minimum Anticipated Biological Effect Level (MABEL)*. Presentation at the European Federation of Pharmaceutical Industries and Associations - European Medicines Agency Preclinical Assessors Meeting, Oslo, Norway.

32. IQ Minimum Anticipated Biological Effect Level (MABEL) Working Group. (2019, November). *A Data-Driven and Risk-Based Approach to FIH Dose Selection*. Presentation at the 2019 American Association of Pharmaceutical Scientists PharmSci 360 Conference, San Antonio, TX.

33. IQ Minimum Anticipated Biological Effect Level (MABEL) Working Group. (2019, October). *A Data-Driven and Risk-Based Approach to FIH Dose Selection*. Presentation at the 2019 Annual Mid-Atlantic Society of Toxicology Fall Meeting, Edison, NJ.

34. IQ Minimum Anticipated Biological Effect Level (MABEL) Working Group. (2019, October). *Determination of Dose, Dosing Frequency and Duration for Repeated Dose Toxicity Studies of Biologics*. Presentation at the ICH S6 Safety Assessment for Biologics Training Symposium, Beijing, China.

35. IQ MPS Affiliate. (2019, April). *Microphysiological Systems in Pharma: Evolving a Paradigm*. Presentation at the Northern California 2019 Spring Symposium of the Northern California Regional Chapter of the Society of Toxicology, San Francisco, CA.

36. IQ MPS Affiliate. (2019, June). *Implementation of Multi-dimensional Cellular Tumor Models with Increased Translational Relevance in Pre-clinical Oncology Drug Development*. Presentation at the World Preclinical Congress, Boston, MA.

37. IQ MPS Affiliate. (2019, March). *Update on IQ Microphysiological Systems (MPS) Affiliate*. Presentation at the 14th National Center for Advancing Translational Sciences Tissue Chip Consortium Meeting, Bethesda, MD.

38. IQ MPS Affiliate. (2019, May). *Application of iPS-Derived Neural Spheroids in Drug Discovery*. Presentation at the Applied Pharmaceutical Toxicology meeting, South San Francisco, CA.

39. IQ MPS Affiliate. (2019, May). *Industry Perspective on the Use of MPS in Drug Safety Assessment*. Presentation at the Applied Pharmaceutical Toxicology meeting, South San Francisco, CA.

40. IQ MPS Affiliate. (2019, October). *Update on IQ Microphysiological Systems (MPS) Affiliate*. Presentation at the 15th National Center for Advancing Translational Sciences Tissue Chip Meeting, Bethesda, MD.

41. IQ MPS Affiliate. (2019, September). *IQ Consortium - Latest Developments and Challenges*. Presentation at PREDiCT: 4th Annual 3D Tissue Models Summit, Boston, MA.

42. IQ MPS Affiliate. (2019, September). *Microphysiological Systems in Pharma: Evolving a Paradigm*. Presentation at the 9th China Society of Toxicology National Congress, Taiyuan, Shanxi Province, China.

43. IQ Nonclinical Safety Assessments to Support Development of Combination Products Working Group. (2019, September). *Combination Toxicity Studies: Results from an Intra-Industry Survey*. Presentation at the 9th China Society of Toxicology National Congress, Taiyuan, Shanxi Province, China.

44. IQ Nonclinical to Clinical Safety Pharmacology Translation Working Group. (2019, September). *Safety Pharmacology Working Group Nonclinical Respiratory Studies*. Presentation at the 2019 Safety Pharmacology Society Meeting, Barcelona, Spain.

45. IQ Nonclinical to Clinical Translational Database Working Group. (2019, December). *Concordance of the Toxicity of Pharmaceuticals in Animals and Human: The IQ DruSafe Translational Database*. Presentation at the U.S. Environmental Protection Agency Conference — State of the Science on Development and Use of New Approach Methods for Chemical Safety Testing, Washington, DC.

46. IQ Nonclinical to Clinical Translational Database Working Group. (2019, July). *Setting the Bar for Positive and Negative Animal Predictive Values: The IQ Translational Database*. Presentation at the International Union of Toxicology 15th International Congress of Toxicology, Honolulu, HI.

47. IQ Nonclinical to Clinical Translational Database Working Group. (2019, September). *Setting the Bar for Positive and Negative Animal Predictive Values: The IQ Translational Database*. Presentation at the 9th China Society of Toxicology National Congress, Taiyuan, Shanxi Province, China.

48. IQ Organ Impairment PBPK Working Group, Itraconazole PBPK Working Group, and Food Effect PBPK Modeling Working Group. (2019, November). *PBPK 360: The State of the Science - Industry Perspective*. Presentation at the Workshop on Development of Best Practices in Physiologically Based Pharmacokinetic Modeling to Support Clinical Pharmacology Regulatory Decision-Making sponsored by the Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, MD.

49. IQ Patient Centric Product Design Working Group. (2019, April). *Challenges and Opportunities with Patient Centric Drug Product Design: Industry Perspectives*. Presentation at the 4th U.S. Food and Drug Administration/Product Quality Research Institute Conference on Advancing Product Quality: Patient-Centric Product Design, Drug Development and Manufacturing, Rockville, MD.

50. IQ Patient-Centric Sampling Working Group. (2019, November). *IQ Patient Centric Sampling*. Presentation at the European Bioanalysis Forum Open Meeting, Barcelona, Spain.

51. IQ Phase-Appropriate Specifications Working Group. (2019, April). *IQ Consortium White Paper: Expectations for Phase-Appropriate DS and DP Specifications for Early-Stage Protein Therapeutics.* Presentation at the CASSS Netherlands Area Biotech Discussion Group meeting, Utrecht, The Netherlands.

52. IQ Phase-Appropriate Specifications Working Group. (2019, December). *IQ Consortium Biologics Phase-Appropriate Specifications Working Group*. Presentation at the International Alliance for Biological Standardization meeting, Rockville, MD.

53. IQ Phase-Appropriate Specifications Working Group. (2019, December). *IQ Consortium Biologics Phase-Appropriate Specifications Working Group*. Presentation at the International Society for Pharmaceutical Engineering Global Pharmaceutical Regulatory Summit, North Bethesda, MD.

54. IQ Phase-Appropriate Specifications Working Group. (2019, January). *IQ Consortium Biologics Working Group on Specification Setting Strategies*. Presentation at the CASSS CMC Strategy Forum 2019 - The Development of Patient-focused Commercial Specifications through Understanding of Clinical Relevance and Criticality of Quality Attributes, Washington, DC.

55. IQ Predictivity of in vitro Teratogenicity Working Group. (2019, September). *Concordance between in vitro Teratogenicity Assessments and in vivo Findings: The IQ DruSafe Assessment.* Presentation at the 47th Annual Meeting of the European Teratology Society, Cologne, Germany.

56. IQ Quality Leadership Group. (2019, September). *GMP Roundtable Benchmarking: The Power of Collaboration.* Presentation at the 2019 Development Good Manufacturing Practices Roundtable, Itasca, IL.

57. IQ Risk Based Predictive Stability Working Group and Lean Stability Working Group. (2019, October). *Risk-Based Predictive Stability*. Presentation at the Science of Stability meeting, Amsterdam, The Netherlands.

58. IQ Severely Debilitating or Life Threatening Diseases Working Group. (2019, November). *Cross-Divisional Guidance for Development of Therapeutics for Severely Debilitating or Life-Threatening (SDLT) Indications.* Presentation at the meeting of the Promoting Effective Drug Development Program: Opportunities and Priorities for the Food and Drug Administration's Office of New Drugs, Silver Spring, MD.

59. IQ SLG Biostatistics Forum. (2019). *Anti-Drug Antibody Cutpoints, Part 1* [Webinar].

60. IQ SLG Biostatistics Forum. (2019). *Anti-Drug Antibody Cutpoints, Part* 2 [Webinar].

61. IQ SLG Biostatistics Forum (2019). *Anti-Drug Antibody Cutpoints, Part 3* [Webinar].

62. IQ SLG Biostatistics Forum. (2019). *Software Supporting Personalized Dosing Regimens* [Webinar].

63. IQ SLG Biostatistics Forum. (2019). *Thorough-QT Waivers, Part 1* [Webinar].

64. IQ SLG Biostatistics Forum. (2019). *Thorough-QT Waivers, Part 2* [Webinar].

65. IQ Small Molecule Impurity Considerations for ADC Development Working Group. (2019, October). *Proposed Development and Regulatory Guidance for ADC Payload-Linker Registration Starting Materials, Impurities, and Degradation Products for Oncology Indications.* Presentation at the 10th Annual World Antibody-Drug Conjugates Conference, San Diego, CA.

66. IQ Species Sensitivity to Convulsive Effects of NCEs Working Group (2019, September). *Nonclinical Species Sensitivity to Convulsions: An IQ DruSafe Consortium Working Group Initiative.* Presentation at the 2019 Safety Pharmacology Society Meeting, Barcelona, Spain.

67. IQ Subvisible Particles Working Group. (2019, November). *A Multi-company Assessment of Submicron Particle Levels in Biotechnology-derived Protein Products.* Presentation at the 2019 American Association of Pharmaceutical Scientists PharmSci 360 meeting, San Antonio, TX.

68. IQ Thermal Hazard and Process Safety Working Group. (2019, May). *Pharmaceutical Companies Working Together to Make Their Facilities and the World a Safer Place.* Presentation at the Pharmaceutical Industry Process Safety Conference, West Lafayette, IN.

69. IQ Use of CSTDs for Biologics on the NIOSH List Working Group. (2019, October). *Use of Closed System Transfer Devices with Biological Products.* Presentation at the IQ Meeting for Closed System Transfer Devices, Rockville, MD.

70. IQ Use of Emerging Safety Biomarkers in Nonclinical and Clinical Studies Working Group. (2019, November). *IQ DruSafe Pharma Survey on Nonclinical and Clinical Use of Emerging Safety Biomarkers.* Presentation at the 2019 American College of Veterinary Pathologists, San Antonio, TX.

71. IQ Use of Emerging Safety Biomarkers in Nonclinical and Clinical Studies Working Group. (2019, November). *The Use of Emerging Safety Biomarkers in Nonclinical and Clinical Safety Assessment – the Current and Future State: An IQ DruSafe Industry Survey.* Poster presentation at the 2019 American College of Toxicology meeting, Phoenix, AZ.

72. IQ Use of Emerging Safety Biomarkers in Nonclinical and Clinical Studies Working Group. (2019, September). *The Use of Emerging Safety Biomarkers in Nonclinical and Clinical Safety Assessment – the Current and Future State: An IQ DruSafe Industry Survey.* Poster presentation at the 2019 Safety Pharmacology Society Meeting, Barcelona, Spain.

73. IQ Use of Emerging Safety Biomarkers in Nonclinical and Clinical Studies Working Group. (2019, September). *The Use of Emerging Safety Biomarkers in Nonclinical and Clinical Safety Assessment – the Current and Future State: An IQ DruSafe Industry Survey.* Presentation at the 2019 Safety Pharmacology Society Meeting, Barcelona, Spain.

What our members are saying...

IQ participants share perspectives on their engagement in the consortium.

See the full interviews at iqconsortium.org/about/annual-reports/ar-2019

"IQ adds value to the industry when scientists can get together and share information across barriers – it adds value to the science so everyone can move forward. When new ideas come up, the first thing we ask is, is this something we could bring to IQ so that we could do some work with our scientists from around the industry. "

Timothy Watson • Pfizer, Inc.

"The value that I see for IQ is the collective experience and in-depth expertise that exists across all of the IQ companies and I see we can really leverage that expertise for the company as well."

Sandhya Girish • Genentech, Inc.

"For individuals joining IQ, the benefit really is the ability to interact with other members of the pharmaceutical industry and get exposure to other companies. Having that ability to be able to connect and create networks with people outside of your own company is always going to be very valuable."

Dennis O'Connor • Boehringer Ingelheim Pharmaceuticals, Inc.

"The value of IQ to my company is really two-fold. One is the ability to really constructively engage with health authorities. The second is an avenue to benchmark practices across our industry. [My company] can look at what other companies are doing, and through our interactions learn different pain points that we all going through, and figure out how we can benchmark those things and be better."

Brent Kleintop • Bristol-Myers Squibb

"The value of IQ to my company can be captured in three areas. The first one is that scientists that are within IQ are kept up to date on the latest advances in science, so we can be better prepared to take advantage of these innovations. The second value for my company is that IQ offers multiple opportunities to engage with regulatory agencies worldwide so we can identify potential roadblocks to innovation and start finding solutions to address those. Another value for my company has to do with leadership development. Any scientist working within IQ will be offered tremendous leadership development opportunities."

Pierre Boulas • Biogen

"IQ stands out from other consortia in that not only are we reaching out to regulatory agencies, but [that the] agencies are coming to us directly and asking for input. Trust and credibility [has] been garnered within these agencies to be able to put forth a white paper or some sort of strategy that gets the conversation started with those agencies."

Philip Floyd • GlaxoSmithKline

"IQ brings value to my company as a forum that we participate in that allows high level technical scientific engagement in a pre-competitive environment. We get the opportunity to discuss innovative approaches and ideas with peers and competitors, and we bring knowledge and insight into our company as well as working collectively to advance science.

Joining IQ as a member company allows us to amplify our voice either in the publication of scientific literature or in conversations with regulators or other agencies, so collectively coming together amplifies the individual company voice."

Carl L. McMillian • Eli Lilly and Company

"IQ's ability to build consensus and data sharing capabilities really stand out from other organizations.

IQ is definitely an organization that has a strong technical reputation within the industry, and we have been able to take the outputs from IQ and incorporate them into our internal practices and strategies as well."

Saroj Ramdas • GlaxoSmithKline

Member Companies

AbbVie

Agios Pharmaceuticals

Allergan

Alnylam Pharmaceuticals, Inc.

Amgen, Inc.

Astellas Pharma Inc.

AstraZeneca

Bayer U.S. LLC

Biogen

Blueprint Medicines

Boehringer Ingelheim Pharmaceuticals, Inc.

Bristol-Myers Squibb

Celgene (now Bristol-Myers Squibb)

Cyclerion Therapeutics, Inc.

Daiichi Sankyo, Inc.

Eisai, Inc.

Eli Lilly and Company

EMD Serono, Inc.

F. Hoffman-La Roche Ltd.

Ferring Pharmaceuticals

Genentech, Inc.

Gilead Sciences

GlaxoSmithKline Pharmaceutical R&D

Incyte Corporation

Janssen Research & Development, LLC

Merck

Mitsubishi Tanabe Pharma Corporation

Novartis

Otsuka

Pfizer, Inc.

Sanofi

Sarepta Therapeutics

Seattle Genetics, Inc.

Sunovion Pharmaceuticals Inc.

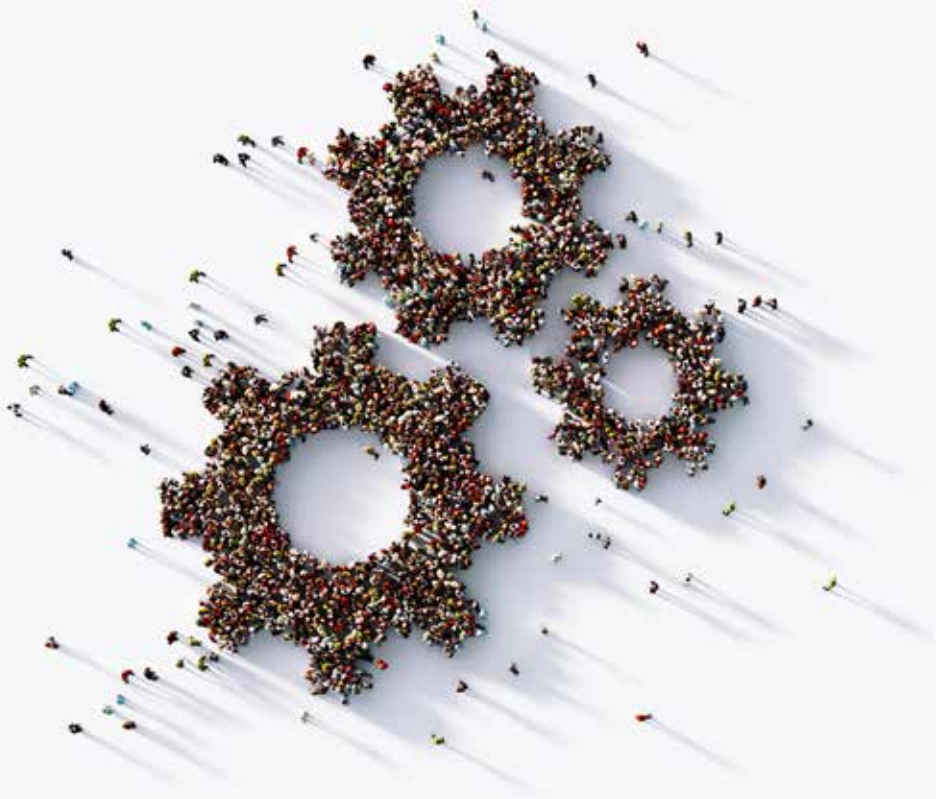
Takeda Pharmaceuticals International, Inc.

Teva Branded Pharmaceutical Products R&D Inc.

Theravance Biopharma

UCB Biopharma

Vertex Pharmaceuticals Inc.



Board of Directors

The IQ Board of Directors provides strategic oversight of the consortium's project portfolio and ensures alignment with IQ's vision and mission. Our board members champion their companies' engagement in IQ and facilitate outreach between the consortium and regulatory authorities and other organizations.

Chair • Carl L. McMillian • Eli Lilly and Company

Vice Chair • Margaret Faul • Amgen

Leslie Anthony • Eli Lilly and Company

Maryssa Attar • Allergan

Eric Blomme • AbbVie

Phil Bonasia • Sunovion Pharmaceuticals Inc.

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Pierre Boulas • Biogen

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Philip Floyd • GlaxoSmithKline

Michael Garvin • AstraZeneca

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Theresa Goletz • EMD Serono, Inc.

Peggy Guzzie-Peck • Janssen Research & Development, LLC

Takayuki Hara • Mitsubishi Tanabe Pharma Corporation

Timothy Hart • GlaxoSmithKline

Jim Hartke • Gilead Sciences

Ling He • Daiichi Sankyo, Inc.

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Vivek Kadambi • Blueprint Medicines

Douglas Keller • Sanofi

Chi (Anther) Keung • Cyclerion Therapeutics, Inc.

Brent Kleintop • Bristol-Myers Squibb

Gondi Kumar • Bristol-Myers Squibb (formerly Celgene)

Sanjeev Kumar • Vertex Pharmaceuticals Inc.

Daniel Lapadula • Novartis

Qun Lu • Bristol-Myers Squibb (formerly Celgene)

Suresh Mallikaarjun • Otsuka

Raja Mangipudy • Bristol-Myers Squibb

James McShane • Eisai, Inc.

Mark Milton • Novartis

Hiroshi Mizuuchi • Mitsubishi Tanabe Pharma Corporation

Thomas Monticello • Amgen, Inc.

Dale Morris • Biogen

Dennis O'Connor • Boehringer Ingelheim Pharmaceuticals, Inc.

Palani Palaniappan • Sarepta Therapeutics

Judith Prescott • Merck

Chetan Pujara • Allergan

Ian Pyrah • Seattle Genetics, Inc.

Arash Raoufinia • Otsuka

Mark Rogge • Takeda Pharmaceuticals International, Inc.

Gregory Rullo • AstraZeneca

Marlowe Schneidkraut • Astellas Pharma Inc.

Anita Shah • Bayer U.S. LLC

Dana Shuey • Incyte Corporation

Lee Silverman • Agios Pharmaceuticals

Wataru Takasaki • Daiichi Sankyo, Inc.

Srini Tenjarla • Takeda Pharmaceuticals International, Inc.

Kimberley Treinen • Sunovion Pharmaceuticals Inc.

Gaurav Tyagi • F. Hoffmann-La Roche Ltd.

Csanad Varga • Blueprint Medicines

Thomas Visalli • Eisai, Inc.

Dora Visky • Ferring Pharmaceuticals

Timothy Watson • Pfizer, Inc.

Markus Weigandt • EMD Serono

Philip Worboys • Theravance Biopharma

Jing-Tao Wu • Alnylam Pharmaceuticals, Inc.

Paul Wu • Bayer U.S. LLC

W. Peter Wuelfing • Merck

Mehran Yazdanian • Teva Branded Pharmaceutical Products R&D Inc.

Gorm Yoder • Janssen Research & Development, LLC

Tong Zhu • Astellas Pharma Inc.

IQ Planning Committee

Margaret Faul • Amgen • Chair
Pierre Boulas • Biogen
Anne Chester • Gilead
Olympe Depelchin • UCB Pharma
Brent Kleintop • Bristol-Myers Squibb
Carl McMillian • Eli Lilly and Company
Dennis O'Connor • Boehringer Ingelheim
Timothy Watson • Pfizer

IQ Communications Committee

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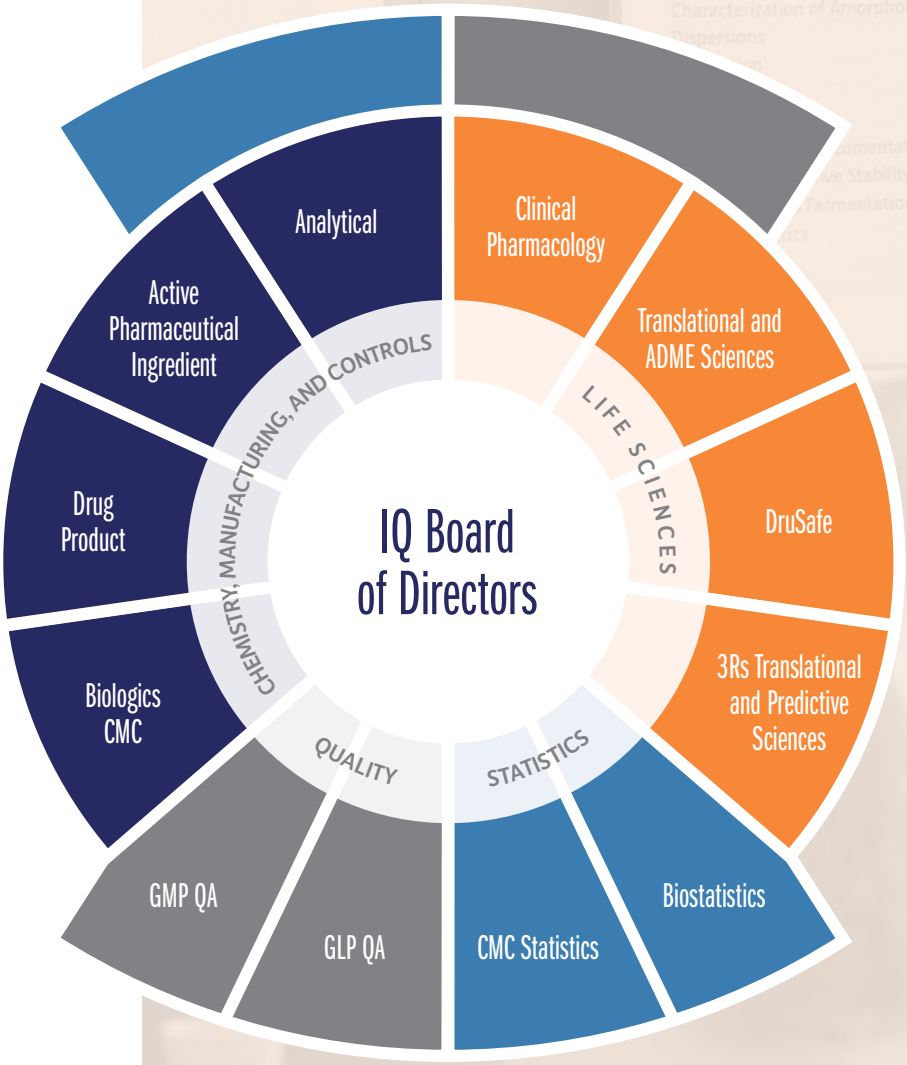
Ray Bakhtiar • Teva
Szczepan Baran • Novartis
Ling He • Daiichi Sankyo Inc.
Nathan Ide • AbbVie
Ingrid Mergelsberg • Merck
Lars Pampel • Novartis
Maryam Rafie-Kolpin • AstraZeneca
Vikram Sinha • Merck
Robert Ternik • Eli Lilly and Company
Mehran Yazdanian • Teva
Tong Zhu • Astellas

Leadership Groups

The IQ Consortium's Leadership Groups (LGs) are standing, technical area-specific forums for scientific exchange. Leadership groups comprise representatives of member companies with expertise and vested interest in the subject area. IQ has 10 Leadership Groups distributed across four disciplines: Chemistry, Manufacturing and Controls (CMC), Quality, Statistics and Life Sciences. The Quality and Statistics leadership groups are further divided into focus groups or forums.



Leadership Group Leads 2019

IQ Leadership Group Leads provide guidance to Leadership Groups and Working Groups on their activities and initiatives. Leadership Group leads liaise with the Board of Directors to manage IQ's project portfolio and ensure that it aligns with the consortium's strategic objectives.

CMC

Analytical LG

Mark Argentine • Eli Lilly and Company

Brian Regler • Ferring Pharmaceuticals

Active Pharmaceutical Ingredient LG

Timothy Curran • Vertex Pharmaceuticals Inc.

John Traverse • Bristol-Myers Squibb

Drug Product LG

Ahmad Almaya • Eli Lilly and Company

Keith Horspool • Boehringer Ingelheim Pharmaceuticals, Inc.

Biologics CMC LG

Saroj Ramdas • GlaxoSmithKline

Barbara Rellahan • Amgen, Inc.

Quality

Quality Coordinating Committee

Dennis O'Connor • Boehringer Ingelheim Pharmaceuticals, Inc.

Chris Turner • Bristol-Myers Squibb

GMP QA Focus Group

Mark Butchko • Eli Lilly and Company

Chris Grosso • Merck

Sunita Iyer • Merck

GLP QA Focus Group

K. Scott Dunham • Merck

Jeff Beebie • Pfizer, Inc.

Statistics

CMC Statistics Forum and Biostatistics Forum

J. David Christopher • Merck

Life Sciences

Clinical Pharmacology LG

Sandhya Girish • Genentech, Inc.

Vikram Sinha • Merck

Tong Zhu • Astellas Pharma Inc.

Translational and ADME Sciences LG

Nancy Agrawal • Merck

Jens Sydor • GlaxoSmithKline

DruSafe

Thomas Monticello • Amgen, Inc.

Mazin Derzi • Pfizer, Inc.

Joanne Birkebak • Gilead Sciences

3Rs Translational and Predictive Sciences LG

Szczepan Baran • Novartis

Natalie Bratcher • AbbVie

Sean Maguire • GlaxoSmithKline

Norman Peterson • AstraZeneca

IQ Affiliates

IQ affiliates provide a mechanism for member companies to work on next-level initiatives within the IQ framework, taking advantage of the benefits it provides. These include an established cross-pharma governance structure as well as data-sharing agreements and a shared database that can support collaborative work.

IQ affiliates address challenging pharma topics that require special focus to deliver the IQ mission of transformative solutions and innovation for drug development. The pharma industry is recognizing the potential of IQ affiliates to transform and expedite the drug discovery and development processes.

Current IQ affiliates are the IQ Consortium Drug Induced Liver Injury Initiative (IQ DILI), established in 2016, and the IQ Microphysiological Systems Affiliate (IQ MPS), created in 2018. Affiliates have an independent budget, distinct objectives and a steering committee that provides oversight of the affiliate.

Affiliate Benefits

IQ Affiliates provide a mechanism for member companies to take on next-level initiatives within the IQ framework. Affiliates also:

- Provide a means for IQ members to take on different or larger projects that go beyond that of an IQ Working Group
- Provide opportunities to collaborate with other IQ Leadership Groups
- Receive scientific, project management, legal and administrative support from the Secretariat

IQ DILI • iqdili.org

Monitoring and diagnosing drug-induced liver injury (DILI) in clinical trials and new drugs presents a critical challenge to the pharmaceutical industry and patient care. Hepatotoxicity has been the most frequent single cause of drug marketing safety withdrawals for the past 50 years, and is the most common cause of aborted drug development. IQ DILI, established in 2016, is the first industry-led effort that is focused on clinical aspects of DILI not sufficiently covered by existing guidance.

IQ MPS • iqmps.org

Microphysiological systems (MPS) are small microfluidic systems engineered to replicate the physiology of human organ systems. Also known as "organs-on-a-chip," MPS are potentially transformative tools for drug development and present alternatives to animal testing for the evaluation of drug safety, drug efficacy and disease modelling. The objectives of IQ MPS, an IQ affiliate established in 2018, include developing a framework for cross-organization testing and evaluation of human-relevant MPS platforms through either data-sharing or prospective collaboration.

Secretariat Support

The law firm of Faegre Drinker Biddle & Reath LLP (Faegre Drinker) serves as secretariat and legal counsel to the IQ Consortium.

Consisting of attorneys, scientists and project managers, Faegre Drinker's consortium management team executes central legal and administrative tasks. Team support includes:

- Facilitating member company decision-making processes to develop consensus positions on strategic initiatives and projects
- Ensuring antitrust compliance by providing training, oversight, and ad hoc legal counsel
- Providing broad scientific, project management, legal, and administrative support
- Providing the Board of Directors with robust strategic, operational, and planning support
- Supporting the exploration and scoping of various data-sharing initiatives
- Implementing and executing data-sharing projects through custom-designed databases and surveys
- Reviewing manuscripts under development to ensure antitrust compliance
- Facilitating external engagements with key stakeholders
- Managing internal and external communications
- Managing the public website and internal collaboration portal
- Providing venue and logistical support for in-person meetings

For more information about IQ membership, including related fees, please contact Mary Devlin Capizzi or Maureen Cruz at the IQ Secretariat.

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INTERNATIONAL CONSORTIUM for
INNOVATION & QUALITY
in PHARMACEUTICAL DEVELOPMENT
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