

Webinar

Find the proven path to your
cloud-based future:

Focus on ERP

CONSULTING | TECHNOLOGY | MANAGED OPERATIONS

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What we do:

Epista Life Science continuously improves compliance and business

by turning compliance obstacles into business opportunities.

In this way, we increase the contribution of Life Science to society.



Sample Vendor for Compliant GxP Cloud Services

Hype Cycle for Life Sciences (2018)

Hype Cycle for Life Science Research & Development (2018, 2019, 2020)

Hype Cycle for Life Science Commercial Operations (2019)

Hype Cycle for Life Science Manufacturing, Quality and Supply Chain (2020, 2021)

Representative Vendor

Market Guide for Track-and-Trace and Serialization Providers in Life Sciences and Healthcare Value Chain (2019, 2020)

Cited in

“Leveraging the Cloud Validation Package Model for Regulated Applications” (2017)

We have been saying it for a while...

- The **cloud is here** – even in Life Science

Cloud means incremental changes (after go-live)

= VALUE – but you have to move out of your silos

Cloud means change to what we used to do - continuous updates mean:

- Better system fit with business requirements – and we are forced!
- Changes to how systems are maintained and operated
- Challenges to maintain the validated state

Winning platforms in Life Science are cloud-based, even on business systems:

- Veeva for Commercial and R&D
- SAP S4/HANA
- Microsoft Dynamics 365
- Tracelink

A small update on cloud-based systems in Life Science...

- A general perspective – where are we and what are the opp?

Market:

- Cloud penetration in Scandinavia is now substantial
- Germany is slowly beginning to pick up its pace on cloud

Operational Models:

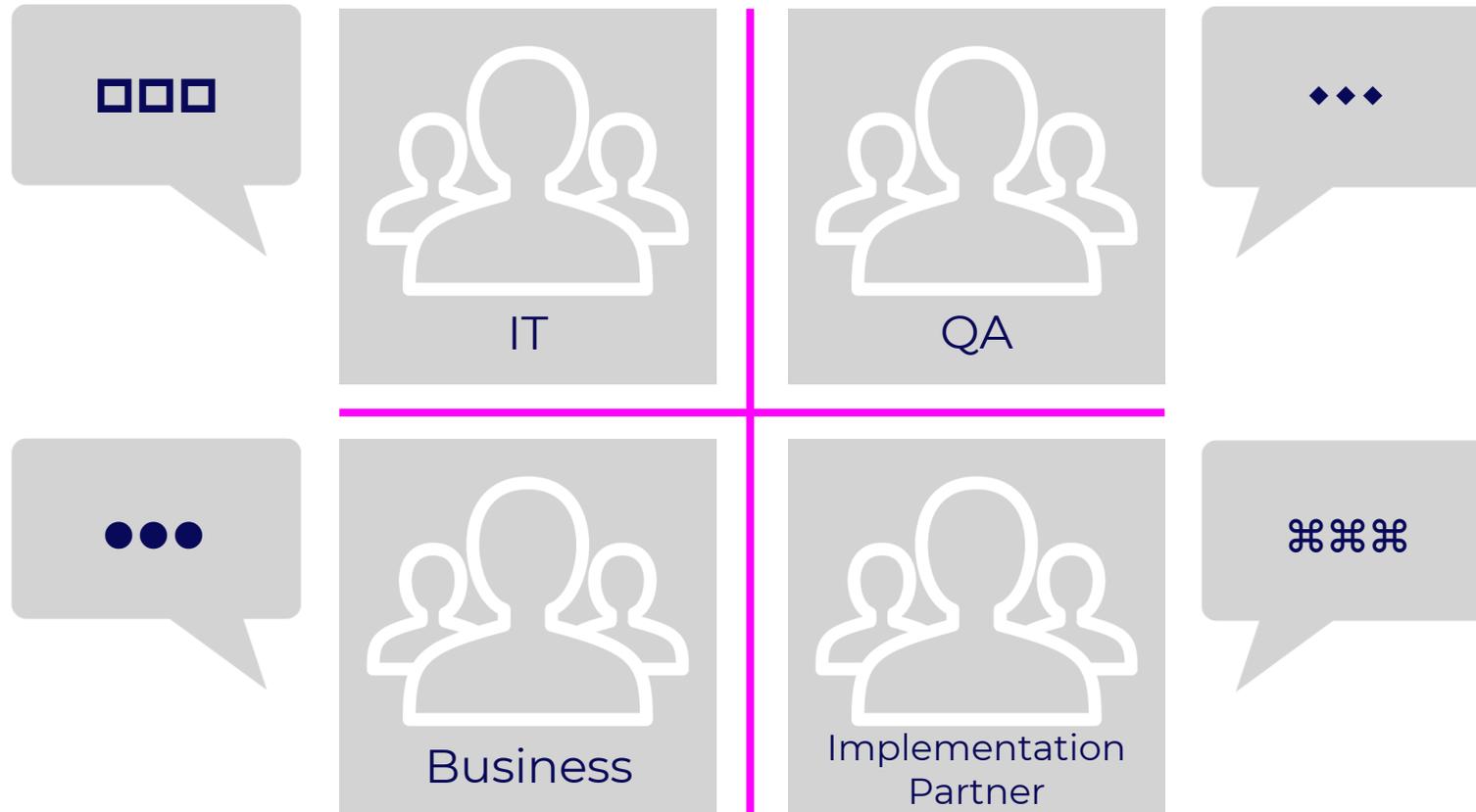
- The big vendors have professional operation – maybe even better than on-prem?
- Vendor documentation can, in fact, be adopted
- Operational cost higher than project cost

Regulatory Bodies:

- Recognition of 'the cloud'
- CSA guidance 'released' from the FDA

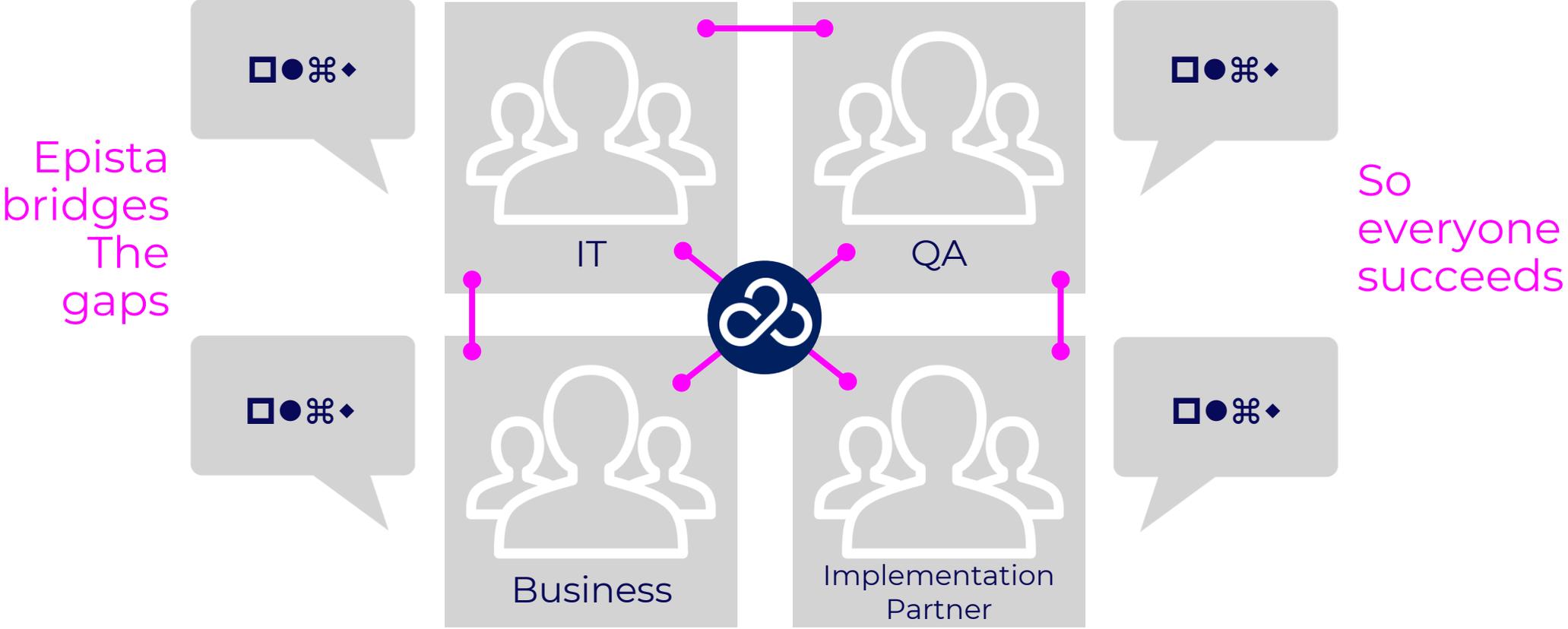
Moving ERP to the cloud is complex, and risky

There are many stakeholders with own priorities,



Not speaking the same language...

Epista guides you on the proven path to your cloud-based future



Implementation projects are changing considerably

- Several new things to consider

Vendor role:

- Rely on vendor for continuous operation of the system
- Rely on integrator for project support and system operation

Project execution:

- Project is now 'only' preparation for operation
- Validation strategy must be closely planned – impact on operation considerable
- Regression testing is paramount!!

One thing is theory – what is practice??
Let's look at ERP as an example

Implementing and running a cloud-based system...

- 4 main disciplines to control – preparing for operation

Processes (Business):

- Good, optimized and compliant business processes
- Focus on GxP critical processes

Applications:

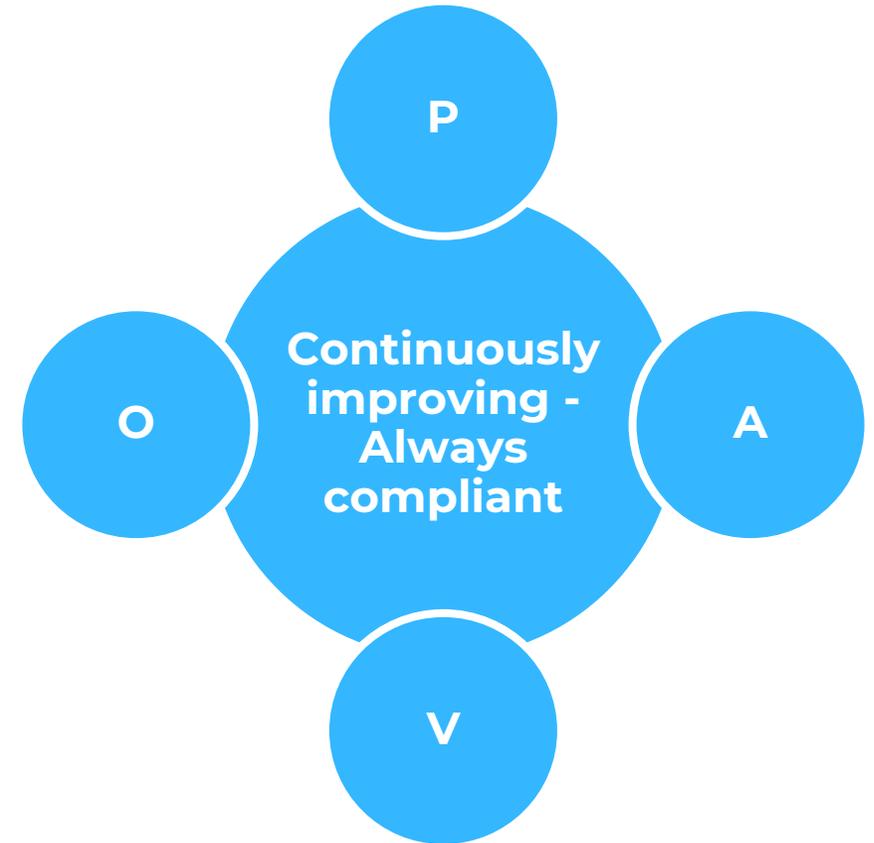
- Accelerators or best practice packages
- Technical or non-technical

Validation:

- Validation of functionality – prepare for operation
- Wide use of vendor documentation
- Apply risk assessment

Operation:

- Robust model for forced changes (new functions)
- Focus on regression testing, CM, and RM
- Test automation

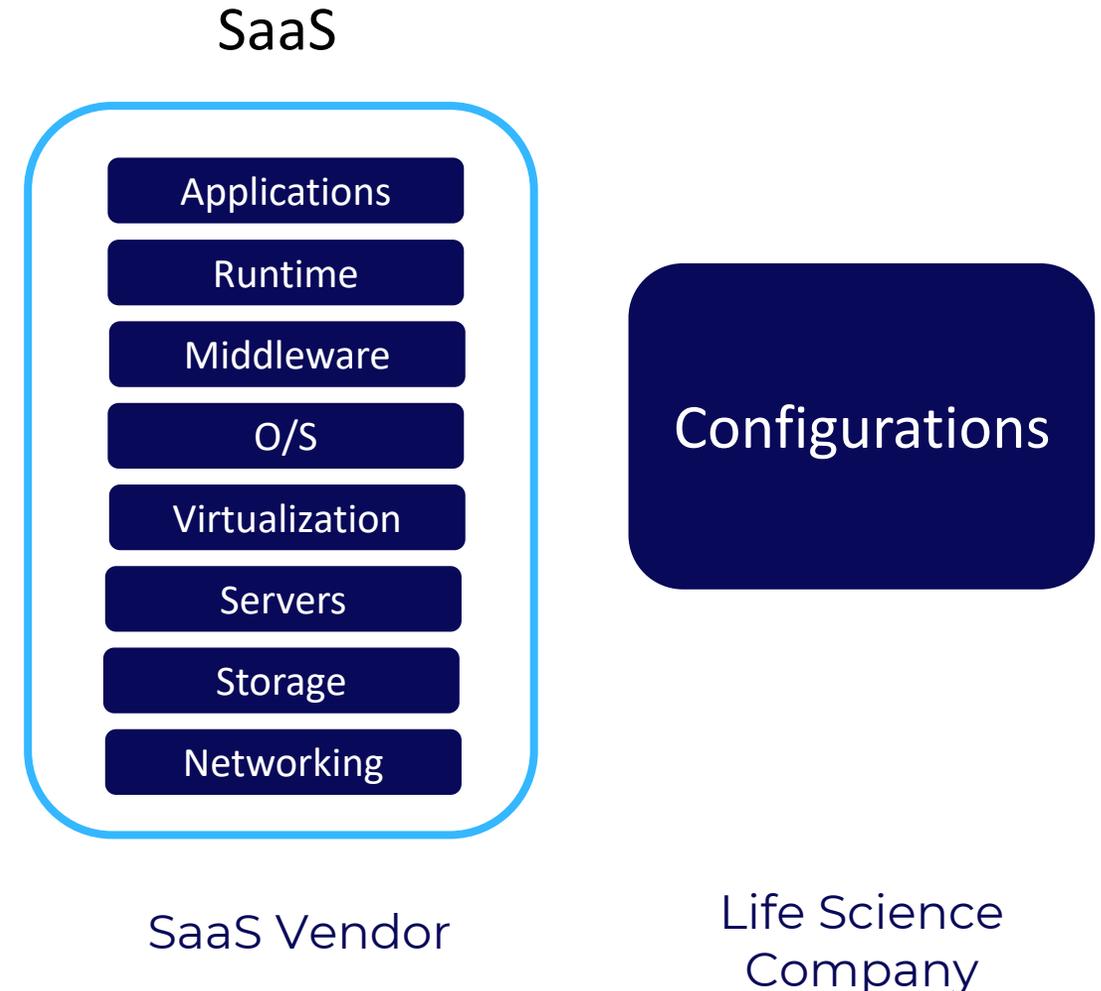


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Cloud Transformation

The structure of a cloud-based system is different

- Part of it is governed by the vendor

- The control of SaaS is the **responsibility of a vendor**
- There will **be forced changes** to the platform, and we need to be in control
- We need to **establish evidence of control** of the platform
- Configurations are individual modifications and extensions to the platform
- We need to be in control of the configurations and, therefore, regressions



The vendor plays a significant role in cloud...

- Every project begins with selection between several good vendors

Software provider of standard software – SaaS (SAP and Microsoft)

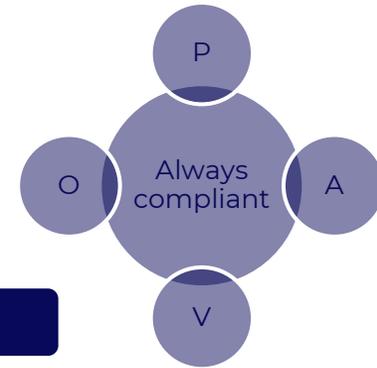
- Typically,
 - Responsible for the system operation
 - General system functionality (not Life Science specific)
- Can be equipped with Life Science best practices or supporting applications

Implementation partner – provider of implementation services

- Sometimes,
 - Not Life Science specific (sometimes a good thing)
 - Needs to be trained on GMP and GAMP
- We recommend controlling the implementation partner through a quality plan or equivalent

Needs analysis and system selection

- Simple checklist for ERP vendors



Processes (Business)

- Does the vendor or implementation partner have a specific process library for your LoB?
- Does the vendor have specific competence within the business side (GxP knowledge)??
- Standard process model principle
- Does the vendor support gathering requirements in an electronic format?

Applications

- Does vendor have a Life Science best practice?
- Accelerators – software packages with specific support of e.g., 21CFR11 or GMP
- Automatic test tools for regression testing?

Validation

- Can we rely on vendor documentation for testing and validation?
- Will we adopt CSA or cloud validation principles (rationale)?
- Will we adopt automatic testing? How?

Operation

- Evaluate vendor's operational model (fit/gap with our own operational requirements)
- Create annual control wheel

Relying on the vendor is crucial

- but we still have the responsibility...

We need to rely on the SW vendor's performance:

- Ability to produce quality standard software
- Ability to produce reference documentation
- Ability to serve as an operational partner!

Hence, we need to extend our 'auditing principles':

- Auditing SaaS provider for good software development processes
- Auditing integrator for project implementation methodology!
- Extended risk assessment of operational model – cloud qualification
- Establish quality plan for implementation partner

Getting an overview of who does what when it comes to validation!

Extended risk assessment

- Map 21CFR11 and EU annex 11 on the vendor and identify gaps

Overall regulatory operational requirement	Our responsibility (based on vendor response, white-paper, or equivalent)	Our potential gap
Potential integrator gap	How do we handle?	Reference to our process
Reference to supplier process	Covered by SLA (Y/N)	Mitigation action

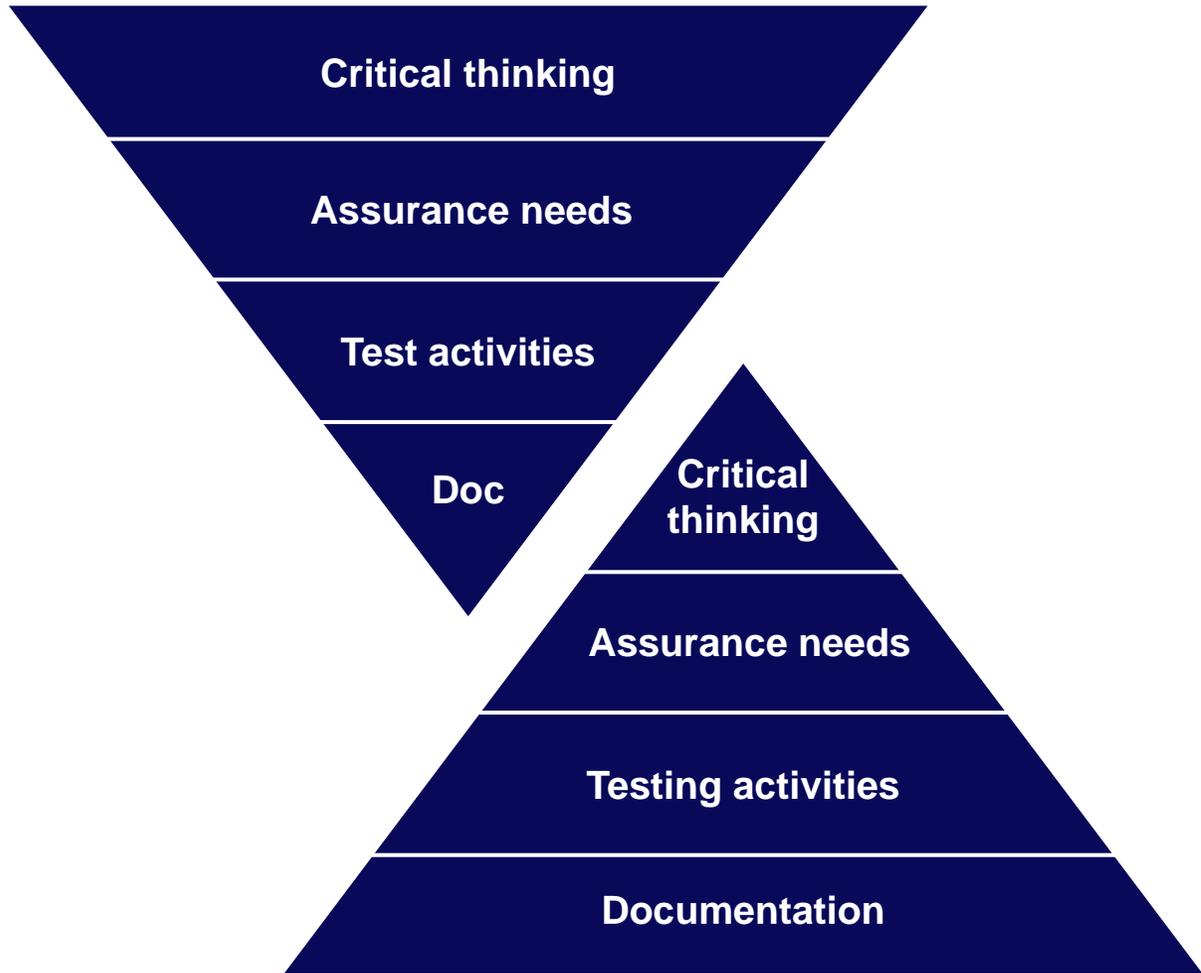
- Record the list in e.g., Microsoft Excel
- Map process responsibility for each ITIL process (you/vendor/integrator)
- Define 'annual control-wheel' to establish controls and monitor the performance of the

D365 example – from Excel

Line #	Review	Process	Overall Requirement	Customer responsibilities - As defined by MS in Azure GxP Guidelines	Customer Specific Requirements	GAP	GAP (IP)	GAP handled as a part of the project	Customer Process	Supplier Process	SLA	Quality Agreement	Mitigation of residual risk	Action
2	Change Management	Change Management	<p>Valid and approved Change Management procedures are in place</p> <p>Covering (but not limited to):</p> <ul style="list-style-type: none"> Roles and responsibilities Process for Interfacing to the Incident / Problem management Process for Change Control, hereunder patch management (including security patches of system components) and updates/upgrades Process for Change Impact Assessment Process for Testing (incl. traceability) and qualification Review and approvals Training Process for Rollback Management of controls 	<ul style="list-style-type: none"> - Implement formal change control and deviation management processes in conjunction with validation of GxP applications. - Ensure controls are established to maintain current copies of any system documentation required to manage applicable GxP computerized systems - Ensure that appropriate logical security policies are established, and training has been documented. - Ensure that appropriate security controls are defined to govern application/system/Azure access along with permissions related to data. - Ensure appropriate system administration practices are followed for applications/systems installed within the Azure environment. - Ensure appropriate governance of system administration activities around the management of Microsoft Azure services. 	N/A	Change management procedure needed for Azure platform (incl. appropriate security controls are defined to govern application/system/Azure access along with permissions related to data.	N/A	D365 Operations handbook	SOP-00515 SOP-00631	Yes Microsoft (see VA= vendor agreement) for cloud infrastructure Yes Microsoft (see VA) for D365FO	No	No	<ul style="list-style-type: none"> Yearly review of Microsoft certifications Regular review of incidents Ensure a Change management procedure is established to ensure alignment with Operation Handbook 	<ul style="list-style-type: none"> Anchor regular review of change log in cloud year wheel Anchor regular review of MS change log in cloud year wheel Anchor yearly review of MS certifications in cloud year wheel Anchor regular review of incidents in cloud year wheel Ensure that "Operation handbook" is up to date Ensure a cloud policy document ('Azure Governance and Policies') is established Ensure a Change management procedure is established, including review of release notes (can be included in 'Azure Governance and Policies')
3	Configuration Management	Configuration Management	<p>Valid and approved Configuration Management procedures are in place</p> <p>Covering (but not limited to):</p> <ul style="list-style-type: none"> Roles and responsibilities Process for interfacing to Change Management process activities Process for baselining and reviews Process for identification of items under configuration control Blacklisting/Whitelisting aspects Inventory structure (incl. documentation format to be used) Review and approvals Maintenance (incl. how to keep information updated and ensure traceability to relevant documentation) Management of controls 	<ul style="list-style-type: none"> - Ensure that appropriate logical security policies are established, and training has been documented. - Ensure that appropriate security controls are defined to govern application/system/Azure access along with permissions related to data. - Ensure appropriate system administration practices are followed for applications/systems installed within the Azure environment. - Ensure appropriate governance of system administration activities around the management of Microsoft Azure services. - Ensure that backup infrastructure and policies are in place and have been tested for GxP system(s) hosted the Azure environment. 	N/A	Configuration management procedure is needed	N/A	D365 Operations handbook to include configuration management-link to MS documentation for configuration management	SOP-00631	Yes Microsoft (see VA) for cloud infrastructure Yes Microsoft (see VA) for D365FO	No	No	<ul style="list-style-type: none"> See line 2 (Residual risk already listed/handled under previous steps) 	<ul style="list-style-type: none"> See line 2 (Actions already listed/handled under previous step) Ensure a configuration management procedure is established including review/controls (can be included in 'Azure Governance and Policies') Anchor regular review of audit trail for admin users in administration module in cloud year wheel

FDA is pointing us in a better direction with CSA

- Paradigm shift moving from documentation to more testing



- “We want companies to spend **more time on testing** and less time on documentation. Test the hell out of it. The effort and value is in the testing and not in the documentation generation.”
- “Let's move away from **documented screen dumps**. These are very time consuming not reusable and **do not add significant value**.”
- “Testing tools for **automated assurance activities** should be encouraged over manual testing.”

CSA gives us new ways of looking at risk

- a more common-sense approach

Implementation Definitions	
Custom	Feature requires programming or change to software code
Configured	Feature is enabled through the setting of parameters without changing the code of the software
Out of the Box	Feature works simply by installing the software and adding necessary master data (e.g., products, BOM, routes, etc.)

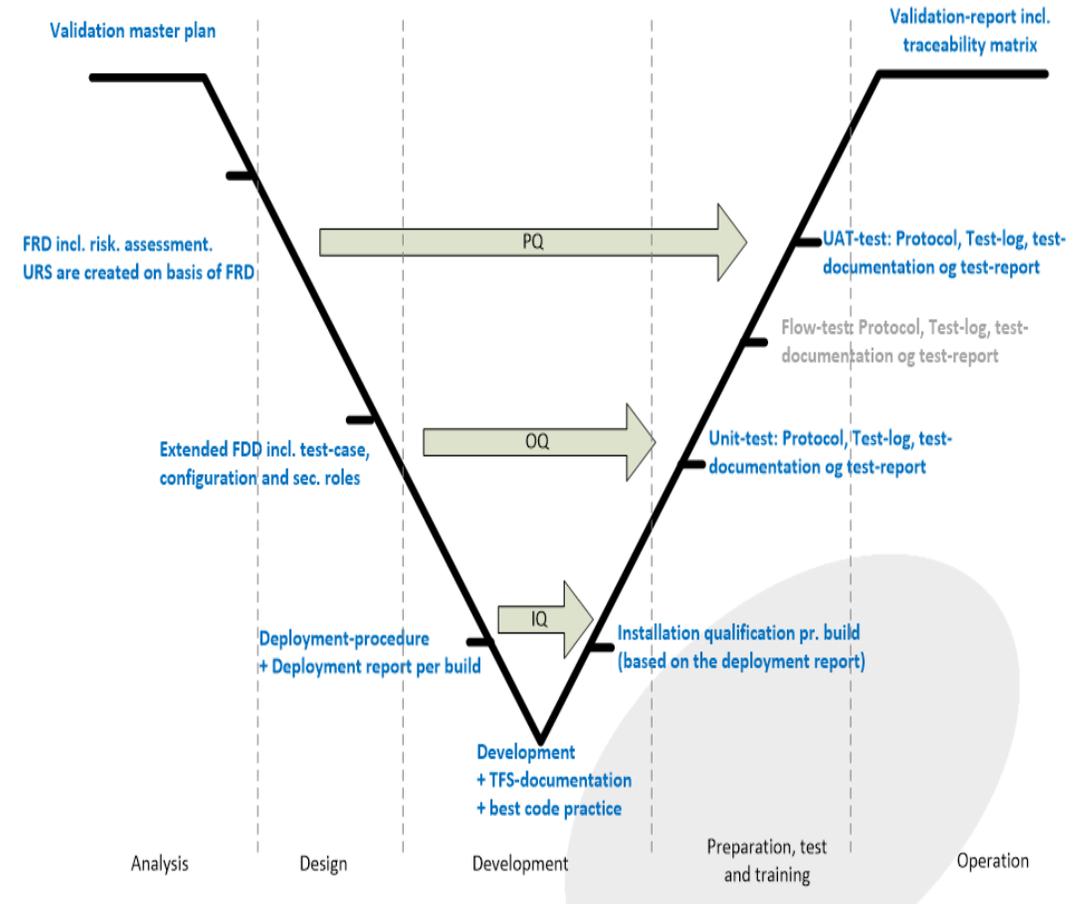
		Implementation Method		
		Out of the Box	Configured	Custom
Patient Risk	High	3	4	5
	Medium	2	3	4
	Low	1	2	3
	None	1	1	1

Risk Rating	Assurance Activities
5	Requirement validated through robust scripted testing
4	Requirement validated through limited scripted testing
3	Requirement validated through unscripted scripted testing
2	Requirement validated through ad-hoc scripted testing
1	Relies on vendor audit and base-line assurance

Implementation

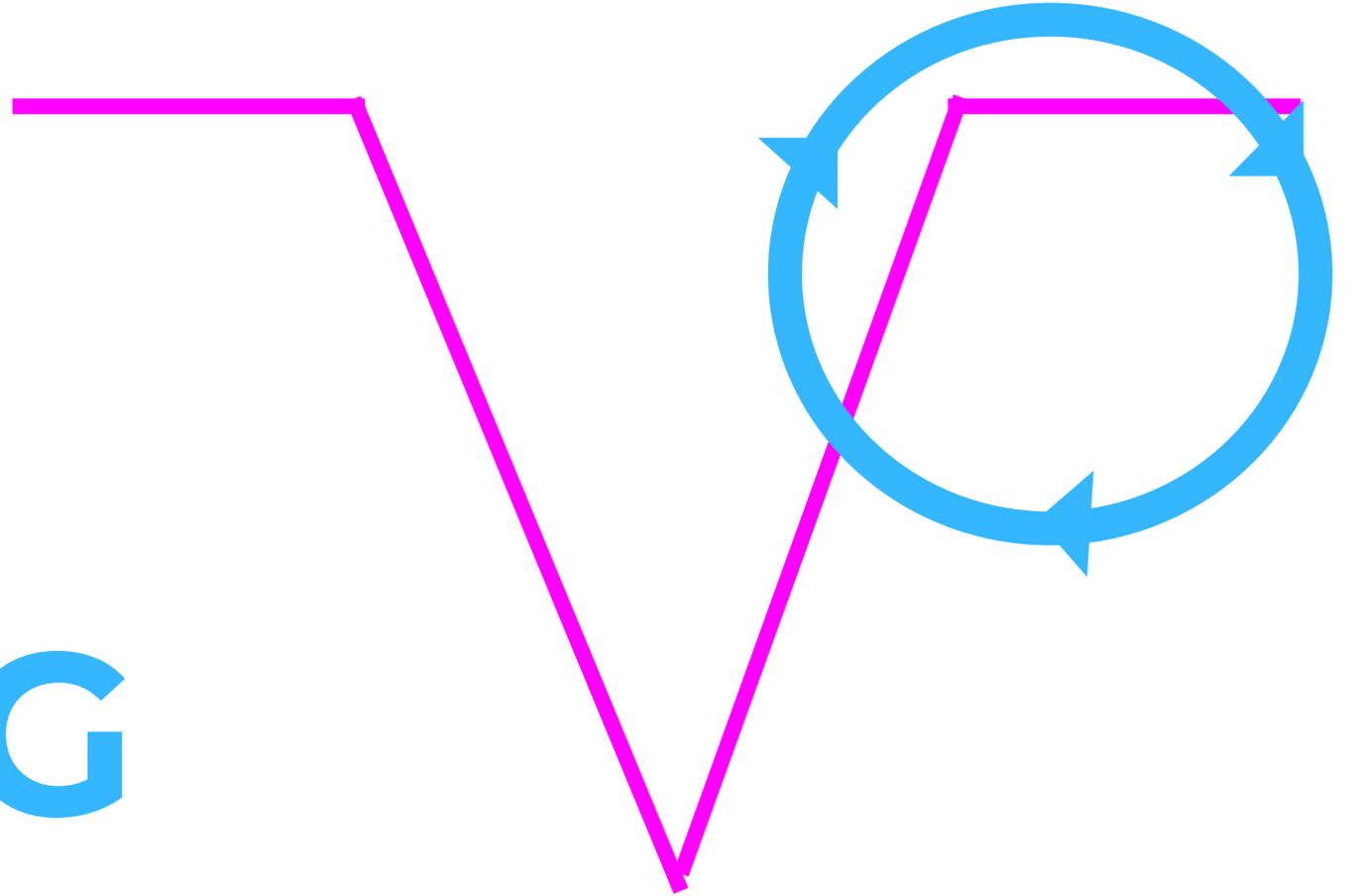
- Typical considerations for ERP configurations

- Utilize two-dimensional risk assessment
 - GxP/n-GxP
 - Fit/Gap
- Rely on vendor documentation and build traceability as part of the project
- Build automated test scripts for OQ and PQ
- Beware of release management
 - The platform may be changed during the project
- Use DevOps/SolMan for their intended use
 - You will be writing documents in Word!



Think about your operational state
- the operational way of proving compliance

AUTO- MATED TESTING



Operational model

- maintaining the validated state

Your platform is governed by the vendor and qualified as described using Life Science cloud transformation tools – annual control wheel

Two main challenges exist:

Evaluation of software changes
and new functionality

Regression test after each new
release

Recommendations:

- Utilize automated testing for PQ – maintain scripts as part of operation
- Clear structure with GxP savvy CM and RM personnel – documentation needs to be updated

ERP Projects

- Need for alignment



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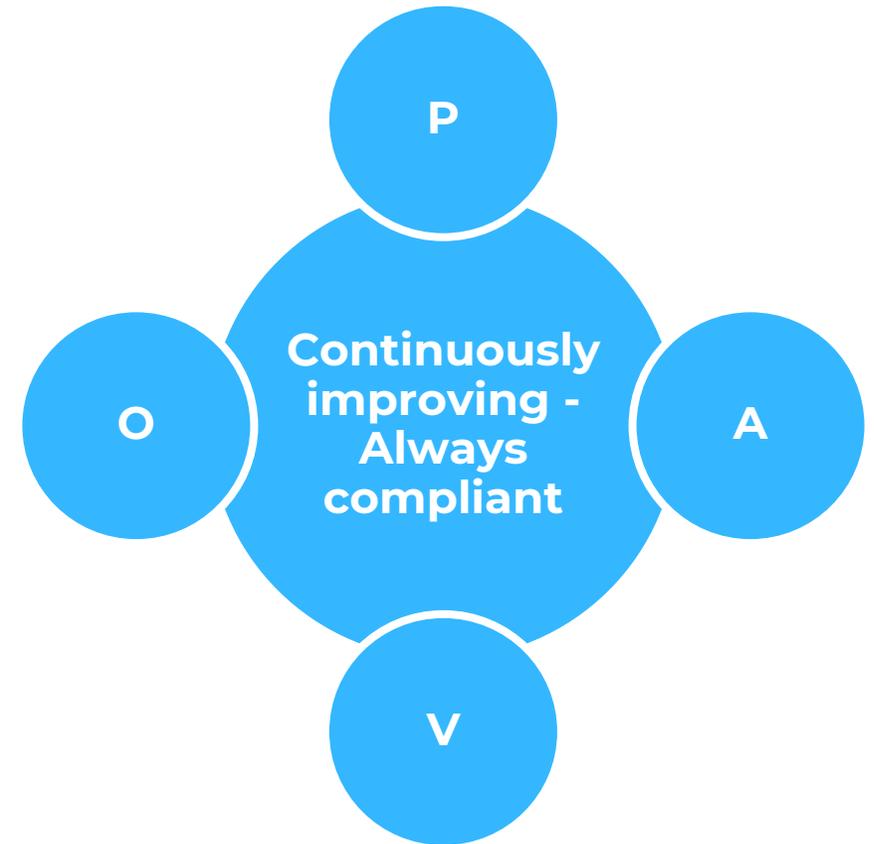
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Test automation



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Cloud Transformation

Wrap-up

More Cloud related events **coming soon:**

- Webinar: Cloud Transition with ECM Focus – March 24
- In-person Cloud Transition Events - coming near you
 - May 4 – Copenhagen, Denmark -with an ERP case
 - May 10 - Lund, Sweden - with an ERP case
 - May 11 - Stockholm, Sweden - with an ERP case
 - May 17 - Frankfurt, Germany - with an Electronic Content Management (ECM) case
(More locations are on the way!)

Any Questions?

Life Science Cloud Transition: Focus on ERP

Thank you!

If you have more questions or are ready to make the transition to the cloud, reach out: info@epista.com



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