Session 9.2

Data Integration Platform – Implementation & Validation Challenges

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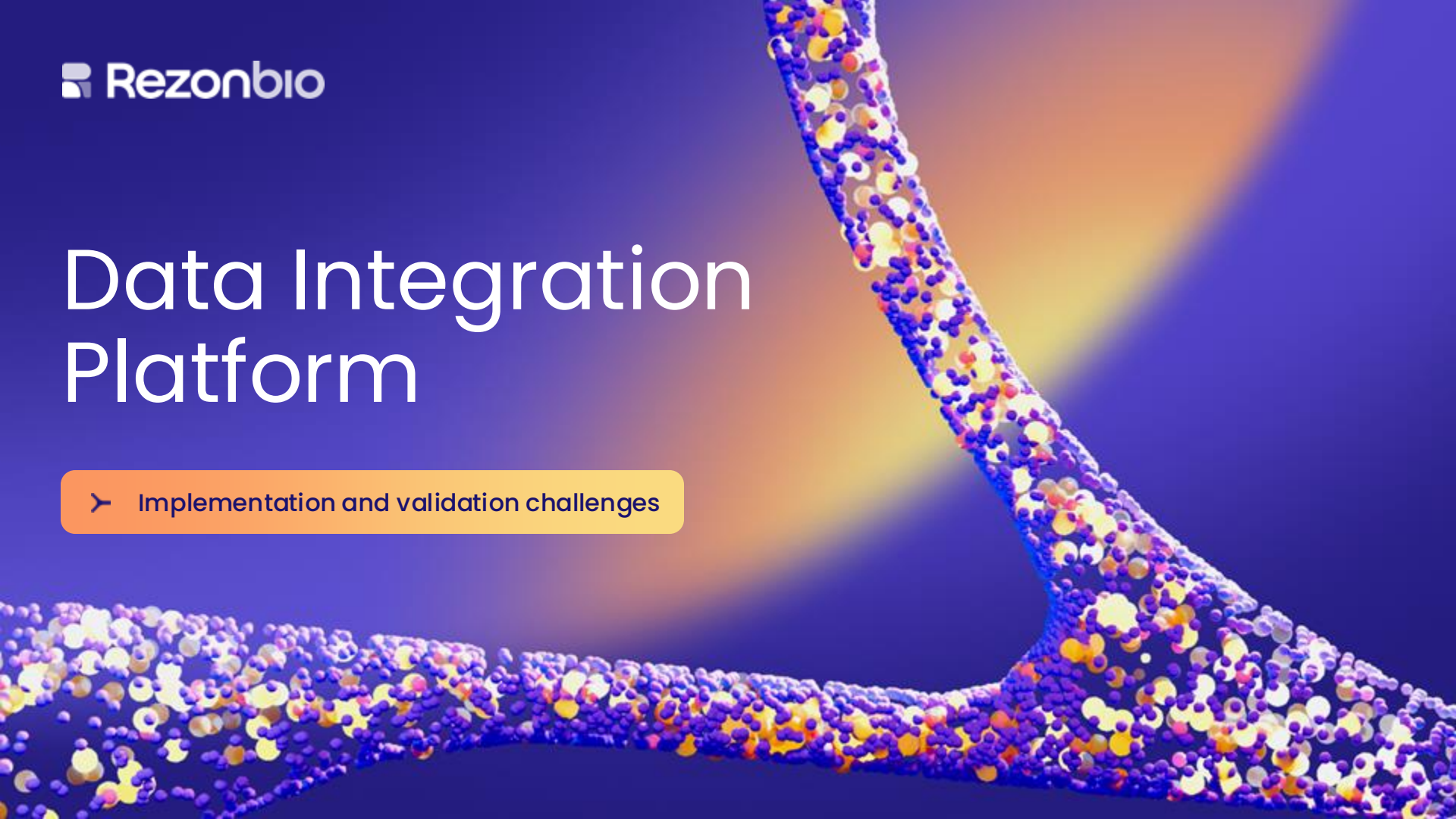
Data Integration Platform

Implementation and validation challenges



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End-to-End CDMO solutions for scalability, speed & quality

Cell line development

High-yield mammalian cell lines tailored for fast timelines & manufacturability*

Clinical & commercial drug substance GMP manufacturing

Flexible capacity, inspection-ready operations, highly competitive pricing

Drug product development

Expertise aligning formulation, device, and packaging strategies with clinical needs

Drug substance process development

Scalable upstream and downstream processes built for robustness

Analytical capabilities

Development and Quality Control: Phase-appropriate method development, CQA-driven assay strategies, qualified release testing.

Drug product GMP manufacturing

Ready-to-fill formulations, supply of vials or assembly of drug devices*

Supporting Services

- Device development
- Tech transfers (analytical/process)
- PAI support
- Regulatory support
- Process characterization
- PPQ

* Delivered by trusted and qualified external partners

Integrated state-of-the-art facilities & services

Phase-appropriate services, spanning from cell line development to commercial supply. Mirrored equipment, processes, and analytical approaches enable seamless scale-up to serve clients worldwide.

Clinical development & manufacturing

Gdańsk, Poland

- AI-supported manufacturing lines
- Fast, first-in-human batches
- Analytical & process development for quality, robustness & scalability
- FDA, EMA, ANVISA, MHRA approved
- Up to 2×1,000L SU scale

Commercial scale GMP manufacturing

Warsaw-Duchnice, Poland

- Extensive capacity supports increasing scale
- Fast & flexible scheduling
- Cost-efficient
- Quick multi-product turnover
- FDA, EMA approved
- Up to 2×2,000L SU scale

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Why data-driven?

Market saturation

CDMO market is growing

… so as the number of competitors

Growing expectations

Clients expect more

… and faster

Cost pressure

Budgets are smaller

… but the workload is growing

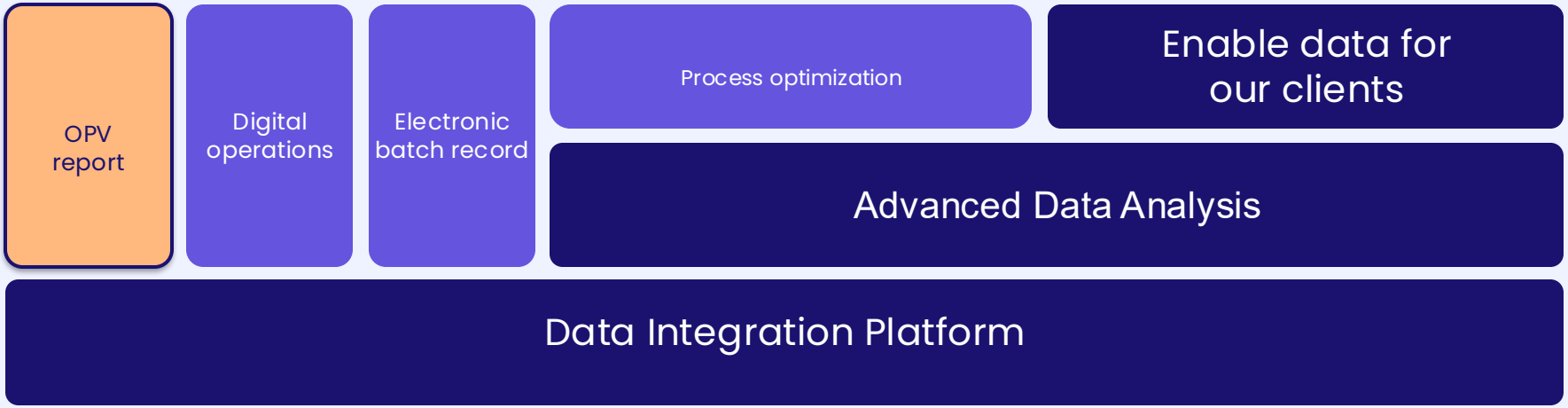
Staying competitive requires data-driven organization

Removing data access barriers

Increasing cross org data visibility

Preparing for the era of Artificial Inteligence

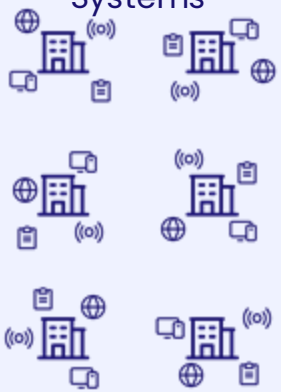
From idea to operational reality



Business purpose and intended use

Digital Maturity Growth

Data Silos Systems



Data Integration Platform

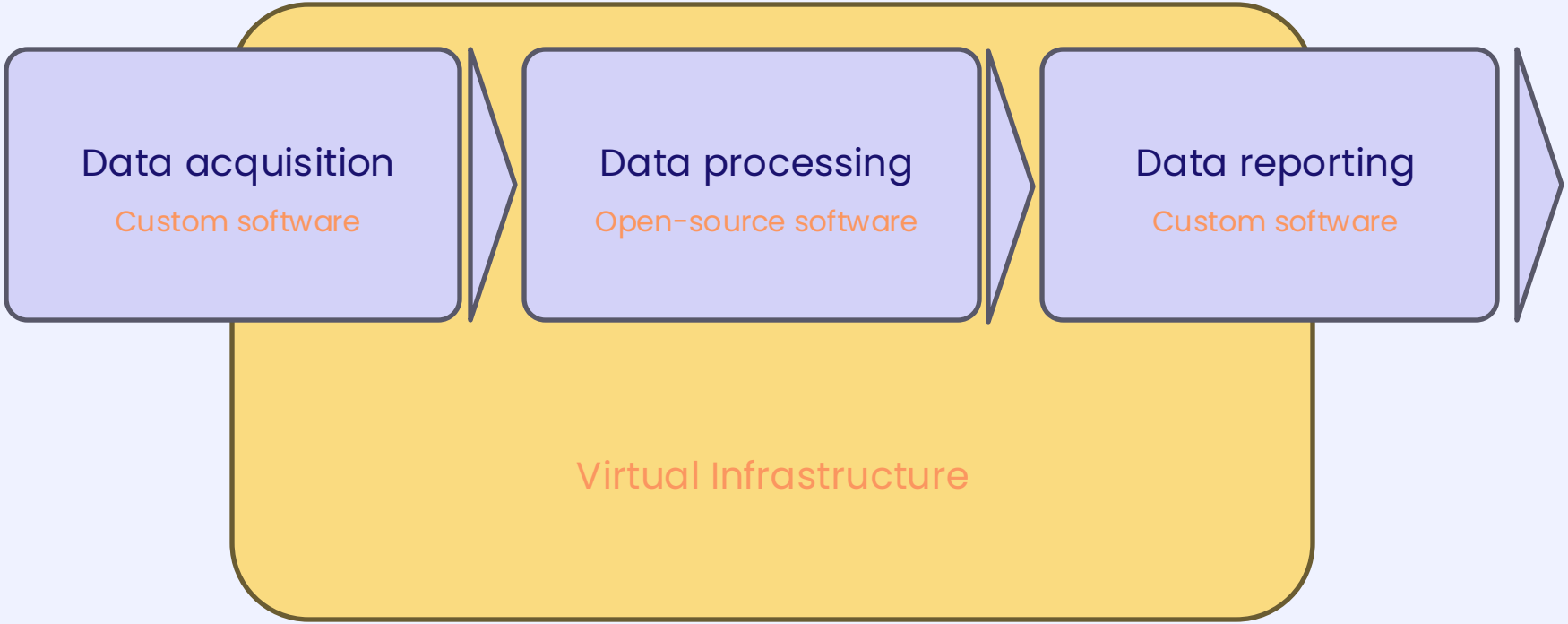
System applications

System infrastructure

Business Use

- Operational analytics & reporting
- Predictive maintenance & optimization
- Financial planning & forecasting
- And more

System architecture



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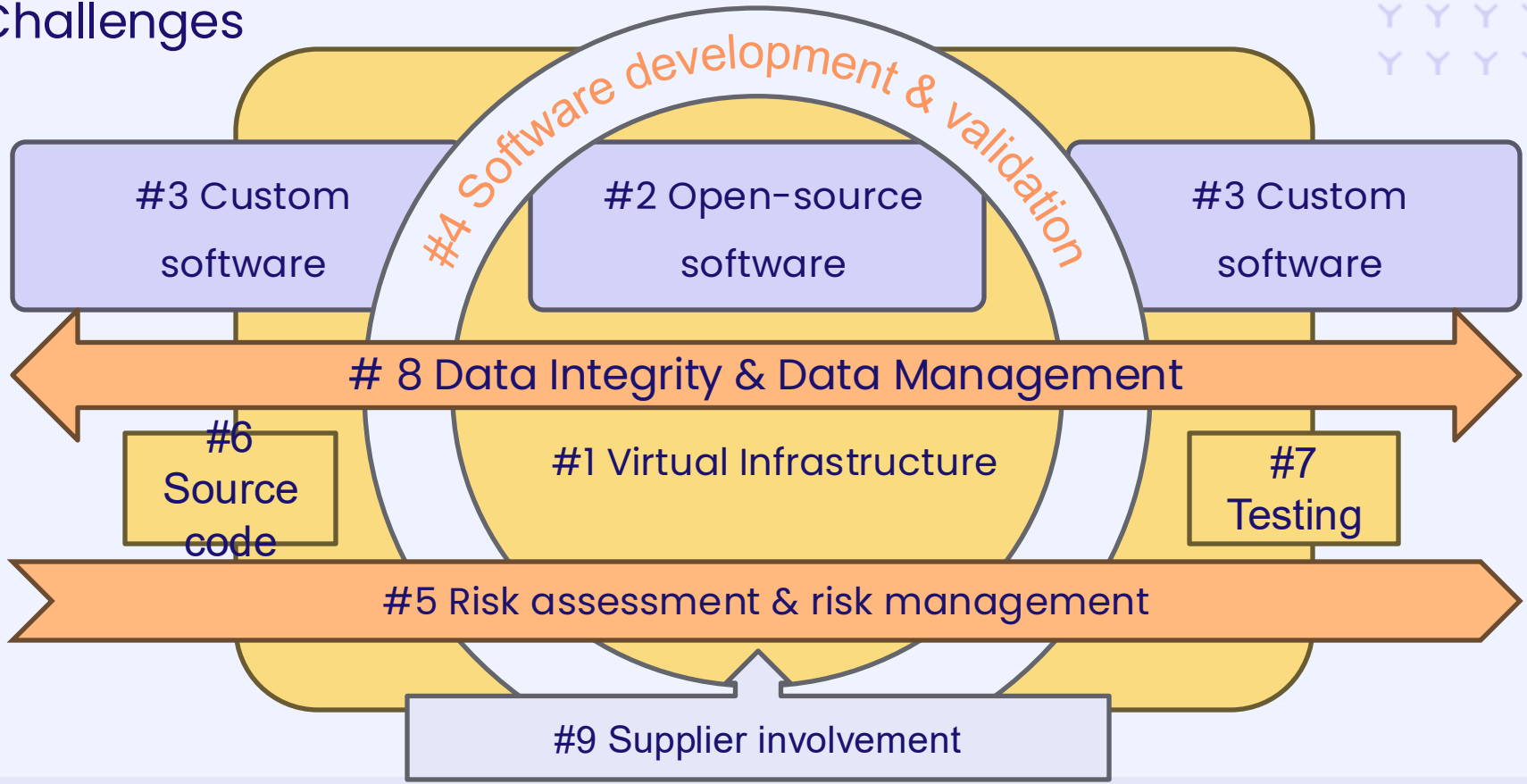
Challenges


#4 Software development & validation
#3 Custom software
#2 Open-source software
#3 Custom software
8 Data Integrity & Data Management
#6 Source code
#1 Virtual Infrastructure
#7 Testing
#5 Risk assessment & risk management
#9 Supplier involvement

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Good practices

#1 Virtual infrastructure

ISPE GAMP Good Practice Guide: IT Infrastructure Control and Compliance, Second Edition
Appendix 12 – Virtualization: Compliance and Control

- "… infrastructure platforms and components may be qualified independently of the validation of the dependent systems, as long as the infrastructure is properly specified, verified, controlled, and maintained …."
- „ … risks are unique to the virtualized environment and will require specific risk assessments to be conducted …"
- "…. procedures should be specific to the virtualized environment"

Solution

#1 Virtual infrastructure

Initial risk assessment
–
complexity and GxP impact.

Information security risk analysis
–
potential vulnerabilities.

User requirements
–
20 requirements for network and infrastructure.

Specifications

- Data Platform Infrastructure specification
- Data Platform Infrastructure deployment specification

Maintenance processes

restore and disaster recovery,
change and patch management,
access management

Good practices

#2 Open-source software

ISPE GAMP 5 Guide: A-Risk-Based approach to Compliant GxP Computerized Systems, Second Edition
Appendix D4, Section 24.3.3. Third-Party Software

- "Note that commercial software may contain open-source components …"
- "Evaluation of software control for OSS is similar in scope and approach to that of purchased software"
- "…a risk assessment should be performed to determine the business and GxP risk…"
- "Such software should be implemented in accordance with the appropriate life cycle activities as for commercial software …"

Solution

#2 Open-source software

Functional Risk Assessment	Specification	Version control	Vulnerability	Testing
• Risk assessment for every OSS	• each OSS is specified and configured	• installed On Prem, • patches are fully under control	• OSS not exposed to the internet, • each OSS was assessed by Information Security team	• limited to the intended use • appropriate to the results of functional risk assessment

Good practices

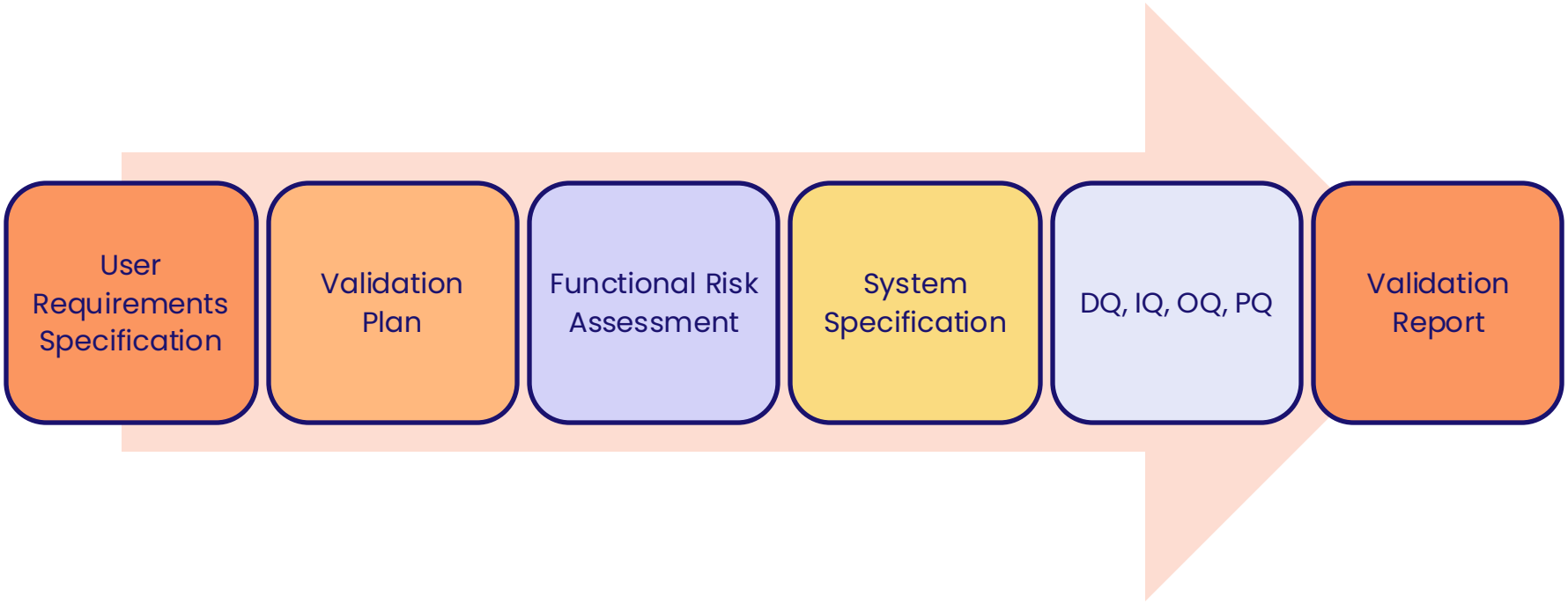
#3 Custom software

ISPE GAMP 5 Guide: A-Risk-Based approach to Compliant GxP Computerized Systems, Second Edition Appendix D8 Agile Software Development

- "Agile is not a reason to accept the lower level of quality or GxP compliance.
- "For agile, testing is always performed (…) an untested product is not shippable."
- "The regulated user must ensure the computerized system is fit for intended use."
- "Evidence of this may be generated and maintained in tools and supporting systems"

Solution

#3 Custom software



#4 Software development & validation

Eudralex Volume 4 Annex 11

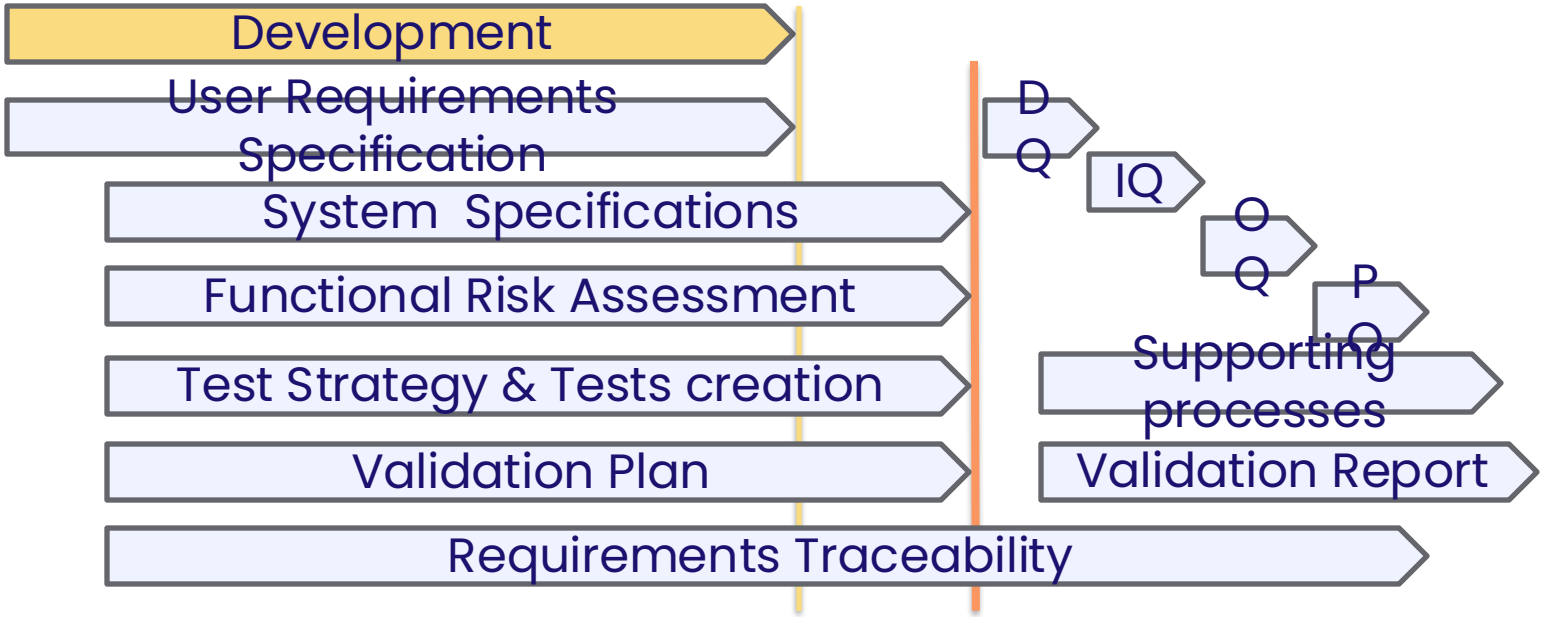
- 4.6 "For the validation of bespoke or customised computerised systems there should be a process in place that ensures the formal assessment ...".

Eudralex Volume 4 Annex 15

- 1.2 "Qualification and validation activities should only be performed by suitably trained personnel who follow approved procedures."
- "Verification of the correct installation [IQ] against pre-defined criteria"

Solution

#4 Software development & validation



#5 Risk assessment & risk management

ISPE GAMP 5 Guide: A-Risk-Based approach to Compliant GxP Computerized Systems, Second Edition
Appendix M4 Categories of Software and Hardware

- There are two main ways to use the categories:
  - Whole-system assessment
  - Functional risk assessment

- Functional risk assessment
  - Increasing risk of failure occurrence from standard to custom software
  - Increasing risk of failure detection from standard to custom software

#5 Risk assessment & risk management

Occurrence and detectability depends on function implementation types:

Catagory 3	• Standard function – the risk should not be high
Category 4	• Configurable function – the risk might be medium
Category 5	• Custom-made function – the risk should not be low

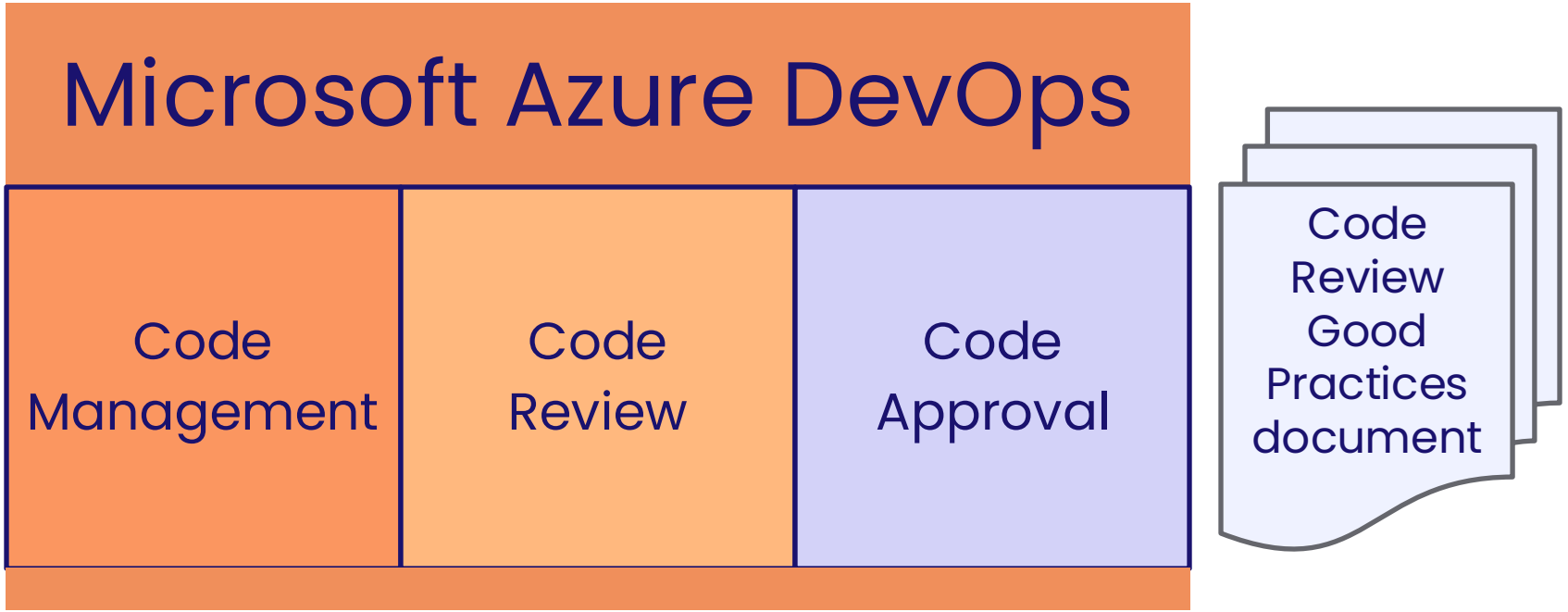
#6 Source code

ISPE GAMP 5 Guide: A-Risk-Based approach to Compliant GxP Computerized Systems, Second Edition

- Appendix D4: Management, development, and review of software
  - "The [source code] review should be performed by at least one independent person with sufficient knowledge"
- Appendix M12: Critical thinking
  - "Information and test evidence in the form of artifacts within (…) automated test tools have the same status as formal documentation„
- Appendix D9: Software tools
  - "Tools, like system supporting IT processes, are all GAMP category 1"
  - "Such tools and systems supporting system life cycle, IT processes and infrastructure should not be subject to specific validation"
  - "GAMP and FDA Case for Quality program strongly encourage the use of software lifecycle management tools"
  - "Tools should have sufficient controls to preserve the data/records"

Solution

#6 Source code



Good practices

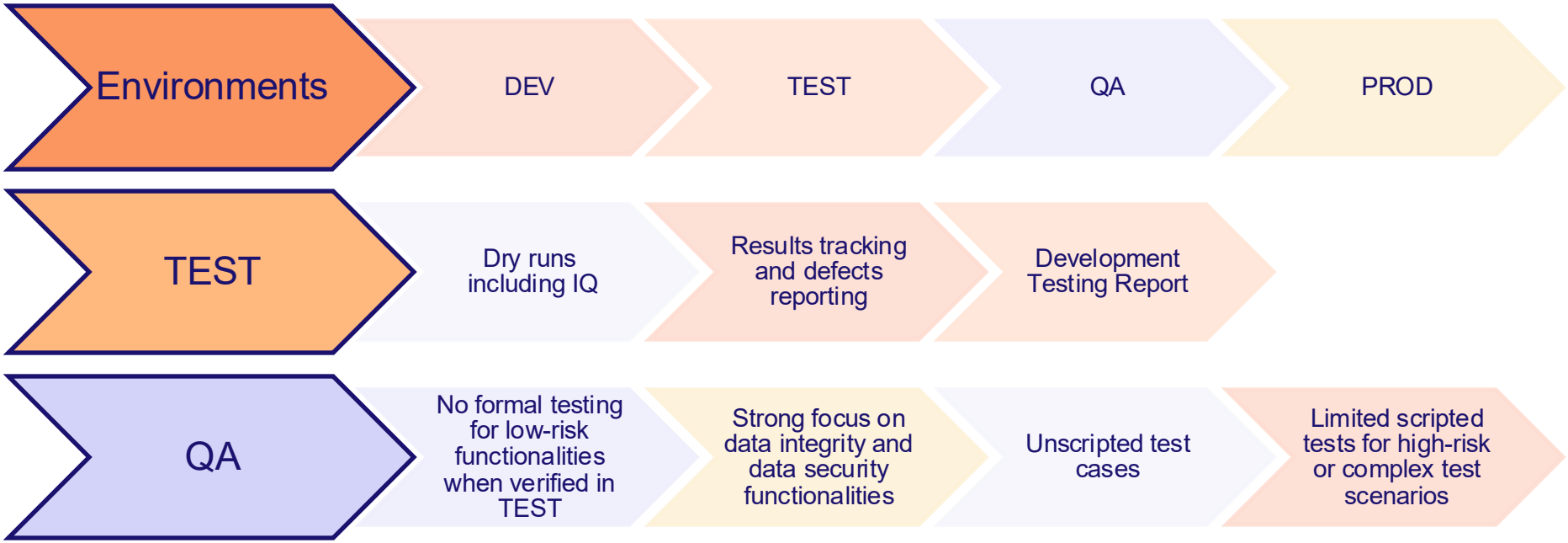
#7 Testing

ISPE GAMP 5 Guide: A-Risk-Based approach to Compliant GxP Computerized Systems, Second Edition
Appendix D5: Testing of computerized systems

- "Testing may take place in different environments during a project: development, formal testing, operational.
- "The test environments (…) need to be functionally equivalent for the testing to be representative…"
- "…there is no benefit to repeating testing already performed in another, but still adequatelly controled environment just because it was not the formal test environment,"

Solution

#7 Testing



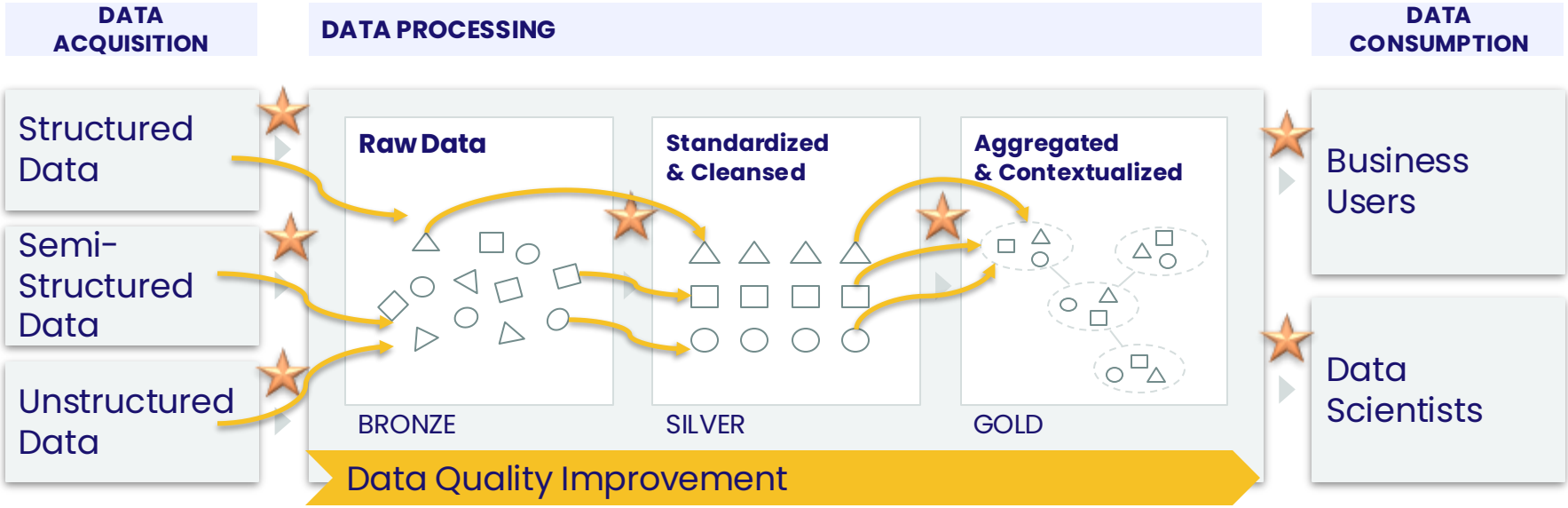
#8 Data integrity

Eudralex Volume 4, Annex 11

- 4.8 If data are transferred to another data format or system, validation should include checks that data are not altered in value and/or meaning during this migration process.

Solution

#8 Data integrity & data management

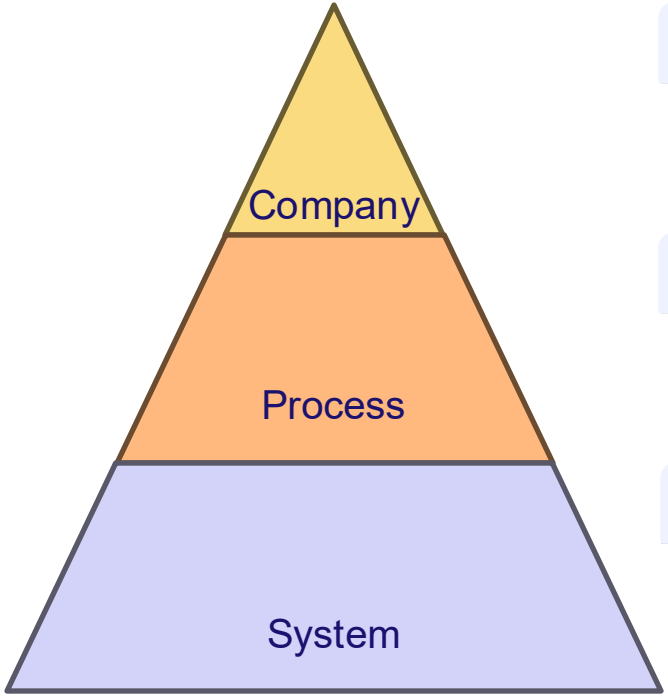


#8 Data integrity & data management

- MHRA (UK) GMP Data Integrity Initiatives
- WHO Guidance on Good Data and Records Management Practices
- PIC/S PI-041 Data Integrity Guidance
- FDA Guidance on Data Integrity and Compliance with CGMP
- EMA Guideline on computerised systems and electronic data in clinical trials
- ISPE Records and Data Integrity Guides
- DAMA Data Management Body of Knowledge

Solution

#8 Data integrity & data management



Company

- New unit within IT department
  "Data Intelligence & Data Platforms"

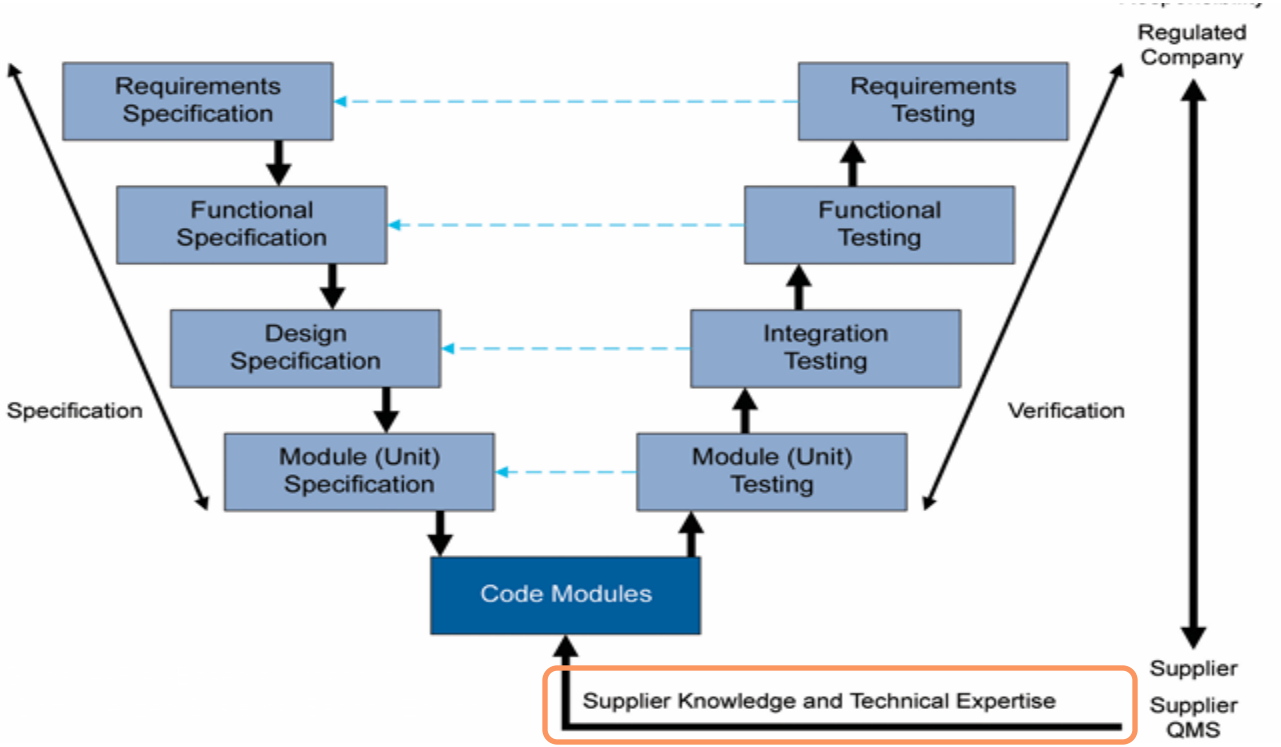
Process

- Data policy and procedures update

System

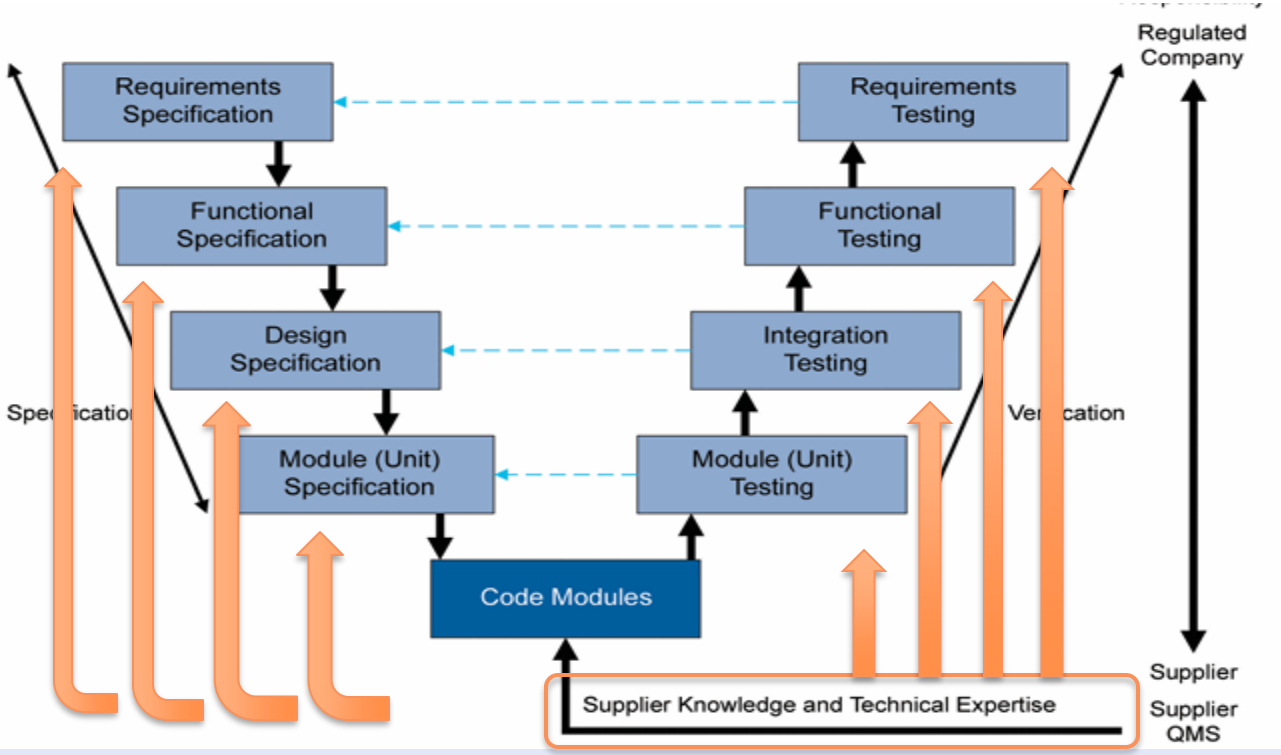
- Data integrity control points and mapping

#9 Supplier involvement



Solution

#9 Supplier involvement



Takeaways

1. Regulations do not limit your validation process - your procedures do.
2. A risk-based validation approach is crucial for custom software.
3. You are not alone; your supplier can provide significant support.
4. Data integrity and data management must be ensured at

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Experience

Kneat Gx experience

- SPECs – we have started in SharePoint and documents were moved to Kneat Gx (import from Word) for review, corrections, and approval.
- FRA – created in Excel and attached to Kneat Gx. I regrate not using Risk Entities.
- Traceability – Kneat Gx is a useful tool to create the requirements traceability (but we made a mistake)
- RTM – fully generated by Kneat Gx, over 1200 rows
- Test cases – created in SharePoint and moved to Kneat Gx test protocols
- Review & approval process – very efficient, users were satisfied
- User license consumption – improved due to active / inactive switch
- User experience – positive for both Standard Users and Review & Approval User

Thank you! Questions?

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Where dedication delivers program success

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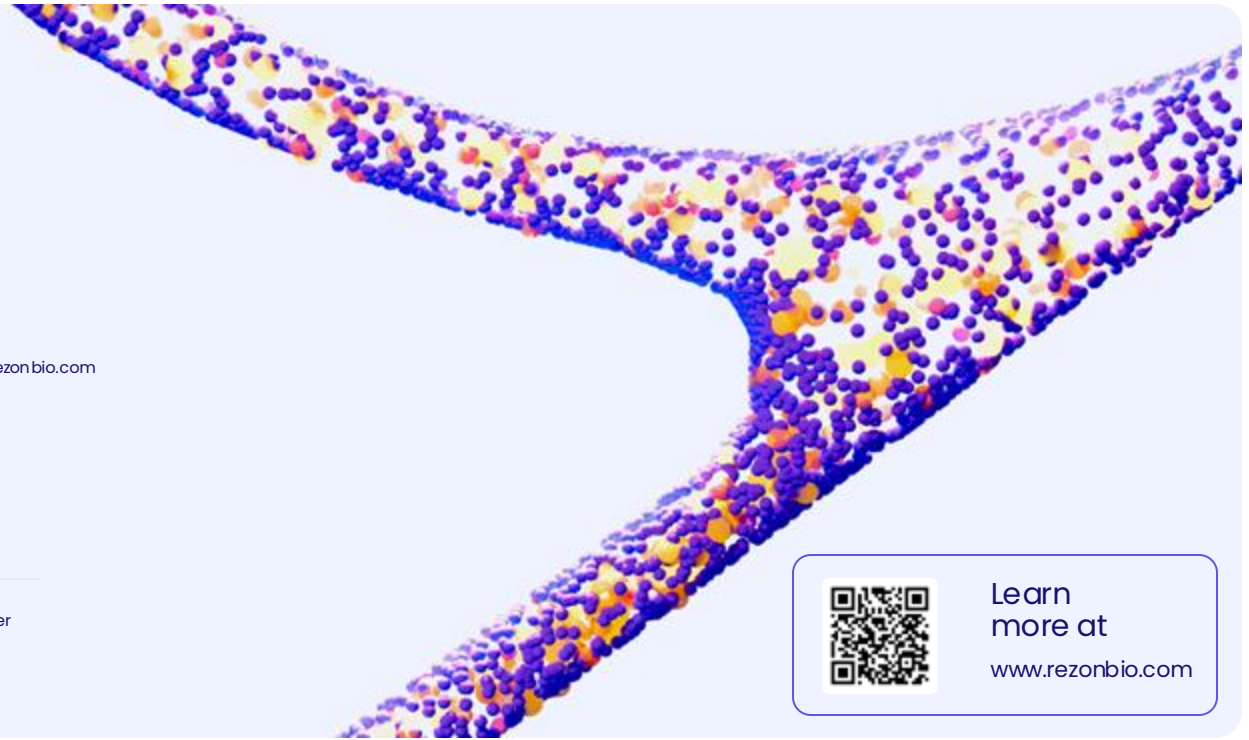

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