# UPDATE ON GAMP5 SECOND EDITION

David Margetts, ISPE Malaysia Affiliate

28th November 2022

# DAVE MARGETTS

- **Dave is the CEO and co-founder of Factorytalk and brings his advice, consulting and technical experience to improve quality, technology adoption and operational performance.**
- **He has lived in Asia since 2004, and is active in the ISPE both for GAMP, Validation 4.0 and as a regular speaker at the ASEAN affiliates.**
- **His professional motivation is to lower the costs of GxP systems to ensure all manufactures can move from paper and to leverage IIoT thinking and tools.**
- **In his personal life he loves activities in the outdoors and is kept very busy helping raise young twins!**

# DISCLAIMER

This presentation contains both direct references from GAMP5SE, third parties and own statements by the author based on experience of applying lean approaches to the validation of legacy and modern IT solutions across GxP.

# Seminar overview and timing

8.30 am to 9.00 am – Networking

9.00 am to 9.45 am – Presentation by Mr David

9.45 am to 10.00 – Q & A

10.00 am to 10.15 am – BREAK

10.15 am to 11.00 am – Presentation by Mr David

11.00 am to 11.15 am – Q & A

# Seminar overview and timing

8.30 am to 9.00 am – Networking

**9.00 am to 9.45 am – Presentation by Mr David**

9.45 am to 10.00 – Q & A

10.00 am to 10.15 am – BREAK

10.15 am to 11.00 am – Presentation by Mr David

11.00 am to 11.15 am – Q & A

# GAMP5SE: why change?

- The initial version of GAMP5 was published in 2008, since then there have been continuous changes in the way that software is developed and deployed and the prevalence of IT in Pharma has grown dramatically
- In August 2022 the ISPE published a new Second Edition (GAMP5SE) that contains updates through the guide to capture the major differences in systems and ways of working, the objective is to ensure GAMP continues to be relevant and the defacto industry best practice for IT systems GxP compliance

# Why change?

- "*Operating in a highly regulated industry may lead practitioners to apply prescriptive and rigid compliance-based approaches that are not commensurate with and not effective in managing any actual risk to the product and the patient*" – GAMP5SE

  - Producing documents to pass inspections instead of improving software suitability and quality…

# Why change?

- *"The industry approach to validation has in some cases been overly burdensome, despite the best effort of the GAMP Community of Practice, the US FDA and other regulators to reinforce through presentations and guidance that the validation of computerized systems should be focused on 'intended use' and scaled commensurate with the risks to patient safety, product quality and data integrity. Validation projects have often been documentation focused exercises, more befitting a grammar exercise than artifacts supportive of regulated activity."*



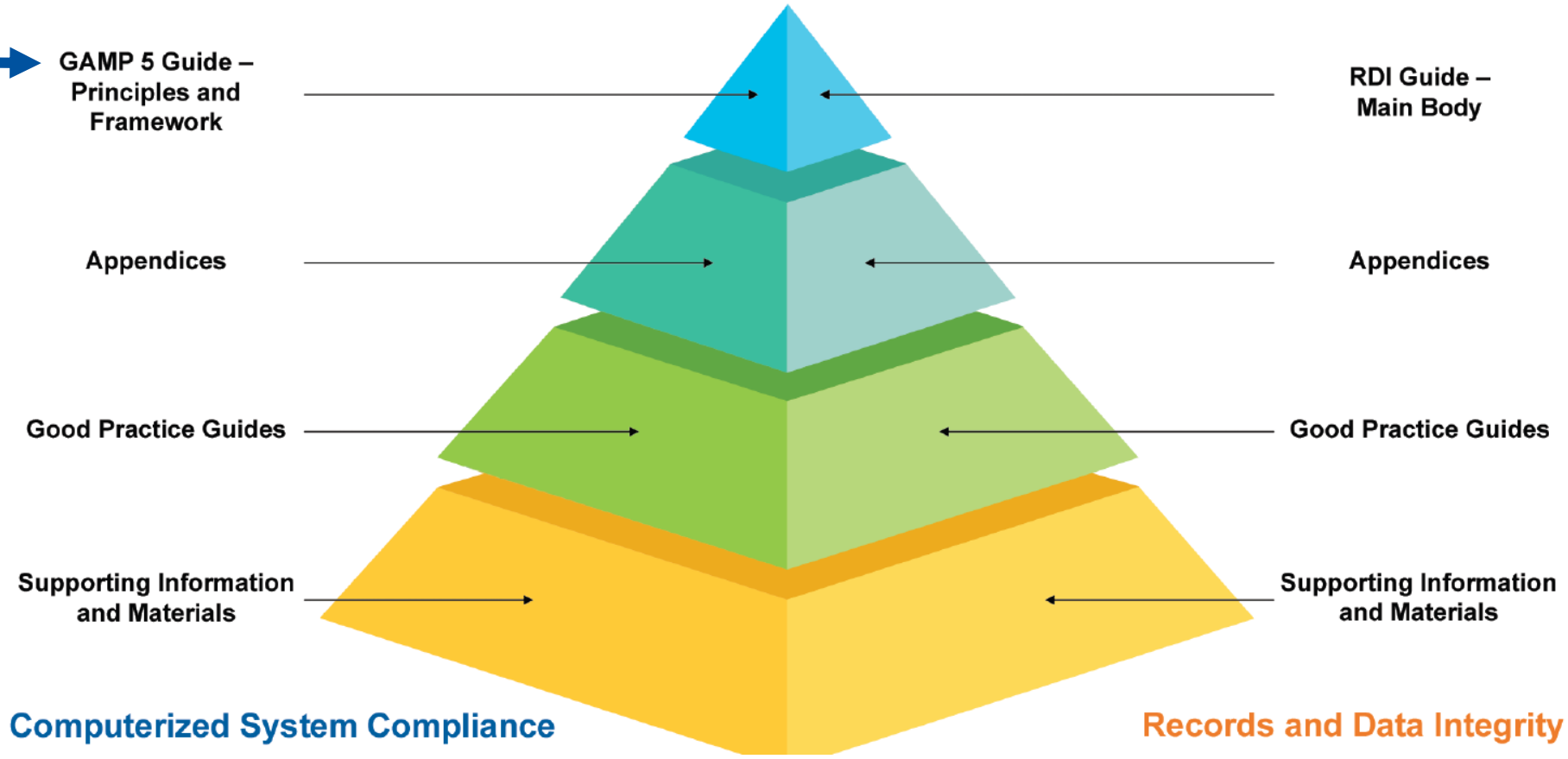
*https://www.europeanpharmaceuticalreview.com/article/176422/ispe-gamp-5-second-edition-computerized-system-expectations/*

# GAMP structure

**Chapter 4:**

- Planning
- Specification, configuration and coding
- Verification
- Reporting and release

Figure 1.2: GAMP Documentation Structure [20]

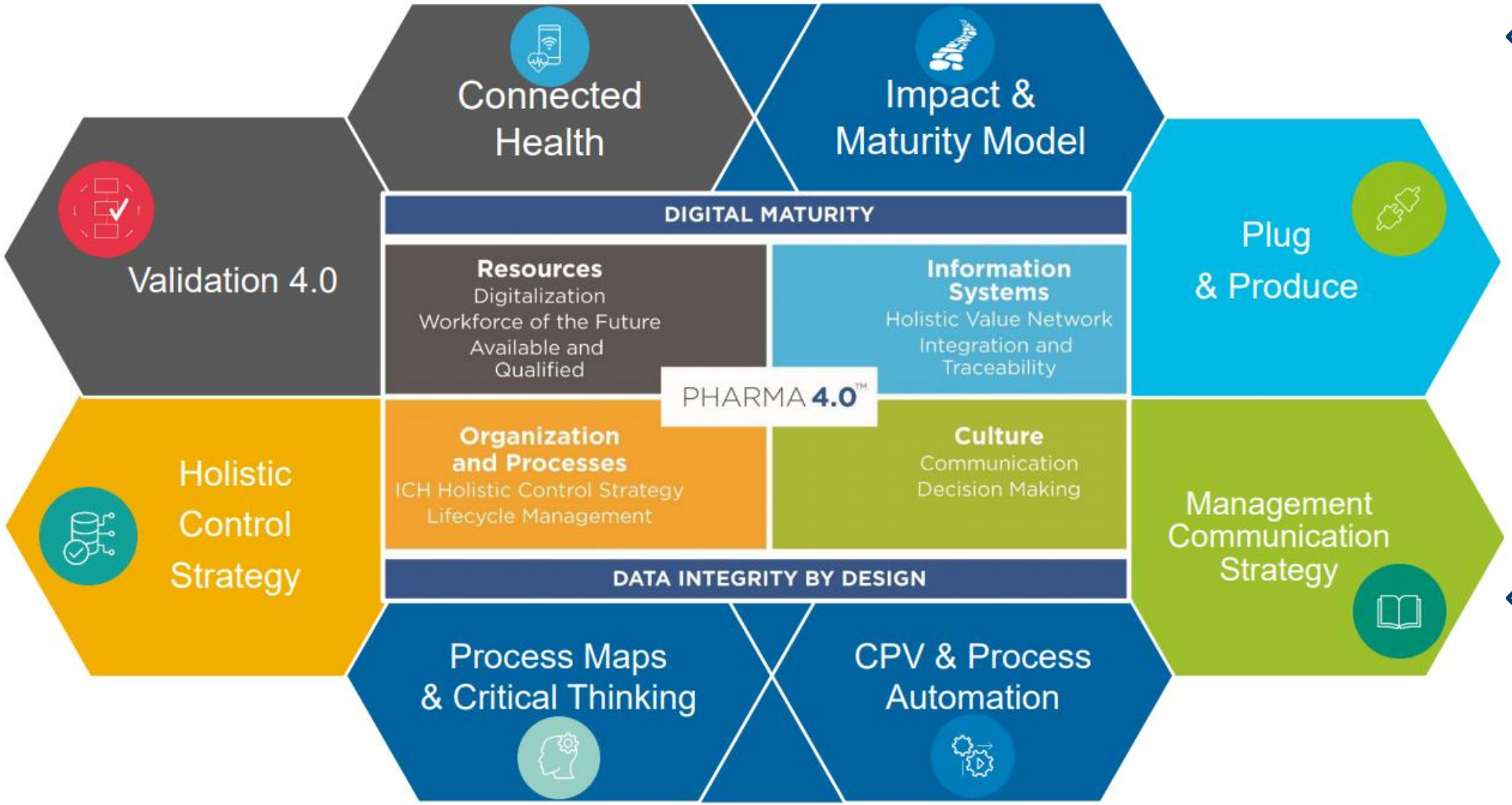



*GAMP5SE ISPE*

# What has been updated?

- Overall approach and framework is the same as initial GAMP5, SE is updated with a focus on:
  - Critical thinking, does the validation scope and effort make sense considering the role and use of the system and help improve and contribute positively to quality?
  - The move from customised software projects to standard configurable products
  - The importance of IT service providers, particularly the increased role of software suppliers and Cloud Service Providers
  - To directly address modern software industry practices:
    - Development approach's including Agile, iterative SDLC's (not only waterfall)
    - Software tools and automation used for development, deployment and control
  - Updated case studies for current IT systems
  - Initial guidance on emerging technologies (AI, Blockchain)
  - Latest ISPE initiatives (knowledge management, Pharma 4.0)

# ISPE Pharma 4.0 > now a Community of Practice (CoP)





SIG, AI /ML WG

Biotechnology SIG, Data and Process Science Working Group

*Pharma4.0 ISPE*

# GAMP5SE: what is updated?

- Sections and topics that are new:
  - Appendix D8 – Agile
  - Appendix D9 – Software Tools
  - Appendix D10 – Distributed Ledger Systems (BlockChain)
  - Appendix D11 – AI and ML
  - Appendix M11 – IT Infrastructure
  - Appendix M12 – Critical Thinking

Alignment to current software industry ways of working

New tech

Change in focus

# GAMP5SE: what is updated?

- Sections and topics that are updated:
  - Appendix D1 – Specifying Requirements
  - Appendix S2 – Electronic Production Records

- Sections and topics that are removed:
  - ~~Appendix D2 – Functional Specifications~~ > Combined with Requirements
  - ~~Appendix O7 – Repair Activity~~
  - ~~Appendix S5 – Managing Quality within Outsourced IS/IT Environment~~

# Main takeaways (General)

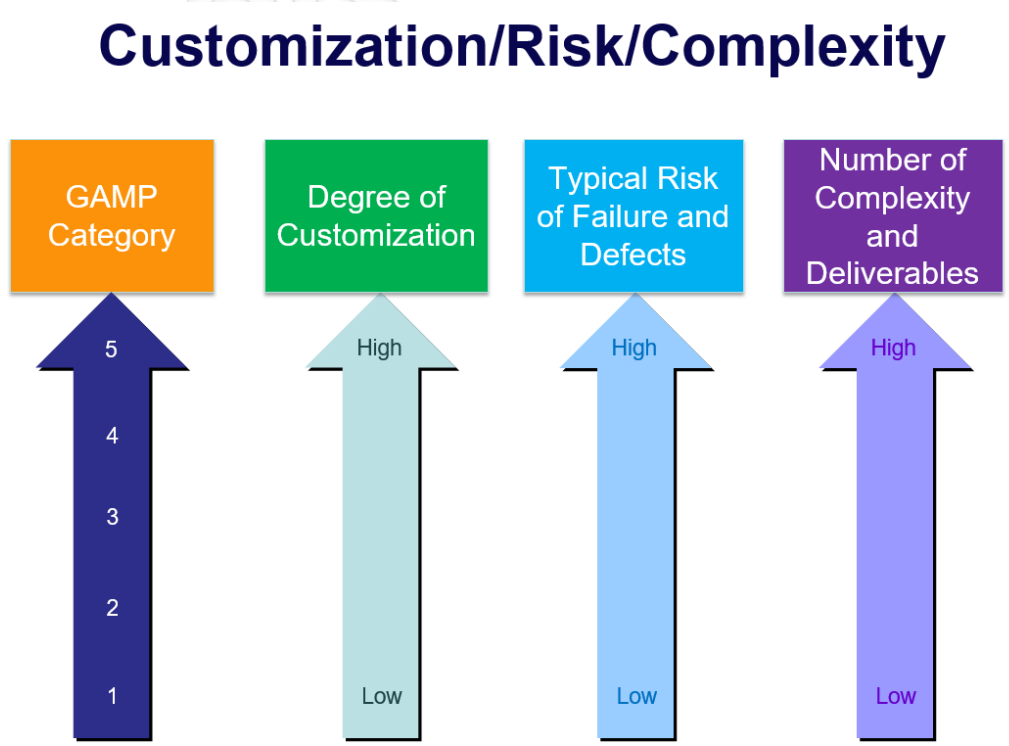
- Suppliers perform an important role, it may be third party (vendor) or internal service team > in case of internal IT department are they managed and operating as you would an external supplier?
- Relationship with supplier is not mandated under a specific model or process > the V-model was commonly misunderstood to be a prescribed approach rather than a basis for the links and activities between regulated companies and its suppliers

# Main takeaways (General)

- Quality Risk Management is a key tool to scale validation activities throughout a systems lifetime
- GAMP categories are still defined in SE and are a useful guide towards the general direction for a type of product or function (configuration/customization), however the focus and method for working out what and how deep to validate shifts to QRM

# Benefits of configurable software

- Less/no customization required is less direct cost in projects
- Customer can learn and apply best practices configuration
- Leverage supplier qualification documentation to reduce validation
- Faster and less complex project implementation
- Operational: less risk of failure and effects, less effort in upgrade




Process + Risk Assessment

# GAMP5SE: main takeaways (General)

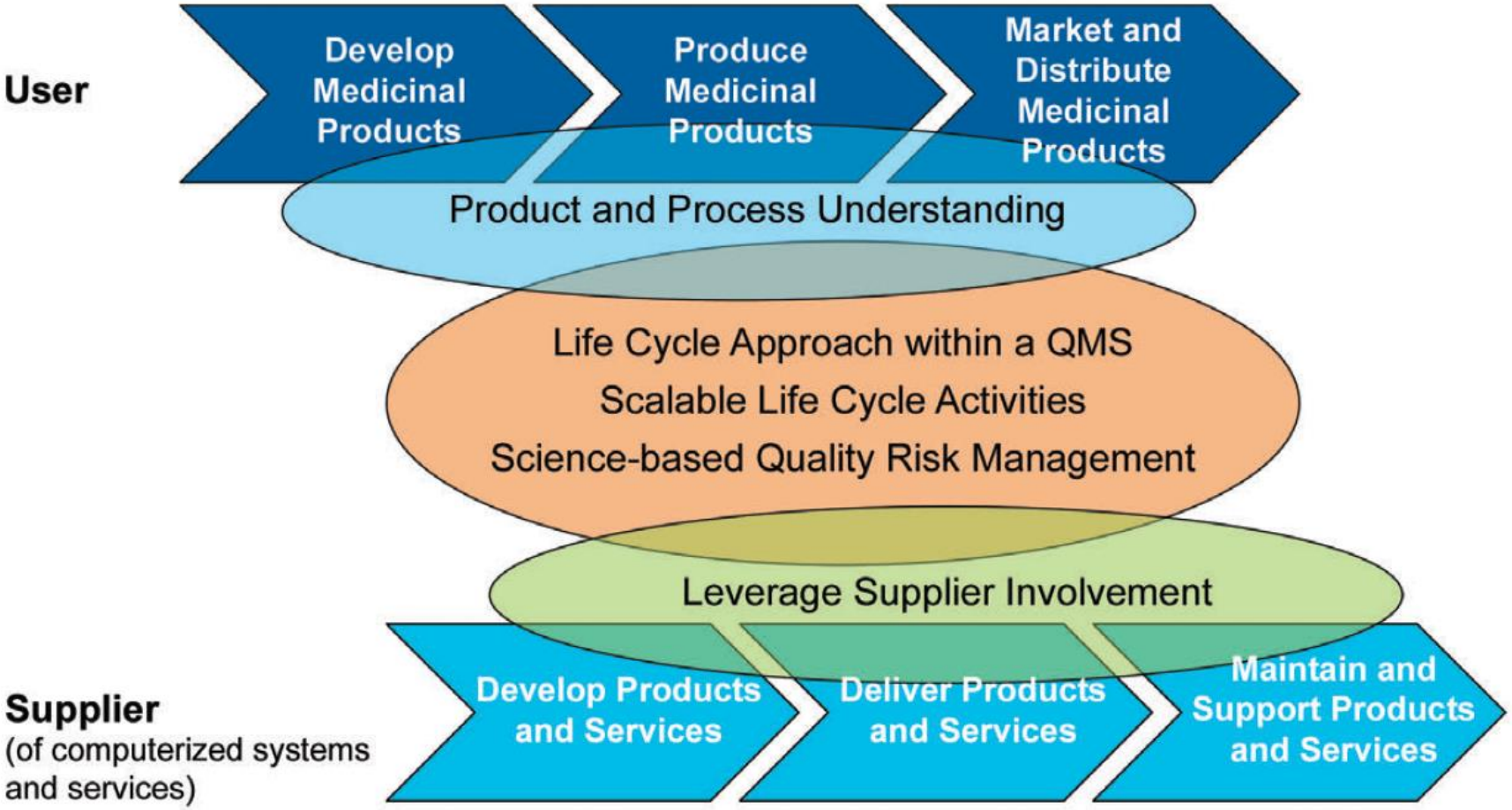
- Compliance and fitness for purpose of a system is the responsibility of the regulated company:
  - The decision to release a system for GxP use relies on assessment of the combined activities by both the company and supplier
  - Not everything can be proved by design + test evidence! supplier assessment of their application and QMS are therefore key aspects to build on your CSV approach to ensure system suitability and fitness
  - With suitable suppliers the focus for regulated company validation shifts to intended use from functional description and testing

# GAMP5SE: main takeaways (General)

- Terminology:
  - GAMP5SE does not prescribe any specific terms for the validation activities, particularly in specification/testing different suppliers and regulated companies may use own/other terms
  - For example traditional terms IQ, OQ, PQ are mapped loosely to:
    - IQ = Installation and configuration
    - OQ = Business process and ranges
    - PQ = Intended use and acceptance
  - Goal: activities are successfully completed to accept and release the system

# Key GAMP concepts (unchanged)

**Figure 2.1: Key Concepts of this Guide [20]**



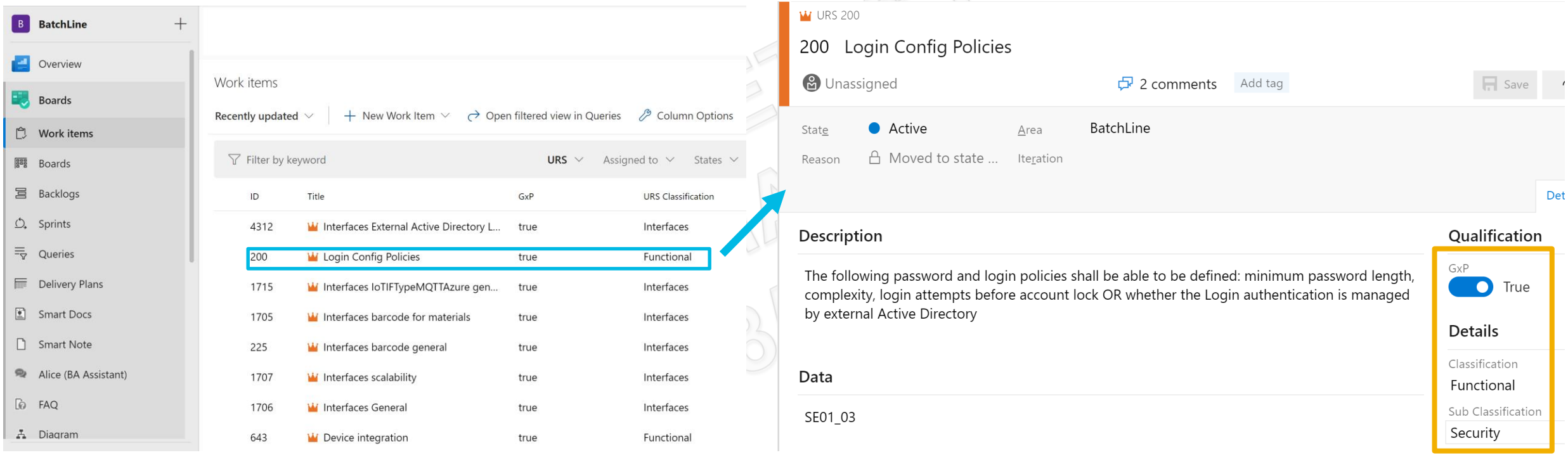

*GAMP5R2 ISPE*

# GAMP5SE: main takeaways (Appendix D1 – Requirements)

- Requirements may be independent of a specific solution and/or based on an actual solution in case of highly specific or pre-selected vendor
- Requirements will evolve! and may start as not fully defined, especially when using iterative approaches, if controlled this is fine and better reflects the evolution of software and projects
- Specifically mentions Agile terminology and hierarchy (Epic > User Story) as an alternative to URS and FS etc
- Requirements can be captured as a document or managed electronically as artifacts in a system, this can be done by extract report from suppliers existing SDLC tools

# GAMP5SE: main takeaways (Appendix D1 – Requirements)

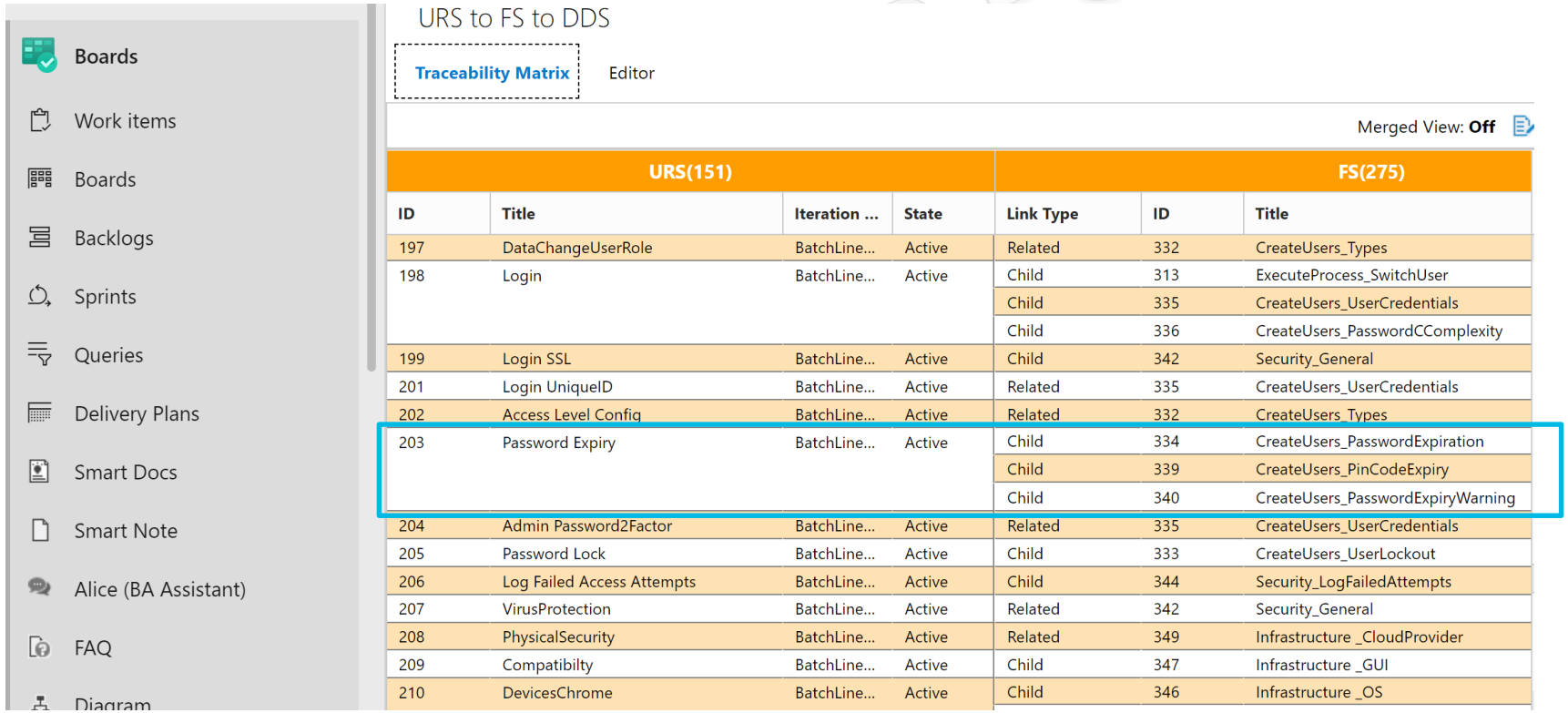
## Example of a managing requirements electronically




**Requirements are referenceable objects in the development tool, benefits are electronic version control, automatic generation of reports, linking to specifications, code and testing for traceability and full audit trails**

# GAMP5SE: main takeaways (Appendix D1 – Requirements)

## Example of managing requirements traceability electronically




URS to FS to DDS

Traceability Matrix | Editor

Merged View: **Off**

| URS(151) | | | | FS(275) | | |
|---|---|---|---|---|---|---|
| ID | Title | Iteration ... | State | Link Type | ID | Title |
| 197 | DataChangeUserRole | BatchLine... | Active | Related | 332 | CreateUsers_Types |
| 198 | Login | BatchLine... | Active | Child | 313 | ExecuteProcess_SwitchUser |
| | | | | Child | 335 | CreateUsers_UserCredentials |
| | | | | Child | 336 | CreateUsers_PasswordCComplexity |
| 199 | Login SSL | BatchLine... | Active | Child | 342 | Security_General |
| 201 | Login UniqueID | BatchLine... | Active | Related | 335 | CreateUsers_UserCredentials |
| 202 | Access Level Config | BatchLine... | Active | Related | 332 | CreateUsers_Types |
| 203 | Password Expiry | BatchLine... | Active | Child | 334 | CreateUsers_PasswordExpiration |
| | | | | Child | 339 | CreateUsers_PinCodeExpiry |
| | | | | Child | 340 | CreateUsers_PasswordExpiryWarning |
| 204 | Admin Password2Factor | BatchLine... | Active | Related | 335 | CreateUsers_UserCredentials |
| 205 | Password Lock | BatchLine... | Active | Child | 333 | CreateUsers_UserLockout |
| 206 | Log Failed Access Attempts | BatchLine... | Active | Child | 344 | Security_LogFailedAttempts |
| 207 | VirusProtection | BatchLine... | Active | Related | 342 | Security_General |
| 208 | PhysicalSecurity | BatchLine... | Active | Related | 349 | Infrastructure _CloudProvider |
| 209 | Compatibilty | BatchLine... | Active | Child | 347 | Infrastructure _GUI |
| 210 | DevicesChrome | BatchLine... | Active | Child | 346 | Infrastructure _OS |

**Traceability report provided SDLC tool, helps to ensure that every change/release of software follows the required QMS process from design to test**

# GAMP5SE: main takeaways (Appendix S2 – Electronic Production Records)

- Incorporation of electronic capabilities:
  - Review By Exception
  - Real-Time disposition
  - Cloud and Blockchain

- Clarification of use and review of Audit Trails
  - Who should review?
  - How often should review?
    - Unless stated explicity in the GMP, then use Risk Assessment, if someone was attempting to access by brute force would you know and what impact would this have? Modern infrastructure can detect this and handle many typical security risks so can be designed out by using Process + Risk assessment

# GAMP5SE: main takeaways (Appendix S2 – Electronic Production Records)

- Within EPR only the data required by the regulations is considered GxP
  - eSignatures are different from user identification!
  - OEE, improvement and financial data is usually not GxP..
- Trends and warnings, information for continuous long term improvement etc are not GxP unless used to make GxP decisions..
- Systems with functionality relevant for EPR:
  - EBR / MES
  - Document and Quality Management
  - Supply Chain Management
  - Data Historian
  - ERP
  - Process Control
  - LIMS

# GAMP5SE: main takeaways (Appendix S2 – Electronic Production Records)

- Specific mention of the importance of understanding your process:
  - Data and workflow mapping to identify what data is required for which business process, what is critical and the role of system(s)
  - Design and transformation from paper to EPR requires verification of the processes used to perform transformation and confirm equivalence to paper > MBR verification
  - ALCOA+ principles should be applied
  - Verified method to generate reports in timely, human readable form



After the break we will look at a Process + Risk Assessment example

# GAMP5SE: main takeaways (Appendix S2 – Electronic Production Records)

- Review By Exception:
  - Is positioned as a pre-step to Real Time Release

- RBE expectations related to CSV:
  - RBE processes must be well-defined (ie: part of procedures)
  - Operational experience is established (can be part of user testing)
  - Data that would be manually reviewed in non-RBE reports is retained
  - Evidence that computerized review is at least as comprehensive and accurate as manual
  - When no critical exceptions occur, a report is still generated and shows operations completed without error
  - Exception instances should include sufficient context to allow for review and to support investigations

# Seminar overview and timing

8.30 am to 9.00 am – Networking

9.00 am to 9.45 am – Presentation by Mr David

**9.45 am to 10.00 – Q & A**

10.00 am to 10.15 am – BREAK

10.15 am to 11.00 am – Presentation by Mr David

11.00 am to 11.15 am – Q & A

# Seminar overview and timing

8.30 am to 9.00 am – Networking

9.00 am to 9.45 am – Presentation by Mr David

9.45 am to 10.00 – Q & A

**10.00 am to 10.15 am – BREAK**

10.15 am to 11.00 am – Presentation by Mr David

11.00 am to 11.15 am – Q & A

# Seminar overview and timing

8.30 am to 9.00 am – Networking

9.00 am to 9.45 am – Presentation by Mr David

9.45 am to 10.00 – Q & A

10.00 am to 10.15 am – BREAK

**10.15 am to 11.00 am – Presentation by Mr David**

11.00 am to 11.15 am – Q & A

# GAMP5SE: main takeaways (Waterfall / v-model and Agile)

Figure 3.3: Linear Approach

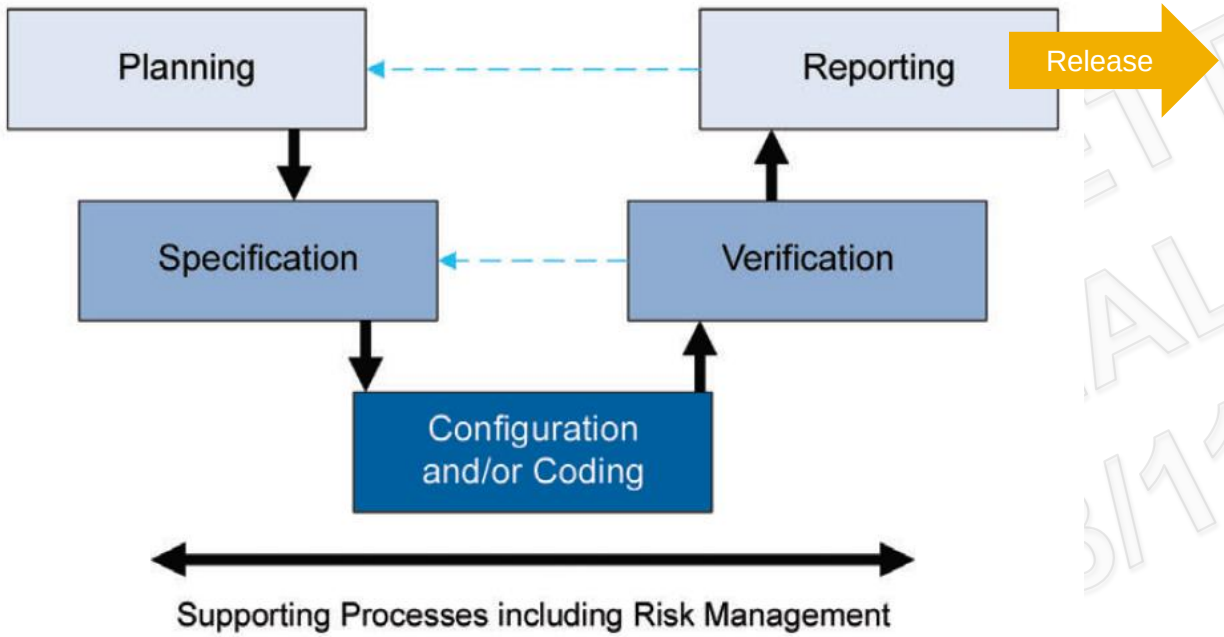


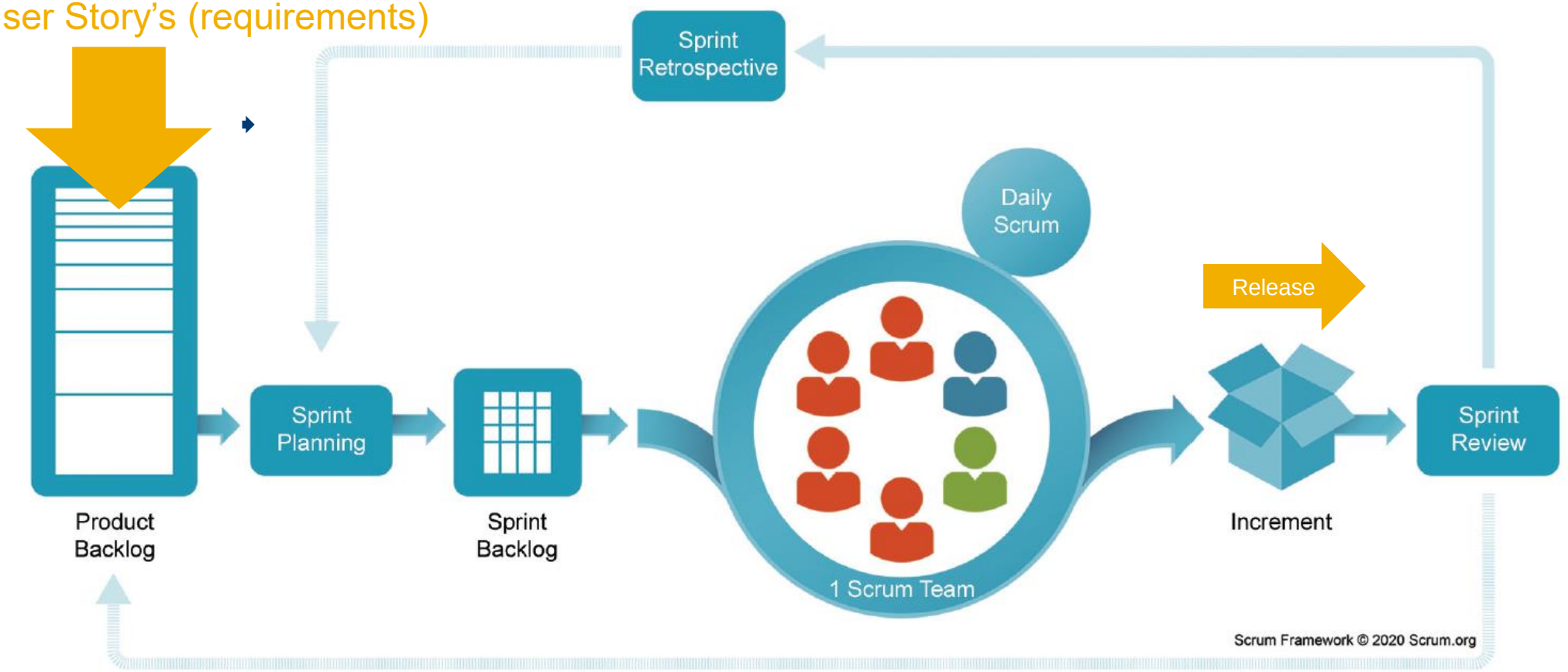

Figure 3.4: Iterative and Incremental


Figure 3.4: Iterative and Incremental


*GAMP5SE ISPE*

# GAMP5SE: main takeaways (Appendix D8 – Agile)

Epics / User Story's (requirements)




Agile software development is iterative not one-way sequential / waterfall, GAMP5 was often misunderstood to be relevant for waterfall due to the V-model but this was never prescribed or mandated *Scrum.org*

# GAMP5SE: main takeaways (Appendix D8 – Agile)

- Do not need to change SDCLC terminology into traditional life-cycle documents, ie: use Epic/User Story not Requirements
- URS in Agile is an identifiable set of fulfilled requirements for that release
- Can be an output report from the development system, does not have to be a URS document or reformatted/adjusted to suit legacy validation definitions
  - Highlighting what is GxP critical is still recommended and tracing this through specification and testing

# GAMP5SE: main takeaways (Appendix D8 – Agile)

- Key agile tools / capabilities:
  - Backlog management and grooming (features that will be added in the next releases)
    - Real-time status of requirement and traceability
    - Includes audit trails for changes
  - Test management
    - Evidence of test status
    - Typically using automated regression testing (more efficient and thorough
  - Code repository
    - Reduces the risk of error due to configuration and parallel development by several teams/people

# GAMP5SE: main takeaways (Appendix D9 – Software Tools)

- Software that is used to develop/test/deploy GxP applications are generally not in the scope for validation
  - Company assessment and good IT practice:
  - Prevalence of the tool and usage
  - Controls related to DI (eg: logging, versioning)
  - Workflow and configuration
  - Automation and alerts/notifications
  - Tool failure
  - Cybersecurity

# GAMP5SE: main takeaways (Appendix D10 – Distributed Ledger)

- Pharma companies are already using DL's to ensure information that is shared internally and externally between parties can be trusted
- There are many potential use cases in Pharma including in Clinical, Supply Chain and Manufacturing
- Use GAMP methods to control the development and deployment of Distributed Ledger (or Blockchain) systems
- Aspects to verify when using BlockChains for GxP
  - Assessment of the maturity and governance of the blockchain and vendor, as an emerging technology vendors and platforms may change frequently and requirements for business stability needs to be assessed
  - Process and data mapping, understand the system and data relationships and responsibilities
  - Ensure controls on input data, verify accuracy before it reaches the DL
  - Ensure validity of data output, verify accuracy and use once off the DL

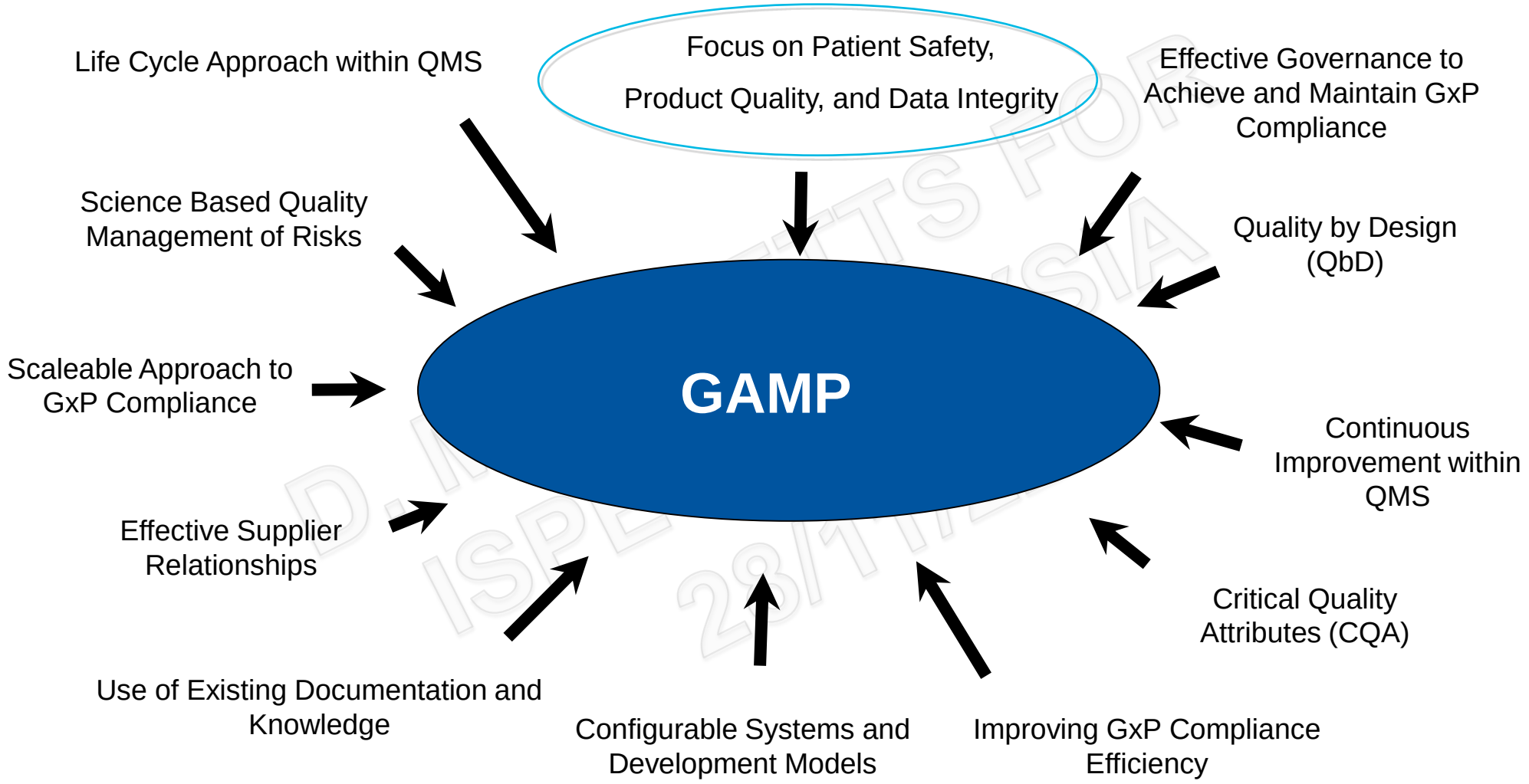
# GAMP5SE: and Computer Software Assurance (CSA)

- “The US FDA Center for Devices and Radiological Health (CDRH) Case for Quality program promotes:
  - Risk-based
  - Product quality–focused
  - Patient-centric approach to computerized systems.
- This approach encourages critical thinking based on product and process knowledge and quality risk management over prescriptive documentation-driven approaches”.
- The Agency published in September 2022 a draft entitled “Computer Software Assurance for Manufacturing, Operations, and Quality System Software”
- The scope of this guide is specifically on Medical Devices, however it is expected to influence and develop towards Pharma/Bio



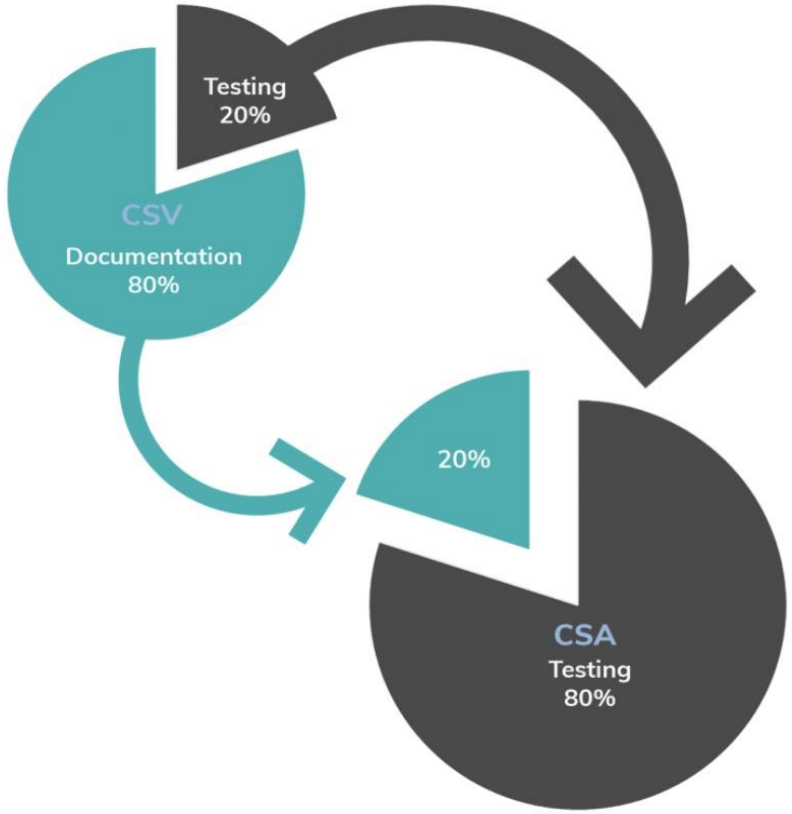
*https://ispe.org/pharmaceutical-engineering/why-ispe-gamp-supports-fda-cdrh-case-quality-program*

# The initial CSA guidance offers guidance on the scaling and types of testing

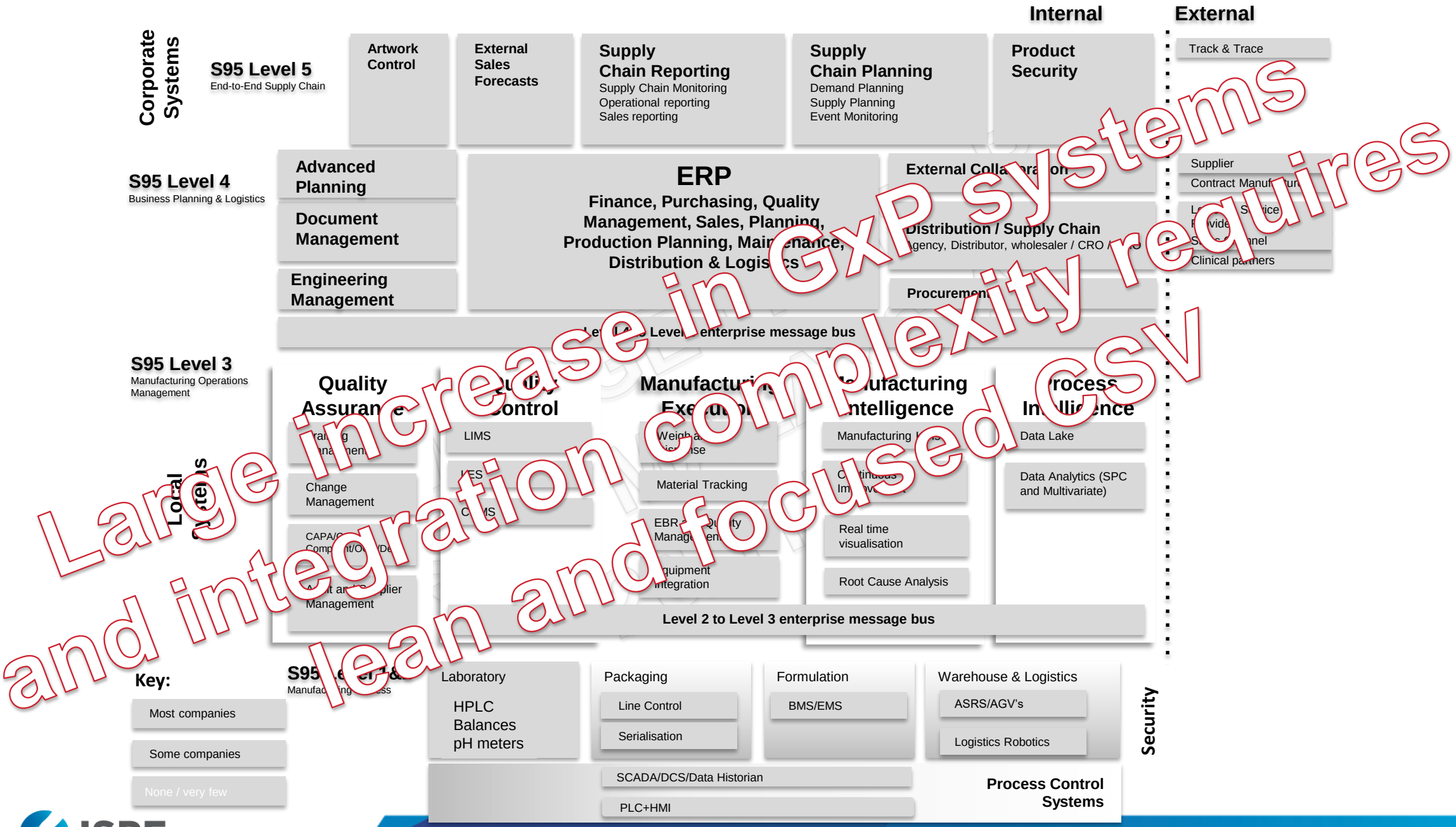



*https://www.fda.gov/media/161521/download*

# CSA vs. CSV?




- The CSA guidance covers Medical Devices
- The main practical input in CSA is the promotion and use of unscripted testing based on risk/maturity of software
- Several members of the CSA initiative are actively engaged with GAMP and working in CSA SIG, this will reduce the risk of unaligned approaches for CSV



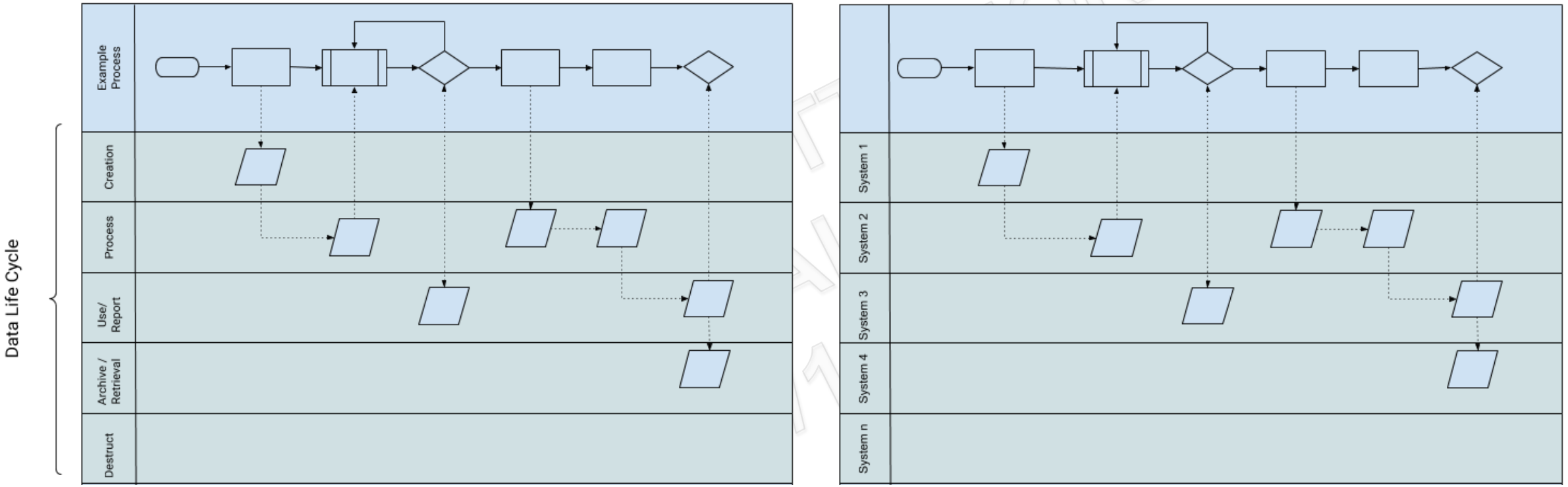

Large increase in GxP systems and integration complexity requires lean and focused CSV

# Input from recent work: Process and Risk Assessment to understand process, systems and scale test activities


- Process + Risk Assessment approach combines Data and Workflow mapping with assessment against Data Integrity, Vulnerability and Criticality to define corresponding Functional (Install, Config, Test) and Procedural controls (SOP, training)
- Based on the result we may a) change Requirements and/or Design to ‘design out high risks’ and/or b) refocus and change the type of testing to increase the amount of time testing (either scripted or unscripted) and reduce documentation only activities = increase the value-added

# Input from recent work: Process Data Maps for PRA

Pharma typically has good detail at unit operation level, but less ‘big picture’, multiple systems/equipment models on which to make assessment on what is significant and where controls are required




## Examples

- Organise the entire process to the stages in the Data Lifecycle / organise the process to the components
- Benefits are to 1) easily review the component scopes, the required integrations and usage of data 2) easily identification of common controls / risks and overall vulnerabilities

*Validation 4.0 ISPE*

# Data Source, Integrity and Vulnerabilities: Risk?

| System Setup (Source) | Data Transfer (Mode / Technology) | Target | A | L | C | O | A | CC | E | A | Vulnerability / Criticality |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Stand alone scale, not connected | **Manual, verified by 2 operators; recorded on paper** | Paper Batch Record | - | - | - | - | - | - | - | - | • Incorrect manual process + input of data<br>• Incorrect measurement<br>• Incorrect / missing unit of measurement<br>• Missing Meta Data (“Content of Creation”) (Higher)<br>• Falsification of action |
| Stand alone scale, not connected | **Manual, verified by 2 operators; recorded on paper ➔ Via HMI / Keyboard** | Electronic Batch Record | + | + | + | - | - | - | + | + | • Incorrect manual process + input of data<br>• Incorrect measurement<br>• Missing Meta Data (Reduced)<br>• Data loss due to technical issues<br>• Falsification of action |
| Connected scale (results) | **(confirmation by operator) ➔ data interface** | Electronic Batch Record | + | + | + | + | + | + | + | + | • Incorrect manual process<br>• Incorrect system design (e.g. field length)<br>• Data loss due to technical issue<br>• Falsification of action |
| Connected scale (recipe / instructions / results) | **(confirmation by operator) ➔ data interface** | Electronic Batch Record | + | + | + | + | ++ | + | + | + | • Incorrect system design (e.g. field length)<br>• Data loss due to technical issue<br>• Falsification of action |
| Connected scale (recipe / instructions / results) + Bio. + Vision | **(confirmation by camera vision) ➔ data interface** | Electronic Batch Record | ++ | + | ++ | + | +++ | + | + | + | • Incorrect system design (e.g. field length)<br>• Data loss due to technical issue |

# Entering Data and Rigour (strictness) of Confirmation


**Review**

Examination of data or evidence after the event by a second person to ensure correct action

**Check**

Observation just after the event by a second person to check the result of an action, event or behavior

**Verify**

Direct observation of the action, event or behavior by a second person, i.e. a witness

**Automated Check**

Human witness of a machine generated record to ensure correct Operation (i.e: remove the 2nd verifier)

**Automated Control**

Correct operation incorporated into the function of device or equipment. Equipment is qualified

**Automated Verification!**

# Input from recent work: Process + Risk Assessment

**Problem statement:**

- How to define the validation strategy for personalized medicine packing line, small batch size including batch size of 1

- Systemisation of masterdata, process recipe, operation, Work Instructions and records
- Electronic Batch Record, IoT, SCADA and automation of all operations
- Review by Exception
- Full systems integration to reduce manual data entry and errors
- Pick and place for tablet blistering
- Validation approach starts at design stage using Process + Risk Assessment to define the required controls and design out high criticality functions and data



*Validation 4.0 ISPE*

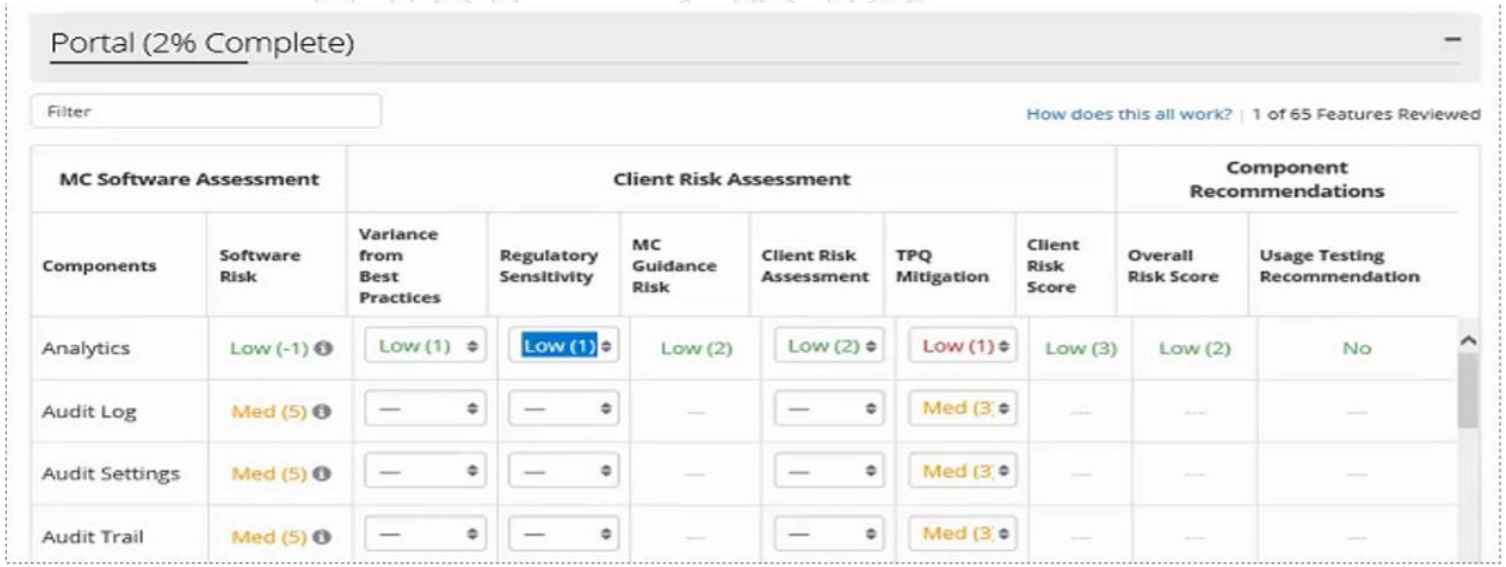
| URS PROCESS FLOW | | | | | | DATA INTEGRITY | | | | | | | | | VULNERABILITY ASSESSMENT | | | CRITICALITY ASSESSMENT | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Process Step ID | Process Name | System | Process Description | Process & Technology Capability | Data | A | L | C | O | A | C | C | E | A | Source of Data | Control (Technical / Procedure) | Data Vulnerability (H / M / L) | Data Criticality (GxP) (Direct (D), Indirect (I), No Impact (N) | Data Criticality - Justification | Severity (High (H) / Medium (M) / Low (L)) |
| Step 16 | Cut | Automated Line Control + SCADA + EBR | Process that cuts the sealed blister section to the final profile | High - Automation | Cut quality : dimension, leakage, properly cut/not | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | Interface | Technical | Low | Indirect Impact | GxP Record | Low |
| Step 17 | Cut QC/QA | Automated Line Control + SCADA + EBR | Process that inspects the cutting process to ensure it is free from cutting errors | High - Automation | Inspection setting | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | Interface | Technical | Low | Direct Impact | GxP Record | Medium |
| Step 18 | Seal QC/QA | Automated Line Control + SCADA + EBR | Process that inspects the sealing area to ensure it is free from sealing errors | High - Automation | Seal Quality: Leakage rates | ✓ | ✓ | ✓ | ✓ | × | ✓ | × | ✓ | ✓ | Manual | Procedure | Medium | Direct Impact | GxP Record | High |
| Step 19 | Final Rejection system | Automated Line Control + SCADA + EBR | Final rejection process that collects all rejects and defective products | High - Automation | Quality data of previous QC/QA Process (feed QC/QA, form QC/QA, fill QC/QA, mark QC/QA, Print QC/QA, Cut QC/QA) | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | Interface | Technical | Low | Direct Impact | GxP Record | Medium |
| Step 20 | Conveying | Manual Step | Process that moves discrete blister packs between processes | Low | - | - | - | - | - | - | - | - | - | - | - | - | - | - | | - |
| 021 | Finished Product | Manual Step | Process until get Finished Product (blister product). Move finished product to | Low | Production Batch Record | - | - | - | - | - | - | - | - | - | - | - | - | - | | - |
| 022 | Finish Operation, reconciliation and Post Consumption | Tulip IoT / Batchline EBR | Finish the operation in Batchline and Tulip, calculate the material consumption and operation yield. | High - EBR & EWI | - Batch ID<br>- Quantity<br>- no of defect | ✓ | ✓ | ✓ | ✓ | × | ✓ | ✓ | ✓ | ✓ | Manual | Technical & Procedure | Low | Indirect Impact | GxP Record | Low |
| 023 | KPI and process improvement | Tulip IoT | Dashboard in Tulip | High | Mnaufacturing Data | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | Automatic | Technical | None | No Impact | - | Low |
| 024 | Batch Record Review | Batchline EBR | Authorized user reviews batch record by exception and results from QC then decide to approve/reject the batch in Batchline | High - EBR | - Production Batch Record | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | Automatic | Technical & Procedure | None | Direct Impact | BRR product then Release | Low |

# Automating validation within systems (1)

**Problem statement:**

- How to deploy frequent updates for cloud eQMS users without large delay and effort to validate each release?

- System identifies critical/high risk configuration parameters, incorporates vendor testing coverage, and proposes customer validation testing only for high risk configuration / not covered by vendor testing
- Well managed infrastructure can ensure match between deployed customer environments and what is already qualified by the vendor.



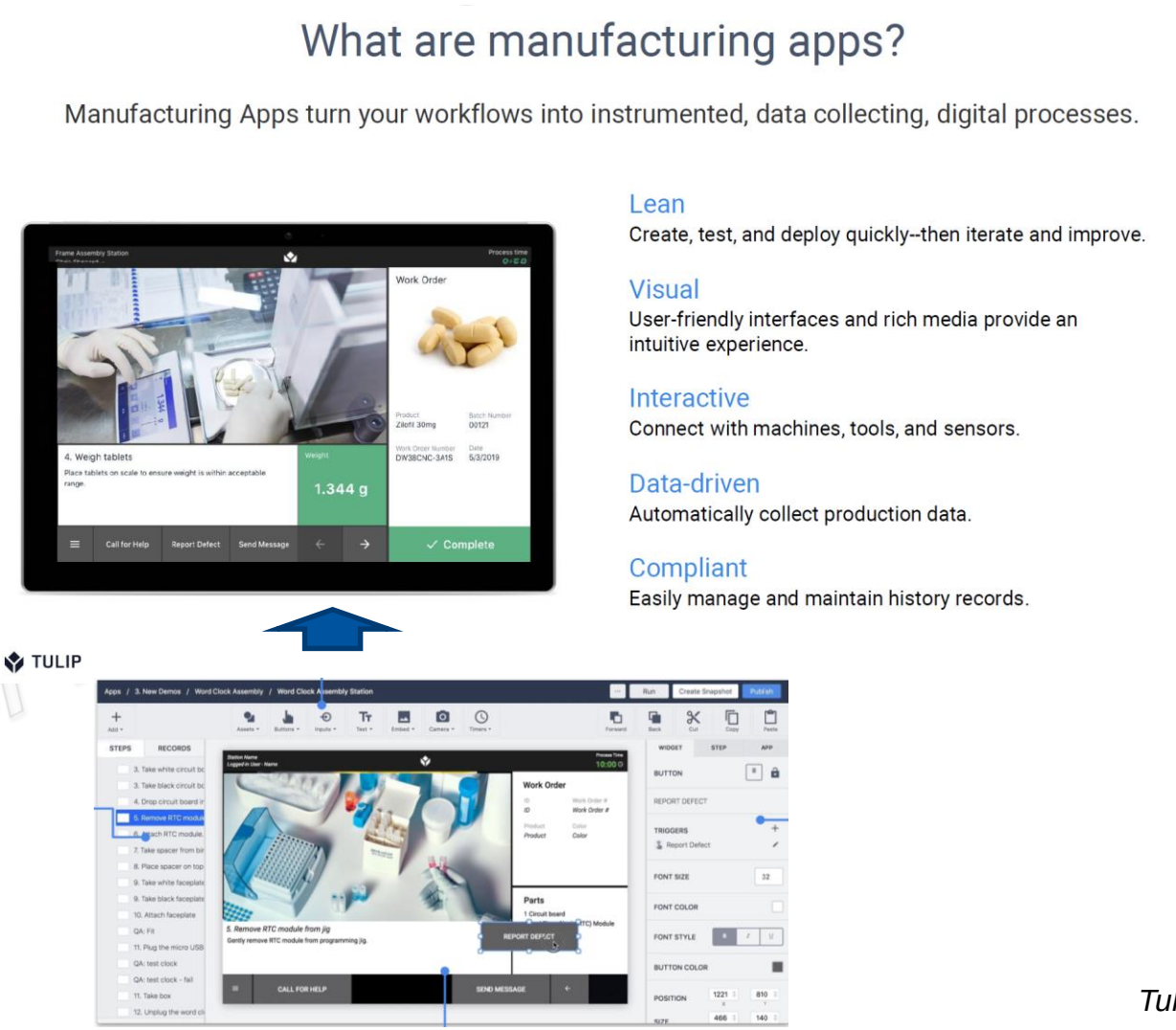

*MasterControl*

# Automating validation within systems (2)

## Problem statement:

- Rollout of a IoT manufacturing application platform to 28 global sites that allows end users to build their own use cases, how to support validation of each app?

- Replace paper documentation lifecyle with systemized control and guidance through the relevant CSV approach as the application is built and tested within the platform
- Ensures traceability
- Enforces standardization at all global sites
- Supports users with ‘how to validate’ a new and novel toolset with low training effort and zero paper..




*Tulip*

# Seminar overview and timing

8.30 am to 9.00 am – Networking

9.00 am to 9.45 am – Presentation by Mr David

9.45 am to 10.00 – Q & A

10.00 am to 10.15 am – BREAK

10.15 am to 11.00 am – Presentation by Mr David

**11.00 am to 11.15 am – Q & A**

# Contact us!

www.factory-talk.com

dma@factory-talk.com