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Computerised Systems

Wholesale Distribution Information Day, 28th September 2012

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Inspector

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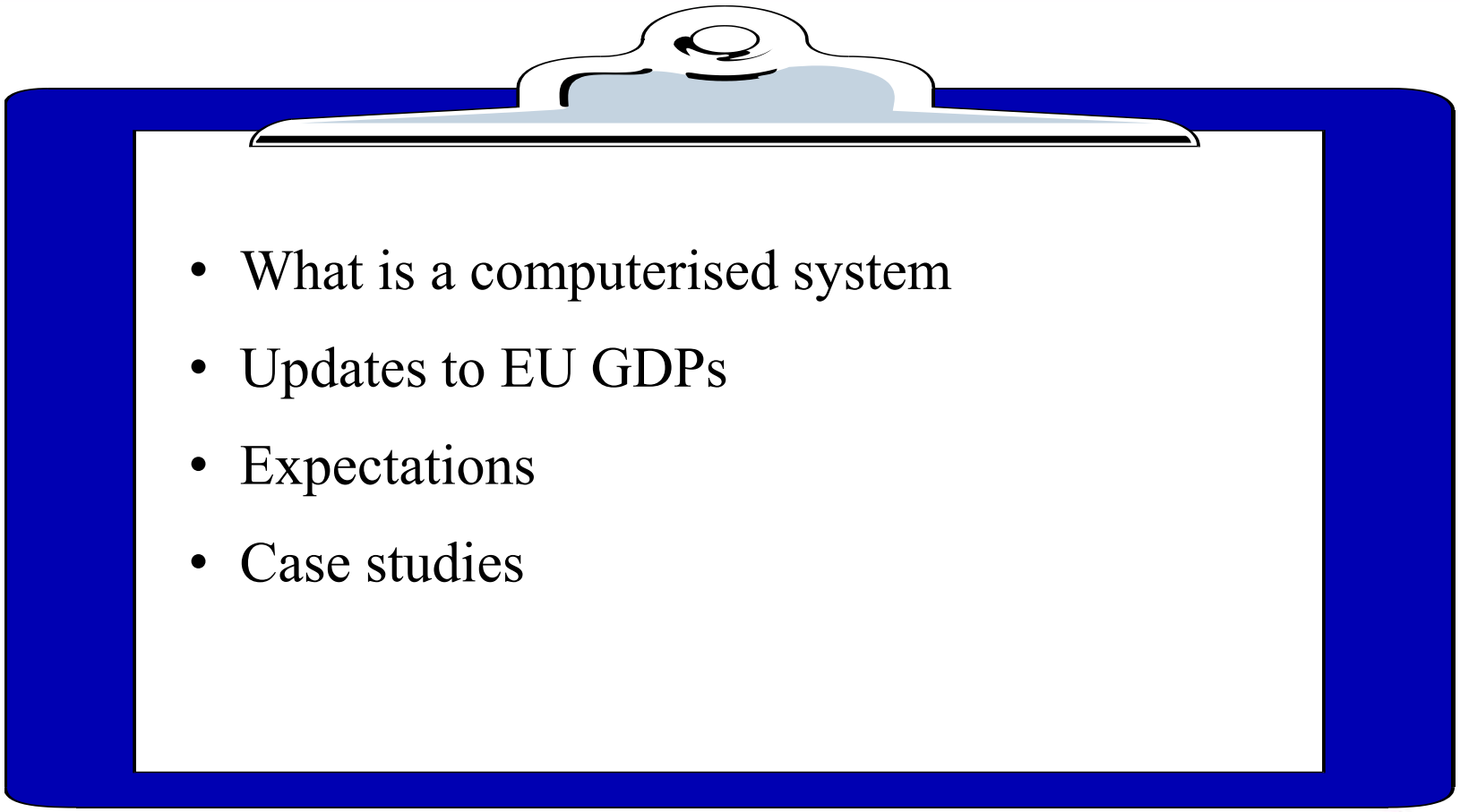

- What is a computerised system
- Updates to EU GDPs
- Expectations
- Case studies

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Will I ever see you again?

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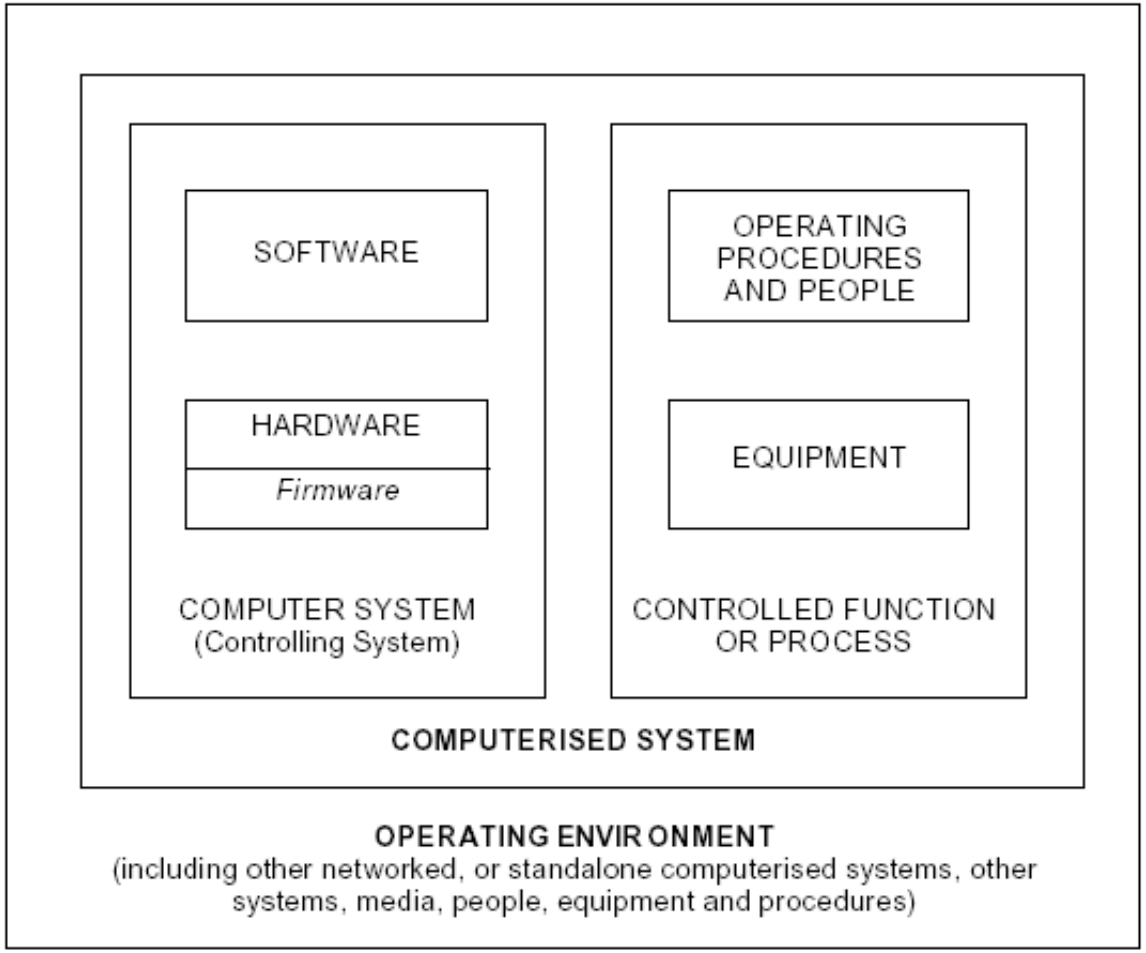
What is a Computerised System



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Computerised Systems within Wholesaling

- Systems which may impact on product quality
- Provide safety or quality data
- Impact operational reliability
- Maintain regulated data
- A few examples
  - Inventory Management Systems
  - Sales and Invoicing Systems
  - Temperature Monitoring Systems
  - Document Management Systems

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Question

In the event of a recall how would you identify who you supplied the affected product to?

a) By manually checking through all paper invoices
b) By manually checking a goods-out logbook
c) By manually checking through electronic records
d) By running a product search on an electronic inventory / invoicing system?

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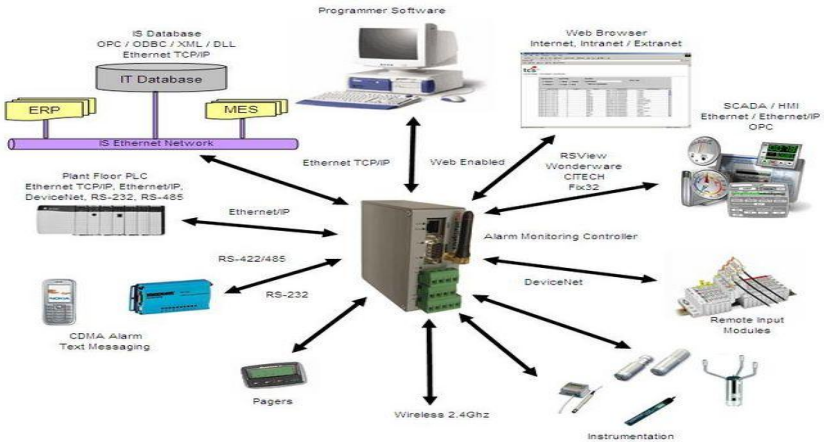
Why New Requirements?



- Patient safety
- Product quality
- Data integrity
- Where a computerised system replaces a manual operation, there should be no resultant decrease in product quality or quality assurance
- Did we build the right system & did we build it correctly?

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Revised EU Guideline on GDP (Draft)

Section 3.19

Before a computerised system is brought into use, it should be demonstrated through appropriate validation or verification studies, that the system is capable of achieving the desired results accurately, consistently and reproducibly.

Revised EU Guideline on GDP (Draft)

Section 3.20

Written detailed description

- Diagrams
- Kept up-to-date
- Principles
- Objectives
- Security Measures
- System scope
- Main features
- How the system is used
- How the system interacts with other systems

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Revised EU Guideline on GDP (Draft)

Section 3.21

Data should only be entered or amended by persons authorised to do so

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Revised EU Guideline on GDP (Draft)

Section 3.22

Data should be secured by physical or electronic means and protected against accidental or un-authorised modifications. Stored data should be checked periodically for accessibility. Data should be protected by backing up at regular intervals. Back up data should be retained for a period stated in national legislation but at least 5 years at a separate and secure location.

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Revised EU Guideline on GDP (Draft)

Section 3.23

Procedures to be followed if the system fails or breaks down should be defined. This should include systems for the restoration of data.

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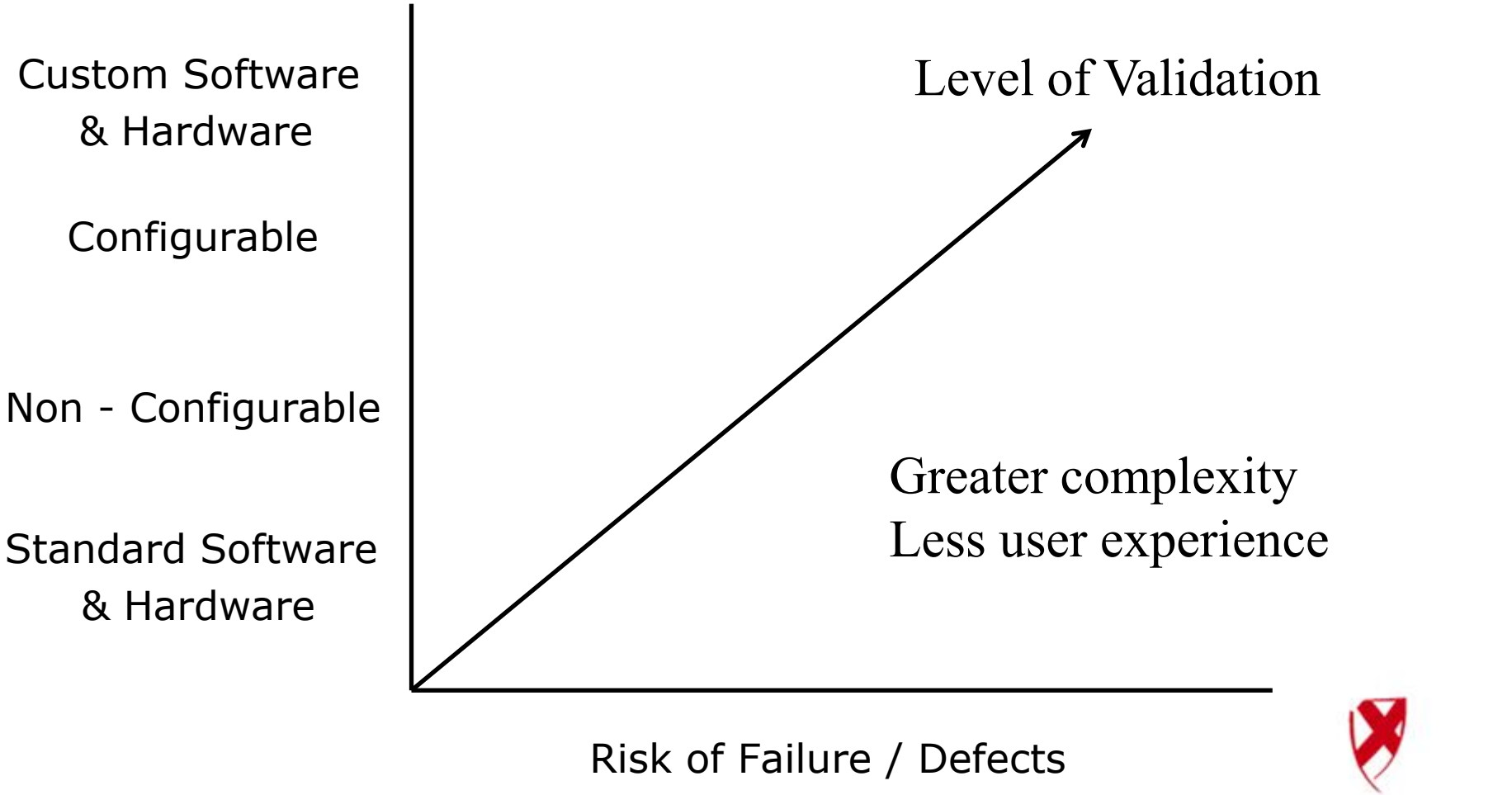
What to Do???



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Life Cycle Approach

1. Concept
   (User Requirement Specification - URS)
2. Project
   (Functional Specification, Design Specification)
3. Operation
   (Ongoing maintenance systems)
4. Retirement

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Supplier Involvement

Is the system being validated the same as the proposed system?

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User Requirement Specification

- A document that specifies the requirements for a computerised system – what it should do
- Should be commensurate with level of risk, complexity and novelty of system
- Should be detailed enough to allow for subsequent verification of system requirements
- May include operational requirements , functional requirements , data requirements, technical requirements, interface requirements, performance requirements, security requirements, maintenance requirements, retirement requirements
- For commercially available systems - may be part of purchasing document

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Software Validation

Category	Validation Approach
1 Infrastructure Software	●Record version (include service pack). ●Verify Correct Installation
3 Non - Configured	●URS ●Record version and verify installation ●Risk based tests against requirements ●Procedures put in place for maintaining compliance ●Consider auditing supplier for critical and complex applications
4 Configured	●As above, plus… ●Life cycle approach ●Supplier questionnaire – Adequate QMS ●Risk based tests against requirements in a test environment ●Risk based tests against requirements within the business process
5 Custom	●As above, plus… ●Full life cycle documentation ●Design and source code review

GAMP 5 Appendix M4

Hardware Validation

- Hardware Category 1 - Standard Hardware
  - Installation and connection
  - Record model, version number, serial number
  - Change Control

- Hardware Category 2 - Custom Built Hardware
  - As above plus...
  - Design Specification and Acceptance Testing
  - Verification of compatibility of interconnected hardware
  - Supplier audit

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Load Reviews

Ensuring that your system can cope with all eventualities

- Minimum level through to greater than expected load
- Repeat if new area / site added
- Growth modelling
- Number of users – number of transactions – memory capabilities

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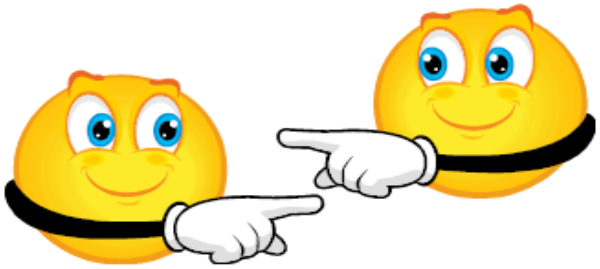
Suppliers

- Provide / Install / Configure / Integrate / Validate / Maintain / Modify / Retain
- Suitability?
- Competence?
- Technical Agreements
- Audit



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Case Study 1

A wholesaler uses an off-the-shelf software package for inventory management and accounting purposes. The system was installed on a standard networked IT system. All wholesaling transactions are processed using the system and it is used as their primary method of traceability.

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Case Study 1

Step 1 –

Determine category of system

Software – Category 3 (Non-configurable system)

Hardware – Category 1

Step 2 –

Determine approach to be taken (may include…)

Functionality versus URS

Record version of software/hardware, verify correct installation

Allowable users

Verify data entry capability (product, code, quantity, location…)

Verify processes (orders, picking, FEFO, returns)

Verify data is retrievable and accurate

Run systems side-by-side if upgrading

Training, Procedures etc

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Case Study 2

A wholesaler installs a temperature monitoring system into their warehouse. The system consists of wireless probes which send a signal to a relay box which in turn sends a signal to a receiving unit linked to a PC. The data is uploaded via broadband to the system supplier's hosting site. In order to access the data the wholesaler must log in to the suppliers website.

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Case Study 2

Step 1 –

Determine category of system

Software - Category 4 (Configurable system)

Hardware – Category 2

Step 2 –

Determine approach to be taken (may include…)

URS / Functional Specification (may be combined)

Operation and performance of system versus URS & FS

SLA with supplier, consider audit

Record version of software, hardware details

Verify operation of system under load conditions

User access levels

Ensure data storage is secure

Verify data is retrievable and accurate

Verify hardware is compatible and functioning (commission and calibrate)

Run systems side-by-side if upgrading

Training, Procedures etc

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Other Requirements

- User procedures
- Training
- Software package documentation
- Hardware package documentation
- Passwords
  - Routinely change (Different cases, numbers, characters)
  - Not to be shared!
- Usernames specific for person & not ambiguous

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Change Management

- Changes to a part of the system pose a risk due to interdependencies
- Does the process owner know if supplier makes a change? (SLA)
- Version controlled
- Record, assess, approve and document changes

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Retention

- 5 years (Depending on products!)
- Regulatory duty
- Preserve content and meaning
- Back-ups (archiving / long term retention) – validation of data and media integrity (number of uses etc)
- Restoration (time, routine verification)
- Separate and secure location

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Ongoing Maintenance

- Ongoing monitoring of system's performance
- Error Logs
- Operator training
- Change control
- Maintenance of user manuals / SOPs
- Updates to system

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Recovery after failure

- Restoring system to correct state
- Log file of transaction records
- Incomplete transactions
- Protocols and procedures for testing
- Manual data entry
- Outage investigation

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Retrospective Validation

- Legacy systems / Reclassification
- Focus attention on those computerised systems with most impact on patient safety, product quality, and data integrity
- Risk assessments
- History of use
- Maintenance
- Error logs
- Validation plan / Gap assessment

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Risk Management

- Useful for retrospective validation
- Assess risks – Apply controls
- Linked to the protection of the patient
- Level of effort, formality, documentation should be commensurate with the level of risk

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Databases

- Databases and repositories should also be validated
- Database integrity – size?
- Compatibility with other systems

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Commercial Spreadsheet Applications

- Highly configurable
- Difficult to validate
- Audit trails
- Changes

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Outsourced Services

- E.g. Temperature monitoring
- Security of data
- Control of data / ownership
- Access
- Service Level Agreements
- Disclaimers

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Considerations

- Patient safety is priority
- Audit trail
- Ease of validation
- Electronic signatures
- Support from supplier

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Further Guidance!

- PIC/S Good Practice for Computerised Systems in regulated "GXP" Environments www.picscheme.org
- Eudralex Volume 4 GMP Guide Annex 11: Computerised Systems
- GAMP 5 - Good Automated Manufacturing Practice

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Thank you

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