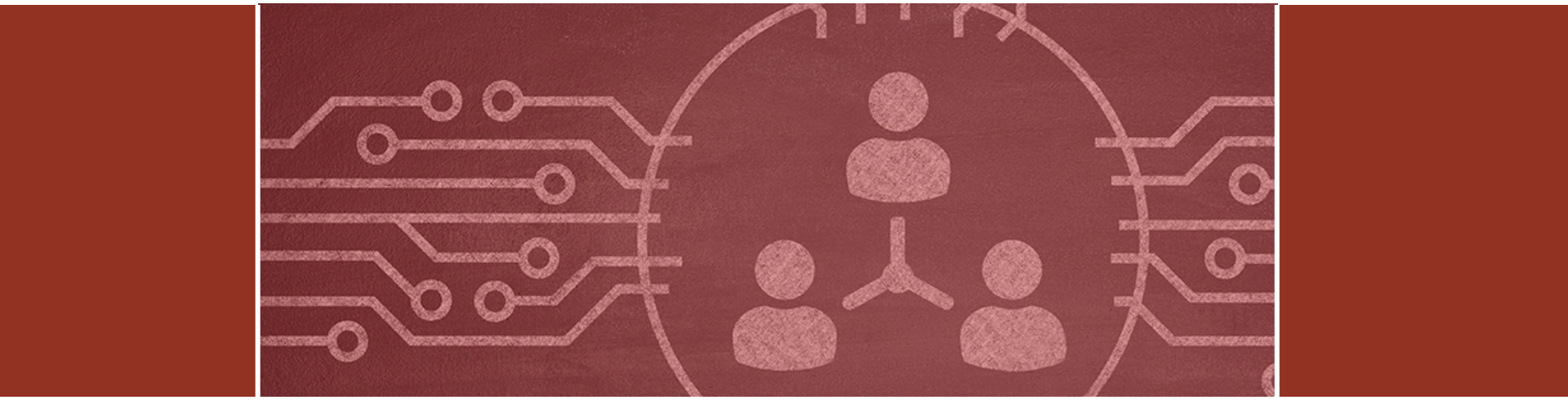

Data Integrity Local Implementation

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Barcelona , 27/10/2015

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Data Integrity Local Implementation

1 Education and Communication

2 Detection and Mitigation of Risks

3 Technology and IT Systems

4 Governance of DI

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Project overview

Project execution

1. Identify GxP data
2. Develop and execute test protocol in order to evaluate the system robustness
3. Implement actions to improve the system robustness
4. Do the risk analysis and define type / frequency of the audit trail review
5. Take action to implement the audit trail review in the business processes

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Methodology

Workshops/Training	• All employees • Specific trainings
Scope	• All relevant GxP systems
Assessment Tool	• Security level • Audit trail review
Audit guides	• Knowledge of data lifecycle • Verification test
Remediation Plan Template	• CAPA plan • Implementation Tracking
Continuous Improvement	• 483 revisions • Auditors focus

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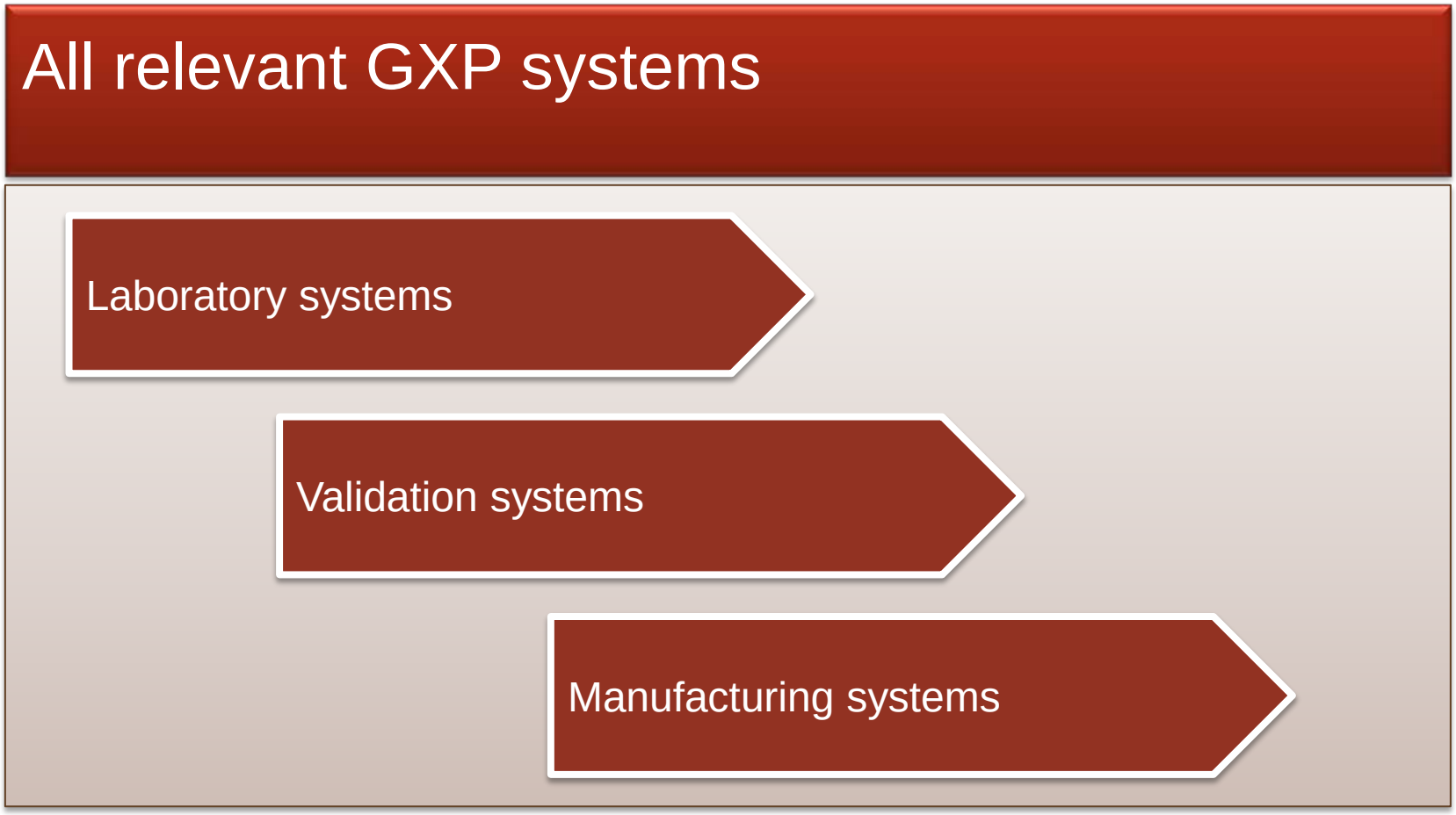
Scope



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Assessment tools

Annex		Test Script	
1	Security level of the computerized system	CP-OQ-01	Verification of the segregation of duties
		CP-OQ-02	Verification of the complexity of passwords
		CP-OQ-03	Verification of the password expiration
		CP-OQ-04	Verification of the account deactivation after unsuccessful access attempts
		CP-OQ-05	Verification that the system does not allow the use of the latest passwords
		CP-OQ-06	Verification lock the account after a period of inactivity
		CP-OQ-07	Verification of the vulnerability of data outside the application
2	Audit trail compliance	CP-OQ-01	Verification of user accounts traceability
		CP-OQ-02	Verification of GxP data traceability
		CP-OQ-03	Verification of the audit trail characteristics

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Assesments tools

Two types of review:

Technical Audit trail review

- As part of the system periodic review
- Standard review with defined frequency

Business Audit trail review

- As part of the business process
- Specific to the system and frequency adapted

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Assessment tools

Business Audit trail review

The definition of the business review is done according to a risk based-approach which takes into account data integrity risks:

1. **Probability of occurrence** of a non accurate data:

   → related to the robustness of the system

2. **Criticality** of handling a non accurate data generated from the system:

   → direct/indirect impact in the product quality

3. **Probability of detection** of a non accurate data generated from the system

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Assessment tools

Risk Analysis :

			Criticality and detection		
			LOW	MEDIUM	HIGH
Probability of occurrence = System robustness	Robustness **HIGH**		**A**	**A**	**A**
	Robustness **MEDIUM**	Organizational measures are in place.	**A**	**B**	**B**
			B	**C**	**C**
	Robustness **LOW**	Organizational measures are in place	**B**	**C**	**C**
			The system should be used in a "paper based approach". It should be replaced or updated.		

A: Technical review
B: Technical review / Business review each year
C: Technical review / Business review before batch release

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Defining a CAPA Plan (Example)

System	Owner	Deviations*		CAPAs *(including due date)*
		Number	**Description**	**Description**
System A (equipment ID)	Department or responsible for the actions	1	General account	Create personnel accounts
				Create new profile as a administrator
		2	Inactivation mode doesn't work	Activate the option in Windows XP
		3	Back up copies maintenance not adequate	Maintain Back-up copies in a safety place. Define frequency.

- * Examples of frequent deviations in GxP equipment in industry
- ** colors code according accomplishment

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Tracking implementation of the CAPA Plan (Example)

	Step 1					Step 2		
Computerized systems	**Audit trail remediation plan**	**Protocol OQ**	**Test execution**	**Corrective actions definition**	**Risk**	**actions Implementation**	**Audit trail review implementation action**	**First audit trail review execution**
SYSTEM 1	Indicates # document	Indicates # protocol	% of completion	% of completion	A, B or C **AUDIT TRAIL REVIEW TYPE (defined according the risk analysis)**	% of completion	% of completion	date defined according risk analysis
SYSTEM 2			% of completion	% of completion	A, B or C **AUDIT TRAIL REVIEW TYPE (defined according the risk analysis)**	% of completion	% of completion	date defined according risk analysis
SYSTEM 3			% of completion	% of completion	A, B or C **AUDIT TRAIL REVIEW TYPE (defined according the risk analysis)**	% of completion	% of completion	date defined according risk analysis

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Continuous Improvement

Usual auditors' questions

1. Which profiles and privileges are defined?
2. Who could change the data?
3. Is the e-data reviewed, or only paper data?
4. How do you manage your automated IPC controls?
5. Where do you keep your back-ups?

Auditors apply forensic approach & critical thinking

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Continuous Improvement

Published FDA 483 observations written from industry:

1. Results discarded without explanation
2. Overwriting electronic raw data files for on-going sequences
3. EM plates without evidence of contact (finger prints)
4. Operators with several profiles in a system
5. Dates of # print outs without appropriate correlation

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Continuous Improvement

Lessons Learned: Focus Areas

- Data Lifecycle understanding
- Culture on relevance of data
- Prevention of intentional and nonintentional changes
- Justifications of data changes and tracking of these changes
- Security of small/ stand alone systems
- Verification of calculations and how these are reviewed

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Questions?

THANKS!!

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