Pharma IT
A ProductLifeGroup Company

PLG ProductLifeGroup DIGITAL

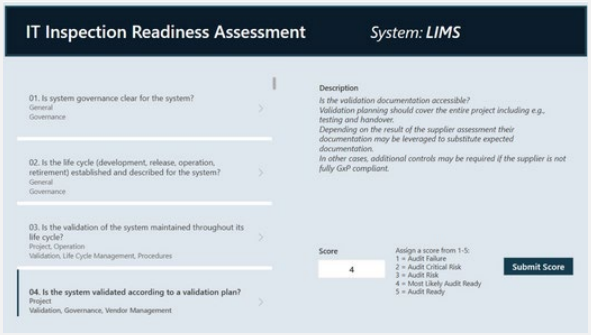
IT Inspection Readiness Assessment

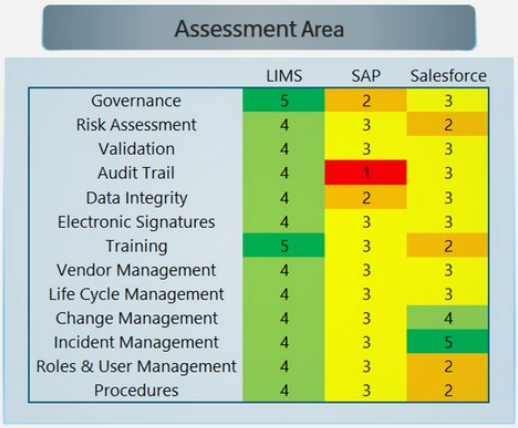
An IT inspection readiness assessment is a structured evaluation of the current state and use of existing IT systems and computerized equipment, measured against pharmaceutical regulations and industry standards. It covers the GAMP5 guideline and all relevant regulatory requirements from 21 CFR Part 11, MHRA, and USP, with specified section references. The assessment plays a crucial role in ensuring compliance with the regulations that safeguard data integrity, patient safety, and product quality. At the same time, it helps identify documentation for improvement and areas that are not adequately in control, which could threaten the company's license to operate.

BENEFITS

- Assess the organization's readiness for regulatory inspections and audits.
- Set the direction for where to focus the company's resources.
- Highlight and prioritize areas for improvement.
- Ensure alignment with industry- specific standards and best practices.

Cost per System **2000€**





	LIMS	SAP	Salesforce
Governance	5	2	3
Risk Assessment	4	3	2
Validation	4	3	3
Audit Trail	4	1	3
Data Integrity	4	2	3
Electronic Signatures	4	3	3
Training	5	3	2
Vendor Management	4	3	3
Life Cycle Management	4	3	3
Change Management	4	3	4
Incident Management	4	3	5
Roles & User Management	4	3	2
Procedures	4	3	2

AUDIT READINESS STEPS

1. Define scope and stakeholders.
2. Run workshops per system to review and improve documentation.
3. Score systems using our Audit Readiness Assessment tool.
4. Report with visualization of compliance gaps in HEATMAP.
5. Wrap-up meeting with report handover

Start your readiness assessment today and Contact

Stig Ragborg

SGRG@pharmait.dk