ManageEngine

ManageEngine solutions for ISPE GAMP 5 (2nd Edition, 2022) compliance

GAMP 5 at a glance

The ISPE GAMP® 5 Guide 2nd Edition (July 2022) is the globally accepted, risk-based framework for delivering and maintaining compliant good practice (GxP) computerized systems in regulated life sciences environments. Regulators worldwide treat GAMP 5 as the de facto implementation standard for Title 21 CFR Part 11, European Union GMP Annex 11, PIC/S Annex 11, and World Health Organization data integrity guidance.



Applies to

Pharmaceutical companies, biotech organizations, medical device companies, contract research organizations, contract development and manufacturing organizations, and healthcare manufacturers plus their software, cloud, SaaS, and service suppliers.



Enforced by

The United States Food and Drug Administration, European Medicines Agency, Medicines and Healthcare products Regulatory Agency, Agência Nacional de Vigilância Sanitária, Pharmaceuticals and Medical Devices Agency, and other national health authorities through GxP inspections.



Core focus

Patient safety, product quality, validated states, electronic records and audit trails, and life cycle security of GxP computerized systems.

How ManageEngine can help

Appendix and clause	Description	ManageEngine solutions	Key features
O4 – Incident Management	Record, classify, investigate, and resolve every incident impacting a GxP system	**Log360 and AD360**	Real-time correlation across 750+ sources, alerting aligned with MITRE ATT&CK®, an integrated incident console, SOAR playbooks, one-click account containment, and forensic AD change reports
O6 – Operational Change and Configuration Management	Every change to a validated system must be assessed, approved, documented, and reviewed	**Log360 and AD360**	Real-time auditing of AD, GPOs, servers, registries, files, databases, network devices, and cloud configurations; alerts for changes outside of approved windows; approval-based workflows for admin changes; and delegated administration with a full audit trail

O8 – Periodic Review	Periodically confirm the system remains in a validated, compliant state	**Log360 and AD360**	Scheduled compliance and audit trail reports; incident, change, and access trend dashboards; recurring access certification campaigns; and dormant account and privilege creep reports
O9 – Backup and Restore	Implement adequate, tested backup and restore procedures and integrity monitoring	**Log360 and AD360**	Backup job auditing for Veeam systems, Veritas systems, Commvault systems, and Windows Backup; alerts on failed jobs, shadow copy deletions, and restore operations; and automated AD backups with granular, point-in-time recovery
O10 – Business Continuity	Plans must ensure the availability of GxP systems and be regularly tested	**Log360 and AD360**	A high-availability SIEM deployment, alerts on critical log sources, rapid AD forest and object recovery, and hybrid AD and Entra ID resilience
O11 – Security Management	Logical and physical security controls protect GxP systems, data, and electronic records	**Log360 and AD360**	Vigil IQ correlation with 2,000+ detection rules; UEBA; integrated threat intel (STIX/TAXII, Webroot, etc.); MITRE ATT&CK coverage; adaptive MFA across endpoints, VPNs, Outlook on the web, IIS, and cloud apps; strong password policies; and just-in-time privileged access
O12 – System Administration	Admin activities must be controlled, segmented, and auditable; account life cycles must be managed	**Log360 and AD360**	Admin action auditing across AD, Entra ID, Microsoft 365, Linux, UNIX, databases, and network devices; service account and scheduled task monitoring; automated provisioning and deprovisioning; RBAC with OU-level delegation; and privileged group audits
O13 – Archiving and Retrieval	Records and audit trails must be securely retained, retrievable, and tamper -evident	**Log360 and AD360**	Encrypted, hash-stamped, timestamped log archives; configurable retention; fast forensic searches; archive tampering alerts; and long-term AD change history with forensic reporting

For more information, contact us at sales@manageengine.com.

ManageEngine Log360

Personalized demo

ManageEngine AD360

Personalized demo