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Concentriq® LS
GxP Ready by Design

The transition from traditional glass slide workflows to digital pathology has enabled unprecedented levels of speed, scale, and precision in research settings. Digital pathology platforms serve as critical infrastructure for organizations seeking to streamline histopathology workflows, unify imaging and metadata, and enable remote review or collaboration across life science organizations.

These systems often act as hubs, integrating with laboratory information management systems (LIMS), artificial intelligence (AI) algorithms, cloud storage solutions, and other enterprise systems to form a cohesive digital ecosystem. While powerful, this digital transformation introduces new layers of complexity, data integrity requirements, and regulatory expectations.

Proscia's Concentriq LS is ready to support the demands of digital pathology in a GxP environment. Our platform acts as an integrated information and data hub to manage, view, annotate, and analyze high-resolution whole slide images (WSIs) at scale while ensuring that data remains secure, compliant, and accessible. **Customers leverage Proscia's flexible architecture to integrate image data with structured clinical metadata, support diverse workflows, and collaborate across departments or institutions without compromising traceability or performance in a GxP environment.**

This white paper provides quality, regulatory, and IT professionals with the primary considerations for selecting and implementing digital pathology software in regulated IT environments, and demonstrates how Concentriq LS addresses these requirements. **While the ultimate responsibility for system validation resides with each organization based on intended use, Proscia delivers robust platform features and functionality, extensive documentation, validation accelerators, and ongoing support to reduce implementation burden and maintain validated state.**

Digital Pathology in a GxP Environment

Concentriq LS is a digital pathology solution designed to support a wide range of research workflows, including features that facilitate compliance with GxP principles **when appropriately configured and validated by the customer for their specific intended use.** For teams engaged in clinical trials and translational research, GxP compliance means applying the rigorous standards used in traditional laboratory workflows to a digital environment.

GxP refers to a collection of quality guidelines and regulations where the "x" represents various standards for the biomedical industry. For digital pathology systems used in the context of drug development — such as clinical trials, biomarker research, or preclinical studies — **the two most relevant GxP domains are Good Clinical Practice (GCP) and Good Laboratory Practice (GLP).** These standards guide the expectations for data quality, documentation, system validation, and integrity, ensuring that digital tools contribute reliably and traceably to regulated decision-making.

At the core of GxP compliance is information security and data integrity. Both are necessary to preserve the accuracy, completeness, reliability, and confidentiality of data. Below, we outline the primary ingredients used to achieve information security and data integrity in the context of digital pathology.

At Proscia, we recognize that digital pathology customers in certain research settings must meet these stringent GxP requirements. Our platform is thoughtfully designed to facilitate compliance in these environments. **We work to align our products with international standards, regulatory guidances, and industry best practices to promote secure, reliable, and effective performance.** This approach empowers our customers to validate and deploy our platform in a GxP environment.

Cybersecurity Measures	**Necessary to maintain data confidentiality both at rest and in transit.** Safeguards typically include: • Data encryption • Use of cryptographic protocols • Application of encryption keys	**System Backup and Recovery**	**Critical to maintain system and data availability, including data restoration in the event of a failure.** Features typically include: • Automated and incremental backups at regular intervals • A formal Data Recovery Plan • Periodic testing of procedures
Access Controls	**Essential to prevent unauthorized access, protect confidential information, and ensure system integrity.** Safeguards typically include: • Role-based access controls • Strong authentication mechanisms (e.g., passwords or multi-factor authentication [MFA]) • User activity monitoring • Features and approaches that meet recognized standards	**System Validation**	**Risk-based validation approaches that demonstrate systems are reliable and auditable. Customers are responsible for validating for their intended use.** Approaches typically include: • Verification of features necessary for a GxP environment • Controlled feature introduction through a sandbox-validation-release environment to implement improvements
Auditability	**Required to ensure that system actions are traceable and to demonstrate that digital records maintain their integrity.** Features typically include: • Audit trails of system actions and records with relevant metadata (e.g., timestamps, user IDs, revision actions) • Tamper-resistant audit logs stored and available in accessible formats	**Documentation**	**Establishment of processes and records that prove quality is embedded in the entire software development lifecycle.** Approaches typically include: • Design and implementation of a quality management system (QMS) that meets industry standards • Maintenance of records that demonstrate fulfillment of QMS requirements

Concentriq LS Features Support GxP Workflows

Concentriq LS is designed with robust security and privacy controls to support GxP compliance, using technical safeguards and cybersecurity measures to maintain data confidentiality and integrity. **Concentriq LS meets the fundamental requirements that remain constant: cybersecurity measures, access controls, auditability, validation, back-up and recovery, and documentation.**

Cybersecurity Measures

Concentriq LS uses encryption of data both in transit and at rest to achieve strong data protection. All communications between the application server and customer devices are protected using Transport Layer Security (TLS) protocols, delivering end-to-end encryption for transmitted data regardless of deployment model. In cloud deployments, data at rest — including images and database content — are encrypted using the AES-256 block cipher, a widely recognized standard for data security. **Proscia also leverages Amazon Web Services (AWS) or Microsoft Azure, both of which are aligned to numerous industry and government standards, such as SOC 2, ISO 27001, GDPR, PCI-DSS, HIPAA/HITECH, FedRAMP, and NIST 800-171.**

Proscia's security and privacy programs and quality systems are **externally audited on an annual basis,** providing assurance of ongoing adherence to best cybersecurity practices.

Access Controls

Access controls are applied across the Concentriq LS platform to ensure data use can be assigned through role-based authorization. As a means of being able to apply a least privilege principle, administrators can assign roles that control access to system settings, repository management, annotations, and other core functions. In addition to controlling actions, roles can also restrict visibility of specific pages or modules within the application — such as administrative dashboards, user management, or the analysis tab — allowing organizations to tailor the user experience based on role and responsibility. **Permissions are granular and can be scoped to specific users or groups, ensuring appropriate separation of duties and data access boundaries.**

Auditability

Concentriq LS and Proscia support traceability, accountability, and security of system use through comprehensive audit logs stored within Proscia's records. Concentriq LS maintains comprehensive audit trails for all user actions and system-initiated events. **Each audit record includes timestamps, user identifiers, and detailed change histories, ensuring that all data interactions are attributable and reviewable.** The platform supports Reason for Change tracking, along with metadata audit coverage, to further enhance transparency.

Audit logs are exportable in both human-readable and electronic formats, enabling integration with external compliance or reporting systems. All records are retained by Proscia for the full duration of the customer lifecycle, supporting long-term compliance with regulatory recordkeeping requirements.

System Backup and Recovery

Proscia implements a robust Backup and Disaster Recovery process to protect regulated data and ensure business continuity. Automatic backups are performed on a regular basis, with incremental backups executed to optimize efficiency while minimizing data loss risk. The backup strategy is tailored to each system deployment, whether cloud-based or on-premises, and is aligned with customer-specific requirements.

In the event of system failure or data loss, Proscia's disaster recovery procedures are designed to restore full operational capability in a timely and controlled manner, ensuring minimal disruption to GxP-regulated workflows.

Validation You Can Rely On

From access controls to secure audit trails, Concentriq LS provides a reliable and auditable platform users can validate to meet their intended use within research environments.

To create a platform ready for a customer to tailor to their needs, **Proscia performs robust validation activities as part of its software development lifecycle and system deployment process.** These efforts are designed to reduce the burden on customers while ensuring that the system can be efficiently validated for its intended use within each organization's unique operational context.

As part of every implementation, Proscia's Services team works closely with customers to configure the platform according to documented user requirements and intended workflows. **System setup is guided by GxP best practices, and Proscia provides comprehensive quality validation documentation to support implementation.** This includes a completed Installation Qualification (IQ) package to confirm that the platform is installed correctly and operates as expected in the customer's target environment.

While Proscia provides foundational validation deliverables, final system validation for the customer intended use — such as Performance Qualification (PQ) or User Acceptance Testing (UAT) — remains the responsibility of the customer. However, Proscia actively supports customers throughout this process. Our team provides guidance and assistance in drafting and completing PQ/UAT documentation, if needed. This collaborative approach ensures that customers can confidently complete validation activities without duplicating foundational efforts already performed by Proscia.

To help maintain a validated state over time, Proscia follows a controlled software release process that includes quarterly system updates and the issuance of patches on an as-needed basis, based on the urgency and impact of the issue addressed. Each release is accompanied by supporting documentation, including release notes, impact assessments, and test summaries to aid in change management and re-validation activities. This ensures customers can plan updates with full visibility and confidence in the continued compliance of their systems.

Together, these practices reflect Proscia's commitment to delivering a digital pathology platform that is not only functionally powerful but also validation-ready, enabling our customers to meet evolving GxP expectations with efficiency and assurance.

Documentation For Your GxP Compliance

Proscia maintains a robust QMS built on industry best practices. Our QMS governs the entire software development lifecycle — from requirements gathering to validation, release management, and post-market support. This structured framework ensures that quality is embedded at every stage of product development and service delivery.

The QMS is designed to support both internal and customer quality objectives. It enables traceability of changes, structured documentation control, and rigorous oversight of development activities. **We maintain detailed records of development, validation, and post-deployment support to prove execution is conducted in accordance with procedures and documented approvals, and to facilitate readiness for audits and inspections.**

Born out of this commitment to quality, Proscia provides customers with a comprehensive tool-kit of GxP documentation that supports tailoring of validation and compliance efforts.

This tool-kit includes:

- **FAQ Sheet –** Answers to common regulatory and technical questions
- **Product User Guide –** Detailed instructions to ensure proper use of the system
- **Product Version History Table –** Chronological record of releases, patches, and key updates that have been tested and validated by Proscia
- **Release Notes –** Version-specific description of enhancements, defect corrections, and known limitations (if applicable)
- **Installation Qualification (IQ) Report –** Evidence verifying and documenting that Concentriq LS has been installed in accordance with Proscia's procedures

This documentation package helps customers efficiently incorporate the Concentriq LS digital pathology platform into their GxP environment while maintaining traceability, clarity, and compliance. It reflects our commitment to transparency, quality, and a long-term partnership with our customers.

Why We Are Right for You

Digital pathology is revolutionizing the way organizations generate, analyze, and share diagnostic data. However, innovation must align with GxP requirements. Proscia's Concentriq LS supports this balance — delivering advanced workflows while maintaining the highest standards quality and regulatory adherence.

Developed under a rigorous, compliant process and designed with robust security, auditability, and validation-ready features, Concentriq LS meets the operational needs of translational research and early clinical trial workflows. By combining a compliant technical foundation with comprehensive validation support and strong documentation, Proscia enables customers to deploy digital pathology solutions confidently and efficiently.

For life sciences teams seeking to harness the full potential of digital pathology in a GxP framework, Proscia's Concentriq LS offers a proven solution. Beyond the platform's technical superiority, Proscia serves as a committed partner — continuously refining the platform and its compliance posture in response to evolving regulatory expectations. As the landscape changes, Proscia remains a reliable ally in helping customers maintain compliance while driving biomedical innovation forward.

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