

INFOSYS PLATFORM FOR REGULATED DOCUMENT MANAGEMENT



Regulatory compliance is one of the top priorities of biopharmaceutical organizations. Regulatory functions hinge on several high-cost contributors like complex and meticulous processes, coupled with collaboration needs across a wide variety of regulatory content. Easy sharing of content across multiple stakeholders and agile and simplified collaborative authoring, review and

approval processes are essential for organizations to efficiently manage regulatory function.

Organizations are increasingly adopting a fully managed cloud-based content management solution that reduces time to market while providing a high degree of service availability, reliability, compliance, and security. Furthermore, having a single

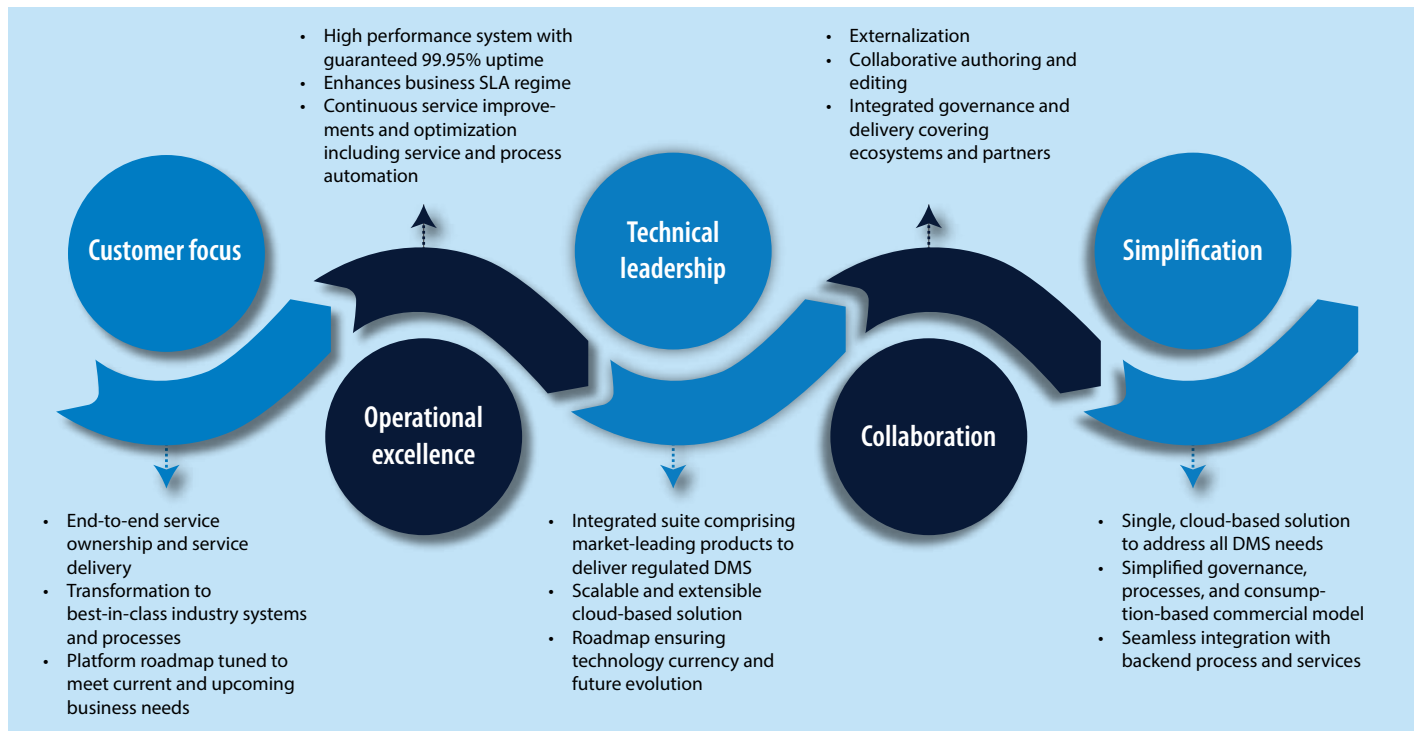
point of service provides a high degree of productivity and agility while ensuring compliance needs.

Infosys Regulated Document Management Platform is a fully integrated and managed cloud-based offering that provides a cost-effective solution offering best-in-class products integrated seamlessly with enterprise backend systems and processes.

Key features of Infosys Regulated Document Management Platform

- Integrated regulated document management platform
- User-friendly and compliant document authoring and tracking
- Rule-based, controlled document management for GxP compliance
- Preconfigured industry best processes
- Seamless integration with backend systems and processes
- Scalable, cloud-based infrastructure for usage expansion and performance needs

Business benefits of Infosys Regulated Document Management Platform



Get unparalleled advantage with Infosys Regulated Document Management Platform

- GxP-compliant solution
- Streamlined creation, review, approval, submission, and tracking of regulatory documents
- Flexibility to create custom workflows to process and route content for approval. Provision for document review and approval in compliance with 21-CFR Part 11
- Support for versioning and audit trails
- Integrated web-based portal for read-only content access across desktop, mobiles, and tablets
- SOA layer to facilitate seamless integration with other enterprise systems
- Secure framework that addresses pharmaceutical security and privacy requirements delivered out of ISO 27001 certified Infosys cloud.
- Proven solution with 99.95% guaranteed uptime in production.
- Currently used at a leading pharmaceutical company
- Pay-per-use model based on volume of usage with minimal initial investment
- Disaster Recovery support with aggressive RPO (Recovery Point Objective) and RTO (Recovery Time Objective) commitments

For more information, contact askus@infosys.com

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