

X-docs

by Formpipe.

Enabling organisations to achieve compliance.

- QMS Document management
- Line of Business configurations
- X-train™ compliance related training management
- X-Forms™ Forms Based Processes
- X-reports™ reporting framework
- Validated Accelerator Tools
- Optional Integrations

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X-docs™

“Electronic quality management systems should balance the people, process and technology triangle of effective organisations. Built on the general functionality of SharePoint, X-docs can be easily configured to do just that.”

X-docs is an EQMS built on SharePoint that can be delivered on Premise or in the Cloud.

X-docs allows organisations to simply and effectively manage everything from documents and templates to quality processes and personnel training. It is the foundation of a fully-functional, fully-integrated, single platform quality management system that allows businesses to measure and show (or not) that quality is continuously improving.

X-docs – GxP Compliant Document Management

The preconfigured QMS document module sitting on the X-docs enterprise platform has been configured to provide the functionality to manage GxP controlled documentation and maintain the necessary framework to satisfy regulatory authority audits.

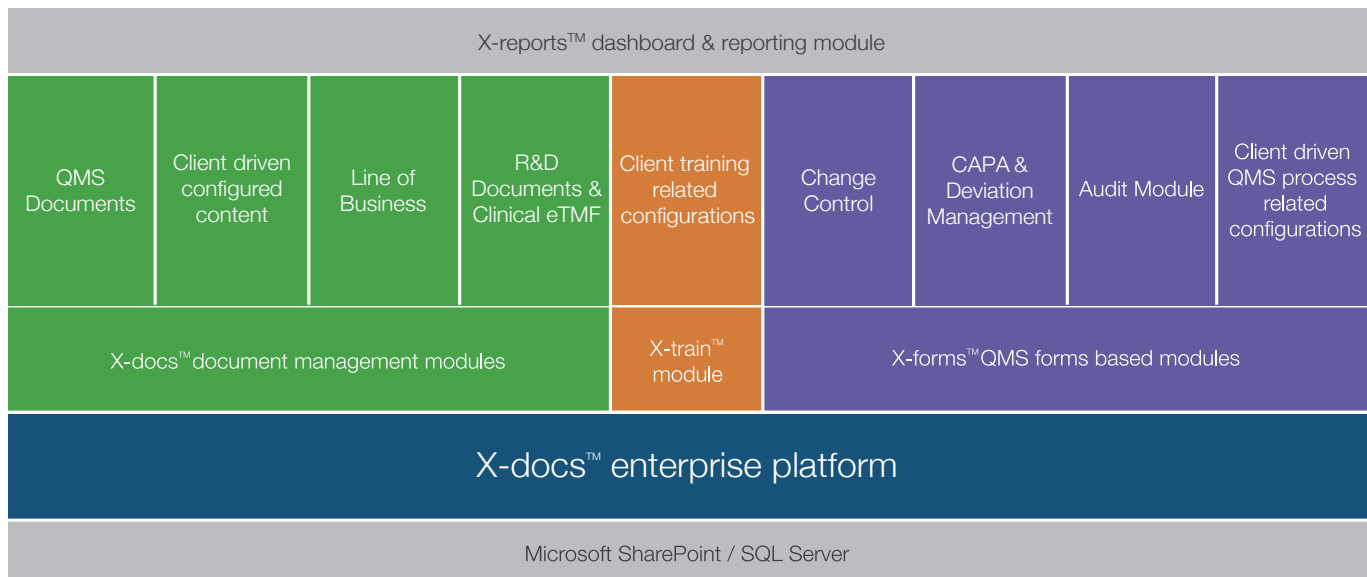
X-train – GxP Compliant Training Management

X-train is a secure web-based compliant training environment with traceable course participation, test recording, certification, training records and roles/competency management. Based on the X-docs enterprise platform, employing its configured document management features for the assembly and control of training materials, X-train brings a number of forms based features to provide confidence in being able to meet the rigorous audit demands for training records in support of employees performing regulated actions.

X-forms – GxP Compliant QMS Process Management

The X-forms configurable process engine allows standard QMS processes to be implemented quickly and easily. Designed to enable the management of complex issues through the use of a multi-threaded framework, X-forms simplifies the job of monitoring and reporting on progress. Designed to meet the requirements of QMS processes such as CAPA, Change Control, Deviations and Audits, X-forms can be configured to route forms around groups and individuals to collect the appropriate input, whether that be impact assessments or root cause analyses, data collection to facilitate reporting and signal detection, or the approvals and authorisations to close out issues.

Our products, X-docs, X-train and X-forms, provide enterprise grade electronic Document, Training and QMS Process management solutions that enable organisations to achieve compliance with 21 CFR Part 11 & Annex 11.



QMS

- Preconfigured QMS structure
- Controlling Documents Management
 - SOP, Policy, Guide, WI Types
 - GxP lifecycle & processes
- Links to CAPA, Audit & X-train
- Full reporting module

X-train

- Compliant Training Management
- Configurable competence evaluation
 - Testing and/or Assessment
 - Certificates & Training Records
- KPI and Reporting for Managers
- Automated retrain and material update handling

Line of Business Configurations

- Configuration for eTMF, Regulatory Submissions and Product lifecycle
- Authored Document Management
 - Lifecycle & approval processes
- Based on Industry Reference Models

X-forms. Forms Based Processes

- Configured process environment
- Preconfigured options
 - CAPA, Deviations, OSS
 - Change Control, Audit Management
- Modular and extensible framework
- Full dashboard and reporting framework

Validated Accelerator Tools

- Site Hierarchy Builder
- Storage Structures
 - Content Types & Site Columns
 - Sets permissions & Views
- Full PowerShell scripted installs
- Validation documents package

Optional Integrations

- Adib rendition engine
- CoSign Digital signatures
- Invu scanning/OCR & Routing
 - Records upload and QA workflow
 - Indexing and metadata enrichment
- ERP systems e.g. AX and SAP



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