Flex Databases Platform

Unified eClinical platform for CRO, biotech, and pharma

GENERAL

- eTMF
- EDC
- Workflow Management

CTMS

- CRA Activity Management
- Investigators & Sites Management
- Subject Tracking & Invoicing

PM & BUDGETING

- Project Management & Budgeting
- Expense Reporting
- Time Sheets & Utilization

COMPLIANCE & SAFETY

- Learning Management System
- Quality Management System
- Pharmacovigilance

About Flex Databases

We develop a comprehensive clinical trial management solution since 2011.

- **10+ years** on the market
- **4 offices** in the US, Europe, and Asia
- **All-in-one platform** from study planning to safety database

What sets us apart

Easy implementation

Full compliance

Complete data safety

Flexible solution

- System implementation in **3 to 10 weeks**
- A robust **backup & disaster recovery and data protection strategy**, including distributed data storages around the world
- All major **international and local regulations** covered, including FDA 21 CFR Part 11, GDPR, etc.
- Reports, workflows, trackers are **under user configuration**. Web-based solution, no installation required

Some of our clients

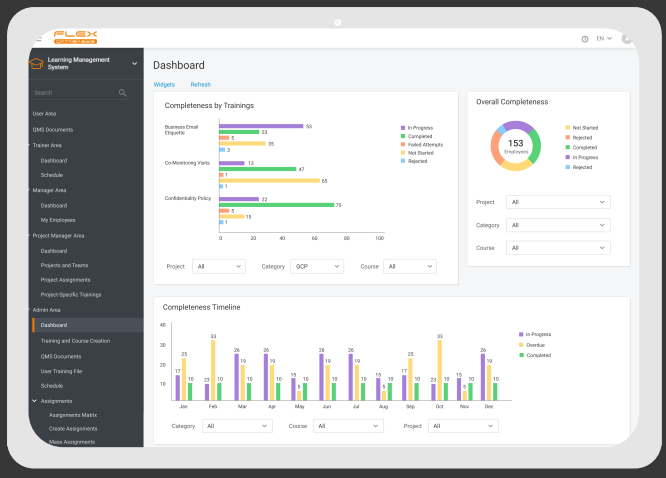
Leading CROs, pharma, and biotech

novo nordisk®
CMIC
FGK CLINICAL RESEARCH
Dr.Reddy's
ERGOMED
OPTIMAPHARM
WORLDWIDE CLINICAL TRIALS

FLEX DATABASES

Learning Management System

Module Overview



Trainings and SOPs maintained and organized in one place

- Automatic training assignments. Training is completed on time and tracked. Training can be in the form of trainer-led, self-training, and courses. CV, Job Description, applicable training, external training and certificates are in one place.
- Training library is available for employees, as well as library of SOPs and other standard documents and company templates.
- Quizzes are here to make sure employees actually opened an SOP or training material. Training files are audit ready and exportable in one click. All problems with training are accessible in one click.
- Get a clear simple picture on any outstanding training of project team members.
- Troubleshoot with subordinates' training – transparent picture of all training and problems of employees.
- Deep business intelligence reporting for all training matters – besides all basic reports you can even see how long it took to answer a specific question in a training quiz.

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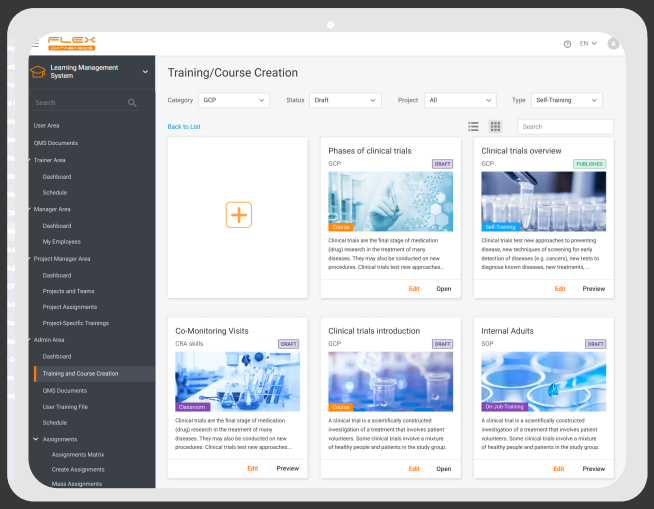
Module Overview



Effortless inspection readiness and compliance

- Inspection readiness and compliance is maintained effortlessly, SOPs process and trainings are transparent by default.
- Audit or inspection is never a problem and do not require substantial preparation.
- Matrixes for trainings and SOPs maintained automatically.
- Simple update for QA documents followed by automated training and documents published for employees in current versions.
- Compliant e-signature is available.

Advanced technology in a simple interface

- Easy scaling and integration of new companies, teams, or members into corporate culture with simplified onboarding.
- Training is easy to go through – videos, presentations, links, documents attached, and SCORM.
- Flexible notifications not to forget about a training, to review and update a SOP.
- Access for different levels of employees and external users – QA view, training manager view, line manager view, project manager view, employees view.
- Take a cup of coffee, then come back to where you left off with a training or SOP reading.
- Go through quizzes and then review the results. Do all of it online and sign electronically.

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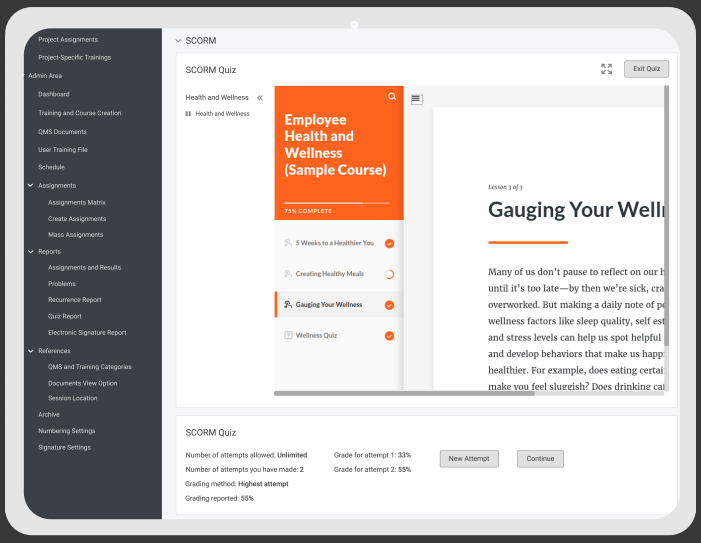
Learning Management System

List of Features



Training management

- Project and line manager areas;
- Electronic employee training records;
- Training matrix management;
- Automatic and manual training assignment for any group: e.g., department, position, project, country;
- Multiple trainings assignment to one employee in a batch;
- Automatic alerts to employees and their supervisors on assignments & overdue trainings;
- Completion confirmation with eSignature

Document management

- Corporate SOPs library management;
- Optional trainings library;
- Possibility to attach images, PDF files, videos, links to external resources, or other documents as training materials;
- Configurable access to view and download PDF files and images

Training types

- Self-trainings, training sessions and courses;
- Project- and sponsor-specific trainings;
- Quizzes with different question types;
- Possibility to use courses in SCORM format;
- Recurrent trainings

Reporting

- Reports and statistics on training results;
- Ad-hoc reporting tool for cross-project and cross-module reporting (graphs, widgets)

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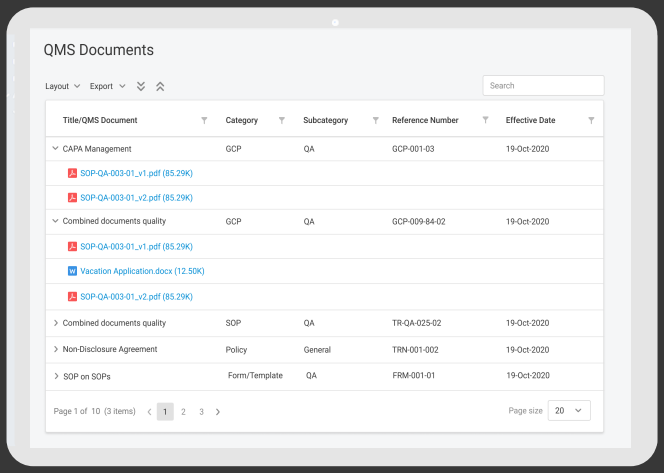
Quality Management System

Manage SOPs, audits, incidents, CAPA, and all the quality-related activities across company and projects within a single module



CAPA management

- CAPA initiating, review, resolution, and follow up
- Assigning responsible team members to tasks and process steps;
- Tracking all the responses and progress of CAPA;
- CAPA observation period scheduling and tracking;
- CAPA effectiveness tracking and evaluation;
- Documents generation and sign-off;
- Actions implementation evidence;
- Various KPIs tracked, performance measured on company level and per project.

Audit management

- Audits planning and scheduling;
- Any type of audits: internal, external, vendor, etc;
- Full audit lifecycle from planning to CAPA tasks resolution and observation period.

Incident management

- Any incident is registered and tracked;
- Incident severity and impact evaluation;
- Tracking the incident resolution, including actions, and timelines;
- Making decisions about the necessity of CAPA based on assessment.

SOPs and other QMS documents

- Create a new QMS document or initiate review;
- Review cycle of documents with comments, revision history and electronic signatures;
- Get notifications regarding periodic review;
- Transparency in review process with reporting on steps of review, responsible employees, and timelines.