




# Flex Databases




eClinical platform for CROs, biotech,  
pharma, and academic research



## CTMS

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



## DOCUMENTS

-  Trial Master File
-  Document Management System
-  Investigator Site File



## EDC

-  Electronic Data Capture
-  Risk-Based Monitoring
-  Randomization and Trial Supply Management
-  Electronic Patient-Reported Outcome


## PROJECT & FINANCE MANAGEMENT

-  Project Management & Budgeting
-  Time Sheets & Utilization

## QUALITY & COMPLIANCE

-  Learning Management System
-  Quality Management System

## SAFETY

-  Pharmacovigilance

## About Flex Databases

We develop a comprehensive clinical trial management solution since 2011.

- 15+ 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, biotech, pharma, and academic research



# Learning Management System

## Module Overview



## Training & qualification for GxP-ready teams

Flex Learning Management System (LMS) helps life sciences organizations keep people trained and qualified, ensuring your studies are always inspection-ready. It connects training content, SOPs, curricula, quizzes, and records in one validated space, so you always know who is qualified to perform which tasks – and can prove it in seconds during an audit

## Why Flex?

- Training and SOPs together – corporate SOP library, project-specific materials and training records live in the same system, built for regulated GxP environments
- Role-based assignments – training matrices and rules assign and re-assign training automatically when people join, change roles or SOPs are updated
- Audit-ready by default – electronic signatures, version control and full training history mean no more last-minute scrambling before inspections
- Aligned with 21 CFR Part 11 and EU Annex 11 expectations
- Engaging formats – trainer-led sessions, self-training, SCORM e-learning, videos, quizzes, and project-specific training keep people engaged and learning

# Learning Management System

## Module Overview

The screenshot shows the 'My Trainings' interface for Peter Beckett. The user's profile is displayed with a photo and details: Position: Project Manager, Department: Project Office, Line manager: Michael Johns. Training statistics include 23 Completions, 2 Classroom sessions, 0 Course, 19 Hours, 0 On-Job-Training, and 21 Self-Training. The main content area is divided into 'Assigned', 'Self-Reported', and 'Documents' tabs. Under the 'Assigned' tab, two training items are listed: 'Close-Out Visit' (TRN-001-003) with a due date of 02-Oct-2023, 1h duration, and 'Who is involved in Clinical Trials?' (GCP-001-03). Both items have 'OVERDUE' status indicators.

### Training Management

- Electronic employee training records – CV, job description, applicable SOPs, and training history stored together for each employee
- Project and line manager areas to manage training for project teams and functional groups
- Automatic and manual training assignment for any group
- Batch assignment of multiple trainings to one employee or group to speed up onboarding and study start-up
- Completion confirmation with 21 CFR Part 11-ready e-signatures

### Training Content & SOP Library

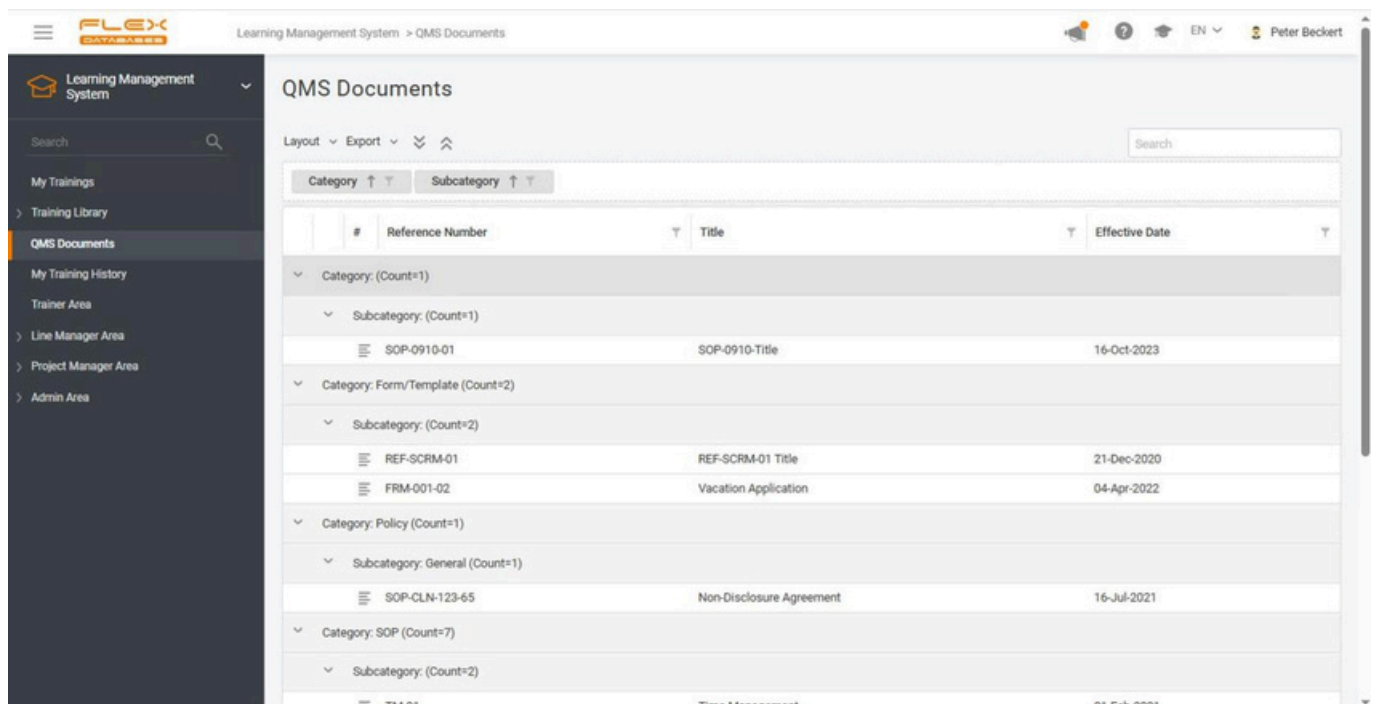
- Central corporate SOP library with version control and access rights
- Optional trainings library
- Training materials of any format and type
- Configurable access – flexibility in view and download options

### Training Types & Experience

- Self-training, trainer-led sessions and structured courses
- Project- and sponsor-specific training for study teams and sites
- Quizzes with different question types to check real understanding

# Learning Management System

## Module Overview



#	Reference Number	Title	Effective Date
Category: (Count=1)			
Subcategory: (Count=1)			
	SOP-0910-01	SOP-0910-Title	16-Oct-2023
Category: Form/Template (Count=2)			
Subcategory: (Count=2)			
	REF-SCRM-01	REF-SCRM-01 Title	21-Dec-2020
	FRM-001-02	Vacation Application	04-Apr-2022
Category: Policy (Count=1)			
Subcategory: General (Count=1)			
	SOP-CLN-123-65	Non-Disclosure Agreement	16-Jul-2021
Category: SOP (Count=7)			
Subcategory: (Count=2)			
	TSL01	Time Management	01-Feb-2021

### Inspection Readiness & Compliance

- Automatic maintenance of training and SOP matrices, including re-assignment when documents change
- Simple update of QMS documents followed by automated training assignments and publication of new versions
- Transparent picture of all training issues per employee, team or project
- Training data and certificates exportable in one click for auditors and inspectors

### Reporting & Analytics

- Clear overview of overdue training for any project team or department
- Standard reports plus ad-hoc reporting tool for detailed analytics

### Technology & Roles

- Web-based, validated LMS with configurable notifications – reminders of training or SOP review
- Dedicated views for QA, training managers, line managers, project managers, and employees