




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.

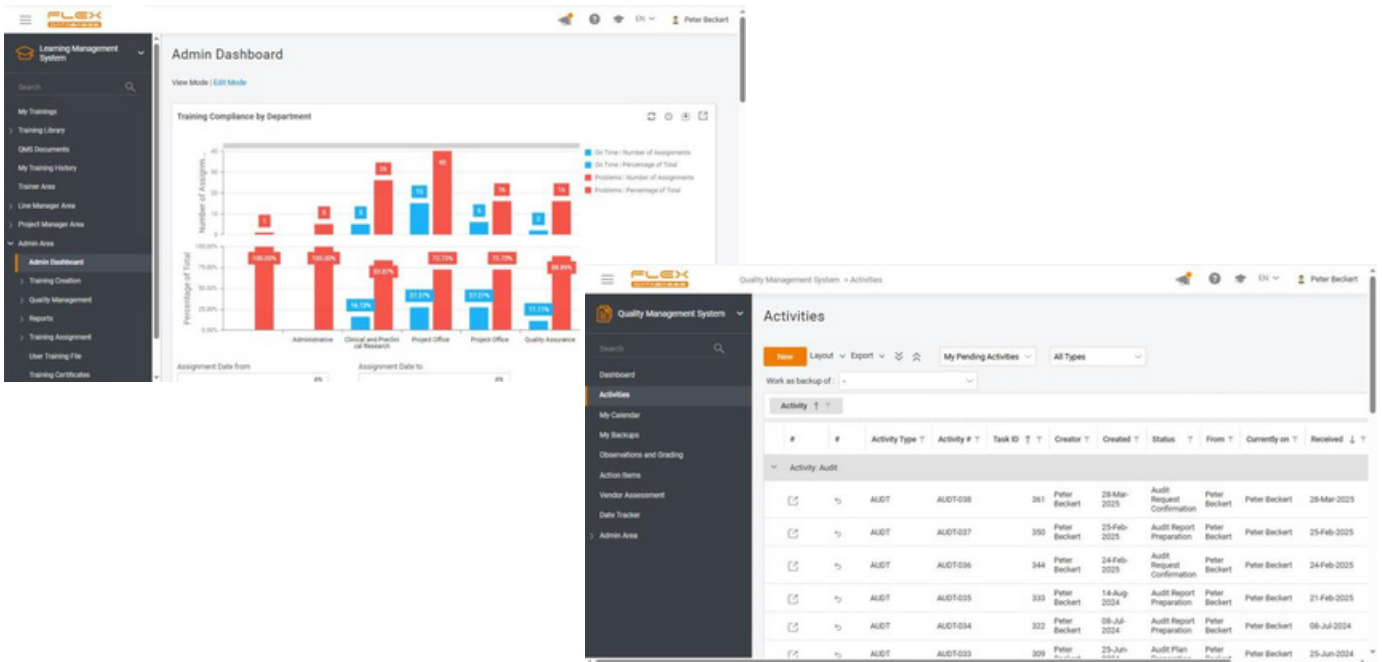
Some of our clients

Leading CROs, biotech, pharma, and academic research



Flex Quality Management & Learning

One Connected Solution



Integrated QMS + LMS for compliant, inspection-ready life sciences teams

Flex Quality Management & Learning combines a full Quality Management System (QMS) with a Learning Management System (LMS) in one connected solution. Quality events, CAPAs, audits and controlled documents live together with training plans, courses and records – so you always know what went wrong, what was fixed, which SOP version is current, and who is trained to follow it

Why Flex?

- One closed quality loop – from incident or audit finding to CAPA, updated SOP and completed training with e-signature, all tracked in one place
- Clear view of competence – at any moment you can see who is allowed to do what, which SOP versions they are trained on, and where gaps remain
- Inspection readiness by design – audit trails, electronic signatures, training matrices and SOP history are always available, not assembled at the last minute
- Risk and improvement visibility – CAPAs, incidents, audits, and trainings come together into a single picture of risks, trends, and effectiveness

Learning Management (LMS)

Training & Competence

Learning Management System > User Part - My Trainings

My Trainings

Peter Beckett
Position: Project Manager
Department: Project Office
Line manager: Michael Johns

23 Completions
2 Classroom
0 Course
19 Hours
0 On-Job-Training
21 Self-Training

Assigned | Self-Reported | Documents

Project: Select... | Category: Select... | Type: Select... | Due Date: Latest | Search...

Close-Out Visit (TRN-001-003) **OVERDUE**
Due Date: 02-Oct-2023 | 1h | NON PROJECT | CRA Skills
Open Training

Who is involved in Clinical Trials? (GCP-001-03) **ASSIGNED** **OVERDUE**

Training Records & Assignment

- Electronic training records for every employee: CV, job description, applicable SOPs and quality documents, internal and external training, certificates
- Automatic and manual training assignment
- Batch assignment of multiple trainings to one person or a group – ideal for onboarding and study start-up
- Training completion confirmed with 21 CFR Part 11 – ready electronic signatures

Experience & Control

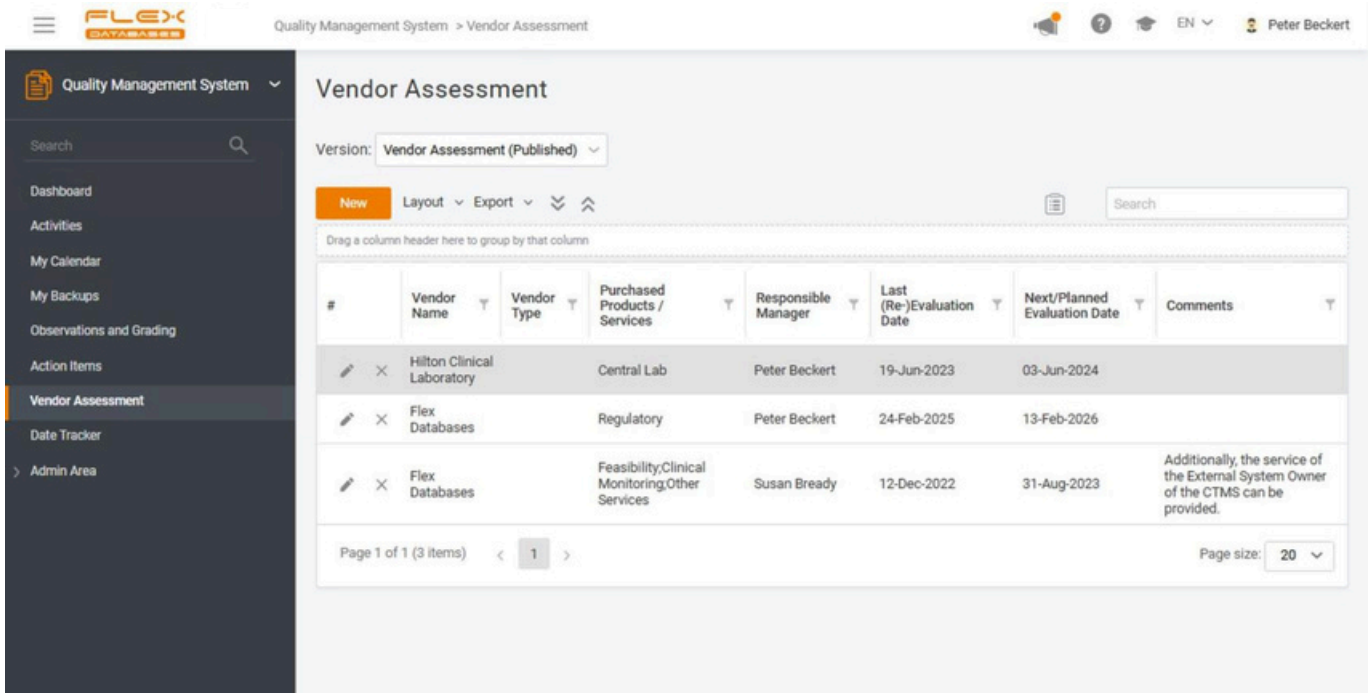
- Dedicated views for QA, training managers, line managers, project managers, employees and external users
- Automatic maintenance of training and SOP matrix when documents change – new versions trigger new training wherever needed

Content & Training Types

- Central SOP and training libraries for corporate, departmental and study-specific content
- Support for multiple training types: self-training, trainer-led sessions, structured courses and recurrent (periodic) training
- Use any content format: documents, slide decks, videos, links, SCORM courses and more
- Quizzes and knowledge checks with different question types to measure understanding, not just file opening

Quality Management (QMS)

Events, CAPA, Audits & Documents



The screenshot displays the 'Vendor Assessment' page in the Flex Databases Quality Management System. The interface includes a sidebar with navigation options like 'Dashboard', 'Activities', and 'Vendor Assessment'. The main content area shows a table of vendor assessments with columns for Vendor Name, Vendor Type, Purchased Products / Services, Responsible Manager, Last (Re-)Evaluation Date, Next/Planned Evaluation Date, and Comments. The table contains three entries, with the last one having a detailed comment about external system owner services.

#	Vendor Name	Vendor Type	Purchased Products / Services	Responsible Manager	Last (Re-)Evaluation Date	Next/Planned Evaluation Date	Comments
	Hilton Clinical Laboratory		Central Lab	Peter Beckert	19-Jun-2023	03-Jun-2024	
	Flex Databases		Regulatory	Peter Beckert	24-Feb-2025	13-Feb-2026	
	Flex Databases		Feasibility,Clinical Monitoring,Other Services	Susan Bready	12-Dec-2022	31-Aug-2023	Additionally, the service of the External System Owner of the CTMS can be provided.

Quality Events & CAPA

- Register any quality event: deviations, complaints, incidents, near misses, process issues
- Structured CAPA workflow: initiation, review, investigation, root cause analysis, action plan, implementation, observation period and effectiveness check
- Assign responsible owners to every CAPA step and task, track status and deadlines
- Store evidence and decision documents for each CAPA to be used in inspections and internal reviews

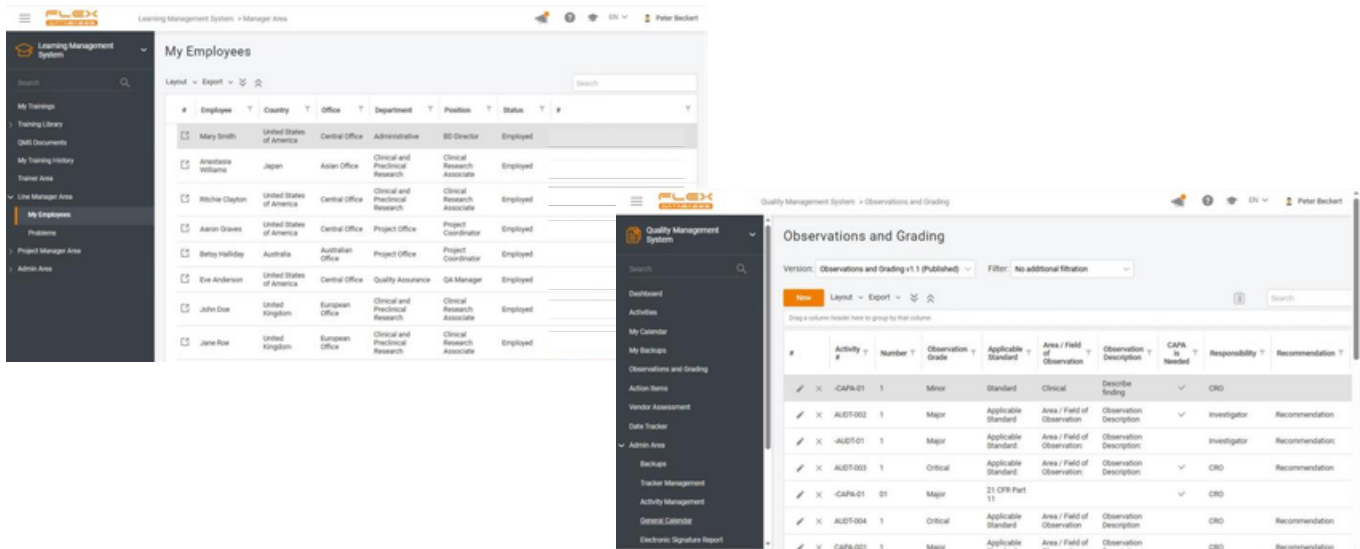
Audit Management

- Plan and conduct any type of audit
- Manage the full audit lifecycle: planning, execution, observations, CAPAs, observation period and closure
- Link audit findings directly to CAPAs and related SOPs or quality documents to ensure no information is lost
- Track audit plans and outcomes



Flex Quality Management & Learning

One Connected Solution



SOPs, Quality Documents & Link to Training

- Controlled lifecycle for SOPs and other quality documents: creation, review, approval, versioning and periodic review
- Collaborative review cycles with revision history and electronic signatures
- Transparent view of review steps, responsible employees and timelines for each document
- Automatic triggers from QMS to LMS: when SOPs or other controlled documents change, related trainings are updated and re-assigned

Reporting, Analytics & Readiness

- Training & quality dashboards
- Ad-hoc reporting across QMS and LMS – for example, correlating training status with quality issues or audit performance
- Fast inspection preparation: export training records, SOP status, CAPA lists and evidence for any period without manual collection

Technology, Roles & Integration

- Fully web-based, validated solution with a common security, backup and disaster-recovery strategy as part of the Flex Databases platform
- Configurable roles and permissions for QA, quality managers, training managers, line managers, project managers, employees, vendors and auditors
- Comprehensive audit trail and compliant e-signatures to support FDA 21 CFR Part 11, GDPR and GxP expectations

