Flex Databases

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

FLEX DATABASES
manage all in one

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

novo nordisk · BIOTRONIK excellence for life · EVEREST CLINICAL RESEARCH · Dr.Reddy's · FGK CLINICAL RESEARCH · WSG Westdeutsche Studiengruppe West German Study Group · ABX-CRO advanced pharmaceutical services · SOLTI Shaping the future of cancer research · ERGOMED

Quality Management System
Module Overview

From incidents and audits to CAPA and controlled SOPs — one connected QMS

Flex Quality Management System (QMS) brings together quality events, CAPAs, audits, incidents and controlled documents into a single, configurable system built for life sciences. It helps QA teams capture issues early, drive effective corrective and preventive actions, and maintain inspection-ready SOPs — while working hand in hand with Flex LMS for training

Why Flex?

- End-to-end quality workflows — from incident and audit finding to CAPA, effectiveness check and closure, fully tracked and reported
- Documented, controlled SOP lifecycle — creation, review, approval, versioning and periodic review in one place, linked to training
- Risk and performance visibility — KPIs and dashboards on CAPA, incidents and audits help you see where risks and bottlenecks really are
- Built for inspections — audit trails, e-signatures and “reason for change” capabilities support regulatory expectations and reduce finding rates

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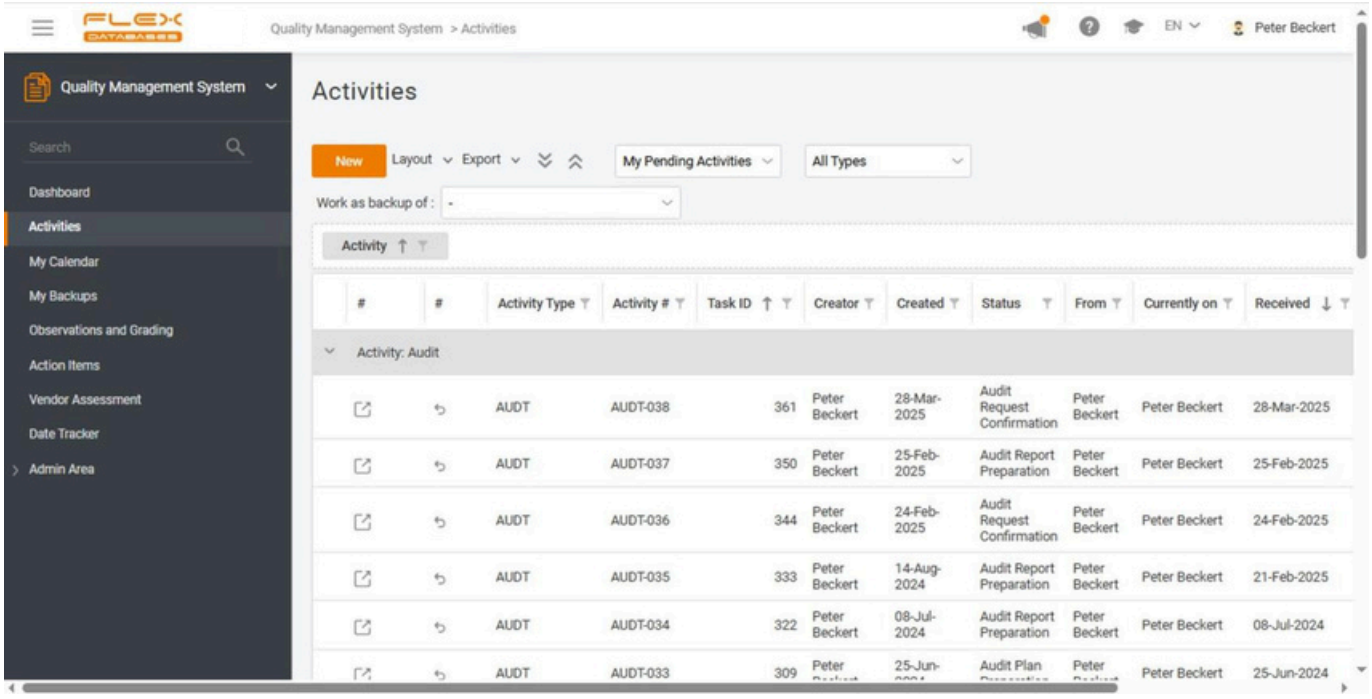

CAPA Management

- Initiate CAPAs from any quality event
- Structured workflow for review, investigation, root cause analysis, action planning, implementation and follow-up
- Assign responsible team members to tasks and individual process steps; track all responses and progress
- Schedule and track CAPA observation periods and effectiveness checks
- Store evidence of actions taken and generate documents for sign-off and inspections
- Monitor CAPA KPIs at company and project level to see trends and recurring issues

Audit Management

- Plan and schedule any type of audit
- Manage the full audit lifecycle: planning, conduct, recording of observations, CAPA tasks, observation period and closure
- Link audit findings directly to CAPAs and quality documents to ensure nothing is lost
- Track audit schedules and outcomes

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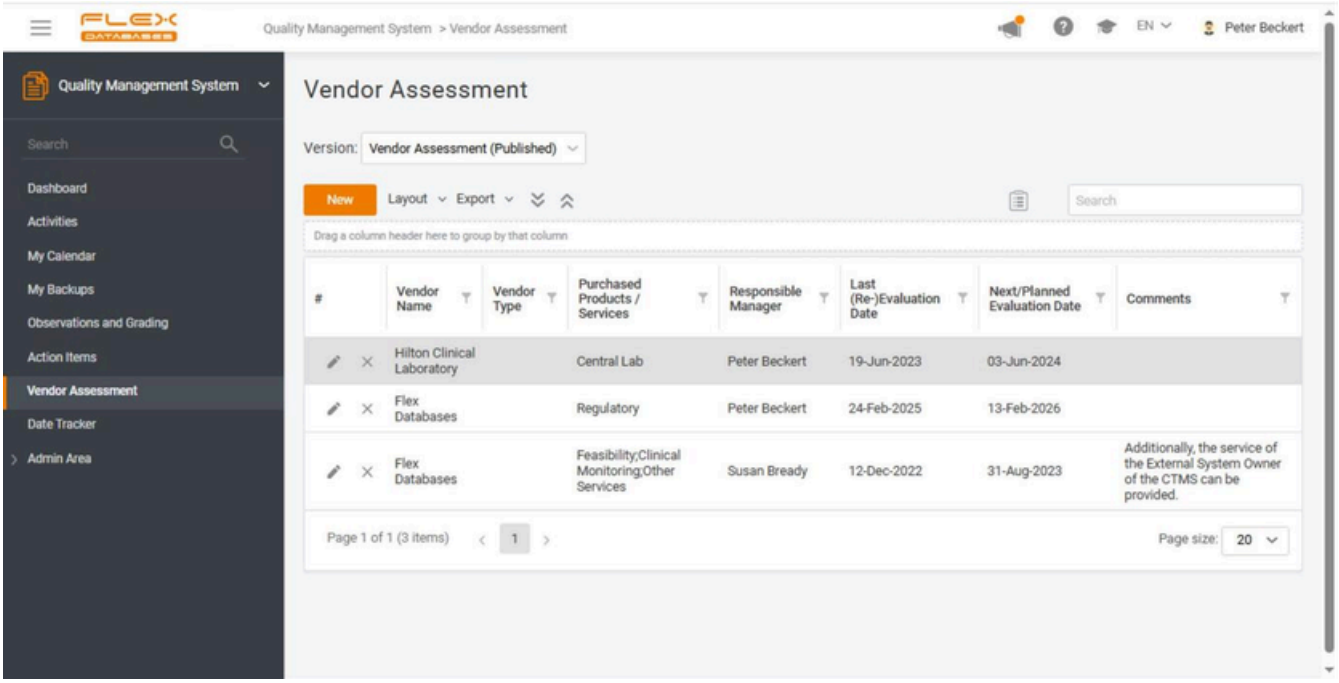

Incident Management

- Register any incident — deviations, complaints, process issues — in a single, structured log
- Evaluate incident severity and impact to decide on escalation and need for CAPA
- Track incident resolution, actions taken and timelines end-to-end

SOPs & Quality Documents

- Create new QMS documents or initiate review of existing ones with full version history
- Collaborative review cycles with comments, revision history and electronic signatures
- Notifications for periodic review and upcoming expiry to keep SOPs up to date
- Transparent view on review steps, responsible employees and timelines for each document
- Automatic triggers to Flex LMS: when SOPs or QMS documents change, related trainings are updated and re-assigned

Compliance, Security & Integration

- Cloud-based, validated QMS tailored to life sciences quality processes
- Configurable roles, permissions and views for QA, line managers, auditors, vendors and other stakeholders
- Full audit trail, electronic signatures and “reason for change” to meet regulatory expectations

Vendors Management

- Vendor qualification & risk assessment
- Contracting & onboarding — link contracts and quality agreements, assign responsible owners
- Ongoing performance monitoring
- Re-qualification / suspension — periodically re-assess vendor risk and performance, document decisions to extend cooperation, suspend or terminate

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