

The CDMO Digital Lab Infrastructure Guide

Build scalable digital workflows that auditors trust — and clients notice



Deliver faster. Prove control.
Scale without complexity.

Checklist + Digital Workflow Planning
Template Included



2025 EDITION

If you're leading a CDMO lab in the DACH region, you're not looking for more buzzwords about digital transformation. You're already delivering results under pressure, navigating regulatory scrutiny, and juggling custom client needs.

This guide is designed to give you more than an overview, it's a working document. You'll find specific insights, implement-ready ideas, and structured tools that help you move from "we know it's a problem" to "we're solving it."

Think of this guide as a workshop in writing: compact, actionable, and rooted in real, world experience from CDMO labs across the region.

We'll highlight quick wins, longer-term shifts, and give examples of how platforms like Scifeon are already supporting teams like yours, not in theory, but in the real, day-to-day work of delivering data, documentation, and confidence.

Behind closed doors, lab managers and QA leads admit what often stays out of public slide decks: things feel increasingly reactive. One, off client requests derail planned work. Review cycles stretch because data is hard to find. Reporting tools don't reflect what's really happening in the lab.

This isn't a technology problem, it's a systems and visibility problem. It's the result of tools that don't connect, documentation that's over-customized, and workflows that are too brittle to flex.

Labs aren't short on effort, they're short on air. And when even a small client escalation sends three departments scrambling for answers, that's not sustainable.

What's needed isn't more process. It's intelligent structure. Smart defaults. Shared dashboards. And tools that help every team member understand, contribute, and deliver in sync.

About Scifeon

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Where Rigid Systems Fail, Modular Thinking Wins

Rigid systems are good at one thing: repeating what already works. But CDMOs are constantly dealing with exceptions, new client formats, urgent timelines, projects that don't follow a standard model. That's where rigid systems start to cost more than they save.

Modular thinking means designing for change, not just control. It's about creating workflows, templates, and tools that are small, reusable, and combinable. Instead of one big system trying to be everything, modularity gives each part of the lab what it needs, with a shared language underneath.

What Modular Looks Like in a CDMO Lab

Let's say your lab supports both early-stage biotech clients and large pharma sponsors. Each has different expectations for documentation, review steps, and sample metadata. With a modular approach:

- Sample intake is handled through dynamic forms that adjust based on client type.
- QA approval workflows can be cloned and adapted per client.

Signs It's Time for a System Shift

- Client requests derail planned work
- QA reviewing the same data twice
- Reporting tools don't reflect reality

If these resonate, your lab may benefit from modular transformation.

Get a free workflow audit.

BOOK NOW

- Data exports are templated to fit multiple audit or client formats.

This isn't hypothetical. One Scifeon-enabled CDMO implemented modular digital intake and approval flows that reduced project onboarding time by 40%, without any changes to their core LIMS.

Diagnosing the Friction

Before going modular, ask:

1. Where are we duplicating effort?
2. Where do client requests cause exceptions?
3. Where does documentation drift from SOPs?

Mapping these pain points gives you the blueprint for modularization

How to Start Modularizing

Here's a 4-step starter process:

Inventorize the Variants	<ul style="list-style-type: none">• List workflows that change per client or project type• Identify what's stable vs. what flexes
Standardize the Stable	<ul style="list-style-type: none">• Lock down shared elements (approvers, steps, required data)• Use SOP references to back decisions
Build Flexible Modules	<ul style="list-style-type: none">• Create optional fields, toggles, or rules to adapt per project• Store these in a workflow library
Monitor and Iterate	<ul style="list-style-type: none">• Use live dashboards to see where steps slow down• Refactor modules quarterly based on new patterns

4. Make Transparency Operational, Not Aspirational

When visibility is operational, not occasional, labs move faster and make fewer mistakes. But here's the challenge: CDMO labs are already resource stretched. Reporting becomes another burden.

Clients want live status, QA needs traceability, and leadership needs trend data, all from the same messy pool of disconnected systems.

Let's break this down:

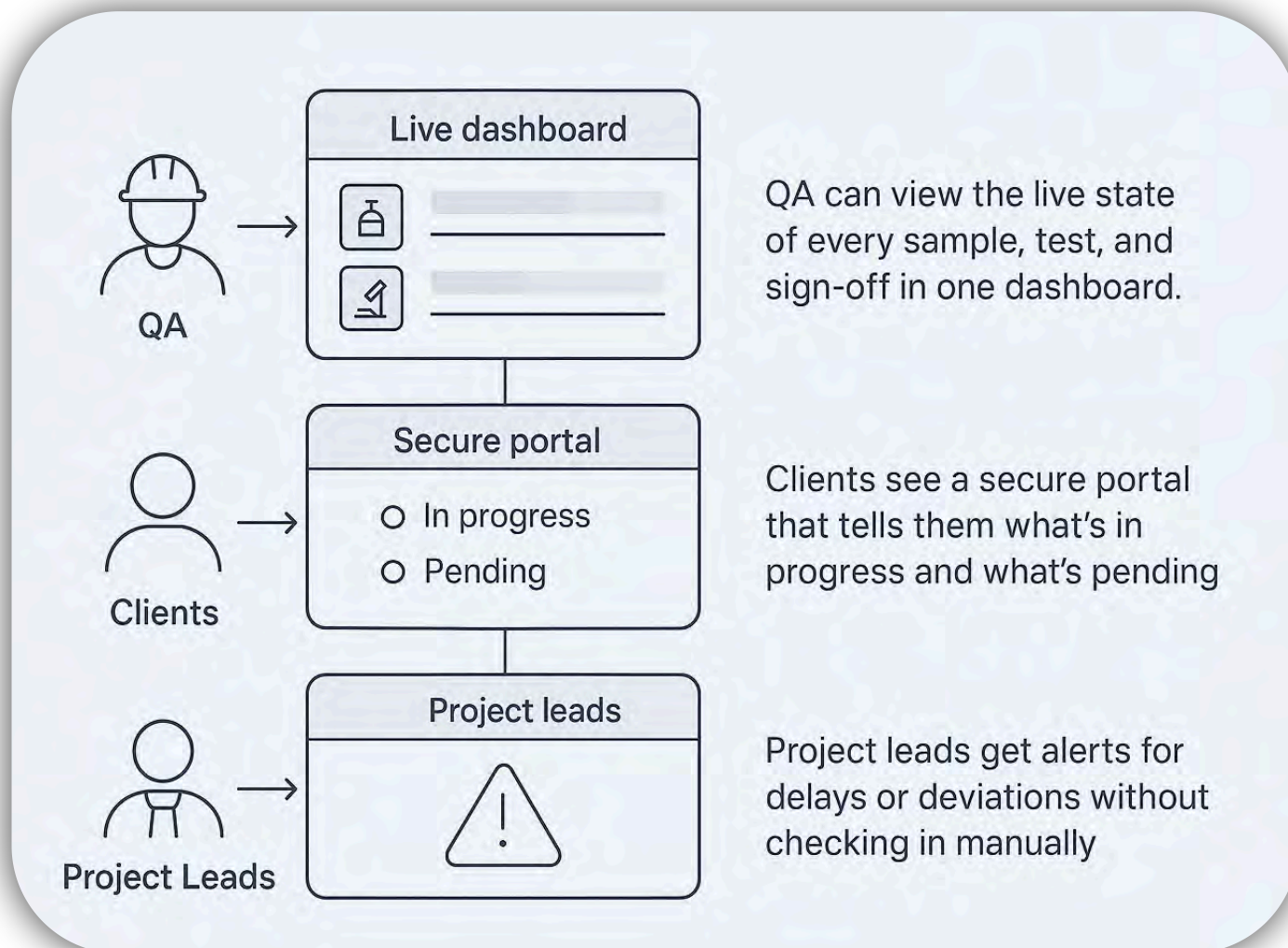
- **Project Managers want to know what's at risk.**
- **Clients want to know what's done.**
- **QA wants to know what changed.**
- **IT wants to know what's being tracked.**

If that visibility only comes from manually compiling status reports or chasing updates via email, your team is wasting valuable hours, and probably missing red flags.

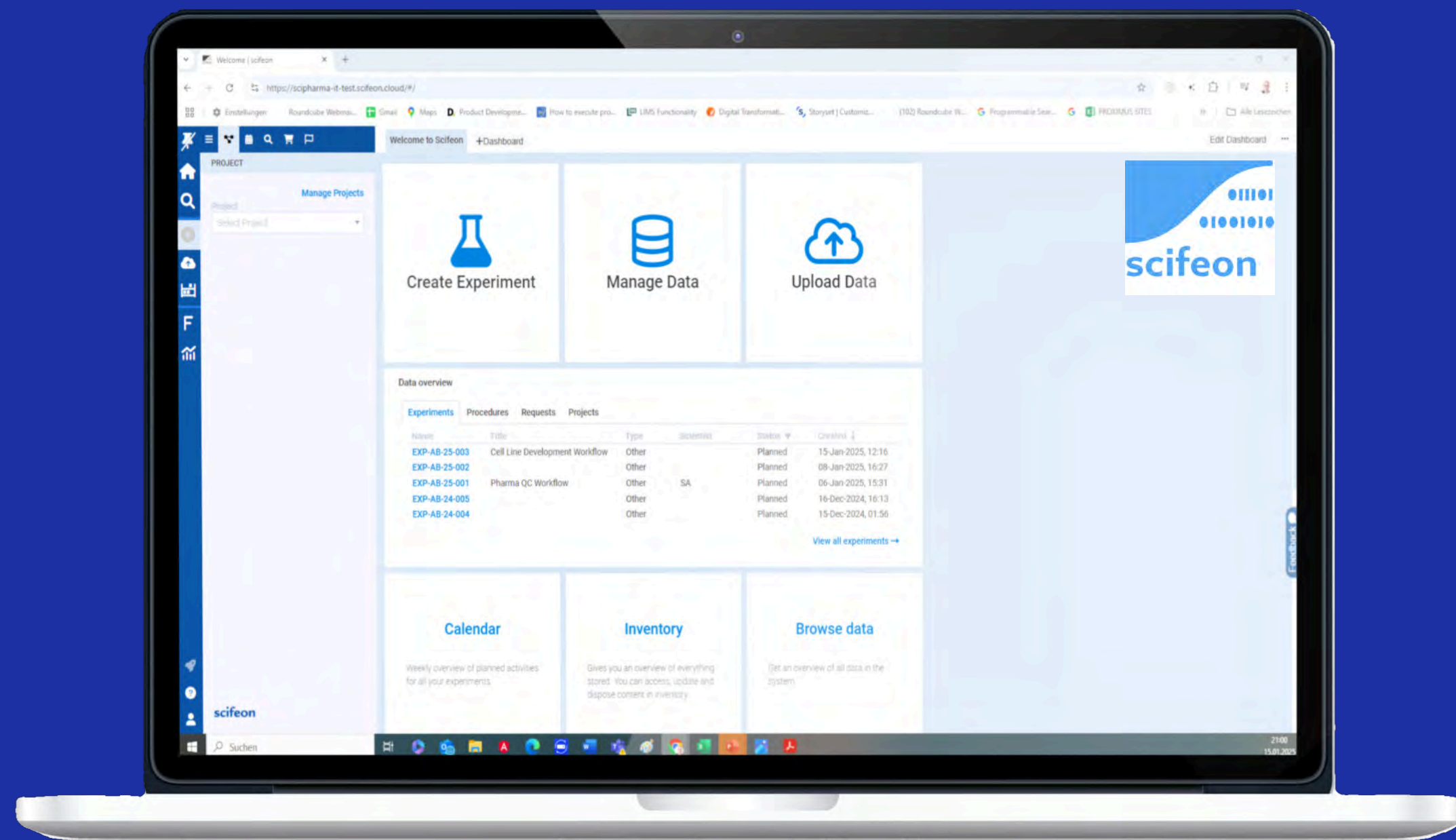
Operational Transparency in Practice

Here's what it looks like in a well-functioning CDMO lab:

This setup doesn't require reinventing your LIMS or ERP, it requires connecting the data that already exists and surfacing it where it's needed.



Why Labs Like Yours Trust Scifeon



200% ROI on digital transformation projects

Trusted by CDMOs across DACH

Seamless modular workflows without LIMS overhaul

Let's Talk About Your Lab's Goals

Three Signals That You're Ready

- You're repeating manual tasks every week.
- Clients are asking for visibility you can't easily provide.
- Internal reporting feels disconnected from lab reality.

If you're seeing any of those, your lab is likely already paying the cost of not acting.

What to Do in the Next 30 Days

1. Pick one recurring frustration.

e.g., Client-specific sample forms that get retyped.

2. Describe the ideal state.

One digital form that branches by client type.

3. Prototype it.

Scifeon's visual builder allows you to create and test flows without dev time.

4. Deploy it to one pilot team.

Review outcome after two cycles. Measure time saved, errors reduced, client feedback.

5. Decide to expand , or iterate.

If it works, clone and adapt for the next area. If not, revise.

Final Word

You don't need a revolution , just a plan that respects your reality. Scifeon is built for labs that want agility, visibility, and control without rewriting their entire stack.

If you can improve one process this month, you're already doing digitalization the way CDMOs should.

Ready to get started?

Visit www.scifeon.com or book a working session with our lab systems team.

How to get started quickly

Digital transformation doesn't have to mean starting from scratch. For CDMOs, the most effective improvements often begin by addressing everyday inefficiencies — the repeated questions, the status checks, the manual updates.

This 4-step approach is designed to help you identify a single, high-impact workflow and turn it into a shared, automated view using Scifeon. No full-system rollout. No disruption. Just a smart, contained starting point that builds internal clarity and external trust.

1. Identify Repeated Questions

What updates are repeatedly requested by QA, clients, or PMs?



2. Choose One Critical Workflow

Start with a workflow tied to client visibility or compliance.



3. Build a Shared View

Create a live dashboard in Scifeon. Add rules, alerts, and roles.



4. Share It Internally First

Launch with your team. Refine. Then expand access to clients.

Actors:
LabOps, QA, Project
Managers, Client Services

Purpose:
Spot inefficiencies and pain
points for automation

Actors:
Digitalization Lead, QA
Manager, LabOps Lead

Purpose:
Focus scope to maximize
early impact

Actors:
Digitalization Team, IT/Data
Integrator, QA Reviewer

Purpose:
Turn manual updates into
automated, traceable insights

Actors:
LabOps, QA, PMs; later
involve Clients

Purpose:
Create value and confidence
before external rollout

Assess Your Lab's Readiness: A Mini Framework



Self-assessment is only useful if it leads to change. Most CDMO labs already know where they struggle, they just don't have the time or structure to fix it. That's why this framework isn't just about scoring. It's about deciding, assigning, and improving, in small, controlled steps.

Step 1: Take the Assessment

Score your lab 1–5 in each of the categories below:

Category	Questions to Ask	Score (1–5)
Workflow Agility	Can we adapt a client workflow in under 1 week?
Traceability	Can we trace a batch result back to source inputs and methods?
Audit Readiness	If an audit was tomorrow, could we provide full digital documentation?
Client Access	Do clients have transparency without emailing our team?
QA Load	Are we doing double work to satisfy client-specific needs?

Step 2: Choose a Focus Area

Pick the lowest-scoring item. This becomes your starting point for change.

Example:

- If QA Load scored lowest: your first goal might be to reduce repetitive review work across clients.
- If Audit Readiness scored lowest: your first action might be to map current documentation gaps.

Spend More Time on Science, Less on Admin



Scifeon's research tools let you focus on what matters. Visualize experimental data with advanced charts, and simplify your workflows by reusing saved procedures.

BOOK A SESSION



Assess Your Lab's Readiness: A Mini Framework



Step 3: Draft a 30-Day Plan

Use this worksheet with your team:

Focus Area	Pain Point	First Fix	Who Owns It	Check-In Date
Traceability	Can't track test-to-result lineage	Configure Scifeon audit trail module	QA Lead	[Date]
Client Access	Do clients have transparency without emailing our team?	Set up client dashboard view	Project Manager	[Date]

Tool Tip: Scifeon's modular setup allows most of these fixes to be tested within days, without touching your core systems.

Step 4: Follow Up and Refine

In 30 days:

- *Measure:* Did the issue improve? Can you show impact?
- *Adjust:* If not, does the fix need refinement, or is the root cause deeper?

What Success Looks Like

By working through one category at a time, you build momentum. Within 90 days, teams often see:

- 20–30% reduction in client status requests
- Fewer QA escalations due to version mismatch
- Shorter turnaround times for onboarding new projects

Digital maturity isn't a checkbox. It's a system that adapts with you. This framework gives you a way to build that system, starting right where you are.

Modular Lab Starter Planner

This planner helps you think modularly and act tactically. One change a month adds up fast , and sets the foundation for scalable, responsive lab operations.

Identify a Candidate Workflow

Think of a client or internal process that routinely causes frustration or delays.

- **What is the workflow?** (e.g., Sample intake for new clients)
- **What triggers it?** (e.g., Client sends a request or project brief)
- **Why is it painful?** (e.g., Requires lots of manual coordination, no standard forms, repeated rework)

List the key steps, people involved, and tools used today.

Step	Responsible	Tools Used	Notes

Map the Current Flow

Spot the Repetition or Variation

Where does this workflow differ by client, region, or product type?

- Input data changes often
- Approval steps vary
- Output format differs
- Communication is inconsistent
- Other observations:

How could this process flex predictably instead of chaotically?

- **What should stay the same every time?**
(e.g., who approves, required metadata, document versioning)
- **What should be configurable?**
(e.g., intake form fields, test parameters, output format)
- **How would success look?**
(e.g., workflow deployable in under 2 hours, no rework, QA sign,off in <24h)

Define the Modular Future State

Plan Your First Modular Prototype

Choose one part of the workflow to digitize or modularize this month.

Module to build:	Owner	Tools needed:	Target Launch Date	Review Check in Date:
(e.g., sample intake form with dynamic fields)	(e.g., QA Lead, LabOps Manager)	(e.g., Scifeon Workflow Builder)		

Transparency Sprint Canvas



Use this 1- week planning tool to make visibility real inside your lab.
Start small, reduce friction, and test operational transparency in action.

Sprint Timeframe	
Start Date	
End Date	
Owner	

1. Define the Visibility Problem

What status questions does your team answer manually , over and over?

Repeated questions or delays:
<ul style="list-style-type: none">• “Has QA approved this yet?” <input type="radio"/>• "What’s the status of the batch?" <input type="radio"/>• “Are we ready for release?” <input type="radio"/>• “Who’s blocking this sample?” <input type="radio"/>• "Did the client get the update?" <input type="radio"/>

Other examples:

2. Choose One Pilot Workflow

Focus on one process where live status could make an immediate difference.	
Pilot Workflow:	(e.g., sample approval, release testing, deviation review)
Why this one?	(e.g., high volume, high risk, lots of email churn)

Transparency Sprint Canvas



3. Build a Shared View

Design what visibility should look like.

What info should be visible at a glance?

- Sample/test status ☐
- Approval step progress ☐
- Assigned owners ☐
- Timestamps ☐
- Flags for delays or missing data ☐

Where will it live?

(e.g., internal dashboard, team board, Scifeon client portal)

Who needs access?

- QA ☐
- Lab Ops ☐
- PM ☐
- Clients (External) ☐

Other Requirements?

4. Go Live and Observe

Commit to running the pilot dashboard or visibility tool for one week.

What worked well?	
What feedback did you receive?	(
What was clearer or faster than before?	



5. Decide Next Steps

At the end of the sprint, use this to make your next move.

Should we scale this dashboard/workflow to...

- More teams ☐
- More clients ☐
- Additional workflows ☐
- Other systems ☐

(e.g., QA tracking, reporting)

Or improve before scaling?

List blockers or ideas for improvement:

Final Note:

Transparency isn't just about data access.

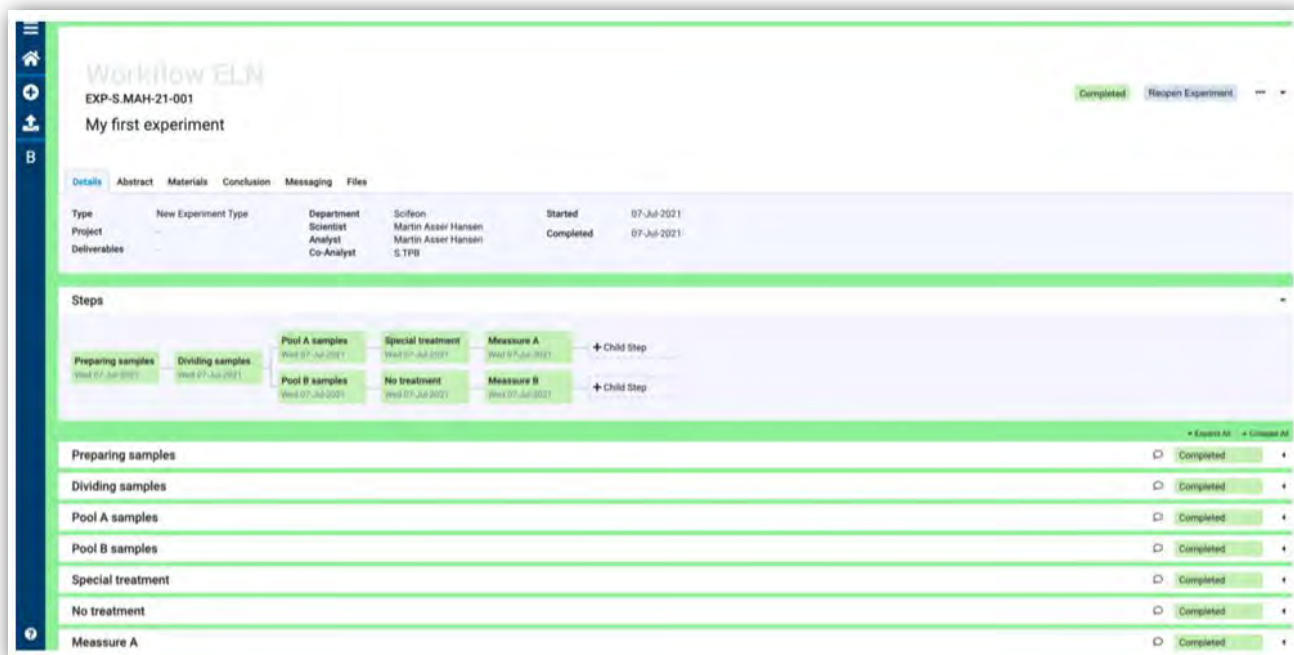
It's about building shared trust and reducing reactive communication.

This sprint gives your lab a way to test and prove that , in one focused, fast cycle.

What It's Like to Work with Scifeon Built for Real Lab Workflows

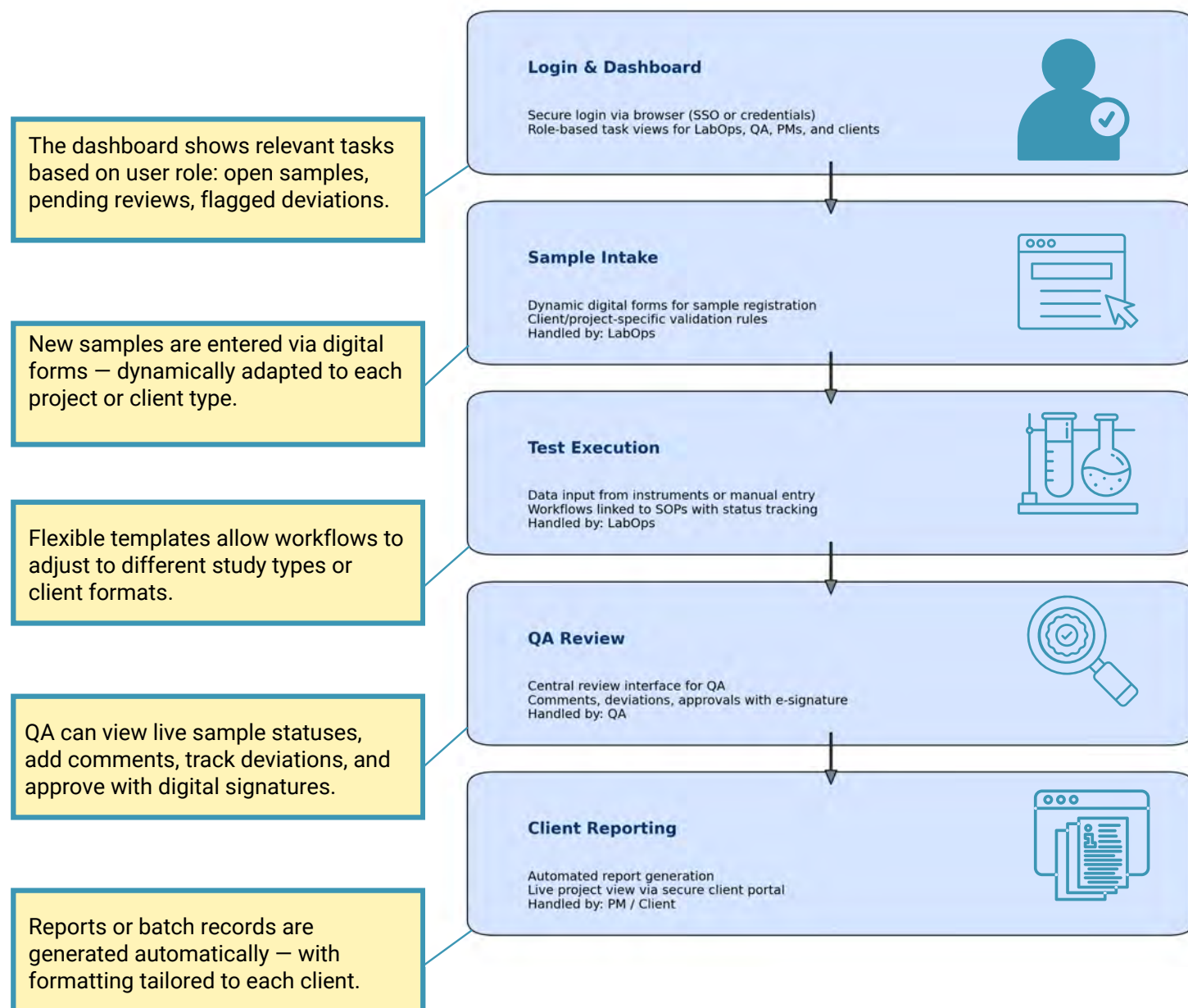
Scifeon is designed to support your lab's operations without disrupting existing processes. It's a modular, cloud-based system that brings LabOps, QA, and project teams onto one secure, compliant platform – fully adapted to the realities of CDMO and GxP environments.

The interface is intuitive and tailored to roles: whether you're in the lab, in QA, or managing projects, you see exactly what you need – nothing more, nothing less.



A Typical Day with Scifeon: From Sample Intake to Result Approval and Reporting

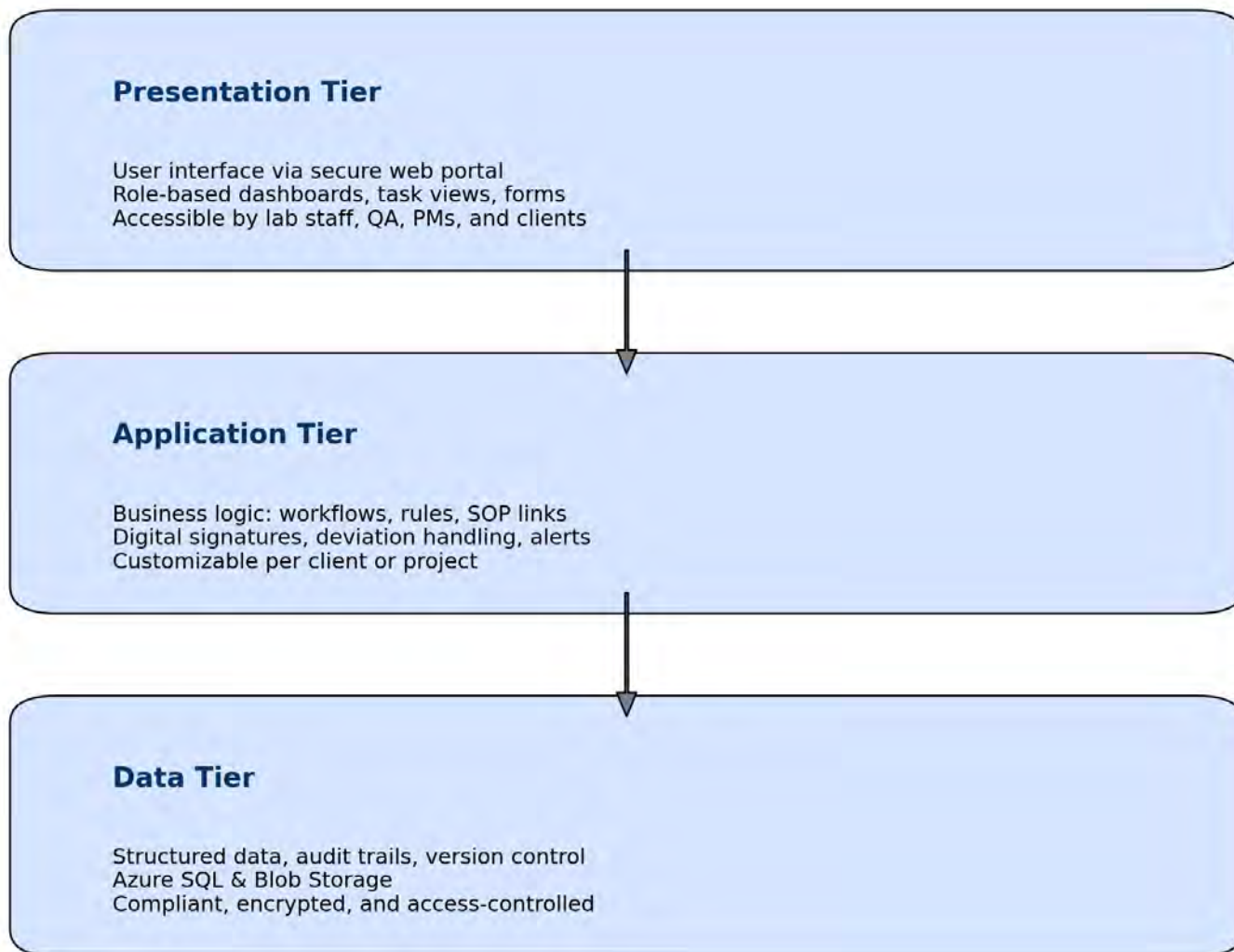
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Our team works closely with yours to map your existing processes, identify points of friction, and co-design a solution that integrates with your current setup. Whether you're looking to streamline QA, improve visibility, or enhance traceability.

Scifeon's Cloud-Hosted Architecture

Scifeon is delivered as a secure, cloud-based application hosted on Microsoft Azure. Its architecture is based on a three-tier model that separates the user interface, application logic, and data storage – enabling scalability, maintainability, and compliance with regulatory standards.



Security & Compliance

- End-to-end encryption (in transit and at rest)
- Role-based access (RBAC)
- Audit trail with versioning and timestamped user actions
- Hosted in ISO 27001 and GxP-compliant Azure infrastructure

Integration & Maintenance

- Supports API-based and file-based integration with LIMS, ELNs, MES
- No local installation required
- System updates and maintenance handled by Scifeon

The architecture ensures controlled, secure, and transparent workflows across the lab – with minimal disruption to existing systems.

Client Communication Tracker: From Reactive Updates to Real-Time Visibility



This worksheet helps you identify where communication with clients is breaking down , and where you can introduce structure, automation, or transparency to improve their experience

1. What Are Clients Asking Repeatedly?

Question Type	Example	How Often?	Manual Effort Involved?
Status Request	<i>"Can you confirm where the sample is?"</i>	Daily / Weekly / Occasionally	Low / Medium / High
Approval Progress	<i>"Is QA done yet?"</i>		
Owner	<i>"Can we get the certificate?"</i>		
Data Delivery	<i>"Can you update us on batch #3?"</i>		
Escalation Follow-up	<i>"This delay , where did it happen?"</i>		

2. Where Do You Store and Send This Information?

Information Type	Source System	Shared With Client?	Updated How Often?
Sample Status	<i>LIMS / Excel</i>	Daily / Weekly / Occasionally	Low / Medium / High
QA Review Status	<i>Email / Manual Notes</i>		
Batch Reports	<i>Word Docs</i>		
Deviations	<i>Not central</i>		

3. Friction Points You Can Eliminate

Friction	Impact	Potential Fix	Time to Implement
Sample Status updates via email	<i>Slows response to client</i>	Live dashboard access	1–2 weeks
Repeated sample status checks	<i>High admin load</i>	Role-based visibility rules	1 week
Last, minute report formatting	<i>High rework risk</i>	Use report templates	2–3 weeks



4. Build a Scifeon- Enabled Visibility Plan

Identify what visibility clients should have , and how Scifeon can deliver it.

Client Need	Scifeon Feature	Owner	Start Date	Go Live Target
View batch status live	<i>Project Dashboard module</i>	PM		
View QA approval progress	<i>Workflow Timeline Tracker</i>	QA Lead		
Download documents	<i>PDF Export / Client Portal</i>	QA / Ops		

Outcome:

Clients get faster answers, your team spends less time sending updates.

The lab builds a reputation for being responsive, transparent, and in control.

Audit Readiness Scorecard



Use this tool to evaluate your lab's preparedness for client, regulatory- or internal audits , and identify gaps you can address with minimal disruption.

Each section below is designed to surface practical improvement opportunities and offer high-leverage fixes that CDMO labs can implement fast.

1. Core Audit Dimensions

Rate each area on a scale of 1–5. Be honest: this is for improvement, not judgment.

Area	Questions to Ask	Score (1–5)
Data Integrity	<i>Can every result be traced to original data, instruments, and approved methods? Are timestamps and ownership intact?</i>	
SOP Compliance	<i>Do workflows automatically reflect SOP changes? Can deviations be tied back to outdated procedures?</i>	
Change control	<i>Are all changes (even minor ones) logged digitally with justification, reviewer sign-off, and timestamp?</i>	
Access Control	<i>Can we instantly show who accessed or edited what , and under which permissions?</i>	
Audit Trail	<i>Do we have system-generated, tamper-evident logs for every critical action?</i>	
Client Reporting	<i>Can we tailor reports to different client templates without reprocessing data manually?</i>	
Issue Resolution	<i>Are all deviations documented in a structured, auditable system , with statuses and closures traceable?</i>	



Audit Readiness Scorecard

Use this tool to evaluate your lab's preparedness for client, regulatory, or internal audits , and identify gaps you can address with minimal disruption. Each section below is designed to surface practical improvement opportunities and offer high,leverage fixes that CDMO labs can implement fast.

2. Key Risk Indicators (KRIs)

These are practical warning signs that your lab may be exposed to compliance risks , especially during client or regulatory audits. Review the list carefully and check any that reflect your current situation.

Risk Indicator	Description	Frequency Observed? (✓)
QA approvals via email/shared drives	No digital traceability or access control	
Documentation spread across formats	No unified version control or audit reference	
Reports built manually in Word/Excel	Prone to inconsistency, rework, and formatting delays	
Inconsistent deviation logging	Missing timestamps or incomplete closure history	
Audit SOPs not linked to workflows	Teams use outdated instructions unknowingly	
Scattered or missing audit trails	Evidence is incomplete or hard to compile	
Manual equipment logs	Maintenance gaps not logged or accessible in audits	
>72 hours to prepare audit docs	Documentation gathering is manual and disorganized	

Action Threshold:

If you've checked two or more, your lab may be facing audit exposure due to fragmented systems or overreliance on manual processes. These aren't just inefficiencies , they're credibility risks.

Audit Readiness



Quick Response Strategy:

Start by identifying one item you checked that occurs regularly. Choose a workflow (e.g., deviation management or QA approval) and run a 30-day improvement sprint to:

- Standardize format and routing
- Embed audit trails and SOP references
- Assign responsible roles with alerts

This approach alone can reduce audit prep time by 30–50% and raise internal confidence in your documentation integrity.

3. High-Impact Fixes Labs Can Apply This Month

These aren't theoretical improvements. They're widely adopted best practices proven to reduce audit friction in CDMO environments..

Problem	Best Practice Fix	Tools Needed
Missing audit trails	Auto- generated audit logs tied to every workflow step	<i>Scifeon workflow engine with audit history enabled</i>
Inconsistent version control	Link SOP versions directly to each task or approval in the digital flow	<i>SOP reference field in Scifeon templates</i>
Rework due to unclear ownership	Assign reviewers/approvers with timestamps and alerts for delay	<i>Role,based task assignment and email triggers</i>
Manual client reports	Use template,driven reporting with dynamic fields pulled from workflows	<i>Scifeon report module or PDF generation</i>
Deviations not fully closed	Track status, owner, and resolution timestamp in a structured log	<i>Deviations tracker app within Scifeon</i>
Training gaps before audits	Link competency assessments to roles and access permissions	<i>Digital training record mapping in Scifeon or HR system</i>
Incomplete equipment logs	Centralize equipment maintenance schedules and audit entries	<i>Equipment & Inventory management module or linked spreadsheet app</i>

PRO Tip:

For most labs, **the fastest fix is standardizing digital QA approval workflows.** It reduces ambiguity, eliminates email,based approvals, and builds confidence with clients and auditors.



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