ADLIB

BRIEFING PACK FOR LIFE SCIENCES TEAMS

# Use more AI. Show where every answer came from.

Your teams sit on decades of protocols, study reports, batch records and SOPs that AI could put to work. Most programs stall on one question: can we show an inspector where that number came from? Adlib turns the documents your systems can't read into usable data, with every value linked to the page it came from. The same team does more, and every record holds up.

Leadership | Regulatory | Clinical | Quality & compliance | IT, data & AI

INSIDE THIS PACK

# One pack, an answer for every team

Each page stands on its own. Pass on the ones that fit the person asking.

| PAGE | PASS IT TO | IT ANSWERS |
|---|---|---|
| 3 | **Everyone** | Why AI stalls in life sciences, and what regulators now expect |
| 4 | **Everyone** | What Adlib does, and what makes it different |
| 5–6 | **Leadership and finance** | The business case, and a worksheet to run it on your own numbers |
| 7 | **Anyone asking whether AI can be trusted** | Why agents do the admin and people lead, with every value traced |
| 8 | **Regulatory affairs and operations** | Submission-ready documents, with the source still attached |
| 9 | **Clinical operations** | What changes for the people managing trial documents |
| 10 | **Quality, compliance and procurement** | Audit trail, validation, where your data lives, and the first step |
| 11 | **IT, data and AI** | Where Adlib sits, what it connects to, and what IT has to do |
| 12 | **Everyone** | Life sciences teams already working this way |

**The next step is a demo built around the documents your team works with. Scan the code on the back cover to book one.**

THE CHALLENGE

# AI is ready for life sciences. The evidence trail isn't.

Leadership has seen what AI can do with a protocol or a 600-page study report, and the pilot looks good. Then quality asks how an output traces back to its source, which version was used, and whether anyone could reproduce it in a year. Most programs have no answer, so the use case stays a pilot.

**$60–110B**

a year in potential economic value from generative AI for pharma and medical products

McKinsey Global Institute, Jan 2024

**<10%**

of drugmakers are scaling AI in clinical or commercial manufacturing

CRB Horizons survey of 400+ R&D and manufacturing professionals, Oct 2026

**~1 in 2**

respondents named accuracy or quality concerns as a major issue holding AI back

CRB Horizons survey, Oct 2026

## What regulators now expect

| WHEN | WHAT | WHAT IT ASKS FOR |
|---|---|---|
| Sep 2024 | **EMA reflection paper on AI in the medicinal product lifecycle** | Sets out how EMA expects AI to be used and governed from discovery to post-authorisation |
| Jan 2025 | **FDA draft guidance on AI to support regulatory decision-making for drugs and biologics** | A risk-based credibility assessment of each AI model, for its specific context of use |
| Jul 2025 | **EU GMP draft Annex 22 (AI) and revised Annex 11, for consultation** | Explainable models, recorded confidence, defined human oversight, and secure, tamper-evident audit trails |
| Jan 2026 | **FDA and EMA joint guiding principles of good AI practice in drug development** | Ten principles, including a risk-based approach and good data governance and documentation |

Status as of November 2026.

**What they share: you have to be able to show where an AI output came from, and who checked it.**

AT A GLANCE

# Documents in. Data you can defend out.

**Adlib is the document-to-data engine for regulated industries.** The documents your systems can't read become AI-ready data, with every value linked to the page it came from. Lower cost, faster answers, simpler compliance.

## The problem

Life sciences runs on documents: protocols, study reports, batch records, SOPs, certificates and correspondence. They arrive as scans, office files and 3,000-page PDFs, from sites, CROs, suppliers and partners. Before AI or any system can use them, someone converts them, checks them and re-keys what matters. Headcount is flat. Volume is not.

## What Adlib does

### Makes every document readable

Adlib converts almost any file into consistent, searchable PDF and PDF/A, keeps structure and bookmarks intact in very long documents, and splits large packets into the documents inside them.

### Turns documents into data, with the source attached

Adlib extracts the values your teams and your AI need, across documents, and links each one to the file, page and version it came from, with a history of who checked or changed it.

## What makes it different

### AI you can check, so you can use more of it

Every value is traced to its source. Reviewers check the page instead of re-reading the document.

### AI-ready, not just converted

The output is data your systems and models can use, not another folder of PDFs.

### Agents automate, people decide

Adlib does the admin. Your people write the submission, release the batch and sign.

### Your data stays yours

Bring your own model and run Adlib in your own cloud.

**$1.7M** a year saved at **one of the world's largest pharmaceutical organizations**, by replacing multiple PDF tools with one shared platform for submission content.

FOR LEADERSHIP

# Lower cost, faster answers, simpler compliance

| THEY'LL ASK | THE ANSWER |
|---|---|
| **What problem does this solve?** | Everything between a document arriving and a person or a model using what's in it: converting it, checking it, finding the values that matter and re-keying them. Skilled people do that by hand today. |
| **We already have AI pilots. Why this?** | Pilots run on clean samples. Production runs on scans, tables, annotations and 3,000-page reports. Adlib prepares those documents for your models and keeps the link to the source, so a use case can get through quality review and into production. |
| **What does the business get?** | **Lower cost:** fewer hours of manual conversion, QC and re-keying, and fewer point tools to maintain.<br>**Faster answers:** data your teams and models can use as soon as a document lands.<br>**Simpler compliance:** every value in the record traces to its page. |
| **Does this replace our people?** | No. The same team handles more. Adlib takes the admin, and your scientists, regulatory and quality staff keep the judgement. |
| **How do we start without a big bet?** | With a demo built around a document set you already know. If it's worth going further, we scope the next step with you. |

## Build the case on four numbers you already know

**01**
**Monthly volume**
Documents converted, checked or re-keyed each month

**02**
**Minutes per document**
Manual conversion, QC and data entry on each one

**03**
**Rework**
Re-publishing, re-runs or technical rejections a year

**04**
**AI on hold**
Use cases waiting on validation or quality sign-off

**<1 min** per product release form, down from 2–3 hours, at **a healthcare products company** that now converts incoming release forms to compliant archive formats and files them automatically.

WHAT IT ADDS UP TO

# Minutes per document add up to a bigger team

Converting, checking and re-keying one document only takes a few minutes. Across a day's volume, those minutes are whole people. Here is an illustration for a mid-sized regulatory or clinical document team.

**400**
documents a day

**10 min**
of conversion, checking and re-keying saved on each

**~67 hrs**
of team time back every day

**~9**
people's worth of capacity, without hiring

Illustrative only, not a customer result. Based on a 7.5-hour working day and 250 working days a year. A demo on your own documents shows what your real per-document saving looks like.

## Run it on your own numbers

**Documents a day** _____ e.g. 400 × **Minutes saved per document** _____ e.g. 10 ÷ **Minutes in an hour** 60 = **Hours back a day** _____ e.g. ~67

**Hours back a day** _____ from above ÷ **Hours in a working day** 7.5 = **People's worth of capacity** _____ e.g. ~9

**Hours back a day** _____ from above × **Working days a year** 250 × **Loaded cost per hour** _____ your rate = **Value of time back a year** _____

**100K+**

documents a month (batch records, quality records, SOPs and inspection reports) processed through Adlib at one class of regulated production site at **a global medical products manufacturer**, repeated across its sites worldwide.

WHY IT CAN BE TRUSTED

# Trust is what turns AI into capacity

Most AI puts a person in the loop to check the machine, so the team does the work twice. Adlib works the other way round: **the agents do the admin, and every value they hand over is traced to its page.** Your people lead the work instead of supervising software.

| HUMAN IN THE LOOP | |
|---|---|
| **The admin** | AI drafts it. A person re-does it to be sure. |
| **Trust** | Only as good as the reviewer's re-read. |
| **Checking** | Nobody can see where an answer came from, so everything gets checked. |
| **Your people** | Spend the day checking the machine. |

**AI adds a review step. Output barely moves.**

| ADLIB: PEOPLE LEAD | |
|---|---|
| **The admin** | Agents convert, split, extract and check it. |
| **Trust** | Every value linked to its file, page and version. |
| **Checking** | Reviewers see each value next to the page it came from. |
| **Your people** | Spend the day on the science, the submission and the batch. |

**AI takes the admin. The same team does more.**

## How every value earns trust

1. **Read**
   Agents render each document, whatever its format, and extract the values that matter.
2. **Check**
   Values are compared across documents, so inconsistencies surface before anyone relies on them.
3. **Trace**
   Each value is tied to the file, page and version it came from, with a full history of who checked or changed it, and when.
4. **Lead**
   Your people make the call, working from a record they can defend.

**3,500** pages processed in under an hour at **a leading pharmaceutical company**, to meet an FDA deadline for a vaccine emergency authorization application.

FOR REGULATORY AFFAIRS AND OPERATIONS

# Submission-ready documents, with the source still attached

Regulatory teams don't lose time on the science. They lose it on documents: files in every format, broken bookmarks, re-publishing, and figures re-keyed from reports into trackers. Adlib takes that work off the team.

| TODAY | |
|---|---|
| **Formats** | Authors and partners send every file type, and someone converts them by hand. |
| **Long documents** | Bookmarks and structure break in 3,000-page reports. |
| **Data** | Figures are re-keyed from reports into trackers and tables. |
| **Years later** | Someone digs through the archive to show where a figure came from. |

**Your team spends the day formatting.**

| WITH ADLIB | |
|---|---|
| **Formats** | Documents are converted to consistent, searchable PDF and PDF/A automatically. |
| **Long documents** | Structure and bookmarks stay intact. |
| **Data** | Values are extracted, each linked to the page it came from. |
| **Years later** | The source is still attached to every value. |

**Your team spends the day on the dossier.**

| YOU'LL ASK | THE ANSWER |
|---|---|
| **Does it write our submissions?** | No. Adlib prepares documents and data. Your people write the content and sign it. |
| **Do we change our publishing system?** | No. Adlib works alongside the document and publishing systems you already run. |
| **Can we show where a figure came from?** | Yes. Each extracted value links to the file, page and version it was read from. |

> **“Due to how heavily regulated life sciences is, 100% of our documents are required to be transferred to and stored as a PDF. This is how we submit them as well … Working with the likes of Adlib keeps us compliant.”**
>
> Associate Director, Protocol & Report Content, a global contract research organization

FOR CLINICAL OPERATIONS

# Agents do the admin. Your team runs the trial.

| TODAY | |
|---|---|
| **Intake** | Site and CRO documents arrive in every format, through every channel. |
| **Packets** | Multi-document scans are split and filed by hand. |
| **Checking** | Someone opens each file to check it's legible and consistent. |
| **Data entry** | Dates, versions and identifiers are re-keyed. |
| **Inspection** | Someone reconstructs where a record came from. |

**Your team spends the day filing, not running the study.**

| WITH ADLIB | |
|---|---|
| **Intake** | Documents arrive converted and consistent. |
| **Packets** | Packets are split into the documents inside them. |
| **Checking** | Values are compared across documents, and inconsistencies surface. |
| **Data entry** | Values are extracted, each linked to the page it came from. |
| **Inspection** | The trail is already there. |

**Your team spends the day on the study.**

| YOU'LL ASK | THE ANSWER |
|---|---|
| **Is this replacing us?** | No. It takes the converting, splitting and re-keying. You keep the work that needs judgement. |
| **What if it gets something wrong?** | Every value comes with the page it was read from, so you check it in seconds instead of re-reading the document. A reviewer corrects it, a second person signs off, and every version is kept. |
| **Does it replace our trial systems?** | No. Adlib works upstream and delivers into the systems you already use. Connections to specific systems are scoped with your IT team. |
| **Who makes the call?** | You do. Adlib never makes a clinical or quality decision. |

**90%** of manual labor removed at **a global diagnostics company**, where around a million documents a year for 12,000 users now run through one process combining SharePoint, PLM and Adlib.

FOR QUALITY, COMPLIANCE AND PROCUREMENT

# Every value traced to its source

Simpler compliance means a record that explains itself, value by value, and data that stays in your environment.

## Quality and compliance

| THEY'LL ASK | THE ANSWER |
|---|---|
| **Does the AI make GxP decisions?** | No. It converts, extracts, checks and traces. Batch release, deviations and submissions stay with your people. |
| **Can we show an inspector where a value came from?** | Yes. Each value links to the file, page and version it came from. Every document keeps a history of who opened, reviewed, changed or downloaded it, whether a person, an agent or a process. |
| **Can an agent see more than it should?** | No. An agent can never see or do more than the person using it, and access follows your folder and collection permissions. |
| **Who validates it?** | You do, for your own context of use, the way you validate any computerized system. We work with your validation team on what they need from us. |
| **Does our data leave our environment?** | Adlib runs in your own cloud, with the model you choose. |

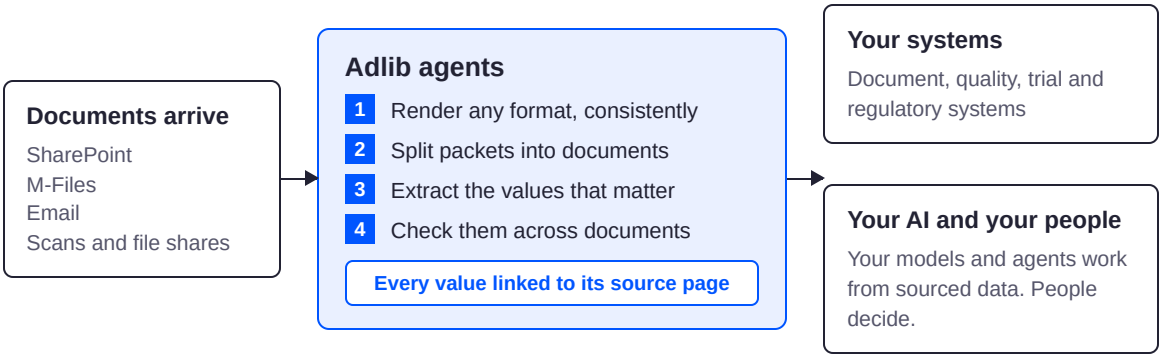
## Procurement and finance

| THEY'LL ASK | THE ANSWER |
|---|---|
| **Who is the vendor?** | Adlib Software, with 25 years in regulated document work. |
| **What's the first step?** | A demo built around a document set you choose. If it's worth going further, we scope the next step with you. |
| **Do we have to replace anything?** | No. Adlib works inside the systems you already run. |
| **What's the return?** | Built on your own volumes, minutes per document and rework, using the worksheet on page 6. |

**$250K** per FDA resubmission, plus 30–60 days of delay to market, was what documentation errors cost **one of the largest pharmaceutical organizations** before it standardized on Adlib.

FOR IT, DATA AND AI

# It runs in your environment, underneath what you already run




| THEY'LL ASK | THE ANSWER |
|---|---|
| **Does it work with our document systems?** | Adlib connects to SharePoint Online, M-Files and Exchange Online, with an integration framework and SDK for the rest. Anything else is scoped with your team. |
| **Which AI models does it use?** | Yours. Bring your own model, and see token use and cost for each job in a dashboard. |
| **Where is our data, and are we locked in?** | In your own cloud. Every document, extracted value and source link stays in your environment. |
| **How do identity and access work?** | SSO with your existing identity provider, such as Microsoft Entra ID. Folder and collection permissions apply, and an agent can never do more than the person using it. |
| **What does IT have to do?** | No model training and no AI team. IT's part is the connection to your document systems, identity setup and the security review. |

**Up to 2M** pages a month rendered through Adlib inside the quality management system at **a global consumer health company**, for product specifications, formulas, raw materials and packaging.

CUSTOMER STORIES

# Life sciences teams already working this way

> **“Adlib is highly embedded into M-Files, so much so that document creators do not even know that Adlib is rendering in the background.”**
>
> Associate Director, Protocol & Report Content, a global contract research organization

**$1.7M**
saved a year

### A top pharmaceutical company: one platform for submissions

Replaced multiple PDF tools with one shared platform, and renders large volumes of submission content with 99.9% accuracy.

**90%**
less manual labor

### A global diagnostics company: one process for 12,000 users

Around a million documents a year run through SharePoint, PLM and Adlib, with compliance workflows standardized to reduce audit failures.

**<1 min**
per form, down from 2–3 hours

### A healthcare products company: release paperwork

Incoming product release forms are converted to compliant archive formats and filed in SharePoint automatically.

**3,500**
pages in under an hour

### A leading pharmaceutical company: an FDA deadline

A full submission processed in time to meet an FDA deadline for a vaccine emergency authorization application.

**100K+** documents a month at one class of production site at **a global medical products manufacturer**: batch records rendered, stamped, signed and barcoded, then routed to ECM, ERP and SharePoint.

ABOUT US

# Who we are

Adlib turns the documents your systems can't read into data your people and your AI can use, with every value linked to the page it came from. Adlib has worked in regulated industries for 25 years, alongside the document, quality and regulatory systems life sciences teams already run.

**25 years**
in regulated document work

**Your cloud**
with the model you choose

**Every value**
linked to the page it came from

# See it on your own documents

Book a demo. Bring a document set your team already struggles with, and we'll show you how Adlib reads it, turns it into data and links every value to its page. Nothing changes in your systems, and there's no platform migration.

**Scan to book a demo**

ADLIB

adlibsoftware.com

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