



COMPASS[®] BIO for CDMOs

Transforming Biopharma Product Development with Structured Content & Data Management, Automated Report Generation, and AI-enabled Workflows

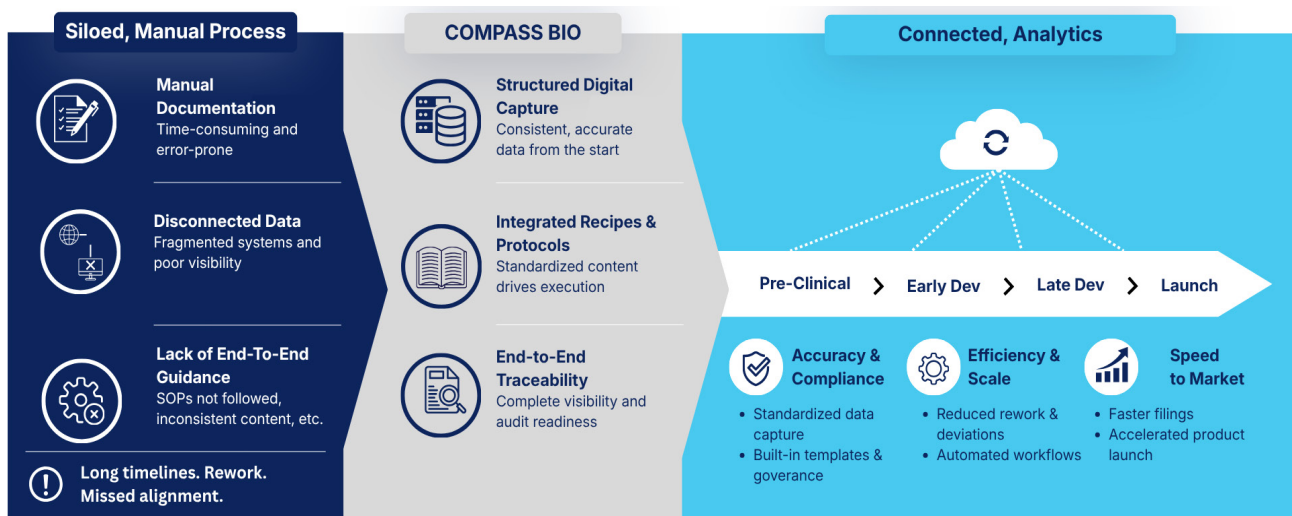
SOLUTION SUMMARY

Compass BIO: The Future of CMC Structured Content & Data Management

Compass BIO is a purpose-built Structured Content and Data Management (SCDM) platform designed for BioPharma and CDMO organizations. It brings rigor, traceability, and connectivity to all CMC data generated during analytical and process development, replacing fragmented spreadsheets and document silos with a single, unified environment. By capturing both process and analytical data and relationships, including from source data systems, Compass BIO drives comprehensive risk management, criticality analysis, and technology transfer, and streamlines regulatory submissions with a compelling ROI. Furthermore, its structured architecture provides the clean, contextualized foundation needed to power AI initiatives.

Throughout the Entire Product Development Lifecycle, Accelerate What Matters.

From fragmented workflows to connected, compliant execution across the lifecycle.



Tailored for the Challenges of CDMOs

Compass BIO is more than an internal efficiency tool — it's a competitive differentiator used by CDMOs to support multiple customers simultaneously, accurately, and with faster response times.

- Most CDMOs deliver results to Sponsors as static PDF reports. Compass BIO supports the creation and management of unique project and final report templates for each customer, so every table, report, and data output is automatically generated to that Sponsor's required format, every time.
- Our competitors compile CMC tables and reports manually. We use Compass BIO's Automated data table and report generation to generate submission-ready data 80% faster than with manual processes.
- A CDMO can open a secure, permission-based portal into Compass BIO for each Sponsor. Access is configured by account, so a Sponsor can log in on their own schedule to review data and generate reports — without the CDMO building or maintaining separate reporting infrastructure for every customer.
- Because Compass BIO's data model is fully structured, a CDMO can deliver information to a Sponsor directly instead of as a static PDF — giving them data they can query, filter, and reuse instead of a document to re-key.
- We have eliminated the silo between process design and risk assessment. In Compass BIO, risk management is supported throughout the product lifecycle, with live FMEA digitally linked to your specific product requirements.
- We eliminate traditional Tech Transfer delay. Instead of manually transcribing static PDFs, we ingest process data directly into the Compass BIO environment, creating a structured, validated digital record immediately — and moving toward production in weeks, not months.
- By maintaining data in a structured digital format within Compass BIO, we leverage AI Agents to instantly draft coherent narrative reports, provide predictive scoring for Criticality Analysis tables, and interpret incoming partner Certificates of Analysis (CoA) — reading them in whatever format they arrive, flagging nomenclature, ontology, and value issues, and mapping every result to the right Specification, Material, and Material Attribute without manual transcription.
- With 0% transcription error, and audit-ready data in minutes, teams "hit the ground running" faster than a competitor using legacy, unstructured systems.

Ready to move faster?

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One Platform. Adopt It On Either Side - Or Both.

A CDMO and Sponsor don't have to standardize on the same system for Compass BIO to deliver value. It can be adopted on the CDMO side, the Sponsor side, or both — creating a shared structured data environment only where it adds value, with nothing required to route through it for the relationship to work.



Up to 80% Less Manual Effort Scientists stop copying results between notebooks, spreadsheets, and CMC tables.	~0% Transcription Error Rate Every value flows from its source into each report - nothing is re-typed.	Minutes To Audit Readiness Chain of evidence is assembled on demand instead of reconstructed.	1-2 Weeks To Submission-Ready Tables After a batch completes, versus 8-12 weeks compiled by hand.	AI Agents Working on Your Own Data Draft report narratives, score Criticality Analysis, and interpret partner COAs.
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Compass BIO Transforms Months of Document-Centric Labor Into a Streamlined Digital Pipeline

Closing the Data Gap Between CDMOs and Sponsors

CDMO Challenges	Compass BIO Solution
"My executives and partners are asking how we are utilizing AI to enhance our capabilities in the market."	Compass BIO leverages AI agents to automate workflows that involve large, complex data sets. These include data table generation, narrative generation, and data ingestion & curation.
"We received data from dozens of clients, each with their own formats. Our expensive scientists spend up to 40% of their time manually copying data from lab notebooks into tables for CMC reports."	Using the approach of structured content and data management, scientists enter data into a structured system. The software then automatically populates the complex tables required for regulatory submissions. This moves the CDMO from "writing reports" to "managing data."
"When a biotech Sponsor hires my company, there is a massive transfer of knowledge that takes place. Usually, this is done via PDFs and other unstructured formats which are prone to misinterpretation or data loss."	Because Compass BIO's data model is fully structured, a CDMO can deliver information to the Sponsor directly instead of as a static PDF. The Sponsor receives data they can query, filter, and reuse — rather than a document to re-key — which reduces misinterpretation and ensures no critical parameters are lost as the project moves from the lab to the factory floor.
"Our Sponsors want visibility into their project's status and data, but we can't afford to build and maintain a custom reporting portal for every account."	A CDMO can open a secure, permission-based portal into Compass BIO for each Sponsor. Access is configured by account, so a Sponsor can log in on their own schedule to review data and generate reports — without the CDMO building bespoke reporting infrastructure for every customer.

CDMO Challenges	Compass BIO Solution
“Small changes during drug development (e.g. a shift in stability storage temperature) can create the need update and maintain dozens of recipes, risk assessments, studies, and other data. In a manual system, if I am missing just one mention of the change it can lead to a batch loss or regulatory “rejection.”	Compass BIO creates real-time traceability. Because the data is linked, if you change a value in the “Master Data” set, Compass BIO automatically updates every single report, table, and filing that references that value. This eliminates human error and ensures consistency across a massive project.
“I have to prove that I have identified every possible risk in the manufacturing process (e.g., “What if the stirrer speed is 5% too slow?”). Documenting this is tedious and often disconnected from the actual lab data.”	Compass BIO integrates Risk Management directly into the development workflow. As the CDMO develops the process, the risks are tracked and linked to the requirements. This provides a “digital thread” that proves to Health Authorities that the manufacturing process is robust and controlled.
“Compiling Criticality Analysis and Drug Stability tables—which alone can run into many thousands of data points—creates a massive administrative drain and resource bottleneck for my technical teams.”	Compass BIO has “off-the-shelf” configurations and provides pre-built templates for compliance which can be easily modified by the CDMO. This allows a CDMO to generate sponsor-ready data, data tables, and documents in a fraction of the time.

Spotlight: Certificate of Analysis (CoA) Management

The Challenge: “Every partner sends us Certificates of Analysis in a different format, and a single Material can arrive with dozens of them across lots and batches. Our scientists re-key those results by hand, and once they are typed in, nothing connects them back to the specifications we are actually testing against — so proving a Material met its acceptance criteria means reopening the PDFs.”

The Compass BIO Solution: Compass BIO manages the full CoA lifecycle inside the same structured data model that governs the rest of the CMC digital thread — ingesting partner CoAs, generating new ones, and linking every result to the specifications and acceptance criteria it belongs to.

- **Ingest CoAs from partners.** Bring CoAs in as PDF, CSV, Word, or API. BIO AI interprets the document, identifies nomenclature, ontology, and value issues, and maps the content to BIO data items — Specification, Analysis, Measurement, Material, Material Attribute, and Recipe. Ingest on demand as a CoA arrives, in bulk when a batch of them lands (e.g., 25 in one week), or on an automated schedule that checks for pending CoAs, ingests them, and reports back on what was brought in. Multiple CoAs for the same Material — across lots and batches, typically from one manufacturing line but supported from anywhere — are merged together in BIO.
- **Generate CoAs from BIO data.** Produce a formal, signature-ready CoA for any Material in BIO — API, DP, Reagent, Starting, Raw, Excipient — built from a combination of data created in BIO and data pulled from ingested external CoAs. The CDMO controls how the document is formatted, styled, and tabled, with BIO AI drafting the narrative summary of the underlying data and data tables.
- **Connect CoA results to specifications.** Incoming CoA tests, requirements, and parameters are associated with Material Attributes on a Material, and the results of any CoA — ingested or generated — are associated with multiple Acceptance Criteria on any BIO item that supports them, such as a Specification or Material Attribute (for Material Attributes, Acceptance Criteria are the MA Design Spaces). Conformance becomes queryable data rather than a document to reopen.

From Fragmented Tech Transfer to a Unified Digital Thread

Using Compass BIO, we protect the scientific intent of your molecule across every stage of the lifecycle—development, pilot, and scale-up. This digital-first approach ensures that nothing is “lost in translation,” enabling the delivery of life-saving therapies to patients with a velocity that legacy paper-based systems simply cannot match. But Compass BIO is not standing still either. With a unified data approach, Compass BIO is primed to leverage AI in the drug manufacturing and reporting process.

About Cognition Corporation

Cognition Corporation provides product development and compliance solutions for the life sciences. With purpose-built software for MedTech, Biopharma, and combination products, Cognition helps teams accelerate development, strengthen traceability, and streamline submissions—all through structured, guided data management. Learn more at cognition.us.