



TRANSFORMING PHARMACEUTICAL MANUFACTURING WITH AI AGENTS FOR QUALITY & COMPLIANCE

Achieving Data Accuracy, Process Efficiency & Patient Safety
with Autonomous AI Agents



Enterprise AI Platform

Empowering Enterprises with Scalable, Secure, and
Industry-Specific AI-Solutions

ABOUT CLIENT

- ▶ A leading global pharmaceutical company headquartered in the US, with a strong presence in biologics, advanced therapies, and small-molecule drugs.

BUSINESS SCENARIO

- ▶ Our client, a leading global pharmaceutical company, specializes in the development and production of cancer medicines, where precision, compliance, and efficiency are critical.
- ▶ The **Manufacturing Science and Technology (MSAT)** division plays a crucial role in ensuring compliance to maintain the **highest standards** in **oncology drug production**.
- ▶ MSAT teams are responsible for:
 - **Batch Genealogy & Traceability** – Ensuring complete visibility of raw materials, intermediates, and final drug products across complex manufacturing processes to maintain quality and compliance.
 - **Manufacturing Data Analytics** – Analyzing large volumes of process data, quality control metrics, and production trends to enhance efficiency and ensure product consistency.
 - **Process Procedure & Change Control** – Managing SOP updates, procedural changes, and compliance documentation to streamline approvals and regulatory adherence.

On an average **36,000** batch genealogy queries, **14.4M** manufacturing records, and **400+ SOP revisions**. Files include **Excel sheets (350+ columns, 3,000+ rows)**, **PDFs**, and **scanned regulatory docs**. Legacy systems can't efficiently handle **SQL automation** or real-time batch tracking at this scale.

BUSINESS CHALLENGES

01

Bottlenecks in Traceability

Manual tracking of batch genealogy across 36,000 queries creates delays and limits the ability to ensure full traceability of raw materials, intermediates, and final products.

02

Data Chaos Across Systems

Diverse datasets spanning multiple fields and million rows in Excel sheets, PDFs, and scanned documents make accurate data extraction and analysis challenging.

03

Compliance Gaps in Documentation

Managing SOP revisions on a regular basis without automated controls leads to inconsistent documentation and limited visibility into procedural changes. Non-standardized processes heighten the risk of regulatory non-compliance and delayed approvals.

04

Scalability Under Pressure

As production grows, manual workflows fail to scale, resulting in inefficiencies in data processing and query resolution.



SOLUTION CONSIDERATIONS

In the deployment of Botminds AI, the following considerations were pivotal to building a robust and scalable solution in a rapid timeframe

- The solution should simplify batch tracking by using Gen AI-powered automation to handle genealogy queries and deliver insights in text, tables, and flowcharts for faster decisions.
- It requires conversational AI for multi-level tracking with response times under 3-5 seconds. The system must process both structured and unstructured data, such as Excel, PDFs, and scanned files, while generating actionable insights through charts and tables for complex datasets.
- Seamless integration with ERP, LIMS, and document systems is crucial, with role-based access to ensure data security.
- Additionally, and most importantly the solution must meet FDA, GMP, ISO 27001, and SOC 2 compliance standards and use encryption to protect critical manufacturing data.

BOTMINDS SOLUTION

- ✓ Botminds AI transforms MSAT operations by leveraging autonomous AI agents powered by Gen AI to automate data extraction, processing, and analysis—eliminating the manual effort involved in batch genealogy tracking, manufacturing dataset analysis, and change control processes.
- ✓ Instead of sifting through spreadsheets, PDFs, and scanned documents, AI agents autonomously process, interpret, and act on data, allowing teams to use natural language queries to get instant insights in text, tables, or visual formats, without rigid templates or manual searches.
- ✓ For batch genealogy tracking, AI agents dynamically map raw materials, intermediates, and final products across multiple datasets, generating flowchart-based genealogy insights that previously required hours of manual work.
- ✓ With built-in AI-driven SQL automation and contextual reasoning, AI agents autonomously validate historical batch records, process datasets, and compliance documents, delivering instant, structured reports and visualized trends—no SQL expertise required.
- ✓ For process procedure and change control, AI agents autonomously track SOP updates, detect compliance risks, and flag regulatory gaps in real time, ensuring faster approvals and seamless audits.



SOLUTION HIGHLIGHTS

- ◉ **Autonomous AI Agents for Document Understanding**—processes complex, unstructured documents across multiple formats without predefined templates.
- ◉ **Conversational AI** for real-time insights—enables instant answers using natural language queries, eliminating manual searches and SQL complexity.
- ◉ **Automated batch genealogy tracking**—instantly maps material flow and generates flowchart-based traceability reports without manual effort.
- ◉ **Proactive Change Control Automation**—AI Agents continuously tracks SOP updates, process dependencies, and compliance risks, flagging modifications for faster approvals.
- ◉ **Seamless integration with enterprise systems**—A one-time setup connects with ERP, LIMS, and document management platforms, after which AI agents autonomously handle data flow, system interactions, and access controls, ensuring smooth workflows and secure, role-based access.

BUSINESS IMPACT



99% Data Accuracy in Batch Genealogy

Precise multi-level tracking of raw materials, intermediates, and final products, eliminating traceability errors.



Error-Free Manufacturing Insights

Standardized dataset fields, preventing inconsistencies in batch records and compliance reports.



Faster and Smarter Manufacturing Decisions

AI-powered data structuring and analysis replace static reports, enabling real-time process optimization.



Accelerated SOP & Change Control Approvals

Automated impact analysis and version tracking reduce approval cycles ensuring compliance without delays.

VALUE DELIVERED

50%

Reduction in SOP
Review Time

5x

Faster Processing Time

99%

Accuracy

100%

Scalability Without
Complexity

80%

Faster Batch Traceability



AI-First
Approach



No-Code
Platform



Vertically
Integrated



End-to-End
Automation



No Code AI platform

To rapidly create AI Solutions

For more information, visit us www.botminds.ai or email us at hello@botminds.ai