

How Connect™ Supports Regulatory Submissions in Life Sciences



Executive Summary

In the Life Sciences industry, regulatory submissions require robust data integrity, traceability, and compliance. This white paper explores how Connect™ provides a comprehensive solution for handling regulatory submissions. By integrating data governance, security, and compliance measures, Connect™ ensures that organizations are prepared for both US FDA and international regulatory submissions.



Introduction to Regulatory Submissions

Regulatory submissions in Life Sciences involve documenting and submitting evidence of product safety, efficacy, and manufacturing quality. Whether for new drug applications (NDAs), biologics license applications (BLAs), or marketing authorization applications (MAAs), regulatory authorities like the FDA, EMA, and other global agencies require structured, accurate, and traceable data.



The complexity of these submissions is heightened by regulatory frameworks like:

- **21 CFR Part 11 (FDA)**
- **Annex 11 (EU)**
- **Good Manufacturing Practices (GMP)**

These regulations govern electronic records, signatures, data integrity, and audit trails, making it essential for organizations to adopt compliant systems.

Challenges in Regulatory Submissions

Key challenges faced during regulatory submissions include:



Data Integrity

Ensuring that the submitted data is accurate, complete, and traceable.



Compliance

Adhering to guidelines such as 21 CFR Part 11 and Annex 11.



Audit Readiness

Maintaining records that are always ready for inspection by regulatory authorities.



Security and Access Control

Protecting sensitive data while providing role-based access for review and submission processes.



Collaboration

Facilitating seamless collaboration between human-generated content and system-generated data.



How Connect™ Addresses Regulatory Submission Challenges

Ensuring GxP, 21 CFR Part 11, and Annex 11 Compliance

Connect™ is designed to fully comply with critical regulations like GxP, 21 CFR Part 11, and Annex 11, enabling organizations to handle electronic records and signatures with confidence. The platform provides:



User Authentication & Access Control

Ensures that only authorized personnel can access sensitive data and documents.



Audit Trail

Tracks every change in data, ensuring full traceability and transparency.



Electronic Signatures

Fully compliant with regulatory requirements for electronic documentation.

Data Integrity and ALCOA+ Principles

Connect™ upholds ALCOA+ (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available) principles, crucial for maintaining data integrity in regulatory submissions. The platform ensures that:



Data is traceable and secure throughout its lifecycle.



Human and system-generated data is merged seamlessly while maintaining compliance.

Batch Genealogy and Traceability

For regulatory submissions involving product manufacturing data, Connect™ offers advanced batch genealogy tracking:



Full Data Traceability

Ensures comprehensive traceability across the entire production process.



Batch Recall & Root Cause Analysis

Provides clear genealogy records to track batches, making recall processes and root cause analysis faster and more efficient.

Data Security and Role-Based Access Control

Connect™ incorporates advanced security features to protect sensitive data. These include:



Encryption

Ensures that all data is encrypted at rest and in transit, safeguarding it from unauthorized access.



Role-Based Access:

Restricts data access based on user roles, ensuring that only qualified personnel can view or modify sensitive data.

Collaboration and Reporting

Regulatory submissions often involve multiple stakeholders, including regulatory teams, manufacturing, and quality assurance. Connect™ facilitates collaboration by:



Single Click Report Generation

Enables users to create customized reports, blending system-generated data with human input, for regulatory submissions.



Version Control:

Ensures that the latest version of all documents is used for submissions, reducing the risk of outdated or inaccurate data being submitted.



Alerts on Mismatches

Automatically flags any discrepancies in data, allowing quick resolution before submission.

E-Logbook for Streamlined Data Entry

Connect™'s eLogbook offers a digital, compliant alternative to paper-based batch records:



Customizable Data Entry Screens

Users can input data directly into validated screens, replacing the need for manual paper records.



Excel Upload with Second-Person Review

Supports uploads from Excel while allowing second-person verification to maintain compliance standards.

Out-of-Box CFR Part 11 Compliance

Connect™ comes ready with **out-of-box CFR Part 11 compliance**, ensuring that organizations do not need to worry about extensive customization or configuration to meet regulatory requirements. This compliance readiness reduces time-to-market and simplifies the regulatory submission process.



Conclusion

Connect™ provides a robust, scalable, and compliant platform that addresses the complex challenges of regulatory submissions in Life Sciences. With its powerful genealogy tracking, data integrity safeguards, role-based access controls, and collaboration tools, Connect™ ensures that organizations can streamline their submission process while maintaining compliance and security.

By adopting Connect™, Life Sciences companies can focus on innovation and product development, confident that their regulatory submission processes are both efficient and fully compliant.

About mareana

Founded in 2015, Mareana is an AI-powered software company with the mission of accelerating digital transformation in manufacturing, supply chain, and sustainability via our connected intelligence platform.

Mareana's platform uses AI/ML to rapidly connect disparate, siloed data across the entire business process, allowing our customers to shift their time and effort from data preparation to making complex business decisions intuitively, in real time.

Our customers are market leaders in life sciences, chemicals, and general manufacturing who have realized over a billion dollars in business value by leveraging our platform.



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