mareana
Connected Data. Deep Insights.

How Connect™ CMC Will Boost Modern Pharmaceutical Manufacturing

Learn how the right technology partner can help you build out a streamlined CMC program to ensure compliance, boost efficiency, and speed up market entry.

Technology Is Revolutionizing Pharmaceutical Manufacturing as We Know It

Today, with everything connected, drug makers face ever-changing rules. Getting safe medicine to people can seem impossible. But new software helps them navigate this tricky path smoothly.

Despite the buzz in recent years around "smart" manufacturing and "Industry 4.0," many forward-thinking pharmaceutical companies still struggle to digitize their operations. The potential rewards are great, but getting every part of the process aligned so the technology helps instead of hinders operations often proves to be a difficult job.

As a result, many pharmaceutical manufacturers continue to rely on error-prone paper systems for recording batch data needed for compliance. The paper-based systems create several pain points including problems integrating data from different sources, missing records, and the potential for transcription errors. In addition, valuable time and resources are wasted on compliance rather than production.

The result is inevitable: manual processes often become a huge source of errors. Most of the batch records might be transcribed correctly, but those with problems will draw all the attention. The problems, however, don't stop there.

After production has begun, resolving batch record problems can be a massive manual effort requiring site visits to different manufacturing locations. Moreover, many organizations use a variety of different data sources, each requiring a different methodology to reconcile disparities in reporting. And, while some paper-based batch record systems may be set up correctly at the beginning of a production cycle, supply chain and logistics issues can lead to the process having to change quickly, or more errors will occur.

The errors caused by paper-based systems can build up and result in quality control issues, delays in shipping the product, product recalls, and warning letters from regulators. Of course, this all occurs when manufacturers are challenged to cut costs and improve efficiencies while maintaining increasingly complex technology systems.

The Solution:

A Digital CMC Software

A Digital CMC software solves these problems by digitizing paper records so that the information they contain is converted into data that's stored in a database. Because the data is stored in a searchable and indexable way in a database, it can be accessed, filtered, and searched much more efficiently than paper records.

The benefits are manifest: Digital CMC batch records limit the need for manual interventions when problems arise. It reduces production downtime, improves product speed to market, and keeps data compliance programs up-to-date and precise.

In addition to those benefits, Digital CMC programs offer the following:

01.

Enhanced Compliance

Digital CMC solutions guarantee conformity to global standards such as FDA and EMA guidelines by incorporating automated compliance checks and real-time monitoring, ensuring regulatory adherence is prioritized.

02.

Improved Efficiency

The automation of routine tasks and data management minimizes manual errors, significantly enhancing operational efficiency. This, in turn, accelerates the time-to-market for new drugs.

03.

Data-Driven Decision-Making

Leveraging advanced analytics, Digital CMC provides profound insights into manufacturing processes. This facilitates data-driven decision-making and the implementation of predictive maintenance strategies.

04.

Scalability and Flexibility

Cloud-based CMC solutions offer scalability and flexibility, empowering pharmaceutical companies to adapt swiftly to evolving market demands and regulatory landscapes.

How Mareana Helps Pharmaceutical Manufacturers Improve CMC Operations

Mareana's Connect™ CMC can automate your batch records processes at scale with end-to-end visibility.

1. Utilizing Scanning and OCR Technology

Initiate the process by converting paper records into a digital format through scanning and Optical Character Recognition (OCR) technology. This establishes a digital archive of historical data, crucial for trend analysis and maintaining regulatory compliance.

2. Validation of Digitized Data

Ensure the precision of digitized data through meticulous validation processes, a crucial step in preserving data integrity.

3. Organizing Data

Structure the digitized data into a well-organized format by categorizing data fields and ensuring consistency across records.

4. Standardization Practices

Implement practices for data standardization to ensure uniformity, especially beneficial for companies operating across multiple sites or regions.

5. Selecting the Right System

Choose a digital platform capable of working with diverse datasets and supporting specific analytics and reporting needs.

6. Seamless Integration

Collaborate with IT specialists to integrate the structured data into the chosen system, ensuring minimal disruption to ongoing operations.

7. Utilizing Data Analytics

Leverage the system's analytics capabilities to gain valuable insights into manufacturing processes, quality control, and compliance.

8. Automation of Reporting

Take advantage of automated reporting features for efficient and accurate regulatory submissions and internal reporting.

Indeed, Connect™ CMC distinguishes itself through its all-encompassing compliance management, handling of paper batch record data, integrated data analytics capability, user-friendly interface, and dedicated customer support. The solution is meticulously crafted to cater to the specific requirements of the pharmaceutical manufacturing industry, positioning it as the ideal choice to address your challenges effectively. Adapting Connect™ CMC provides your team with contextualized historical data that can be used for analysis and future reference.

Our engineers use advanced security measures, including encryption and regular security audits, to ensure your data is always protected. Moreover, Mareana offers comprehensive support including training sessions, a dedicated customer service team, and regular updates.

Best of all, Connect™ CMC is CFR Part 11 compliant and fully validated. It is built in accordance with global pharmaceutical standards.

Modernize Your Pharmaceutical Manufacturing with Automated Data Management

Manufacturing and shipping pharmaceutical products at scale can be an immense and complicated endeavor. But the magnitude of the job creates massive opportunities for digital efficiencies and cost savings.

The success of your data management strategy will depend upon choosing the right technology partner to help you build out the underlying automation framework that will maintain the ideal digital processes for all your batch records. You'll need a partner able to deliver a flexible solution that can work with all data sources that can grow with you over time. Mareana's Connect™ CMC checks all of these boxes.

There's never been a better time to drive transformational change across the manufacturing lifecycle; automated data management of batch records provides the path to do so.

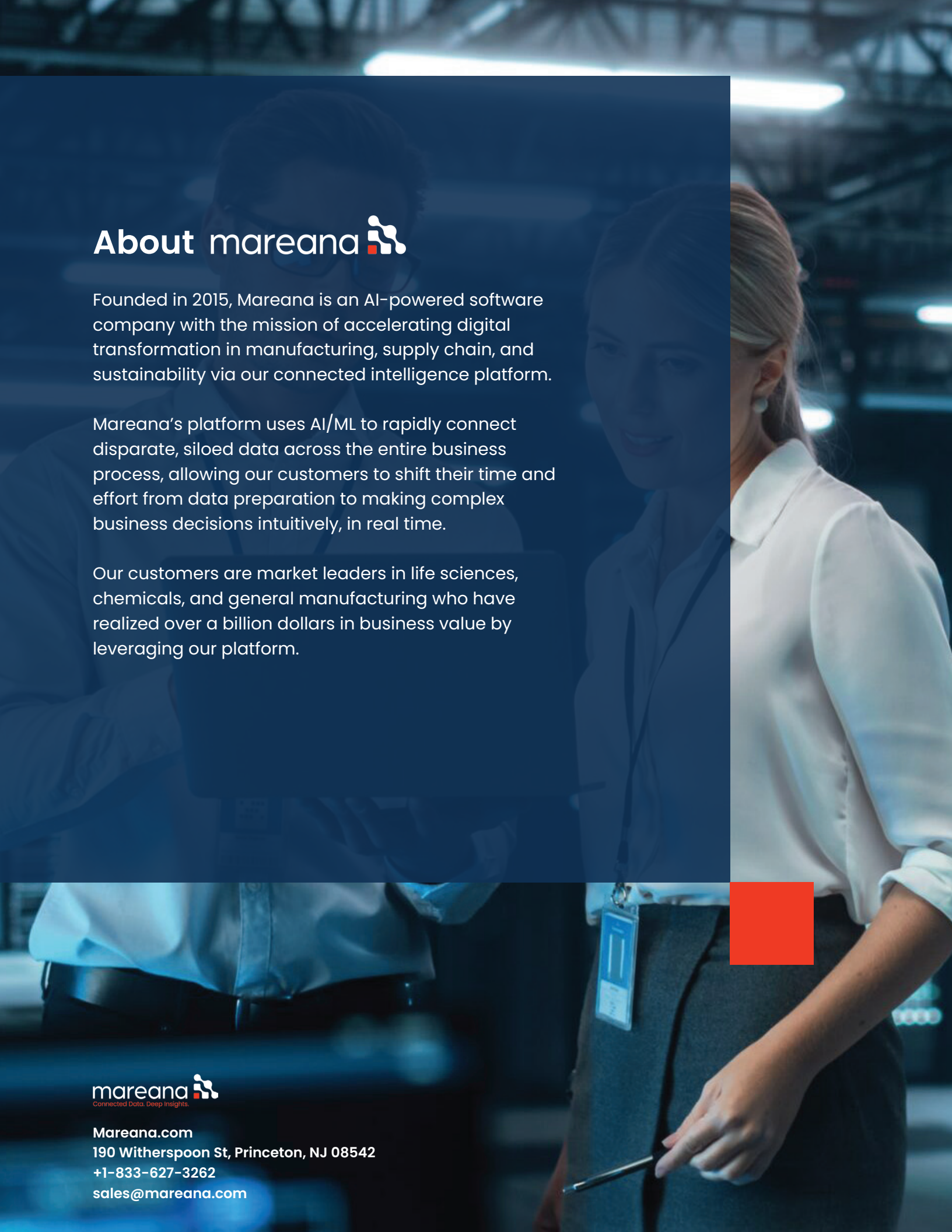
The end results? Reduced downtime from investigations, a much-improved speed-to-market schedule, significant cost savings, and ultimately, happier customers.

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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