



# From Paper to Digital: How Mareana Connect™ Supports EBR Transition

## The Paper Problem in Pharma

### ▶ Errors and Delays:

This reliance on manual paper records increases human error, which brings expensive deviations, batch rejections, and postponements to the product release date.

### ▶ Compliance Issues:

Paper-based processes might significantly hinder the provision of abundant audit trails and ultimately compliance to standards like 21 CFR Part 11.

### ▶ Siloed information:

Information is locked away in paper documents, preventing interdepartmental and technology transfer collaboration and knowledge sharing.

### ▶ Inefficient Tech Transfer:

Digital dossier technology transfer in the pharmaceutical industry has become a slow, error-prone process with paper.

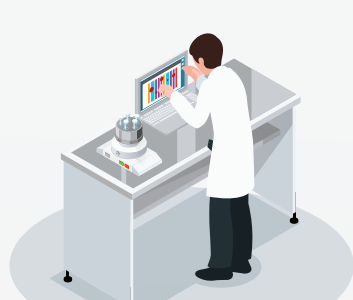


## EBR: The Digital Solution for Pharma

### What is EBR?

EBR stands for Electronic Batch Records. This technology digitizes the entire manufacturing process, providing a centralized, searchable, and secure system for all records.

### Benefits:



#### Enhanced Data Accuracy

Automated data entry and validation reduce manual errors, ensuring data integrity.

#### Real-Time Visibility

Monitor production processes in real time to quickly identify and address any abnormalities.



#### Accelerated Batch Release

Reduce review and approval cycles using easily available electronic records.

#### Streamlined Compliance

Easily demonstrate compliance with regulations through complete audit trails and electronic signatures.



## Mareana Connect™: Your EBR Powerhouse

### The Role of Mareana Connect™ in EBR Implementation

Mareana Connect™ is engineered to address the complexities and regulatory demands of the pharmaceutical industry, facilitating a smooth transition from paper-based systems to advanced digital solutions. This platform enhances the adoption of Electronic Batch Records (EBR) by integrating data across all phases of manufacturing and quality control. With Mareana Connect™, information from raw material intake to final product testing is centralized, ensuring a seamless flow of data. This comprehensive integration is crucial for maintaining transparency and traceability throughout the manufacturing process, essential for both regulatory compliance and operational efficiency.

### Key Features of Mareana Connect™



**Real-Time Data Capture:** Streamlines the collection of manufacturing data, significantly reducing the potential for human error and increasing the accuracy of records.

**Centralized Documentation:** Consolidates all batch records and related documentation within a single platform, facilitating easy access for staff and streamlining management processes. This centralization optimizes the review and approval workflows, enhancing operational efficiency.

**Compliance Support:** Designed to comply with stringent regulatory standards, including 21 CFR Part 11. Mareana Connect™ provides robust audit trails, electronic signatures, and secure data management, enabling manufacturers to meet compliance requirements efficiently.

These features ensure that Mareana Connect™ not only supports the digital transformation of manufacturing operations but also enhances the overall integrity and efficiency of the production process.

## Mareana Connect™ Supports MES Integration for a Connected Enterprise

Beyond EBR, Mareana Connect™ integrates with your current MES (Manufacturing Execution System), creating a fully connected manufacturing environment.

### Benefits:

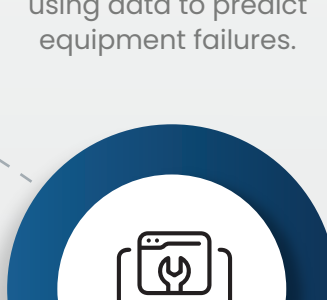
#### Production Optimization

Gain instant visibility into production performance and identify areas for improvement.



#### Predictive Maintenance

Prevent costly downtime by using data to predict equipment failures.



#### Improved Resource Utilization

Rationalize the use of materials, equipment, and personnel.



### Mareana's Vision

Mareana views digital transformation as a key technology for evolving and strengthening business models in the pharmaceutical sector. By leveraging digital technologies, companies are equipped to navigate healthcare's complexities, seize growth opportunities, and significantly benefit patients worldwide.