

# Caliber

MANUFACTURING SUITE



**Caliber**

Deliver More. Deliver Excellence

## The Need to Digitalize Manufacturing

For years, paper has been a mainstay in the manufacturing process. At every stage, a piece of paper must be passed on from person to person for signatures and reviews to complete the manufacturing cycle of a batch. For years, this paper gave way to low productivity, non-compliance, human errors, audit observations, and inefficiency. A lot can be achieved by removing this unreasonable dependence on paper.

Digitalizing the batch manufacturing process is a key step towards making factories tomorrow-ready. A digitally enabled factory is efficient, compliant, and well-prepared. More importantly, a system that seamlessly integrates with instruments and equipment. This system meets every important step of the process, and ensures full compliance for successful digital transformation.



### Why Paperless Manufacturing?



#### Quicker Time to Market

Digitalization saves time, effort & resources to ensure that products can reach the markets quicker



#### Higher Productivity and Profits

Unproductive dependencies & recurring expenses can be removed by a robust digital system



#### Audit-Ready

Reliance on a compliant system ensures GMP adherence at every stage



#### More Innovation

With thorough analytics, processes and product can be monitored and improved through process innovation



#### Better Visibility

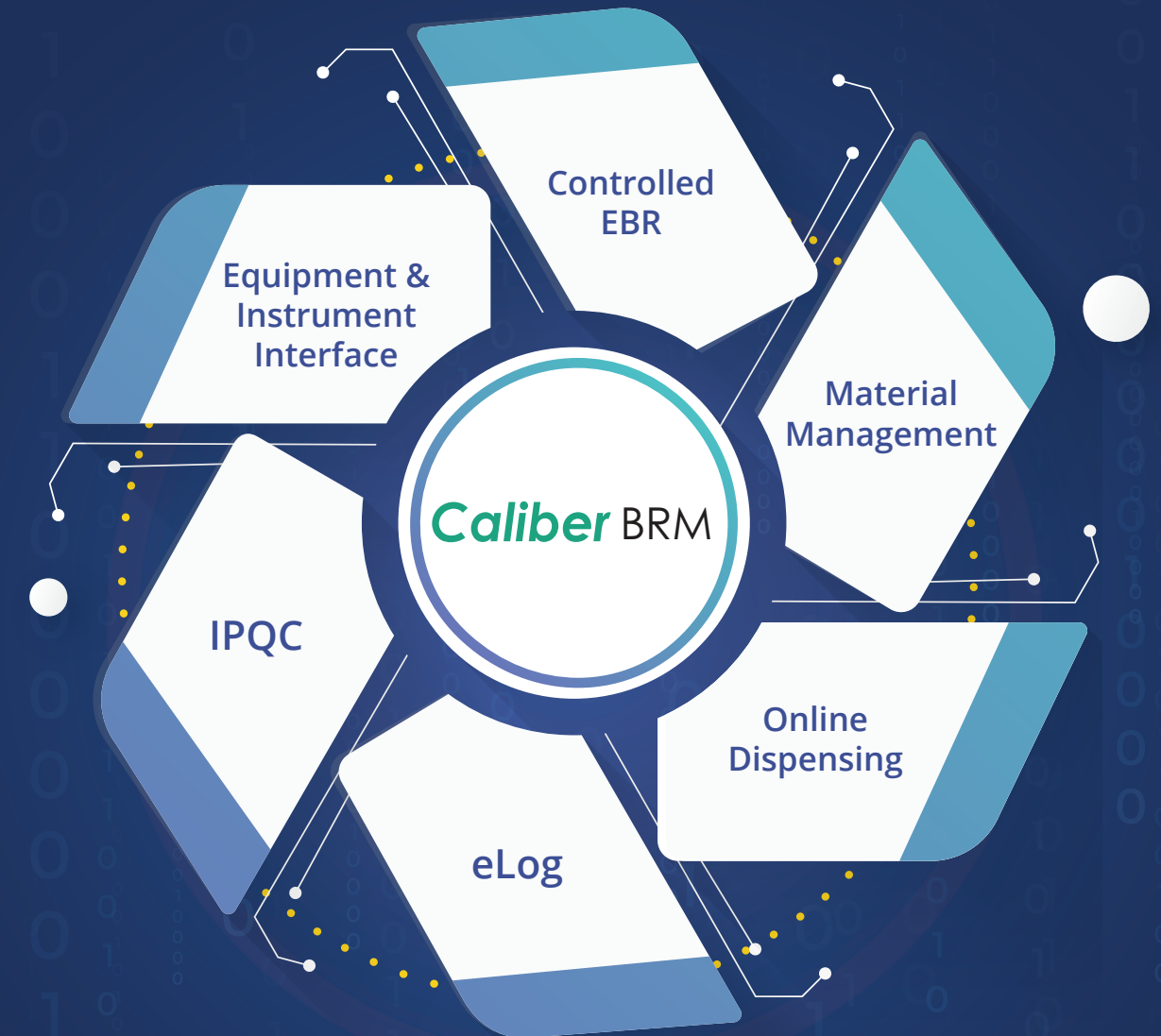
When all processes, instruments, and equipment are integrated, management can have a full view at every stage



#### Tomorrow-Ready

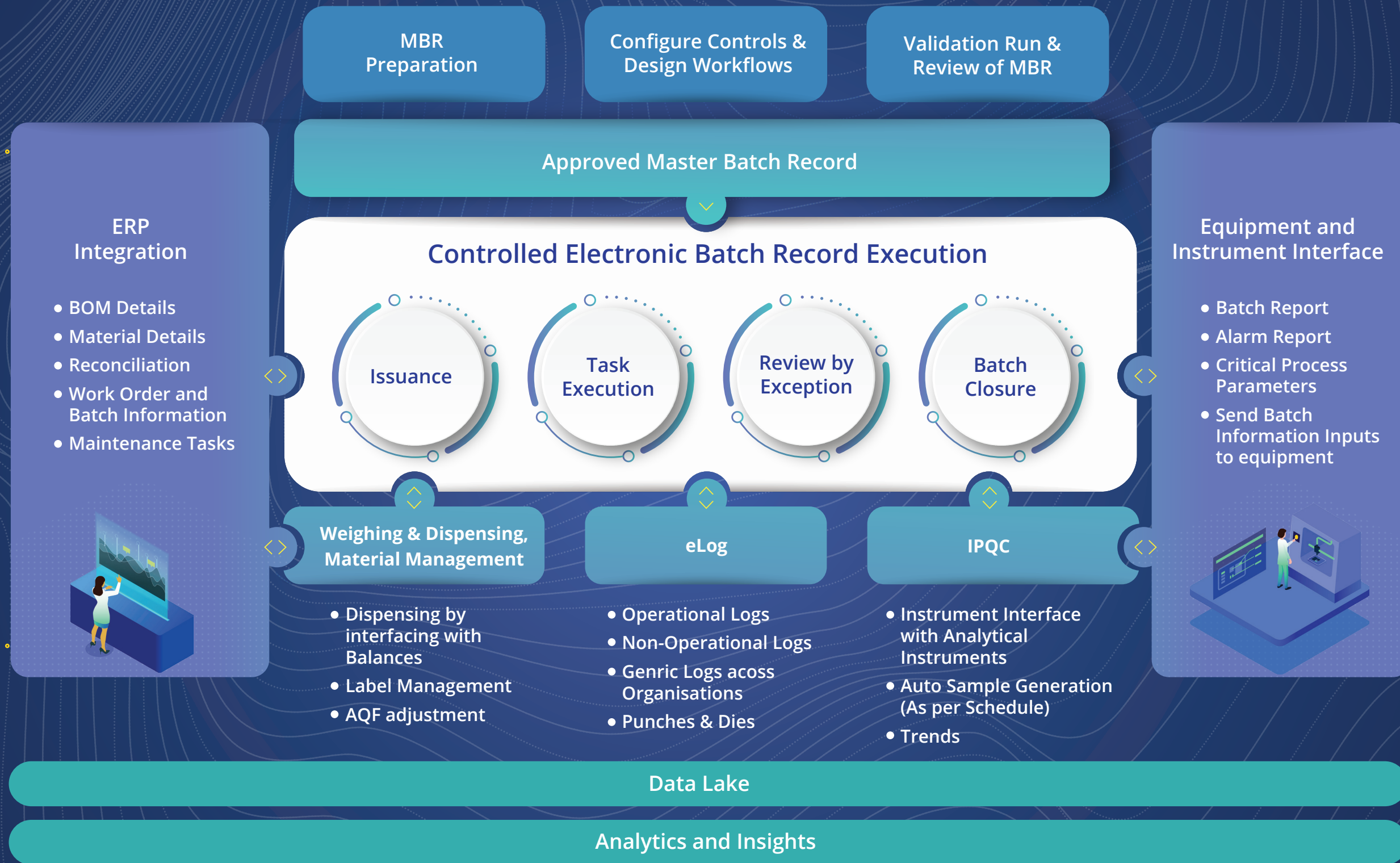
Digital solutions help companies be better prepared for any changes

## Manufacturing Suite Offerings



Caliber's Manufacturing Suite is built to digitalize the end-to-end batch manufacturing process for regulated products. It is designed to offer greater productivity, higher compliance, and quicker time-to-market. This suite brings together robust modules like Batch Record Management, Controlled EBR, In-Process Quality Control, and Electronic Logbooks that can integrate with various systems, instruments, and equipment. This creates a strong foundation for further analytics like APQR, CPV, CPP, and CPK.





## End-to-End Control Over Every Batch

Caliber's Manufacturing Suite is a scalable solution that manages the entire lifecycle of the manufacturing process right from preparation to product release while ensuring compliance with regulatory requirements like GMP and S88. This suite automates batch manufacturing records, making them free of transcriptional errors, tedious reworks, batch recalls, and the consequent delays and costs.

## Integrate with Instruments, Equipment, and Other Systems

Caliber's extensive Manufacturing Suite works seamlessly alongside other systems, instruments, and equipment. This robust functionality makes real-time data available to and from instruments, equipment, ERP, and other systems like document management system, QMS, etc. With this data, users gain phenomenal value with the system's data analysis of every Critical Process Parameter (CPP) which helps in the continuous improvement of the manufacturing process.

## Feature Highlights

### **Controlled Electronic Batch Issuance & Execution**

Manages the batch record issuance and exercises control for effective batch production

### **In-Process Quality Control (IPQC)**

Provides streamlined checks (trend generation) to the batches to assess product quality while batch production is in progress

### **Electronic Logbooks (eLog)**

Log data, track, and generate reports for operational and non-operational activities like area usage, equipment usage, report configuration, etc.

### **Cleaning & Validation Rules**

Effectively reduce downtime and batch failures by eliminating cross-contamination with the help of cleaning & validation rules

### **Punches & Dies**

Maintain punches & dies issuance logs, send alerts, define Inspection & Discard rules of punches, and restrictions on the number of punches

### **Material Weighing & Dispensing**

Provide detailed information on material qualified status, billed materials, etc. by directly interfacing with balances, etc.

### **Maintenance Activities**

Perform calibration, prevention, maintenance, breakdown, and service activities in the batch manufacturing process

### **Batch Closure & Dossier Generation**

Easily view, retrieve, and request dossiers; data integrity and clear visibility of all the used dossier templates in batch closure

### **Seamless Integrations**

Integration with DMS, QMS, CMS, ERP, and other internal and external applications

### **Equipment & Instrument Interface**

Robust integration to ensure automatic one-way and two-way data flow with equipment & instrument interfacing

### **Configurable Stage-wise Templates**

Customized BRT with configurable and re-usable templates, and quality inspection protocol

### **Label Management**

Manage label printing, pre and post dispensing confirmation labels with barcodes, lot sampling, etc.

### **Configurable Reporting Framework**

Pre-configured and configurable reports for all procedures created in the system, allowing for advanced data analysis

### **Review by Exception**

Reduces review time, accelerates batch release, reduces batch recalls, and enhances profitability

### **Reporting Integration**

Option to integrate with reporting engine for detailed analytics and trend analysis on manufacturing process

## High ROI for Every Key Role



### User/Operator

- No redundant works
- User doesn't miss the scheduled analysis
- Better traceability through robust reporting



### Mid-level Managers

- Review time is reduced with Review-by-Exception mechanism
- Resource utilization, planning, and tracking is easier and process driven



### Plant Head

- More control with complete integration
- Assured Data Integrity
- Batch analytics can be easily derived for better decision-making



### Management

- Assured compliance, higher productivity, and quicker time-to-market
- Safeguard brand reputation with successful audits

## Digitalize at Your Preferred Pace

Every company has its own digitalization journey considering various business constraints. Caliber's Manufacturing Suite is made to suit every level of digitalization efforts. An organisation can gradually digitalize its manufacturing process by choosing from the modules of this extensive suite and transform its operations. On the other hand, an organisation that is fully ready for complete transformation can opt for the end-to-end solution with all modules and integration capabilities. Caliber's Manufacturing Suite is a scalable solution that offers tailored implementation options and roadmaps, which will ensure a successful and smooth digital transformation journey.





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Automation | Compliance | Quality

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