



# Manufacturing Operations Management (MOM4)

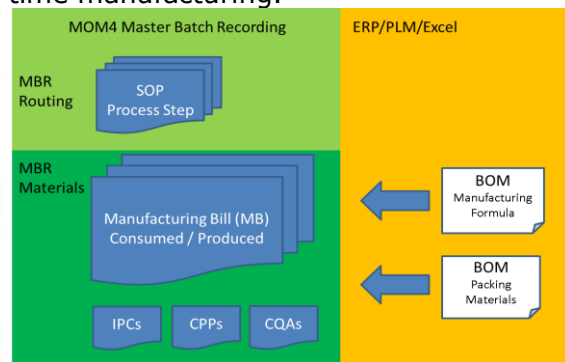
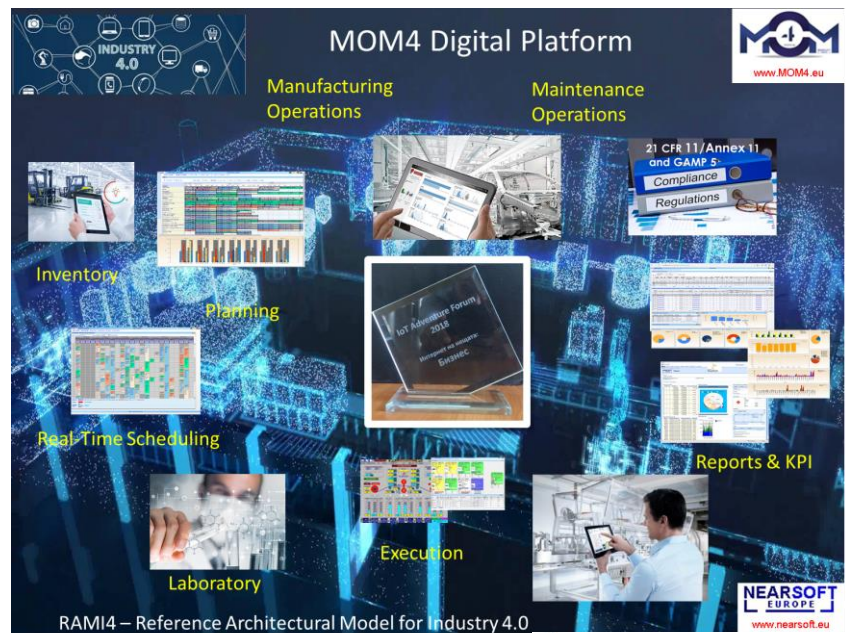
*Relevant Information, at the Right Time, at the Right Place, in the Right Form, to the Right People*

**NearSoft Europe** is an innovative software engineering company that provides the methodology and technology for digitalization and real-time collaborative processing of production information inside an enterprise. The core of our offering is the MOM4 digital platform that combines software, content and services out of the box. MOM4 is entirely based on the Reference Architectural Model for Industry 4.0 – RAMI 4.0 (IEC 62264/ISA95).

In line with regulatory requirements MOM4Pharma meets all requirements set forth by the approving authorities for operating computer systems in regulated industries. This includes the EU GMP guidelines; GMP Annex 11 for Computerized Systems Guidelines; FDA guidelines 21 CFR Part 11; 21 CFR Part 210/211, as well as GAMP5.

## Electronic Batch Recording (EBR)

Efficient electronic batch documentation is one of the most important objectives in introducing a MOM/MES to pharmaceutical production. With **MOM4** Electronic Batch Recording, all EBRs are electronically executed and the processes and results are documented in compliance with the applicable statutory provisions. **MOM4** EBR ensures the error-free and guided execution of the entire production process and right-first-time manufacturing.

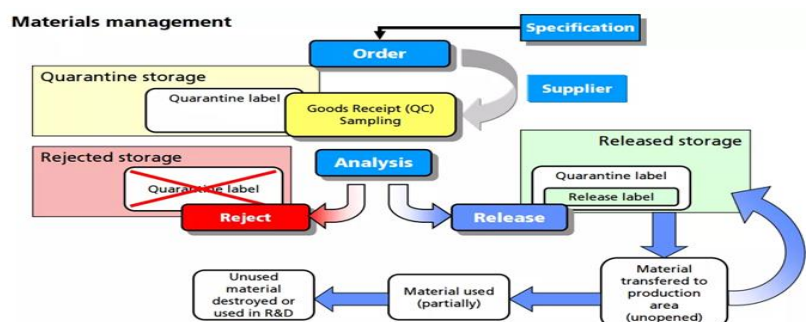


## Master Batch Records (MBR)

**MOM4** Master Batch Records allows you to easily set up and maintain libraries with standardized, reusable specifications for MBR creation. Easy-to-use Routing and Material displays facilitate the MBR creation. They contain all pharmaceutically relevant data: the input material list, valid SOPs, detailed work instructions to be applied in production, and also process data, or process steps, such as in-process controls (IPCs), Critical Process Parameters (CPPs) and Critical Quality Attributes (CQAs). MOM4 MBR simplifies workflows, shortening approval cycles and therefore drastically reduces associated documentation work.

## MOM4 Inventory

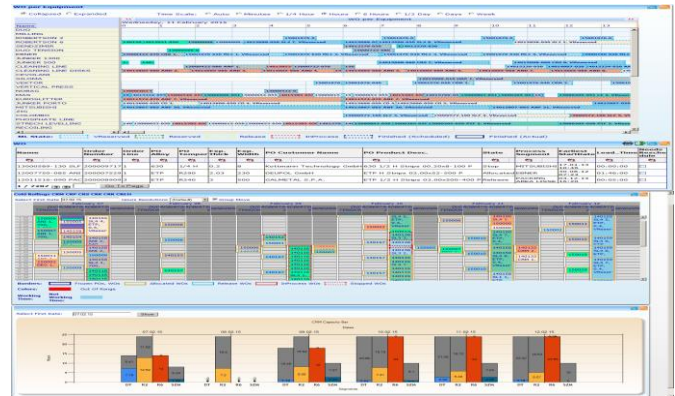
**MOM4** ensures that the materials used in pharmaceutical production are uniquely identified on receipt by means of barcodes or transponders. Through its tracking function, **MOM4 Inventory** supports uninterrupted tracking of the entire material flow and it provides details about material quantities, available batches, batch qualities, and storage locations.





## Planning and Scheduling

MOM4Scheduling is an advance planning and scheduling system with real time feedback from the production process. **Production routings** are automatically generated with the help of predefined rules. The purpose of this module is to determine what products to make, when to make them, and what resources to use. The system will generate complex routings with **working orders** for each process step with associated consumed and produced **material lots**. Each lot is defined by parameters, such as expected weight, quantity, production time, etc.



## Weighing & Dispensing (W&D)

The precise weighing and dispensing of raw materials based on recipe specifications is the core of a pharmaceutical manufacturing processes. Accurate data collection within this first processing step is fundamental to batch tracking and documentation. In a reliable and easy-to-operate way, MOM4 guides the operator through the weighing process and provides the necessary support for compliance with safety regulations and recipes.

## Manufacturing Execution (Track & Trace)

MOM4 enables the management of **real-time** production information, instantly available to everybody. It accounts for execution orders (campaigns), production and order **tracking (WIP)**, **data acquisition (DA)**, **down time (DT)** management, **quality (QA, IPC)** and **equipment management (EQM)**. MOM4 supports manual data entry and/or easy integration with the various SCADA, PLC, and DCS systems through standard OPC interfaces. The information is grouped and stored into database tables for future use in reports, analyses, etc.



## Reports, Performance Analyses and KPIs

MOM4Reports is a flexible report system that includes **shift** and **product** reports, **product genealogy**, performance analyses (**KPIs**), **Statistical Process Control (SPC)**, and many more predefined reports. Using the **MOM4 toolkit**, a user can create and **customize** displays/reports and make them available to other users. The managers perform statistical and analytical analyses based on the stored data, in order to optimize and streamline the production process.

Safeguard  
Regulatory  
Compliance

Reduce  
Paperwork

Improve  
Data  
Quality

Improve  
Manufacturing  
Performance

Accelerate  
Time-To-Market

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