



WHITEPAPER

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The Journey of the Transition: From Role Production Engineer to Role MES MBR Designer

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Executive Summary

The intention of this Whitepaper is to highlight the key differences between the roles and how the Production Engineer's experience can be leveraged. Production Engineers focus on manufacturing efficiency and process optimization, often working with various teams. MES MBR Designers, on the other hand, specialize in creating and managing electronic master batch records within a Manufacturing Execution System (MES), ensuring data integrity and compliance. While the roles differ, the experience in understanding manufacturing processes, identifying bottlenecks, and collaborating with different teams as a Production Engineer provides a strong foundation for the MES MBR Designer role.

Introduction

Transitioning from a Production Engineer role to an MES (Manufacturing Execution System) MBR (Master Batch Record) Designer role requires leveraging existing technical skills and bridging knowledge gaps through focused learning and networking. This often includes learning to use a digital MES product or at least new areas of the system. The shift involves moving from a broad focus on production efficiency to a more specialized role in designing and implementing digital manufacturing processes. Subsequently key aspects of the transitions are listed.

1. Production Engineer Role

A pharmaceutical production engineer's responsibilities include overseeing the manufacturing process, ensuring quality and compliance, and optimizing production efficiency. They manage teams, troubleshoot issues, and implement continuous improvements. Their work also involves managing production schedules, maintaining equipment and adhering to GMP and regulatory standards. Furthermore close collaboration with QA is needed for a Production Engineer role.

Key responsibilities of a Production Engineer include:

1.1 Production Management & Oversight

Supervising Production

Leading and managing production operations, ensuring adherence to quality and safety standards.

Managing Teams

Overseeing production staff, providing guidance, and fostering a productive work environment.

Production Planning

Developing and implementing strategies to meet production targets and business objectives.

Monitoring and Analysis

Tracking key performance indicators (KPIs) to identify areas for improvement and optimize processes.

1.2 Quality Assurance & Compliance

Ensuring GMP Adherence

Implementing and maintaining good manufacturing practices (GMP) and other regulatory requirements.

Quality Control

Participating in quality control testing and documentation to ensure product integrity and compliance.

Regulatory Affairs

Ensuring compliance with relevant regulatory requirements and industry standards.

Troubleshooting

Collaborating with cross-functional teams to troubleshoot and resolve production issues.

Audits

Participating in audits and inspections to assess compliance and identify areas for improvement.

1.3 Process Optimization & Continuous Improvement

Process Improvement

Identifying opportunities to enhance production processes, reduce costs, and improve efficiency.

Technology Implementation

Staying up-to-date on industry trends and technological advancements to improve pharmaceutical production.

Lean Manufacturing & OPEX

Implementing Lean Six Sigma principles to optimize workflows and minimize waste.

Documentation

Maintaining accurate records and documentation of all production processes.

1.4 Other Responsibilities

Equipment Maintenance

Ensuring proper functioning of equipment through maintenance, troubleshooting, and calibration.

Material Management

Overseeing the management of raw materials, inventory, and supplies.

Cross-Functional Collaboration

Working with various departments, including quality control, research and development, and engineering.

Training and Development

Providing training and development opportunities for production staff.

Problem Solving

Identifying and resolving production-related issues, deviations, and complaints.

2. MES MBR Designer Role

An MES MBR Designer (Manufacturing Execution System Master Batch Record Designer) is responsible for designing, developing, and maintaining electronic batch records within a manufacturing execution system (MES). They ensure these records accurately reflect manufacturing processes, adhere to regulatory requirements, and support efficient and compliant operations.

Key responsibilities of an MES MBR Designer include:

2.1 MBR Design and Development

- Creating and modifying Master Batch Records (MBRs) within the MES, ensuring they accurately reflect manufacturing processes.
- Aligning MBRs with global core processes and standards.
- Collaborating with various teams (e.g., process engineers, quality assurance, operations) to gather necessary information and feedback.

2.2 Validation and Testing

- Validating MBRs during verification runs through thorough testing to ensure they function correctly and meet all regulatory requirements.
- Troubleshooting and resolving any issues or discrepancies in MBRs.
- Monitoring Hypercare process for the compatibility of MBR design in the shopfloor.

2.3 Training and Support

- Providing training and support to end-users on how to effectively use the MBRs.
- Developing and refining training materials related to batch record creation.

2.4 Continuous Improvement

- Continuously assessing and improving MBRs and related workflows to enhance efficiency, compliance, and product quality.
- Utilizing lean principles to evaluate information flow and drive improvements.

3. Common areas of Production Engineers and MES MBR Designers

Production engineers and MES MBR designers share common ground in optimizing manufacturing processes, focusing on quality control, troubleshooting production issues, and driving continuous improvement through analysis and data. Both roles require strong communication skills and the ability to collaborate with cross-functional teams, ensuring that the defined production steps and records are effectively implemented and followed on the manufacturing floor.

How They Complement Each Other:

Production Engineer:

Focuses on the "eagle eye view", supervising the overall production process, optimizing workflows, and ensuring resources are used efficiently.

MES MBR Designer:

Focuses on the "micro" view, designing and managing the detailed, digital records (Master Batch Records or electronic batch records) within the MES that guide the operators through each step of the production process.

Together, the production engineer ensures the overall efficiency and quality, while the MES MBR designer ensures the detailed execution of those processes as defined in the digital workflow, leading to consistent and high-quality output.

4. Transition from Role Production Engineer to Role MES MBR Designer

To transition from a Production Engineer role to an MES (Manufacturing Execution System) MBR (Master Batch Record) Designer role, focus on acquiring relevant skills and experience. MES MBR Designers need expertise in MES software, process optimization, and manufacturing execution. Bridging the gap involves developing skills in MES configuration, data analysis, and troubleshooting, while also gaining a deeper understanding of manufacturing processes and quality control. In order to benefit from the experience of an experienced MBR designer during the transformation process, his/her designs can be shadowed.

Here's a breakdown of the key steps and skills involved:

4.1 Gain MES Knowledge and Experience

Understand the MES Functionality

Familiarize yourself with the core functions of an MES, particularly in the context of pharmaceutical manufacturing. This includes understanding how MES manages and controls production processes, tracks materials, and ensures data integrity.

Learn a Specific MES System

Focus on mastering a particular MES platform, such as e.g. Werum PAS-X, which is commonly used in the pharmaceutical industry. Gain hands-on experience with its features, including MBR design, configuration, and integration with other systems.

Understand GMP Regulations

Thoroughly understand GMP (Good Manufacturing Practice) regulations and how they apply to MES and MBR design.

4.2 Develop MBR Design Skills

Learn how to translate manufacturing processes into detailed MBRs within the chosen MES platform. This involves defining steps, parameters, data collection points and ensuring compliance with GMP. This development is facilitated by moving from a less complex MBR to a more complex one. For example, simpler formulas can be used initially and more complex formulas can be created later.

4.3 Acquire Relevant Skills

Technical Skills

While a strong engineering background is valuable, you'll also need to develop skills in areas like:

-> MES Software Configuration:

Be proficient in configuring and customizing the chosen MES platform.

-> Data Management:

Understand how to manage and validate data within the MES.

-> System Integration:

Familiarize yourself with integrating MES with other systems like SCADA, ERP, LIMS, and other automation systems.

-> Programming (Optional):

Knowledge of programming languages like Java, C#, Python, and SQL can be helpful for more complex MES configurations.

Soft Skills

Effective communication, problem-solving, open-minded, proactive, supportive, „hand-holding“ and feedback driven and documentation skills are essential for collaborating with different teams and ensuring clear documentation of MBRs.

5. Advantages of the Role Transition

Transitioning from a Production Engineer to an MES (Manufacturing Execution System) Master Batch Record (MBR) Designer offers several advantages, primarily due to the increased responsibility, higher visibility, and deeper understanding of the manufacturing process. This role allows for a more strategic impact on production efficiency, quality, and compliance.

Advantages of moving from Production Engineer to MES MBR Designer:

Strategic Impact

As an MBR Designer, you move from a more operational role to a more strategic one, influencing how manufacturing processes are designed and executed.

Process Optimization

You gain a deeper understanding of manufacturing processes and can leverage this knowledge to optimize them within the MES, leading to increased efficiency and potentially reduced costs.

Enhanced Quality Control

Designing MBRs requires a strong understanding of quality control procedures and the ability to translate these into the MES system, improving overall product quality and compliance.

Increased Visibility and Influence

The MBR Designer often works with multiple departments, including quality, engineering, and production, giving you increased visibility and the ability to influence decisions across the organization.

Career Advancement

Moving into an MES-related role can be a stepping stone to more advanced positions in manufacturing IT, system administration, or even management.

Technical Expertise

Designing MBRs requires strong technical skills in manufacturing processes, MES software, and potentially some programming, which can be valuable for your career progression.

Reduced Paperwork

MES systems, including MBRs, can automate and digitize many paper-based processes, leading to less paperwork and more efficient workflows.

Improved Traceability

MES systems, like the MBRs, enhance product traceability, which is critical for compliance and can be a significant advantage in regulated industries.

In essence, moving from a Production Engineer to an MES MBR Designer allows you to leverage your existing knowledge and experience while taking on a more strategic and impactful role in the manufacturing process.

Conclusion

Transitioning from a Production Engineer to an MES/MBR Designer involves leveraging your understanding of manufacturing processes to focus on designing and implementing the specific software systems (MES/MBR) that manage and track those processes, a move that emphasizes digital solutions for production efficiency. You should focus on gaining expertise in Manufacturing Execution Systems (MES) and Manufacturing Business Rules (MBR) software, networking with MES/MBR professionals, and updating your resume to highlight transferable skills and new technical proficiencies.

Our Company

FrontWell Solutions is an expert in the digital transformation of the pharmaceutical manufacturing process. Our team of experts is engaged in providing digital solutions to 12 of the 20 leading pharmaceutical, biotechnology, chemical, and medical device companies and suppliers spanning Europe, the United States, and Asia.

Our expertise lies in delivering specialized consulting services, primarily centred around Manufacturing Execution Systems (MES), Laboratory Information Management Systems (LIMS), seamlessly integrating these Level 3 systems with Enterprise Resource Planning (ERP) platforms and driving Manufacturing Intelligence initiatives such as Overall Equipment Effectiveness (OEE) reporting.

Next Steps

Thinking about taking your next steps towards your journey? Our experts are ready to support you! Contact us under ReachUs@frontwell-solutions.com or via +49 (6101) 595 89 85.