



Best Practices

FOR LIFE SCIENCE COMPANIES
EMBARKING IN MES/MOM

Best Practices for Life Science Companies Embarking in MES/MOM

Today's top pharmaceutical, biotech, and medical device companies are seeking the benefits from digital transformation across their operations. The opportunity and benefits are enormous, and there are specific tactics that will reduce the risks inherent in any new solution that may affect how almost everyone does their jobs. We've put together our top nine best practices based on years of experience working with many large and small life science companies on this journey.

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Identify Challenges

Identify specific operational challenges you are seeking to solve or improve upon – process or equipment performance, record-keeping, reducing human error, reducing batch record review time, traceability, scheduling, maintenance management etc. Develop a roadmap that tackles the most pressing issues in a target process or line first, then extend that use case to other areas and incorporate additional functionality. The proof-of-concept doesn't need to be perfect; it needs to demonstrate value.





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Choose a Platform

Pick your MES/MOM platform using a selection criteria that addresses not only the most pressing issues but solves other problems as well. MES/MOM applications are inter-dependent; a best-of-breed approach using various products for different use cases can be expensive and require extensive custom interfaces. The market has matured and now offers platforms that address the major use cases – Electric Batch Records, plant performance, quality, traceability, scheduling, maintenance and workflow – and provide standard interfaces to shop floor control systems that often contain valuable information to be leveraged, as well as enterprise systems that can provide transactional data regarding work orders, inventory, and product specifications.

Collaborate

Seek input from the users, especially those who will be relying on the system to make their jobs easier. You need their buy-in to achieve success. Conduct workshops to gather input and requirements, then offer options on how to visually display the data they said they need.



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Don't Ignore Manual Operations

Automating the workflow – even if the operational steps are performed manually by operators – can reduce human error and get valuable information out of a paper environment and into electronic format that can drive comparisons and faster batch record review. Workflow can visually represent the flow and sequence of process steps, and link to images

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Cultivate Champions

Seek out the potential system users who can influence others and promote a performance-based culture. Win them over and ask them for help in promoting your vision. You need cheerleaders.

A circular inset image showing two individuals in white protective suits and goggles, likely in a laboratory or clinical setting, working together. The image is partially obscured by a green circular graphic in the bottom right corner.

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Make Metrics Matter

In process-oriented applications, key metrics may be batch cycle time and yield. For fill / finish, bottling or packaging areas, TAKT time or OEE may be the best indicators of performance. Automating the collection of the data that drives these metrics and the calculations are a key part of MES/MOM and can provide enormous value. Coupling these metrics with a performance-focused culture can provide incentives and influence behavior. Delivering metrics to users in various formats – large displays on the shop floor, fixed and/or mobile clients – reinforce the message of information-based decision-making.

If the raw data needed for performance metrics is not easily available (ie locked in legacy controllers that lack connectivity tools), seek another path. Sensors with IoT connectivity are widely available, cost effective, and may even be wireless. This is generally the faster and better solution vs. controller migration.

06

Plan for System Validation Early

Most MES/MOM applications are used for at least one GMP-oriented use case – material traceability, electronic record-keeping, quality, workflow management and perhaps others. Solutions where the initial use case is limited to performance may be considered non-GMP; usually these systems can be commissioned and do not require qualification, ask your computer validation team for input early. Ask the platform for any standard IQ/OQ templates you can use as a starting point.

07





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Support Your Corporate Initiative

Corporate initiatives such as LEAN, right-first-time, zero-defect, and operational excellence can be supported by MES/MOM applications. Craft your proof-of-concept to demonstrate the synergy between your corporate initiative and an MES/MOM solution that delivers measurable, sustainable results.

Don't Forget the Infrastructure

Typically, MES/MOM solutions are deployed in multiple environments (this could include development, testing, production, and training). Define the solution hosting requirements (on-premise VM or in the cloud), client hardware, and connectivity. Ask how your organization supports remote system access (this may be important for any third-party MES/MOM implementation and/or support teams, and for your operational leaders once the system is in production). Invite IT to come on-board early.





How IXP Can Help

InflexionPoint helps life sciences companies drive operational improvements and business results through MES/MOM.

A few ways we add value:

- Consulting during planning, requirements definition and platform selection
- Conduct workshops with your users to identify information requirements and functional requirements
- Compile requirements into user stories that define specific needs and objectives
- Advise and plan infrastructure
- Configuration – we can extend the bandwidth of your in-house team or we can take the lead
- Provide the infrastructure (hosting, hardware, licenses, setup) to support the MES/MOM applications
- Provide training and coaching on how to configure, use, and enhance the solution
- Mentoring and coaching of user teams to ensure they are getting the most value from the solution
- Support (variety of support plans for on-call response as well as services to ensure the system continues to run at optimum performance and current technology levels)