



Case Study—Successful Manufacturing Execution System (MES) Projects in the Biotech/Pharmaceutical Industry

Brillig Systems is a privately held company with headquarters in Greenville, South Carolina. It was founded with the underlying principle of providing high quality professional services to manufacturing and industrial clients. Our world-class professionals are recognized throughout North America and Europe as among the finest available.

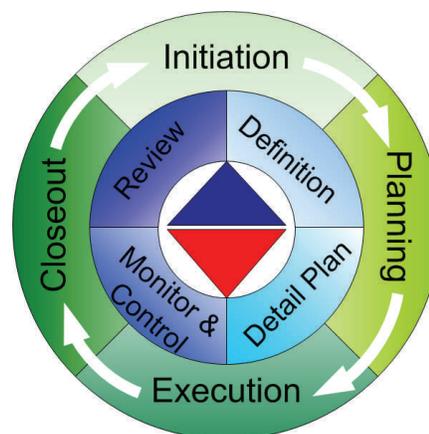
Manufacturing Execution System (MES) projects have special characteristics that make them difficult to define and manage. Typically:

- MES systems provide a rich feature set of business functions. Many projects become derailed when the users want to implement the latest “bells and whistles” without being aware of the consequences to the project timeline and budget.
- Departments that have functioned semi-autonomously now find that they are tightly integrated; therefore Organization Change Management is crucial.
- CSV processes and procedures must be expanded to include the validation of operator actions of the manufacturing process.
- The paradigm shift from “paper-based” manufacturing processes requires detailed analysis and coding of operator actions.

Brillig Systems will make your MES project successful. We bring engineers and technical experts who have years of experience in their fields providing strategic project leadership to your MES implementation.

Further, we provide professionally registered project managers who can not only successfully manage projects but also understand what they are managing.

Look at the following sections of this document to see the experience and wisdom Brillig managers offer that will turn your MES project into an on-schedule, on-budget successful addition to your company’s manufacturing capability.





Primary Considerations to Ensure Successful MES Projects

Life Cycle and Support

1. Have a good scope control process. The tendency is to expand the scope of the project to encompass all possible system integration scenarios. This should be controlled or both cost and schedule will increase significantly.
2. You must get knowledgeable people from manufacturing (operators, process engineers, process control engineers, and information technology) to assist with the development of functional specifications, participate in reviews and complete integrated testing.
3. Life cycle costs must be considered in establishing the degree of software customization, as all custom developed code will need to be reviewed and potentially modified on delivery of vendor enhancements and bug-fixes.

Operations

1. The implementation of MES organizationally impacts Operations, Process Engineering, Process Automation, and Information Technology. The level of integration requires the establishment of a comprehensive control process and organization responsibilities. For example: Who “owns” the operation instructions?
2. Since establishment of detailed data definitions and flows is crucial, ensure that representatives from all impacted systems (e.g. ERP, Historian, Automation, and LIMS) have ownership in defining the boundaries of what is under the control of the MES system.
3. As efficient material flow and traceability are critical to the success of an MES project, ensure that all impacted areas are engaged in setting material handling strategies and processes.

Interfaces

1. Since interface failures could result in the loss of critical information transfer, careful development to ensure robust data delivery and error reporting is required.
2. Integration of development planning with impacted system support teams is a must; care should be given to never underestimate the time to develop, test, and implement the required interfaces.
3. Design and execute a comprehensive validation package that clearly defines and tests the integrated system requirements, including all interfaces and possible process excursions.

Infrastructure

1. As the MES system is required for the execution of the process, you must decide on the appropriate level of “hardware uptime,” driving a decision on the level of hardware redundancy.
2. You must decide on the “operator interface” as this will drive decisions on the need for additional PCs, handheld devices, and the installation of a wireless network.
3. If barcodes are to be used, then consideration must be given to the facility layout and actual attachment of each barcode location.