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Project GEMINI: Achieving Operational Excellence Through Strategic MES/EBR Articulation

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Abstract: *Pharmaceutical and high-speed manufacturing industries' digital transformations necessitate a sound relationship between the physical and digital processes involved in creating a custom-built Manufacturing Execution System (MES) used for all operations. A comprehensive case study was completed for Project GEMINI, for which I served as the Lead Architect for this project. My focus was translating complex physical workflows into structured Electronic Batch Records (EBR). Workflows included material dosing, converting supersacks to Intermediate Bulk Containers (IBCs), in-bins blending, adding scoops, printing case coders, palletizing using robots, and pallet labeling. The study also details the strategic engagement of stakeholders during Conferences Room Pilots (CRP) and User Acceptance Testing (UAT) so that all processes were operationally practical while gaining buy-in from the business. It will also address how mechanical quality inspections (X-Rays; Vision) were integrated with Oracle EBS R12 to create a Digital Birth Certificate for each finished pallet. The results will be quantified with financial ROI, including 20% increased throughput, 30% improved sanitation efficiency, 25% reduced plastic waste, and the elimination or mitigation of potential multi-million dollars recall risks from GxP-compliant design.*

Key Word: *Manufacturing Execution System (MES), Electronic Batch Record (EBR), Custom MES, GxP Compliance, FDA 21 CFR Part 11, Functional Architecture, Digital Transformation, Serialization, Operational Excellence, Throughput Optimization, Oracle EBS R12, Intermediate Bulk Containers (IBC), Robotic Palletization.*

I. INTRODUCTION

Modern pharmaceutical and biotechnology production face a paradox: high demand for both speed and quantity of products must be balanced against zero tolerance for deviations in quality. Within the realm of personalized medicine and increasingly complex global supply chains with strict regulatory compliance, the traditional paperbound manufacturing environment has become a major bottleneck and risk to the business [1][2]. To address this issue, the industry has begun to shift to a fully digital environment with the MES at the center of this transition [4]. The MES is no longer simply a data logger; rather, it is now the factory's central nervous system—the digital orchestra conductor that coordinates all of the disparate and interrelated components of a manufacturing operation, including the physical processes, the automation systems, and the human decision makers [3].

At the heart of this MES-based transformation is the EBR; in the context of Project GEMINI, the EBR is the custom-built MES—a digital solution that will serve as a system on which all manufacturing activities will take place and be recorded and verified [5]. The custom EBR moves away from passive retrospective documentation and enables enforcement of procedures in real time by converting high-level business/scientific objectives (e.g., a recipe to formulate a pharmaceutical product or a protocol for blending excipients) into detailed digital instructions that are auditable, must be performed, and fundamentally change quality assurance from a retrospective activity to a process that is performed in real-time [12].To avoid skipping dispensing steps, ignoring temperature requirements, and allowing nonconforming products to progress along the manufacturing line, this type of active guidance creates an unbreakable connection between a finished pallet of product and the specific raw material lot from which that product was made (also known as a "Golden Thread" of data) [11].

To implement an MES with an EBR in the same way as Project GEMINI, organizations will need to fundamentally redesign their business processes [7]. To achieve this redesign, organizations must consider software configuration as well as how their workflows will be reimagined, how they will train their employees, and how they will integrate all their physical/digital assets to provide a complete manufacturing ecosystem throughout all stages of product development [10].The project involved a wide variety of scopes, one being the Pouch Package, as well as a cohesive suite of operations including:

- A dosing station to accurately dispense ingredients through precision measuring of the ingredients being dosed.
- Replacing legacy supersacks with Smooth 2000L Stainless Steel Intermediate Bulk Containers (IBCs) to streamline material handling and minimize packaging waste.

- Sequential blending of ingredients in IBCs to minimize the number of times a person must change out the ingredients and lose production time to manual changeovers.
- Secondary ingredients can be added via a scoop addition station.
- Printing of case coders helps provide traceability and ensures both primary and secondary dates are serialized.
- Finished cases are stacked via high-speed robotic palletization, where after palletization is completed the pallet is labeled, wrapped, and shipped directly to DCs.

The entire end-to-end scope of this project required a functional architecture that would support fully integrated sharing of information among all nodes in the manufacturing chain, and the custom EBR that became the Digital Platform was the necessary unifying element [4][6]. In addition to the fact that this project was to deploy a custom MES, articulate a robust EBR, and drive operational results are far more than just installing new technical software. It was/ is a very complex Engineering and Organizational challenge that can only be accomplished at the level of complexity at the convergence of Operational Reality, Regulatory Compliance, and IT. It will take a great deal of knowledge to understand how to move powdered materials from a dosing station, how to transfer from supersacks to IBC's, the robotic arm's movement to accurately place product in the proper location (the site where they will be put in a box), and how to keep the pouch seal from being compromised, as well as the creation of Functional Design Specifications (FDS) based on my understanding of how the powders and materials actually flow [7]. Articulation process is connecting the physical and digital worlds; therefore, it will determine if the MES will be a source of efficiency and control or a source of friction and frustration [9].

Case study of the GEMINI project, which is a critically important initiative to deploy a custom, GxP-compliant MES/EBR system for a high-volume, multinational production line, will be presented in this paper [8]. The project was complex due to the requirement of integrating many different physical assets (such as precision dosing stations, IBC blending units, high-speed robotic palletizers, and quality inspection equipment like X-Ray and Vision) to a single digital brain that is connected directly to the enterprise resource planning (ERP) system (Oracle EBS R12) [3][11]. The author was the Lead Architect who designed the functions that would pull all of this together.

This project was more than just an IT project, but rather a business transformation initiative with aggressive goals around financial return, throughput, and regulatory security [10]. Because of the challenges that the GEMINI team faced, the legacy system had a lot of waste (clingage) from the use of supersacks, the downtime between creating batches took too long because of manual work, and product recalls of millions of dollars could result from a nonconforming package slipping through the system [8]. A key goal was to develop a system that not only eliminated significant waste but also provided an auditable digital barrier for nonconformance using quality logic directly in the workflow so that when an X-Ray production line, located in the production line, rejected a defective package, it would also create a digital record in the custom EBR at the same time. This would provide an audit trail that would ensure that no defective product would ever be shipped.

The methodology used to achieve this vision is described in the body of this paper. It begins with an overview of the functional architecture phase of taking all of the complex physical actions and outlining them in digital logic that will be executed in the custom EBR [4]. Next, it describes the important iterative process of engaged stakeholders (Functional Walkthroughs, Conference Room Pilots [CRP], User Acceptance Testing [UAT]) to ensure that the final design is not only technically correct but also is well-received by the operators, quality directors, and plant managers who will use the system daily [9]. Finally, the measurable benefits of the system will be described to demonstrate the direct relationship between a meticulously designed MES/EBR and the production of a 20% increased throughput, millions in raw material savings, increased efficiency in sanitation by 30%, and the establishment of a zero-recall quality assurance framework compliant with FDA 21 CFR Part 11 [10].

II. LITERATURE SURVEY

There is a broad range of information available about implementing an MES/EBR including standardizing processes, ensuring compliance, how to integrate these two systems and what are the operational benefits of these systems [3][4]. It's also important to mention that the project GEMINI used a custom developed solution versus an off-the-shelf solution for implementation of their MES/EBR platform. The literature reviewed provides insight into best practices for industry, regulations regarding implementation and case studies of implementation from digital transformation initiatives that are similar to GEMINI.

1. MES Functional Architecture and Custom Development: The basic principles underlying the architecture of an MES define its purpose as the link or interface between enterprise resource planning (ERP) systems and the control of shop floor production processes in terms of integrating these systems to maintain consistency in data. The Model is an industry model for helping to conceptualize the various layers of an enterprise system to better understand how they integrate with, and are controlled by, the control systems of a manufacturing enterprise [5]. However, as manufacturers become more sophisticated in the use of automated production processes, many will find that their need for specific functional capabilities, unique workflows, or the ability to closely match their current operational paradigms will necessitate the design of custom solutions for their MES application. Therefore, the choice to design and implement a custom MES application based upon the Enterprise Business Rule (EBR) methodology allows manufacturers complete flexibility to create a custom application that can be tightly integrated with all of the currently functioning processes at their manufacturing facility. There are numerous examples within both the pharmaceutical and life sciences industries that have demonstrated that custom-built MES applications can achieve very high levels of end-user adoption, provided that the MES application was developed through direct input from operators and was validated using a process of iterative testing [6].

2. Electronic Batch Records (EBR) and Regulatory Compliance: The electronic systems regulated by the FDA (21 CFR Part 11) regulate and Guide the usage of digital (electronic) records and digital signatures (electronic signatures). Requirements under this part are comprehensive with respect to compliance and require that a total structure of components be included in compliance with FDA 21 CFR Part 11, including, but not limited to: (1) a unique user identity (2) secure password management, (3) access controls for the system (4) complete audit trails, and (5) validated systems for achieving and maintaining the overall integrity of the entire system. Additionally, the ISO and ISPE articulate this guidance in the GAMP® 5 (Good Automated Manufacturing Practice) framework, which establishes a “risk-based” compliance methodology for computerized systems on a GxP (Good Practice) basis. The GAMP® 5 framework also provides that systems should be validated based on their intended use and relative risk of the systems’ use. The validation required for an EBR (Electronic Batch Record) operates in the same manner as a custom MES (Manufacturing Execution System) since the EBR operates and records all critical process parameters. Additionally, the "Golden Thread" method of tracking finished goods through their raw materials, to the processes used to create them, to the people who made the finished goods is the most important method for achieving compliance with GxP practices, and an EBR supports the Golden Thread method of GxP compliance [11][12].

3. Integration with Automated Systems and Quality Inspection: The integration of any type of Manufacturing Execution System (MES)—whether it is commercially available or custom-developed—with automatically-controlled process equipment and quality inspection systems will increase the value of the MES [7]. By integrating an MES with Programmable Logic Controllers (PLCs), manufacturers are now able to perform real-time data captures, initiate automated workflows, and perform closed-loop control of their processes. Similarly, integrating quality inspection systems like X-ray systems or Vision systems with an MES allows manufacturers to automatically log rejected products or parts, automatically record reasons for rejected product and parts, and enforce Quality Hold Logic on rejected products or parts. Examples of this type of integration would include when a Vision system detects a bad 2D barcode on a product or part and an X-ray system identifies a contaminant or seal failure in a product; the integrated systems can automatically reject the product or part at the physical location while automatically creating an audit trail in a digital manner. This type of integration assures that all defective or non-conforming products or parts will not move through the manufacturing process without an associated quality intervention, which is critical to maintaining GxP compliance and protecting against product recalls [8].

- **Integration with Enterprise Resource Planning (ERP):** Integrating MES and ERP systems is essential for ensuring that the data in all areas of your organisation are consistent. ERP systems such as Oracle EBS R12 are designed to manage high-level business processes such as material procurement, inventory management, order processing, and financial accounting [11]. The MES interfaces with the ERP to provide real-time, detailed production data that feeds into the functions of the ERP system [4].

The major points of integration between the MES and the ERP systems will include:

✓ Materials consumed against production orders.
✓ Finished goods received into inventory
✓ Batch disposition and release status
✓ Traceability between the finished product and the original raw materials

To achieve successful integration of a custom MES and ERP, data structure mapping must be performed, master data must be synchronized (material, bill of materials, recipes), and error handling must be put into place to ensure data integrity between both systems [3][6].

- **Measurable Outcomes from MES Implementation:** Manufacturers have established quantitative benefits from MES deployment due to case studies published across the industry [8]. In addition, case studies illustrate broad-spectrum product enhancements resulting from MES implementations.

✓ **Reducing Material Waste and Enhancing Yield:** With systems that track material use accurately and enable accurate reporting for recording usage and for variance analysis, precise dispensing logic, and automated material tracking can reduce material waste and yield improvements [10].
✓ **Increased Productivity Through Workflow Automation:** Through MES-based workflow automation, the use of workflow automation reduces non-value-added tasks such as manual data entry, paper records management and looking for information will increase production throughput from 15-25% within high-speed manufacturing operations.
✓ **Improved Changeover Times Due to Digital Workflow Management And Automated Integration Of Equipment:** Digital workflow management and automated equipment integration can substantially reduce time from an existing customer production process to run a new customer production process. This capability will allow lower batch sizes and provide more flexibility in how you create products.
✓ Automated enforcement of quality holds, capture of electronic signatures, and comprehensive audit trails reduce the costs and risks associated with non-compliance, and expedite the regulatory audit process [12].

- Risk Mitigation and Recall Prevention:In regulated industries, the primary benefit derived from using a Manufacturing Execution System (MES) is to reduce risk. The price of a product recall can range from tens of millions of dollars in direct costs (product destruction, logistics and investigation) and in indirect costs (damage to brand, loss of market share or regulatory investigations) [8][11]. MESs are used to help prevent recalls by:

✓ Automating the enforcement of quality inspection procedures.
✓ Rejecting and segregating non-conforming products in real-time.

✓ Providing complete traceability so that a manufacturer can quickly and accurately identify the recalled products when a quality issue occurs.
✓ Providing an audit trail to prove to regulatory inspectors that the manufacturer was compliant.

III. METHODOLOGY

The design of project GEMINI will be based on a phased development process of four phases. The project has established the following major tenets: functional definition, iterative testing, and technical integration. The project's overall success is dependent on the realization that custom-designed MES/EBR systems require particularly thorough input from all stakeholders to ensure proper alignment between digital and real-world processes and interactions.

3.1 Functional Architecture & Custom MES/EBR Articulation

The first phase of building the custom EBR was to digitally translate all the physical workflows of the manufacturing process for the overall company. As the architect, my primary function was to write the functional design specifications (FDS) by breaking down the complex processes into simple steps and then turning those steps into digital instructions. This process of articulating what the digital instructions would be was critical to developing a single digital platform using the custom EBR to perform all manufacturing activities.

- **Material Dosing and Dispensing:** We took the high-level specifications related to yield recovery and weight compliance and translated them into specific digital instructions on a step-by-step basis regarding how to weigh and dispense materials. The logic of the system was designed to avoid variance related to an overfill (product giveaway) as well as meet regulatory weight compliance, and to ensure that each of the dispensing steps was performed in the proper order and that all of the required quality checks were completed prior to the release of the materials.
- **Supersack to IBC Conversion:** Replaced legacy supersacks with smooth surface 2000L stainless steel IBC's include both physical and digital transformation. The custom EBR will be created to identify every IBC throughout its life cycle during material loading, blending, and cleaning. This digital tracking will allow us to use In-Bin Blending logic to achieve significant throughput improvements later.
- **In-Bin Mixing and Sequential Blending Logic:** The Sequential Blending logic was designed to eliminate the 60-minute delay from normally-occurring manual bag changes. By specifying how the EBR would control movement of IBCs and blend sequences, this solution allowed for virtually no change-over (lost) time between batches, increasing the use of multi-million dollar blending assets.
- **Scoop Addition and Secondary Ingredient Handling:** Methodology incorporated how to add secondary ingredients by utilizing scoop addition stations. The EBR directed operators through the proper sequence to ensure accurate measuring and provided traceability for each addition back to the original lot of material.
- **Case Coder Printing and Serialization:** Functional mapping between the Robotic Palletizers, UBS Casecoders, and Oracle EBS R12 was accomplished to provide accurate and serialized coding that could be traced back through the manufacturing process for each finished case.
- **Robotic Palletization and Pallet Labeling:** The last steps of manufacturing, robotic palletization, pallet label printing/wrapping/shipping, were completely integrated into the customized EBR workflow. This process was designed to ensure the pallet labels were generated and applied accurately, the wrapping process on each pallet was complete, and the status of each finished product was recorded as ready for shipment to the distribution centre.
- **X-Ray and Vision System Integration:** Quality inspection systems were thereby completely integrated with the customized EBR. If a pouch was rejected due to a defective 2D barcode, a seal defect, or a contaminant identified by X-Ray, this event would not only cause the pouch to be physically removed from use but would also be logged by the EBR with the appropriate reason in real-time. This provided one more layer of confirming that quality events were recorded for future audits, thereby ensuring that non-conforming products did not move forward without the appropriate documentation of the disposition.

This also resulted in an MES that would provide on-going guidance to operators through the required GxP-compliant sequences to prevent bypass of essential quality steps while generating a complete digital record of all manufacturing actions.

3.2 Architecture Diagram

The diagram below shows the overall functional architecture of the system interface and the flow of data/control from the physical work area through the automated manufacturing system (or manufacturing execution system) and digital platform back to Enterprise Systems.

3.3 Strategic Stakeholder Interfacing & Iterative Testing

To minimize the differences between the design of a system and how it's going to be used within the business, we engaged with stakeholders at all levels throughout the project lifecycle (scope through installation). This was particularly critical for this custom MES system because its functionality was designed only for the specific workflows of this facility.

- **Functional Walkthroughs**: I led "Functional Walkthroughs" with the plant management team, quality leadership team, and operators to validate that the design about the digital logic was correct and reflected the actual physical operations that would occur. This process also validated that the system would be operationally viable for end-users.
- **Conference Room Pilots (CRPs):** I was the lead for the CRP, in which business users were able to interact with the system in regards to business operations based on real-world scenarios. During the CRP, I was able to demonstrate the functionality of the custom EBR to business users, providing them with a hands-on experience with the custom EBR and validating the design of the custom EBR against actual production conditions.

- **User Acceptance Testing (UAT):** After the CRP, formal User Acceptance Testing (UAT) was then performed in which business users executed full production workflows within the custom EBR. This testing validated that all functional requirements were met and that the system was ready for production.
- **Gap Analysis and Design Refinement:** The direct feedback obtained during the business-related testing allowed me to refine the functional logic of the custom EBR. This iterative process allowed 100% buy-in to the live system by the business, and ensured the system was optimized for zero-error production. One of the primary benefits of the custom MES approach was the ability to incorporate user feedback into the system quickly and efficiently, thus allowing for precise customization to meet the specific operational needs of the business.

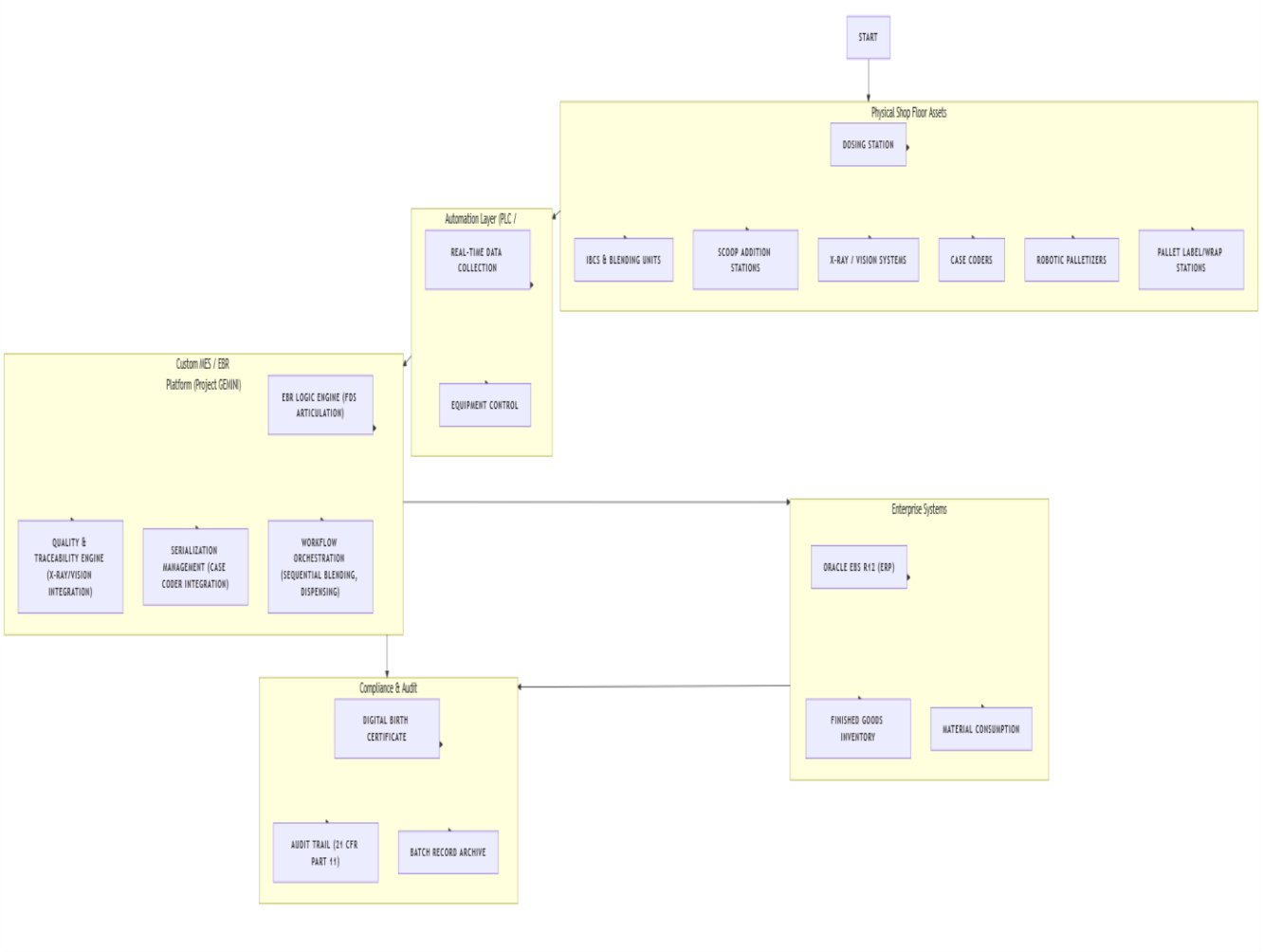

Figure 1: Architecture of the Integrating the MES and EBR

3.4 Quality Inspection Integration & GxP Verification

A significant technical workstream was the interface of automated quality inspection systems with the bespoke EBR.

- **X-Ray/Vision System Integration:** The functional interface for the X-ray and Vision systems. These critical quality inspection points were located within the production stream at locations to detect defects at various stages in the process. If a pouch was rejected for a bad 2-D barcode, a seal defect, or for a contaminant, the system recorded the rejection reason in the custom EBR in real-time. This "Integrated Quality Logic" guaranteed that a physical rejection would be synchronized with its electronic record, thereby creating a full audit trail of the completion of all quality events.
- **Robotics/Serialization Synchronization:** For directing the functional mapping of the Robotic Palletizers, UBS Casecoders and Oracle EBS R12. Synchronization ensured that every finished pallet would have a "Digital Birth Certificate" in the custom MES, and that any pouch could be traced back to a specific raw material lot, piece of equipment, operator, and the quality inspection results associated with it.
- **Validation/GxP Compliance:** The custom MES/EBR was validated following GAMP® 5 principles, thus established that the system was functioning as designed and complete data integrity of all operations was maintained. The validation methodology was risk-based by focusing on critical functions that could negatively impact product quality as well as patient safety.

IV.RESULTS AND REPRESENTATION

The functional management provided by the author over the course of Project GEMINI led to a substantial, measurable improvement in the areas of finance/operations/sustainability/ compliance. The metrics below illustrate the measurable results from the tailored MES/EBR architecture that was developed for this project.

4.1 Key Performance Indicator (KPI) Improvement

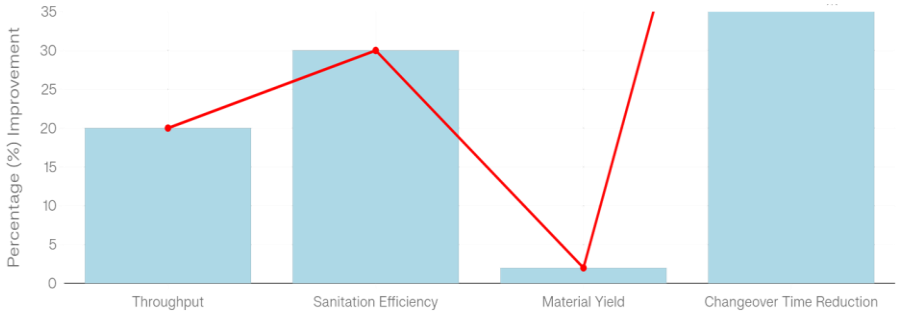

Figure 2: Key Performance Indicators (KPI) Improvement

The following bar chart (Figure 2) illustrates the improvement of the key performance indicators (KPI's) as a result of the implementation of a custom BMS/EBR architecture.

Improvements in material yield will be reflected by an increased percentage point reduction for clingage losses of 1% to 3%. Improvements related to changeover time will demonstrate a 100% improvement in a manual bag change that typically takes 60 minutes.

4.2 Financial and Compliance Impact Analysis

As part of Project GEMINI, a comprehensive assessment of the total impact of each project was made prior to the implementation of the project. Impact assessments are done by measuring how each project impacts the same areas of service delivery. A summary of these impact assessments is provided in the following table1:

Metric Category	Baseline / Previous State	Post-Implementation Result	Financial / Operational Impact
Material Yield Recovery	Material loss due to "Clingage" in supersacks (trapped powder)	**1-3% Yield Recovery** via smooth-surface 2000L stainless steel IBCs	Millions in annual raw material savings
Product Giveaway Prevention	Overfill variance due to imprecise dispensing	**Reduced Overfill Variance** via EBR-integrated precision dispensing logic	Direct financial savings from reduced product giveaway
Operational Throughput	60-minute downtime for manual bag changes	**20% Throughput Increase** via Sequential Blending logic	Maximized utilization of multi-million dollar blending assets
Sanitation Efficiency	Manual cleaning of equipment	**30% Sanitation Efficiency** via automated Clean-in-Place (CIP) stations	Faster IBC return to production stream; reduced labor costs
Risk Mitigation	Potential for defective product release to market	**Zero-Recall "Fail-Safe"** via X-Ray/Vision rejection logic integrated with EBR	Mitigation of potential $10M+ recall costs
Regulatory Compliance	Manual, paper-based audit trails	**FDA 21 CFR Part 11 Compliance** & "Golden Thread" data lineage	Reduced audit time; lower legal and regulatory risk
End-to-End Traceability	Fragmented traceability across systems	**Digital Birth Certificate** for every pallet, tracing to raw material lot	Complete audit readiness; rapid response capability for quality issues

Table 1: Financial and Compliance Impact Analysis

4.3 Sustainability Impact

The use of 2000L stainless steel intermediate bulk containers in place of single-use supersacks has resulted in significant sustainability improvements pertaining to our environmental impact.

- Continues to reduce 25 % of plastic waste from the waste stream annually by preventing thousands of tons from being produced.
- Reduced carbon footprint by cutting down on transportation costs due to not needing to transport waste material and preventing the environmental impacts of manufacturing supersacks.
- Reduced landed cost by eliminating material and labour costs associated with compacting, hauling and disposing of industrial waste.

V.DISCUSSION

Results of Project GEMINI are testimony to the transformational power of an architected (structured) custom MES/EBR system. These findings call for dialog across multiple levels: Relationship between digital orchestration & physical asset utilization; The importance of stakeholder engagement; The value of having integrated quality logic; The consideration of how all of this plays into regulatory compliance.

5.1. Digital Orchestration Unlocks Physical Asset Capacity

The 20% throughput increase resulting from the "In-Bin Blending" logic in the custom EBR confirms the claim that utilizing digital orchestration to access previously unused capacity in physical assets is possible. The elimination of the 60-minute duration for changing manual supersacks allowed for sequential blending that had almost no changeover time. This result complements an observed trend within the industry that indicates that implementing MES-driven workflow automation will lead to a reduction of non-value-added activities and a higher level of asset utilization.

In addition, the 30% improvement in sanitation performance accompanied by the use of automated Clean-in-Place (CIP) stations incorporated into the custom EBR further supports this point. Digital management of CIP cycles, tracking IBCs' cleaning status, and validating appropriate sanitation prior to the reintroduction of containers into the production stream resulted in reduced downtime and increased velocity for IBCs, thus maximizing return on investment from these expensive assets.

5.2 Material Yield and the Physical-Digital Interface

Reduction in the material "clingage" demonstrates the essential connection between operational design and digital control. Through the use of smooth-surface 2000L stainless steel IBCs and joining this physical change with an accurate EBR dispensing logic, we addressed a source of yield loss that could not be solved by software only. This shows the importance of a well-integrated MES architecture combining both the digital and the physical elements.

The custom EBR both recorded actual material usage and helped to control the dispersion of materials for accuracy and consistency, which directly enhanced yield recovery. In addition, the reduction in overfill variance (product giveaway) further illustrates this principle. The combination of EBR's accuracy and the EBR-integrated dispensing logic not only met weight compliance but also eliminated the financial burden of surplus product. This capability is especially helpful in high-volume manufacturing environments, where even a small per-item savings can have a significant overall financial impact.

5.3 Stakeholder Engagement as a Critical Success Factor

Stakeholder engagement throughout the entire project development cycle was critical to the success of the custom mes/ebr project. The functional walk-throughs, crp, and uat were essential to refining the system and validating that the system matched operational realities. There are many advantages of a custom solution versus an off-the-shelf product. With commercially available software, an organization will typically have to change or adapt their existing business processes to fit the software. However, our custom ebp solution was designed specifically to mirror a facility’s workflows. Through the continuous feedback loops with operators, quality directors, and a plant manager, the final result was an intuitive end-user experience with minimal workarounds.

The 100% business buy-in prior to go-live was a direct outcome of this engagement process. Operators who see their feedback incorporated into the design of the system will have less resistance and have a greater likelihood of quickly accepting the new system. This finding is consistent with the change management literature that indicates involving the end-user throughout the entire development process will improve user acceptance of the end product.

5.4 Integrated Quality Logic and Risk Mitigation

By integrating the X-Ray and Vision systems with the Custom EBR, we have established a zero-recall fail-safe. This means that when a quality defect is identified (i.e., incorrect 2D barcode, a seal defect or a contaminant), the product will be rejected physically and also recorded digitally in an auditable manner. The closed-loop QC has ensured that no defects will be allowed to proceed without documented intervention.

The risk mitigation benefit of having this capability is truly immeasurable. The cost associated with one product recall in either the pharmaceutical or food industry can be tens of millions of dollars just in direct costs, and does not include damage to brand image or regulatory issues. The creation of a digital barrier to disallow defective product provides a significant return on investment for the custom MES/EBR based solely on risk avoidance.

5.5 Regulatory Compliance and the "Golden Thread"

A "Golden Thread" of data was created by the custom-built MES/EBR design and fulfilled the requirements of 21 CFR Part 11. Every activity that occurred at the manufacturing level (from dispensing the materials, through blending, through quality inspection and finally palletizing) had all the necessary lineages (attribute), audit trails and electronic signatures (if required) kept. Because the data was present digitally, this reduced the amount of time it took and the risk of legal issues related to regulatory audits because you had instant and traceable proof of all manufacturing activities.

The Digital Birth Certificate assigned to every finished pallet is representative of the entire traceability effort. With one unique identifier, the system was able to trace all pouches back to their original raw material lots, which equipment was used in manufacturing them, which operators were engaged in the process and what the quality inspection results were. This capability not only provides for regulatory compliance, but also allows for rapidness to respond if there are quality issues because the product can be identified at a very granular level without having an extensive recall.

5.6 Sustainability and Total Landed Cost

Switching from disposable supersacks to reusable IBCs resulted in both financial and environmental gains. With less plastic waste (about 25% reduction), the organization met their ESG goals by diverting thousands of tons of waste from the waste stream. Similarly, eliminating costs associated with compressing, hauling, and tipping industrial waste helped lower TCO.

The research shows that sustainability efforts in manufacturing can be done without incurring additional costs. In this situation, the EBR custom provided by the company allowed for operational improvements and both environmentally and financially beneficial use of reusable IBCs. This created a positive cycle of operational efficiencies.

5.7 Limitations and Considerations

Although Project GEMINI has generated remarkable success through the use of an MES solution that was designed specifically for this purpose, there are several issues that need to be addressed: First, custom development will require an early investment in design/development/validation and thus the total cost of ownership should be balanced with the value of flexibility and alignment. Second, the success of the overall project was reliant upon effective engagement from all stakeholders/teams across the project lifecycle; companies lacking change management expertise may find it difficult to achieve comparable results due to failed attempts to engage with stakeholders/teams at various points during the project lifecycle. Lastly, a custom MES will require either in-house resources or an established long-term support partner for ongoing maintenance and enhancement.

VI.CONCLUSION

Project GEMINI illustrates how carefully defined MES/EBR platforms have become the greatest lever for achieving regulatory compliance and operational excellence in the pharmaceutical, biotechnology, and high-speed manufacturing industries. The project was able to serve as the primary link between the technical engineering team and business stakeholders and was developed by the Lead Architect to be a strategic business enabler, rather than just a technology upgrade.

The custom EBR platform was used as a measurable structure for all digital manufacturing activity and has produced extraordinary results, including:

- Financial impacts—the ability to save millions of dollars in annual raw materials through yield recovery and reduced giveaways.
- Operational excellence—the ability to increase throughput by 20% and improve sanitation efficiency by 30%.
- Sustainability—the ability to reduce the amount of plastic waste produced by 25% by eliminating single-use supersacks.
- Risk mitigation—the ability to set a zero-recall quality barrier using integrated X-Ray and Vision rejection logic.
- Regulatory readiness—compliance with FDA Title 21, Part 11 and "Golden Thread" traceability.

By integrating quality inspection systems with the custom EBR and synchronizing robotic palletizers, case coders, and Oracle EBS R12, a digital lineage was created between raw materials and finished pallets. This Digital Birth Certificate for each product will allow the organization to be ready for audits and has created a foundation for continual improvement.

The iterative stakeholder engagement process—Functional Walkthroughs, CRPs, and UAT—has been crucial in creating 100% buy-in from the business and have resulted in a custom MES system that is built to provide zero-error production. The emphasis was placed on ensuring that the custom MES matches the operational realities of the shop floor, rather than forcing the operations to meet the constraints of the software.

As the manufacturing industry transitions to Industry 4.0, AI-enabled manufacturing processes, and more stringent regulatory requirements, the foundational work of defining physical manufacturing processes into digital logic will continue as the keystone for future success. Project GEMINI serves as a blueprint for organizations who are beginning this complicated but rewarding journey of transitioning manufacturing processes to digital platforms.

VII.ACKNOWLEDGEMET

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