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Industry 4.0 - Intelligent Automation of Manufacturing with SAP-Digital Manufacturing

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Profile: A supply chain expert researcher, Seasoned technology based business transformation leader, Subject matter expert for Pharmaceutical Manufacturing & Quality Management.

Abstract - The purpose of this blog is to demonstrate how **SAP Digital Manufacturing and SAP Manufacturing Integration and Intelligence (SAP MII)** can integrate diverse manufacturing processes, machines, and shop-floor systems to bring the principles of **Industry 4.0 and smart manufacturing** into reality.
Approximately **80% of manufacturing data is generated at the shop-floor level**. By systematically capturing, integrating, and contextualizing this data with business knowledge, organizations can transform raw operational data into actionable insights that help achieve:

- Higher manufacturing yield
- Reduced non-conformities
- Improved Overall Equipment Effectiveness (OEE)
- Early prediction of potential disruptions and their downstream impacts

Because every organization has different technologies, systems, and levels of digital maturity, this white paper proposes a **practical, maturity-based framework** for integrating manufacturing processes, machines, and shop-floor systems. The framework enables organizations to capture and contextualize operational data, convert it into meaningful decision-support information, and progressively transform a **responsive supply chain into an intelligent, orchestrated supply chain**.

Keyword: OEE -overall Equipment Efficiency, Non-Conformity, PP-Production Planning, QM-Quality Management, Batch Management, Active Pharmaceutical Ingredients, PLC-Programable Logic Control, SAP-System Application and Products, MII -Manufacturing Intelligence Integration, ERP-Enterprise Resource Planning .

1. INTRODUCTION:

Evolution of Manufacturing Automation: From the Invention of the Wheel to Rockets and Robotics. The manufacturing industry has undergone a remarkable transformation—from the invention of the wheel and basic mechanical tools to today's highly automated systems involving **robotics, artificial intelligence, advanced manufacturing, and space technology**. Each stage of this evolution has fundamentally changed how products are designed, manufactured, and delivered.
In today's globalized and highly competitive marketplace, another significant paradigm shift has taken place: **industries are increasingly becoming customer-driven rather than producer-driven**.

A simple equation illustrates this transformation:

Past — Cost-Plus Approach:
Sales Price = Cost of Goods Manufactured + Profit.

Today — Market-Driven Approach:
Profit = Sales Price − Manufacturing Cost

The key difference is that the **sales price is no longer determined solely by the manufacturer**. Instead, it is largely dictated by **market conditions, customer expectations, competition, and perceived value**.
As a result, manufacturers must continuously improve productivity, quality, innovation, and operational efficiency to reduce manufacturing costs and remain profitable. In this environment, automation, robotics, digital technologies, and intelligent manufacturing have become essential enablers of competitiveness.

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1.1 Industrial 1.0

The **First Industrial Revolution** began in the 18th century with the introduction of steam power and the mechanization of production. Processes that were previously performed manually, such as spinning thread on simple spinning wheels, were transformed by mechanized systems that could produce up to eight times the output in the same amount of time.

Although steam power was already known, its application to industrial processes represented a major breakthrough in increasing human productivity. Instead of relying on human muscle power to operate weaving looms and other machinery, steam engines provided a reliable and powerful source of mechanical energy.

Innovations such as the **steamship** and, about a century later, the **steam-powered locomotive** brought about further profound changes. These technologies dramatically reduced the time required to transport people and goods over long distances, accelerating trade, commerce, and industrial development.

1.2 Industrial 2.0

The **Second Industrial Revolution**, which emerged during the late nineteenth century, was characterized by major advances in electricity, mechanization, and mass-production methods. A defining development was the introduction of assembly-line production, most notably associated with **Henry Ford (1863–1947)** and the early automobile industry. Ford adapted the principles of task specialization and continuous-flow production observed in industrial slaughterhouses, where individual workers performed specific operations along a conveyor system. He applied and refined these principles for automobile manufacturing, transforming production from a process in which a single station assembled an entire vehicle into a sequence of standardized, specialized operations. This approach substantially reduced production time and manufacturing costs while enabling large-scale, consistent production.

1.3 Industry 3.0

The **Third Industrial Revolution** began in the 1970s with the introduction of partial automation through **programmable logic controls, memory-based control systems, and computers**. These technologies gave machines not only mechanical strength or “muscle,” but also a certain level of intelligence, enabling them to perform tasks with greater precision, consistency, and speed.

With the advancement of these technologies, it became possible to automate entire production processes with minimal or, in some cases, no direct human intervention. A well-known example is **Toyota**, which incorporated the **Takt Time philosophy** into its manufacturing practices to synchronize production with customer demand and improve process efficiency.

Another example is the use of **industrial robots and automated manufacturing lines**, which can execute predefined sequences of operations accurately and repeatedly without continuous human intervention.

As automation evolved, manufacturing systems also began to collect and analyze **shop-floor production data**. Theory of Constraints (TOC) had started becoming popular. These systems can establish performance benchmarks, monitor processes in real time, identify anomalies or deviations from expected conditions, and generate alerts when abnormalities are detected. This progression laid the foundation for the transition toward more connected, intelligent, and data-driven manufacturing systems characteristic of **Industry 4.0**.

1.4 Industry 4.0

We are currently witnessing the implementation of the **Fourth Industrial Revolution**, commonly referred to as **Industry 4.0 across the Globe**. This revolution is characterized by the integration of information and communication technologies into manufacturing and engineering processes, building upon the advancements of the Third Industrial Revolution.

Industry 4.0 enhances existing computer-based production systems by connecting them through networks and creating **digital twins** that represent physical assets in the digital environment. These connected systems can communicate with other machines and facilities while continuously generating and sharing operational information. This represents the next major step in production automation.

The interconnection of machines, systems, components, and people enables the development of **cyber-physical production systems** and **smart factories**, where production processes become increasingly intelligent, interconnected, and autonomous.

In such an environment, systems continuously capture and analyze data from the shop floor, establish performance benchmarks, and identify anomalies or deviations from expected conditions. When issues are detected, the system can automatically generate alerts. A **responsive supply chain system** can then recommend corrective actions while providing visibility into potential downstream impacts, enabling faster and more informed decision-making across the organization.

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2. COMPREHENSIVE IMPLEMENTATION METHODOLOGY FOR INDUSTRY 4.0

The industry has a dearth need of expert tools/solutions based on Data science and computer algorithms to FastTrack corrective medicine production & market launch as well as preventive vaccines development. SAP Manufacturing Integration and Intelligence (SAP -MII) and SAP-DM is an SAP application for synchronizing manufacturing operations with both back-office business processes and standardized data. This is the enabler of the implementation of centralized procedural controls in distributed manufacturing and execution facilities.

It functions as a data hub between central SAP ERP and satellite systems of operational applications. Moreover, SAP MII can be leveraged to contextualize the data to prescribe appropriate intelligent responses to Shopfloor machines/applications.

SAP Manufacturing Integration and Intelligence (SAP MII) connects your plant operations and enterprise systems, so employees, materials, processes and machines work seamlessly together. The on-premises solution enables access to the data and analytics needed to make critical business decisions. This greater visibility into your operations supports improving productivity and overall equipment effectiveness.

1. Ability to see all progress of Shop orders
2. Ability to report actual time of consumption of component materials
3. Ability to see nonconformities and open CAPA
4. Ability to see batches on hold with reason code
5. Ability to see downstream Impact on batches on hold
6. Ability to enter/view data related to Imperfection Tracking
7. Ability to see environment exposure and remaining environmental life
8. Ability to create end to end electronic batch records
9. Ability to Integrate with all satellite execution systems/applications such as

- PLC based machines / SCADA
- Environment tracking system
- Laboratory Information System (LIMS)
- Compliance System TrackWise

Refer Figure1- To see integrated shop floor monitoring and control needs

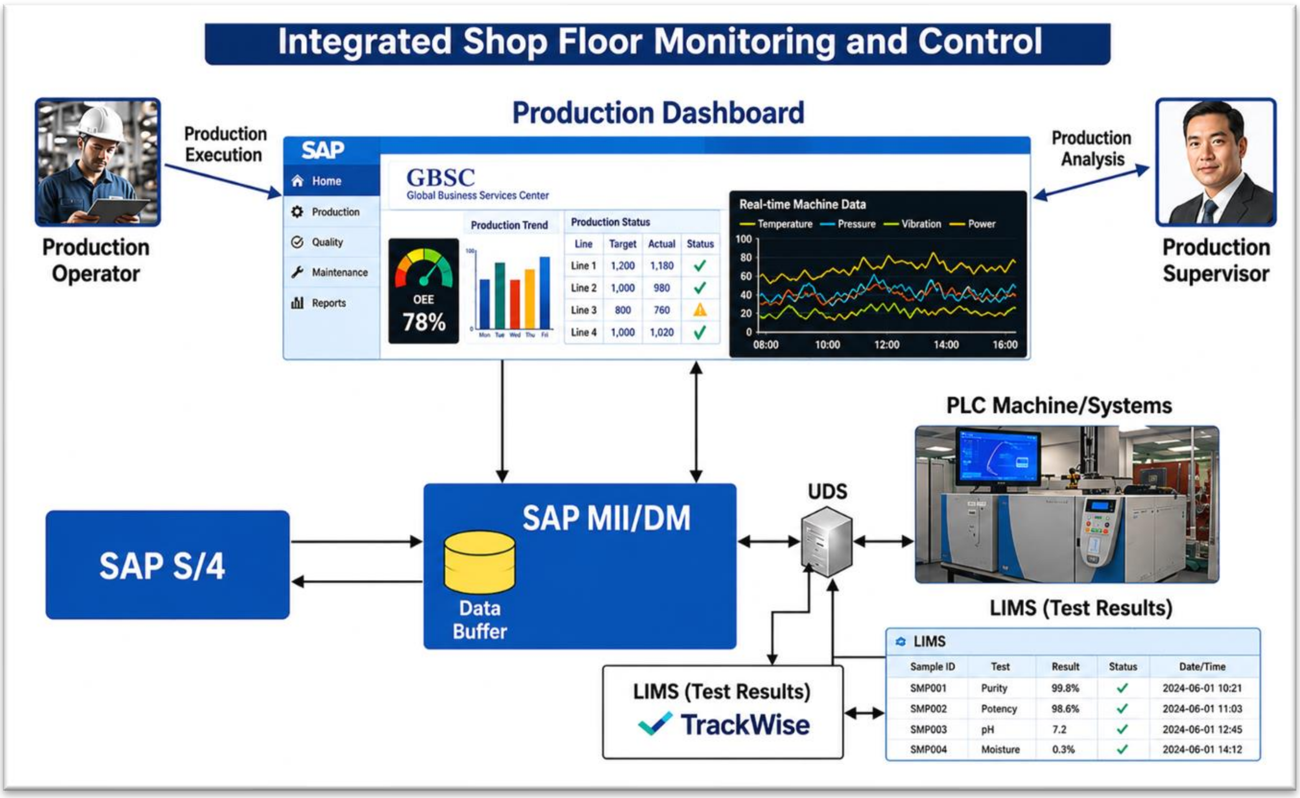

Figure 1- Manufacturing Cockpit

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Every product that reaches an end customer represents the cumulative effort of the entire manufacturing ecosystem. Unless all the systems are integrated seamlessly and overall efficiency and total quality will be ensured.

Please refer to Figure 2 to understand the implementation framework.

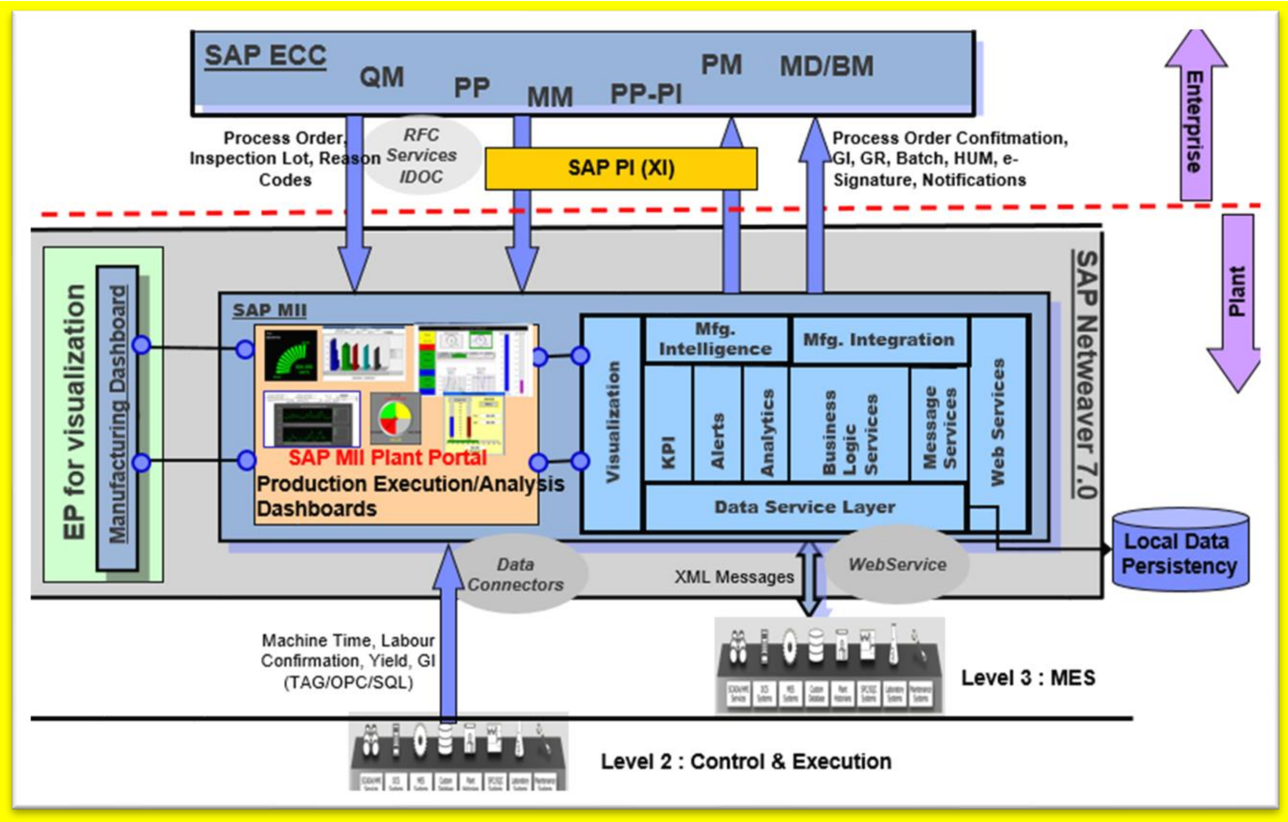

Figure 2: Central ERP system connected with satellite system

1. SAP S/4 will send the control recipes to SAP MII when the order is released.

2. SAP MII receiving the messages from SAP S/4 will buffer them in the system database and subsequently run a pre-defined rule to process the messages to create the work center task-list. SAP S/4 System or S/4 HANA must be the source of truth for master data.

3. Operators can log in to the SAP MII portal and view the resource schedule in the Production Dashboard. This can happen in offline mode to SAP-S/4, as the data are already available in SAP MII.

4. The operator can create order confirmations, quality inspections, and other relevant tasks from the dashboard which will be updated in SAP

S/4. SAP MII can provide guaranteed delivery for asynchronous messages.

5. The dashboard will also provide real-time information about machine status, early warnings for machine failures or quality issues and shall provide the user with possible options.

6. Production Supervisor and Shift Supervisors can have a real-time view of the production process and monitor and analyze different KPIs such as OEE.

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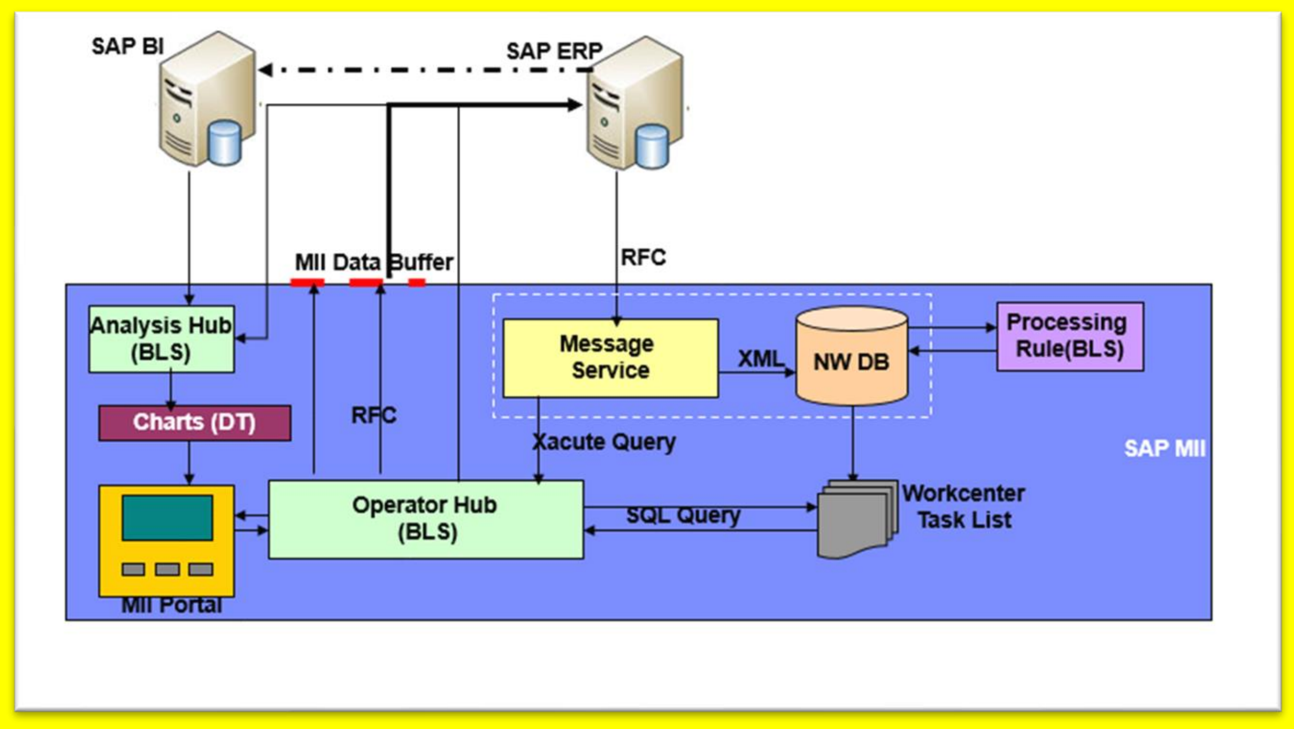

Figure 3: Application Architecture

Refer Figure-4: SAP S/4 Sends Manufacturing Order Information to Execution system Via SAP -MII

- Use control recipe (process order) to send the order data from S/4 to MII.
- If the control recipe is considered what will be the PI categories used.

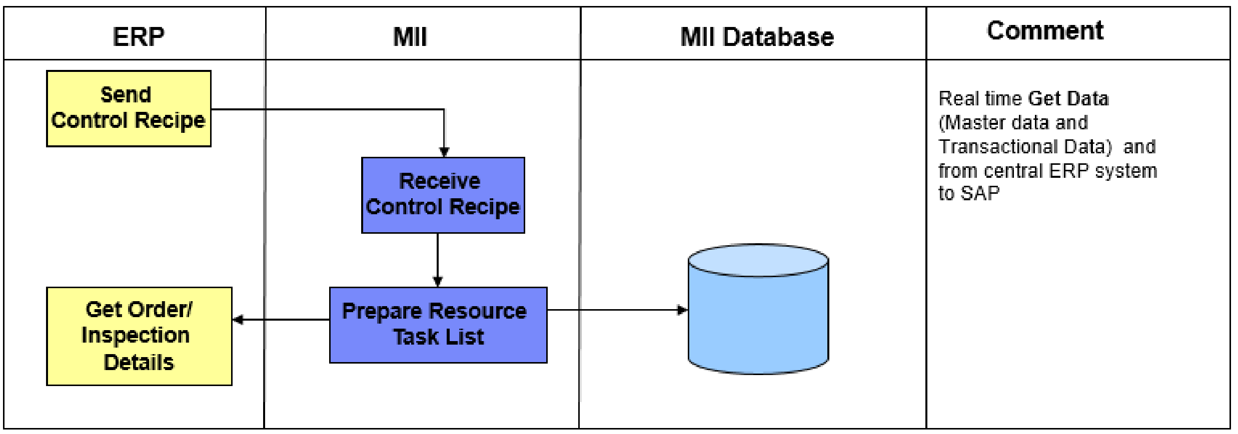

Figure 4: Get Data Function

Quality Inspection schedule to shop floor supervisor. If quality Phases are in place in the master recipe in Case 03 inspection type (We must capture QA11 transaction in Dashboard). Resource task list will display the list of control recipes along with order number, material, start, and end date, status.

Refer Figure 5 & 6: To understand how does SAP Digital Manufacturing Suite buffers message and create Work center, Task List and provides order schedule.

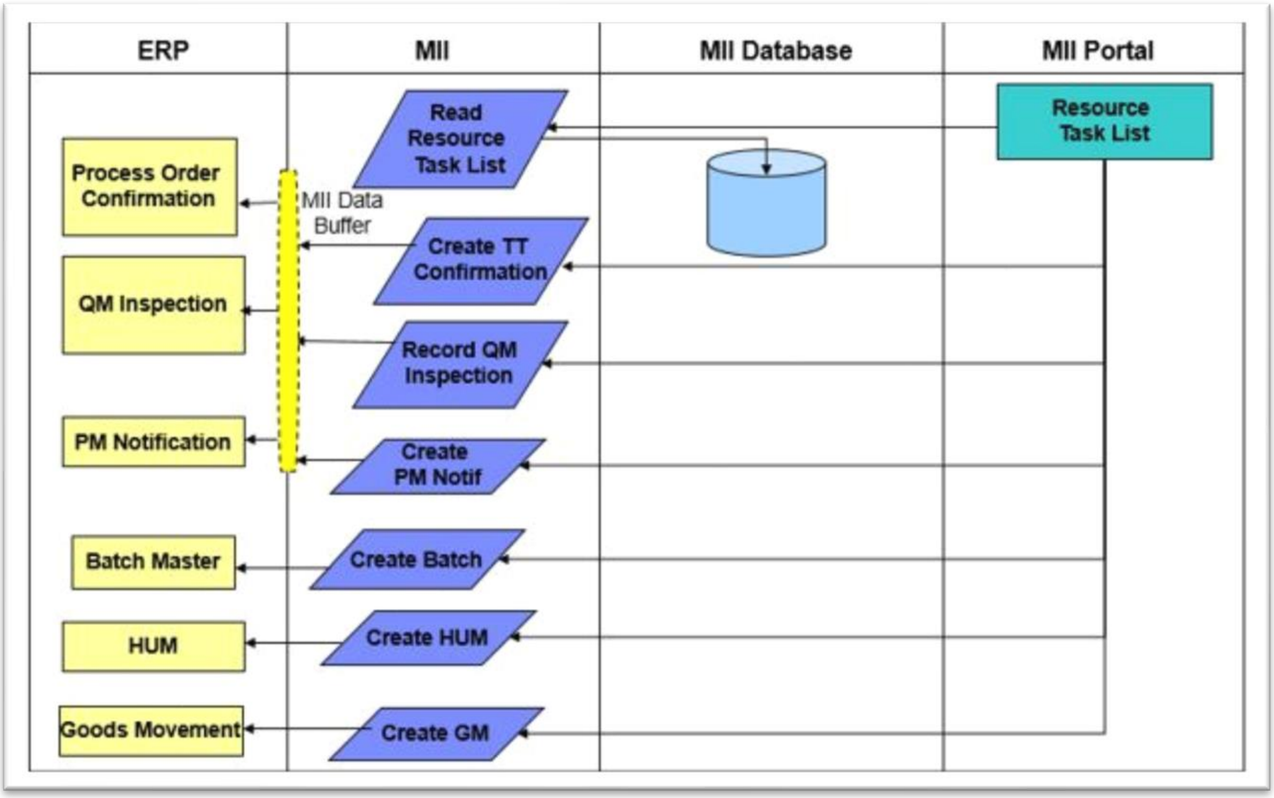

Figure 5: Bidirectional Information Exchange

The success of technology-driven business transformation depends on achieving the appropriate alignment and maturity of **Man, Machine, Material, and Method (4M)**. Because these factors continuously evolve, the digital transformation roadmap for manufacturing and supply chain processes should likewise be viewed as a **continuous, progressive improvement cycle rather than a one-time implementation**.

A **closed-loop feedback mechanism** should continuously evaluate operational performance, redefine process benchmarks, and enable the system to adapt to the next level of maturity, as illustrated in **Figure 6**. The ultimate objective is to progress toward a **smart factory** characterized by:

- **Data-driven, self-service decision-making** based on real-time operational information.
- **Systematic and embedded process controls** that ensure adherence to established procedures.
- **Early detection of deviations**, enabling corrective action before they result in product nonconformity or quality failures.
- **Proactive identification of bottlenecks and self-service remediation**, guided by the principles of the **Theory of Constraints**.

This continuous feedback and adaptation mechanism enables manufacturing and supply chain operations to evolve from reactive process management toward **predictive, adaptive, and increasingly autonomous operations**.

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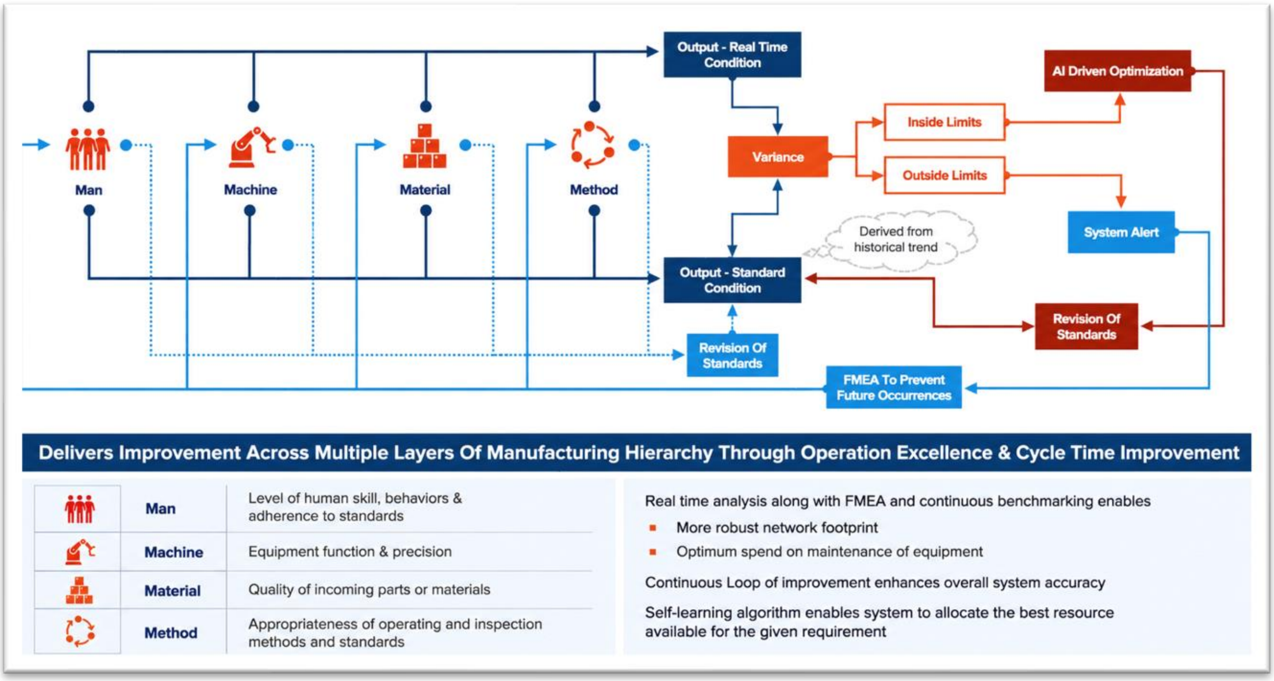

Figure 6: Responsive and Orchestic Supply Chain.

3. RESULT:

This framework will meet functional all common functional requirements

3.1 Functional requirement

- Ability to perform component and batch validation for Slitting and Coating
- Ability to report actual time of consumption of component materials for Coating
- Ability to Report Component Scrap for Slitting
- Ability to Report Header Scrap for Slitting
- Ability to enter/view data related to Imperfection Tracking for Coating and Slitting
- Ability to enter/view data related to Imperfection Tracking for Coating and Slitting
- Report Environmental Tracking relevant data to ERP
- Ability to enter multiple hold codes for batches for quality events

All about integrating shop floor systems involve in manufacturing lifesaving medical diagnostic slides used for sampling using SAP Digital Manufacturing Suite as shown in ***Figure-7***

- Operators equipped with all the information, he needs to perform his/her job:
- What is the information displayed in the Production Dashboard (e.g. Phase list, material list)?
- What are the operations performed from the production dashboard (e.g. order confirmation – Time Ticket or Time Event, QA inspection, batch creation/Update, etc...)?
- What are the plant systems integrated to retrieve relevant data (e.g. Historian, LIMS, etc.)?
- Phase confirmation (time-event) and accountability through electronic signature.
- Confirmation cancellation (Transaction code: CORS should be considered from dashboard).
- GI (Inventory manage).
- Batch Derivative for Expiry date calculation.
- Quality check as per quality plan (Inspection lot)
- GR (digital signature) with batch creation : Batch Creation Should be at or before order release.
- PM notification (phase confirmation – Yield & Operational loss)
- Material Rejection (final or material/component)

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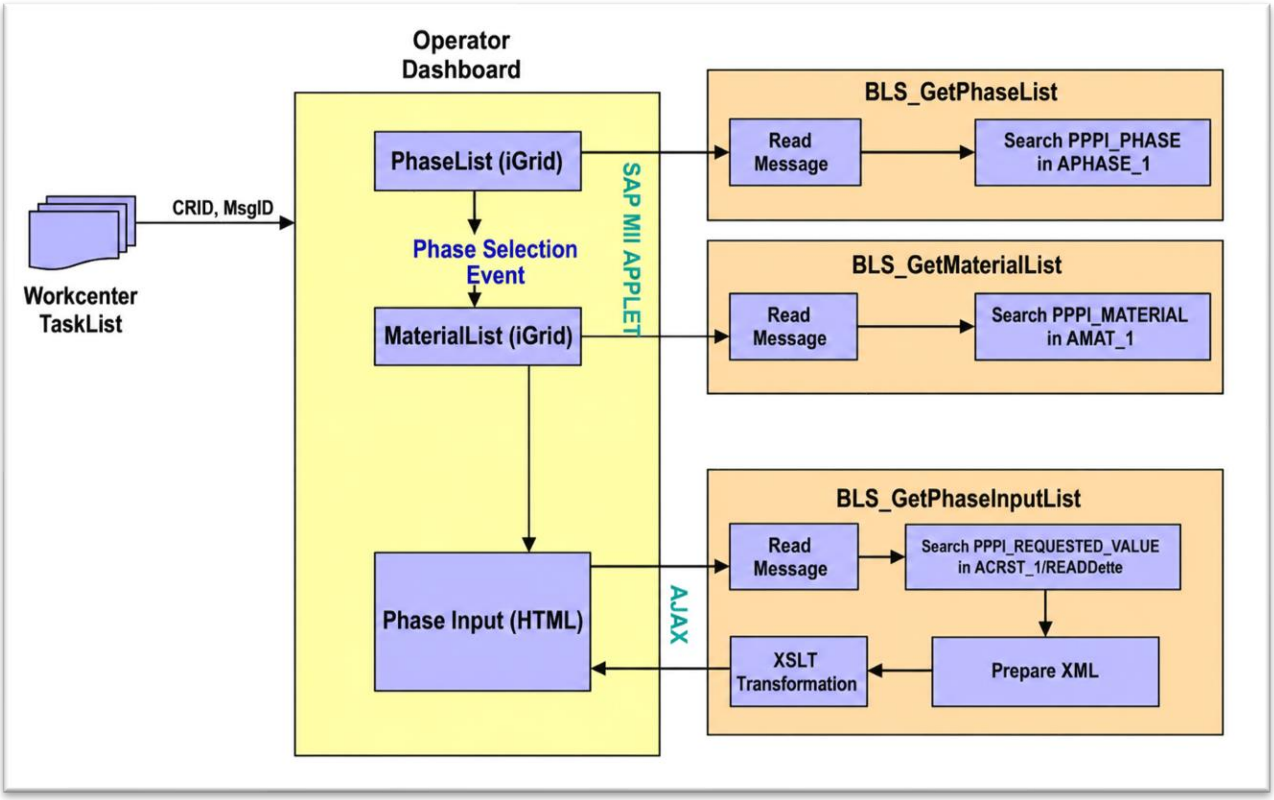

Figure 7 Operational Dashboard

3.2 Value proposition

1. Integrated disconnected shop-floor systems with SAP and Non-SAP systems across the plant.
2. Got rid of complex old R2 based S/4 transactions for entering production execution result.
3. Avoid erroneous manual calculation of manufacturing data causing delay and financial impacts.
4. Improved operator efficiency by providing easy-to-use reporting screens and shortening data reporting time.
5. Timely plan and organize manufacturing operations to satisfy customer demand.
6. Track down and report real-time product expiration information in the system and avoid paper-based tracking.

4. DISCUSSION:

This business case study is all about integrating shop floor systems involved in manufacturing of lifesaving medical diagnostic slides using SAP -MII and SAP Digital Manufacturing Suite.
One of world’s largest medical diagnostic manufacturers serving the transfusion medicine community and laboratories around the world. The client is the leading provider of diagnostic slides for screening, diagnosing chemicals, monitoring, confirming diseases early with presence across the world in laboratories.
Clients wants to build to real-time production execution system along with integration of all shop floor systems including ODS, Machine SQL databases and environment tracking system called Spider, Laboratory testing System (LIMS) and compliance system (TrackWise) with centralized SAP S/4 using SAP-MII/SAP-DM. One of the largest pharmaceutical and Med Tech company wants to build to real-time production execution system along with integration of all shop floor systems including ODS, Machine SQL databases and environment tracking system with SAP with digital Manufacturing suites.

1. Shop floor processes for Slide Manufacturing runs on Process Orders created in S/4 based on production planning, demand from customer sales orders and available material stock.
2. Download released process order from S/4 and stage to ODS staging database.
3. Download relevant process order and operational data to automated work center database.
4. Report process order execution result(Goods Issue, Goods Receipt, Waste) through MII.
5. Calculate and validate critical business data accurately based on reported result.

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6. Post process order confirmation to SAP S/4 via Spider and display real time response.

successful Implementation of Manufacturing Automation for a Major Medical Devices & Diagnostics Client using SAP – Digital Manufacturing and Integration of Complex Processes and Various Systems on a single portal-based platform as Illustrated in ***Figure -8***

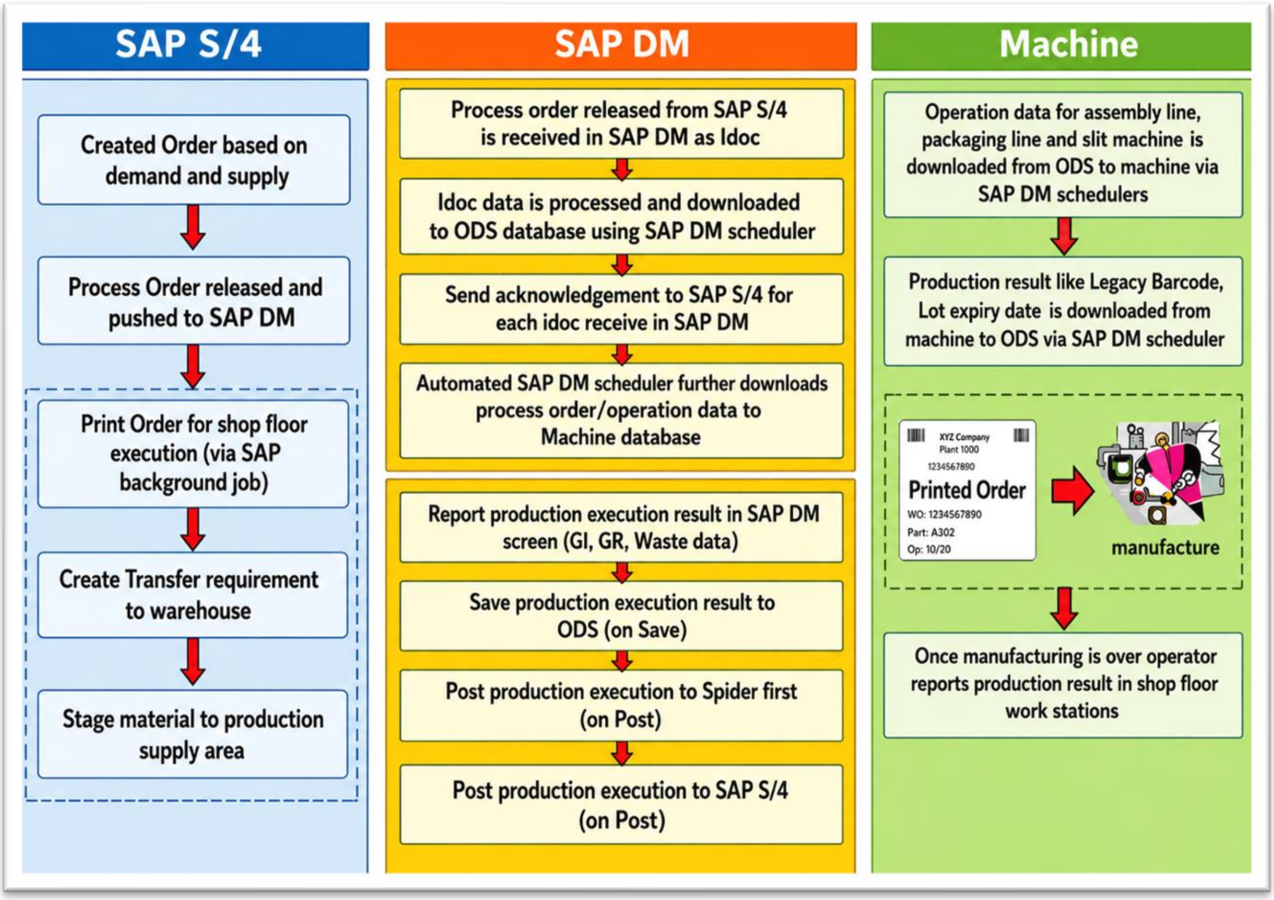

Figure 8: Process Steps

4.1 Manufacturing and Testing running on multiple standalone systems

- These were not well integrated with each other.
- Manual interventions in the process resulted in human error and subsequently caused product non-conformance.
- Outdated systems with scalability, product support, and compliance issues.
- High losses and long elapsed time due to standalone system and application.
- High nonconformities and low quality and regulatory confidence.

This solution framework removing the boundaries of functional system silos.

4.2 Manufacturing starts with a complex Formulation of Diagnostics Pharmaceutical Ingredients as shown in *Figure 9.*

- Formulation Process - for Coating Solution manufacturing
- Calculation chemical quantities based on Potency of active ingredients
- Coating Process – for coating the Solution on film rolls
- Imperfection Tracking Process – for recording non-conformity imperfection tracking across the entire roll
- Slitting Process – to cut coated rolls into slits
- Slide Assembly Process – to cut slits into slides
- Packaging Process - packing of slides
- Manufacturing of Analyzer Equipment.

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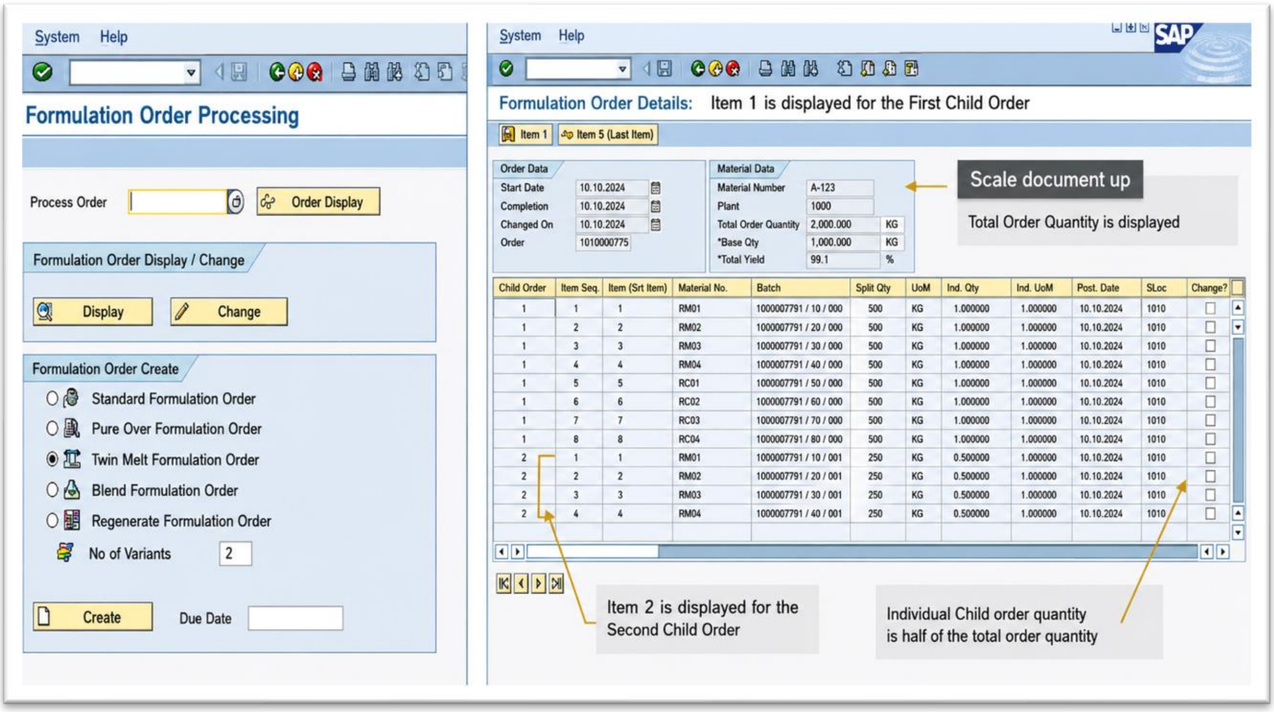

Figure 9 Drug Formulation Screen

4.2 Primary Packaging and Labelling Medical Device

- Sends process Instruction from transaction system to machine and
- Receives labelled and packaged Bottle/Vial/Syringes information from Machine and main transaction system of records.
- Consumption of correct label and Legibility of Labels
- Labelling 100% accountabilities as per FDA-USA 21 CFR 211 Subpart F

4.3 Imperfection/non-conformance tracking and Alert Mechanism

A configurable, custom-logic-based functionality enables systematic tracking of imperfections identified across production batches and supports downstream manufacturing operations in their effective removal or disposition. The functionality provides a geometrical representation of imperfections and nonconformities in both the lengthwise and widthwise directions, enabling manufacturing personnel to accurately identify their location and facilitate appropriate alerts and corrective actions, as illustrated in **Figure 10. Imperfection Tracking**.

This functionality supports compliance with applicable FDA and ISO quality requirements by ensuring that nonconforming material is identified, appropriately segregated or flagged for removal, and prevented from progressing to subsequent manufacturing stages or being released for further processing. The associated monitoring and visualization capabilities are presented through the **Imperfection Tracking Dashboard**, as illustrated in **Figure 11. Imperfection Tracking Dashboard**.

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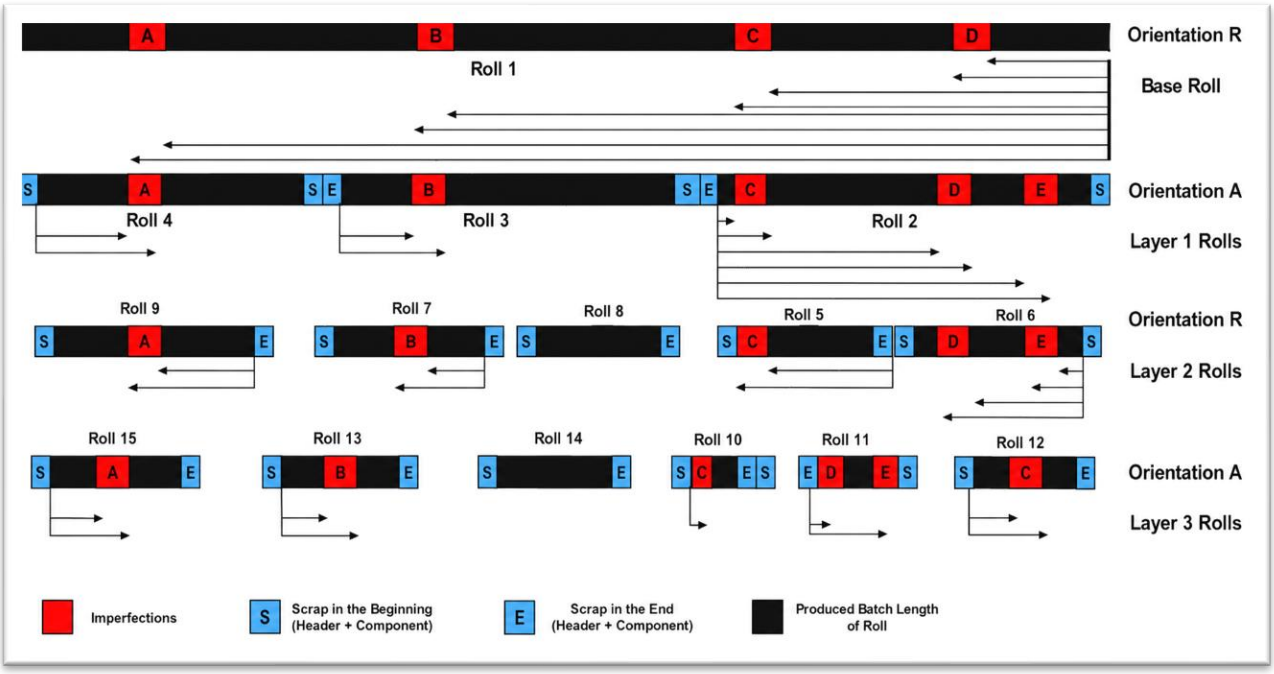

Figure 10 Imperfection Tracking

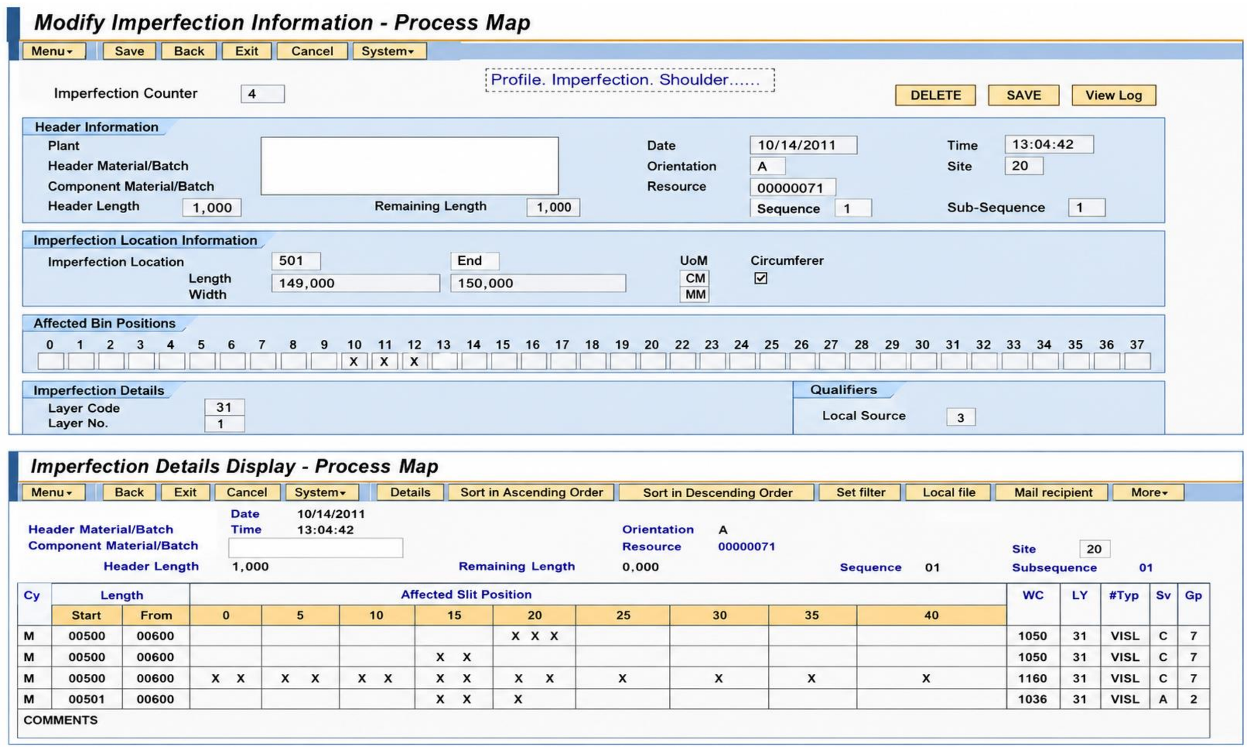

Figure 11 Imperfection Tracking Dashboard

5. CONCLUSION:

The pharmaceutical manufacturing industry is undergoing a fundamental transition toward resilient, and digitally enabled manufacturing systems. This transformation is strongly supported by the U.S. Food and Drug Administration (FDA), which has emphasized the adoption of advanced manufacturing technologies to strengthen the resilience of the U.S. medical supply chain and expand domestic pharmaceutical manufacturing capabilities.

In January 2021, the FDA and the National Institute of Standards and Technology (NIST) further reinforced this direction through a Memorandum of Understanding (MOU) aimed at promoting smart manufacturing technologies, emerging manufacturing processes, and the application of artificial intelligence (AI) and machine learning (ML).

The approach presented in this paper demonstrates how enterprise platforms such as SAP can serve as a foundation for conerting strategic objectives into practical Industry 4.0 capabilities in manufacturing. By integrating manufacturing execution, enterprise resource planning, real-time data, and intelligent decision-making, organizations can progressively evolve from conventional automation toward **adaptive manufacturing, intelligent automation, AI-enabled operations, digital twins, and digital threads**. Such integration creates a connected manufacturing ecosystem in which information can flow seamlessly across planning, production, quality, and supply-chain processes, enabling greater visibility, traceability, agility, and operational resilience.

Ultimately, the convergence of **SAP-based enterprise integration with advanced manufacturing technologies** provides a scalable pathway for realizing the vision of Pharma 4.0. It enables manufacturers not only to automate existing processes but also to establish intelligent, data-driven operations capable of continuously adapting to changing production conditions and quality requirements. This transformation has the potential to improve manufacturing efficiency and product quality while strengthening supply-chain resilience and accelerating the transition toward a more autonomous, responsive, and sustainable pharmaceutical manufacturing paradigm.

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Conflict of Interest: The authors declare that there are no conflict of interest regarding this article.

REFERENCE:

[1] Lasi H, Fettke P, Kemper HG, Feld T, Hoffmann M. Industry 4.0. Bus Inf Syst Eng. 2014;6(4):239-242. doi:10.1007/s12599-014-0334-4.
[2] Lee J, Bagheri B, Kao HA. A cyber-physical systems architecture for Industry 4.0-based manufacturing systems. Manuf Lett. 2015;3:18-23. doi:10.1016/j.mfglet.2014.12.001.
[3] Lu Y. Industry 4.0: a survey on technologies, applications and open research issues. J Ind Inf Integr. 2017;6:1-10. doi:10.1016/j.jii.2017.04.005.
[4] Hermann M, Pentek T, Otto B. Design principles for Industrie 4.0 scenarios. In: Proceedings of the 49th Hawaii International Conference on System Sciences; 2016 Jan 5-8; Koloa, HI. IEEE; 2016. p.3928-3937. doi:10.1109/HICSS.2016.488.
[5] Tao F, Zhang H, Liu A, Nee AYC. Digital twin in industry: state-of-the-art. IEEE Trans Syst Man Cybern Syst. 2019;49(1):1-15. doi:10.1109/TSMC.2018.2876863.
[6] Tao F, Qi Q, Wang L, Nee AYC. Digital twins and cyber-physical systems toward smart manufacturing and Industry 4.0: correlation, collaboration, cognition. Engineering. 2019;5(4):653-661. doi:10.1016/j.eng.2019.01.014.
[7] International Society of Automation. Enterprise-Control System Integration—Part 1: Models and Terminology. ANSI/ISA-95.00.01-2025 (IEC 62264-1 Mod). Research Triangle Park (NC): International Society of Automation; 2025.
[8] International Society of Automation. Enterprise-Control System Integration—Part 5: Business-to-Manufacturing Transactions. ANSI/ISA-95.00.05-2018. Research Triangle Park (NC): International Society of Automation; 2018.
[9] SAP SE. SAP Manufacturing Integration and Intelligence [Internet]. Walldorf (Germany): SAP SE; 2026 [cited 2026 Aug 17]. Available from: SAP Help Portal.
[10] Womack JP, Jones DT. Lean Thinking: Banish Waste and Create Wealth in Your Corporation. Rev ed. New York: Free Press; 2003.
[11] Goldratt EM, Cox J. The Goal: A Process of Ongoing Improvement. 3rd rev ed. Great Barrington (MA): North River Press; 2004.
[12] Ohno T. Toyota Production System: Beyond Large-Scale Production. Portland (OR): Productivity Press; 1988.
[13] Ishikawa K. Guide to Quality Control. 2nd rev ed. Tokyo: Asian Productivity Organization; 1986.