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White Paper on “Shipping under quarantine to use quarantine for transit”

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Abstract - This is a unique supply chain concept of utilizing the quarantine time in productive way to improve efficiency without additional investment by leveraging existed integrated supply-chain technologies. It represents a paradigm shift for MedTech and pharmaceutical companies — moving from extended supply-chain practices to an orchestrated supply chain that strengthens the company’s bottom line, better serves patient needs, and supports environmental sustainability.

In general, standard supply-chain practice entails manufacturing followed by quality inspection and batch-release activities. Production captures, records and documents all product and process related to Critical Quality Attributes (CQAs) documented. Following production completion, each batch is transferred to Quality for inspection and the *batch’s shelf-life countdown commences*. As illustrated in Schematic Diagram 1.

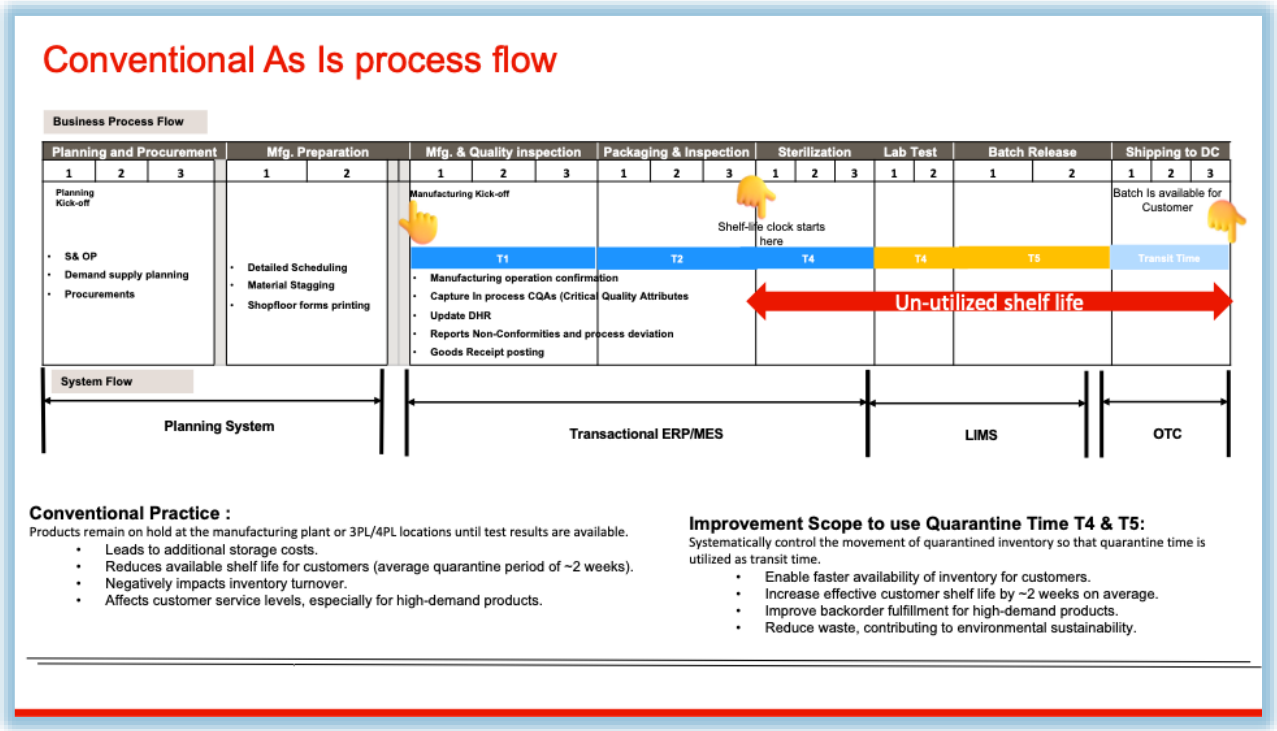

Figure 1-Flow of product from Mfg. Plant to Distribution Center

WHAT IS TRAVEL UNDER QUARANTINE:

Instead of quarantine a finished goods batch under quality stock at the manufacturing facility, or a sterilization site, or a 3PL/4PL logistics location, allowed systematically controlled shipment of inventory prior to final quality release is called “**Shipping Under Quarantine**”. But this is supreme important to ensure the followings

1. Stringent quarantine control complies with quality system requirement ensure 100% patient safety.
2. Comply with all statutory/regulatory guideline across the geographies.
3. Close systematic integration between Manufacturing ERP and OTC system.

Sellable batches can be moved from the manufacturing site to an DC site during unproductive quarantine time This physical inventory deployment typically takes an additional 2–4 weeks to reach global hub DCs. Once the batch is released, the product

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becomes immediately available for customer fulfillment, effectively providing customers with an extra 4–6 weeks of usable shelf life.

WHY DOES THIS IMPORTANT TO INDUSTRY?

On average, the pharmaceutical industry experiences value leakage of about 2% to 5%, which amounts to multi billions annually worldwide, driven largely by expiry and distribution inefficiencies. If the unproductive idle time in the supply chain can be repurposed under appropriate controls, the usable life of medical devices, implants, and lifesaving medicines could potentially be extended by approximately 1–1.5 months and redirected to patients in need, while optimizing supply-chain waste and storage cost.

Furthermore, this approach enhances inventory turnover ratios and improves overall supply chain efficiency without requiring incremental investment.

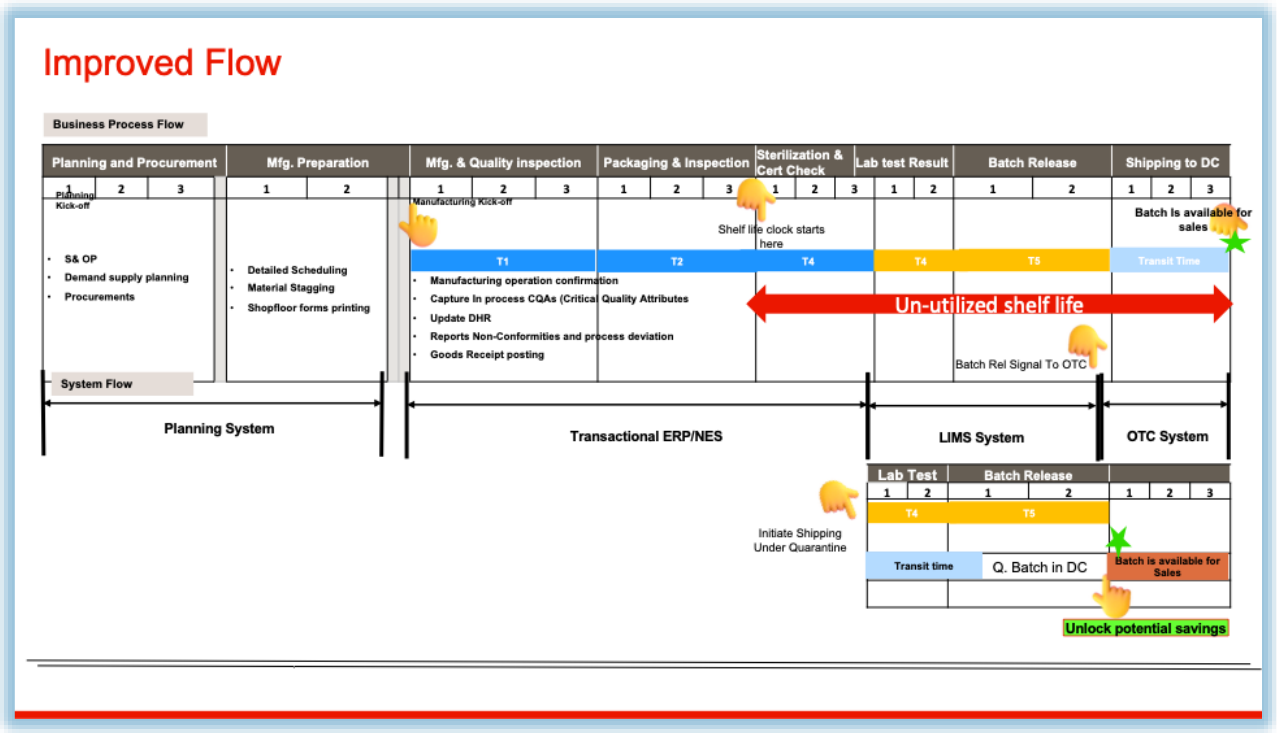

Figure 2- Process flow with SUQ

FUNCTIONAL DESIGN OF SUQ

1. **Define short term Master Inspection Characteristics:** Define inspection parameters to capture in-process and product conformity results prior to granting conditional release for shipment under quarantine.
2. **Long Term Master Inspection Characteristics:** Define inspection parameters to record long lead-time laboratory test results (such as *1 **Bio Burden** and *2 **Endotoxin testing etc..)**
3. **Conditional Release:** Configure a release code to enable conditional release of batch inventory and set the batch status to *Restricted*. Conditional Usage Decision (UD) is granted once all short-term inspection results are approved.
4. **Shipping Under Quarantine:** Allow conditional UD to initiate shipment while long-term test results are pending. Send a systematic ASN to the Order-to-Cash (OTC) system with restricted batch status and appropriate hold codes.
5. **Controlled Stock Transfer:** Establish a systematic stock transfer process to enable controlled movement from the Make (ERP) system to the OTC ERP system.
6. **Quarantine Handling at Distribution Center**: Receive products under restricted status and maintain them in quarantine at the distribution center awaiting final. (Quarantine wait time at the manufacturing plant is effectively utilized for pick, pack, and shipping.)
7. **Final Release:** Provide final release of the batch once all lab test results are approved.

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8. **System Integration:** Batch outbound integration using SAP Business Technology Platform between manufacturing and OTC systems release the batch automatically else manual communication to be sent to DC for release the batch from quarantine.
9. **Customer Availability:** Upon final release, the batch becomes fully available for customer distribution.

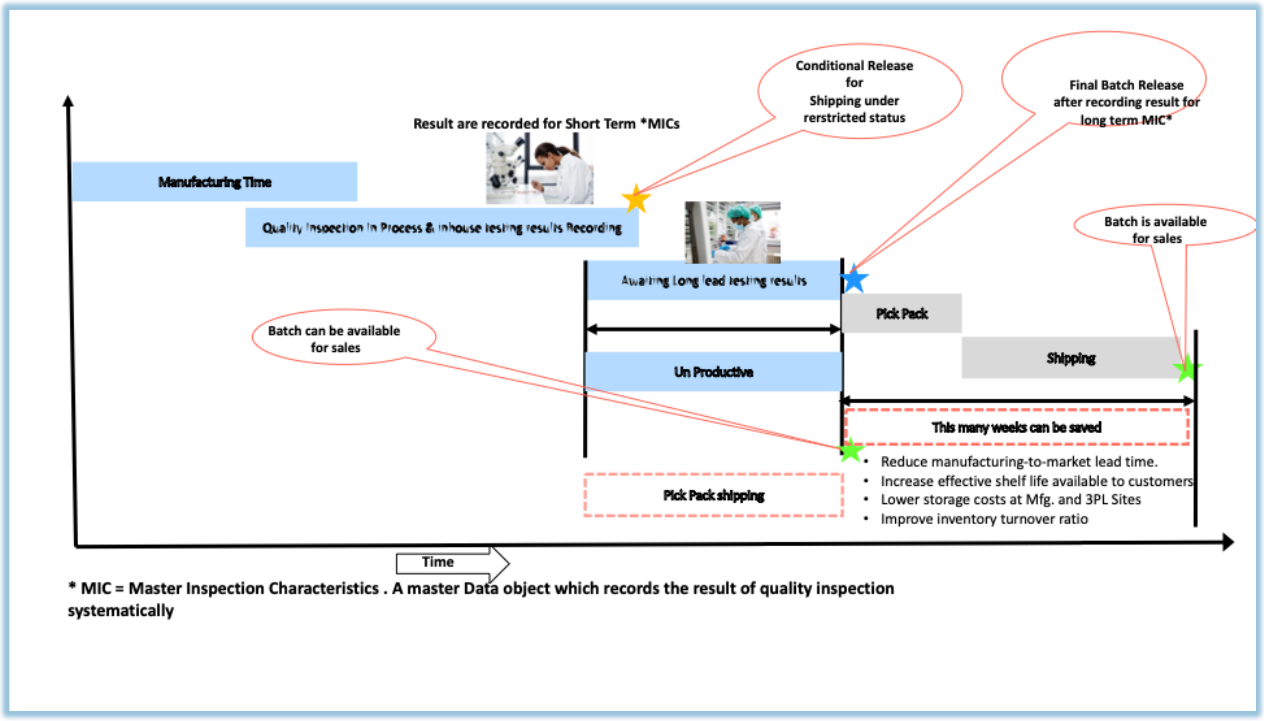

Figure 3- Schematic representation of SUQ concept

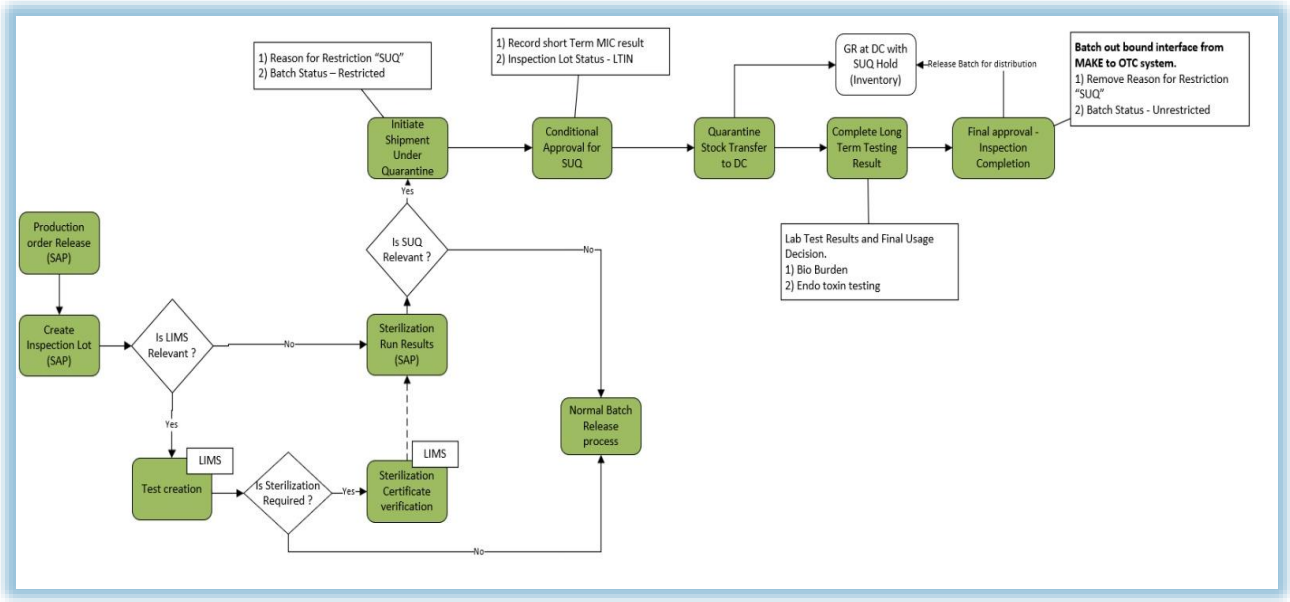

Figure 4 -SUQ Technical process flow

WHAT ARE THE CHALLENGES:

- Conservative mindset; limited evaluation of SAP's integration capabilities.

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- Heterogeneous and fragmented supply chain Eco-system.
- Siloed operations and manual controls across manufacturing and OTC sites, including separate systems and ownership.
- Separate QMS procedures and SOPs for manufacturing sites and distribution hubs.

WHAT IS THE SUCCESS STORY?

This indigenous SUQ design has been successfully implemented in the MedTech sector—particularly in surgical and implant businesses—delivering over **USD 10 million** in tangible benefits. Given its proven impact, the solution is now being scaled for global rollout to unlock its full, multifaceted value across the enterprise.

Appendix

Acronym	Description	Comments
QI Stock	Quality Inspection Stock	Quarantine Stock before final batch release.
CQA	Critical Quality attributes	Dom, Expiry Date, Status, etc..
NC	Non-Conformance	Product deviation from approved product specification.
GXP	Good X Practice	X represents Manufacturing, Laboratory, Clinical etc.
DC	Distribution Center	Supply chain entity responsible for distribution of products for defined geo location.
TUQ	Travel Under Quarantine	Allowed systematically controlled shipment of inventory prior to final quality release.
GR	Goods Receipt	Receiving inventory in systematic locations.
OTC	Order to Cash	System used to serve customer sales order replenishment in distribution center.
MIC	Master Inspection Characteristics	Data elements to store inspection result.
SAP	ERP software	

Table 1 - Key Acronyms

Glossaries:

*1 **Bio Burden** Testing quantifies the number of viable microorganisms present on a product, raw material, or surface before and after sterilization. It is a crucial quality control step in manufacturing to ensure product safety, regulatory compliance, and to inform sterilization processes, such as determining the correct radiation dose for medical devices

*2 Endotoxin **testing** is a critical process in the pharmaceutical and medical device industries to detect and measure bacterial endotoxins.

KEY DEFINITIONS:

1. Shelf Life and Expiry date

Chemical and physical property of pharmaceutical retains its permissible characteristics up to a finite number of days which is determined empirically basis on clinical and laboratory experiments and trials is called Shelf life. Last date marks the last day of the batch's specified shelf life is exhausted.

Expiry Date = Date of Manufacturing + Shelf Life (usually maintained in number days)

2. Remaining shelf life /

No of days left before a batch becomes unusable, calculated from the current date until its expiration date.

3. Customer specific shelf life:

No of days minimum remaining days of life customer wants when customer receives the product.

4. Master Inspection characteristics:

Quality master data to record the qualitative and quantitative inspection results. There are two types of inspection characteristics, i) Short term Inspection characteristics ii) Long Term Inspection Characteristics