

# TAMING VOLATILITY IN PHARMA MANUFACTURING

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**Aligning SKUs,  
changeovers, and inventory  
to unlock capacity and cash**

## Why volatility, not volume, breaks pharma manufacturing

Pharmaceutical manufacturing environments are rarely constrained by nominal capacity alone.

More often, performance deteriorates because demand volatility is not translated into an executable production and inventory model.

Large SKU portfolios and volatile demand erode capacity, inflate stocks, and destabilize service. These utilization losses are hidden in plain sight; chronically low OEE (overall equipment effectiveness) is often accepted as an inevitable 'cost of complexity' rather than a consequence of scheduling and lot sizes that multiply changeovers.

The core challenge is not demand volatility itself. It is the failure to align production, changeovers, and inventory rules to the volatility profile of the SKU portfolio.

**In pharma manufacturing, not every SKU deserves the same production logic.**

## Segmenting the SKU portfolio by demand behavior

Effective execution starts with differentiating SKUs, not treating them as equal.

Pharma portfolios typically contain:

- High-volume, stable SKUs with predictable demand
- Medium runners with moderate variability
- Low-volume, highly volatile SKUs with irregular demand patterns

Without segmentation, scheduling decisions default to local optimization – maximizing short-term throughput while quietly increasing machine changeover frequency and inventory.

A robust execution model explicitly classifies SKUs based on:

- Demand variability and forecast stability
- Volume contribution
- Margin and strategic relevance
- Operational burden (machine changeovers, cleaning, qualification)

This segmentation becomes the anchor for production cadence, lot sizing, and inventory rules.

**Changeovers: the hidden capacity constraint**

In pharma, equipment changeovers are a structural plant capacity

consumer as measured in the OEE (overall equipment effectiveness).

Frequent product switches drive:

- Loss of productive machine hours
- Increased labor intensity
- Higher quality and compliance risk
- Instability in production plans

Execution excellence requires **explicitly linking SKU segmentation to changeover behavior.**

Key principles include:

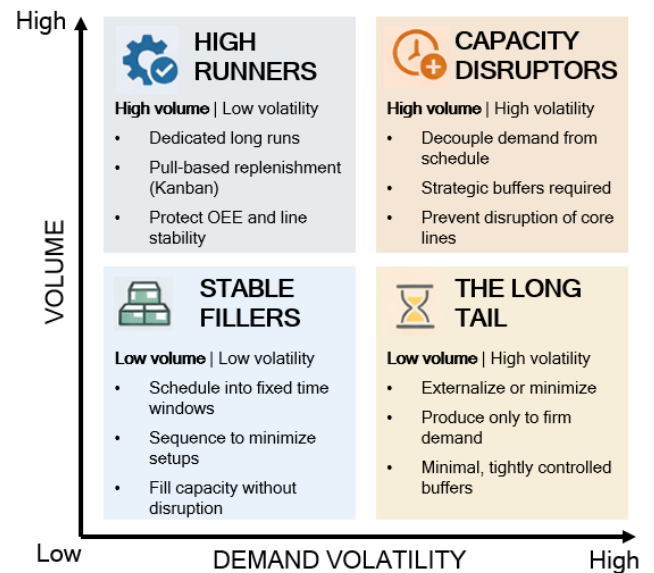
- Concentrating high-volume, stable SKUs into longer production runs
- Bundling similar products to minimize cleaning and setup effort
- Actively limiting the number of SKUs assigned to high-constraint machines
- Scheduling volatile, low-volume SKUs into defined windows rather than continuous interruption or even outsourcing them

This shifts changeovers from an unmanaged consequence to a **steered operational decision.**

**Lot sizing as an execution lever, not a planning artifact**

Lot sizes sit at the intersection of demand, capacity, and inventory – lot sizes determine how often you lose capacity.

SKU EXECUTION MATRIX



Small lots increase flexibility but multiply changeovers. Large lots improve utilization but inflate stock and risk obsolescence.

A disciplined execution model aligns lot sizes to:

- SKU volatility class: Tailoring lot sizes to the specific demand profile to ensure stability across the portfolio
- The cost optimum: balance between changeover costs and the total costs of managing and holding inventory
- Shelf life and regulatory constraints: Ensuring optimal sizes remain compliant with hard stability and quality requirements
- Service level requirements: Protecting supply reliability while

minimizing the cash tied up in buffers

The objective is not theoretical optimization, but **reducing unnecessary changeovers while protecting service and cash.**

### Designing production cadence instead of reacting to orders

High-performing pharma operations move away from reactive scheduling.

Instead, they define **explicit production rhythms**, for example:

- Dedicated time blocks for high-volume SKUs
- Defined windows for volatile or low-volume products
- Clear sequencing rules to minimize setup losses

This transforms production planning from daily firefighting into **a repeatable execution system.**

## Stable cadence beats heroic scheduling.

**Inventory as a buffer – but a deliberate one**

Inventory is often treated as a failure of planning.

In reality, inventory is a **necessary execution buffer** – when deliberately designed.

Effective models distinguish between:

- Strategic buffers for high runners
- Minimal, tightly controlled buffers for volatile SKUs
- Explicit decoupling points between production stages

For stable SKUs, pull-based replenishment mechanisms (e.g., Kanban) help:

- Stabilize production
- Reduce rescheduling
- Smooth supplier interaction

The goal is not minimal inventory at all costs, but **inventory that absorbs volatility instead of amplifying it.**

### Aligning material flow with production logic

Production cadence only works if material flow supports it.

Execution-ready systems:

- Align supplier delivery frequencies to production rhythms
- Size buffers based on consumption, not forecasts
- Use pull mechanisms for high runners to protect flow stability

This reduces expediting, emergency production changes, and hidden capacity losses.

## What this enables

When demand behavior, changeovers, lot sizing, production cadence, and inventory are aligned, pharma manufacturers unlock:

- **Significant capacity gains**, such as transitioning from 3-shift to 2-shift operations and increasing effective utilization without new capital assets
- **OEE breakthroughs**, often increasing from 60% to 80% on high-constraint lines
- **Fewer changeovers** resulting in significantly lower compliance and quality risk
- **Lower inventory levels** paired with improved service reliability.
- **A production system that absorbs volatility** instead of reacting to it; execution becomes predictable and steerable, even in volatile environments