The Pharmaceutical Industry's Supply Chain Planning — Reliability and Risk Management

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Background – Increasing Production Complexity

New challenges, larger global markets, and developing complex compounds are stressing the supply chain of the leading pharmaceutical industry players. Increasing demand and greater complexity of regulatory requirements (e.g., fast to market) are stretching capacity while external events affect capabilities to accurately foresee demand and supply, raising the variability of planned versus actual. All this increasingly complex management is taking place in an industry that is trending toward consolidation.

The main drivers of pharmaceutical products' growth are aging populations in developed markets and growing populations and economic development in emerging markets. New products entail more sophisticated production processing, which complicates end-to-end planning and increases supply lead-time. Fast-to-market represents a key driver in securing market share. It remains a challenge for pharma players to maintain a high service level (measured by On-Time Shipment) and keep inventory under control.

Planning managers must account for events such as demand variability and process instability that can lead to a crisis, switching the leadership team to firefighting mode. Today's planning organization requires agility, flexibility, and foresight. It requires development of tools and practices to manage potential risks and enable management to target a certain service level in order to prevent stock-outs, which affect patients' health, company financials, and reputation.

Planning – a Key Element

Planning plays a key role in fitting demand forecasts and constraints into actions. Its main operational activities can be grouped into three main areas: long-term planning (MPS), scheduling, and requirement planning.

- **MPS** looks at the mid to long-term horizon. It combines inputs such as cycle time, demand volume forecast, operator hours, Bill of Material (BoM), and output per batch to provide a long-term plan to prevent shortages, costly expenditures, last minute scheduling, and inefficient allocation of resources. It is also the main contributor to capacity estimates and scenario analyses. When deciding which software and processes to adopt in the long term, a challenging trade-off is to define which

manufacturing constraints and level of sophistication to take into account. Planning parameters represent a clear example: The more parameters, the more precise the plan; yet, at the same time, the more complex to manage and keep up to date.

- **Scheduling** translates the long-term plan into a more detailed schedule for a shorter time period, normally 12 weeks, although in most complex environments (e.g., multipurpose plants), it may be 5 weeks. The schedule details the plan with all necessary info required by production (e.g., BoM required at a precise hour or minute during the day).
- **Requirement** planning uses the anticipated and actual demand and supply (e.g., supply of raw material) to manage the balance between supply and demand and assist in developing a master requirement plan.

As in many complex environments, these three areas are tightly connected to the rest of the organization's maintenance, engineering, and quality. Synchronization among functions becomes one of the most critical issues for performance losses, especially in the overall operation of multipurpose plants where different departments require constant alignment of tools and routines to prevent working in silos. A common example is preventive maintenance: planning needs to allocate a proper time slot in the schedule for maintenance intervention. Operations must ensure that equipment is free at the requested time or to promptly ask for rescheduling in case of delays. Technicians are required to run the intervention; cleaning and quality teams (although not in all cases) need to be ready after maintenance intervention to ensure equipment can restart immediately. The entire process necessitates extreme synchronization to run smoothly and to prevent idle times when equipment is on standby, waiting for the next operation.

Current planning organizations operate in a deterministic mode to create a master plan for the longer term and detailed schedules for the shorter term while choosing production and inventory levels as a safety buffer. Demand and supply variability are rarely considered in the plan: organizations normally plan at 100% capacity and expect an outcome that is the same as the plan. In reality, however, this rarely happens. Plan attainment is generally around 80%. A structured approach to stress test the plan does not usually occur. This exposes planning organizations to several risks:

- **Unrealistic expectations.** Plans based on the assumption of optimal resource utilization (equipment, operators, materials) entail few or no buffers (e.g., planning 95%-100% of capacity utilization). The organization is likely to end up in a situation where it is constantly under-delivering. As shown in Figure 1, the more aggressive the plan (e.g. assuming 100% capacity utilization), the less feasible it is.
- **Inconsistent expectations.** Plants often practice "lean manufacturing" methods such as low overhead and inventory and maximum equipment utilization, which stretch resources and lead to a greater likelihood of low plan attainment and create mismatched expectations, especially in big pharma where factories are part of global networks.
- **Insensitivity to external conditions.** Plans often pay little heed to external conditions and do not specify adjustments in response to variations.

When these conditions materialize, leadership is forced to act in crisis mode to mitigate the damage.

- **Low visibility of risks as a function of key variables.** Stretched resources carry a certain degree of risk related to service level loss.

Industry Cross-Contamination and Risk Management in Pharma

Risk management refers to the identification, assessment, and prioritization of risks (defined in ISO 31000 as the effect of uncertainty on objectives) followed by coordinated and economical application of resources to minimize, monitor, and control the probability and/or impact of uncertain events or to maximize the realization of opportunities. Risk management's objective is to ensure that uncertainty does not prevent the realization of the business goals*.

Risk management adds value in many industry sectors, including pharmaceuticals. A structured system of risk identification, assessment of impact, definition of scenarios, and identification of mitigation actions allows planning organizations to manage uncertainty more efficiently. Figure 2 illustrates a high-level framework for sensitivity and scenario analysis, simulating a variation of different planning inputs (e.g., demand, cycle times). It is possible to understand the impact on different elements of the plan (MPS, inventory). This is critical to take a proactive approach toward potential adverse events (e.g., describing a worst case).

Inspiration for such approaches can be gathered from other industries such as portfolio risk management in banking and asset management.

As a general rule, the higher the level of variability, the higher the value a structured risk management approach can create. In the pharmaceutical industry, it is especially relevant in clinical supply chain and commercial supply chain sites (particularly when new pharmaceutical ingredients are involved).

Evolving Planning Organization with Risk Management Practices

To cope with variability drivers, pharmaceutical supply chain organizations are undergoing a process structured on around two main courses of action: (1) reduce variability and (2) create a production plan with key parameters

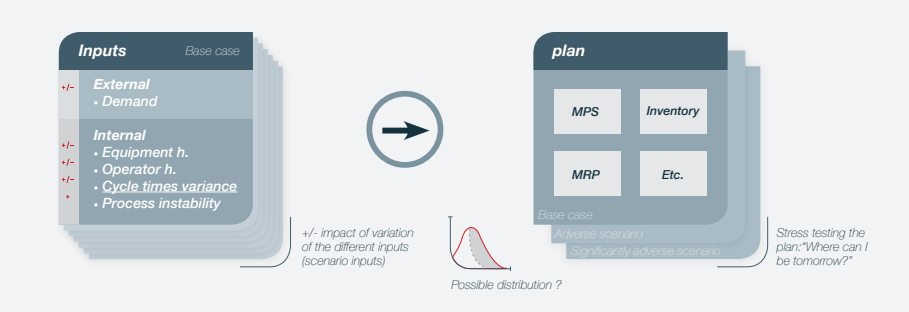

Figure 2. High-level framework for sensitivity and scenario analysis

* Ricardo Antunes , Rand icardo; Vicente Gonzalez, Vicente (3 March 2015),. "A Production Model for Construction: A Theoretical Framework,". Buildings 5 (1) (March 2015): 209–228.

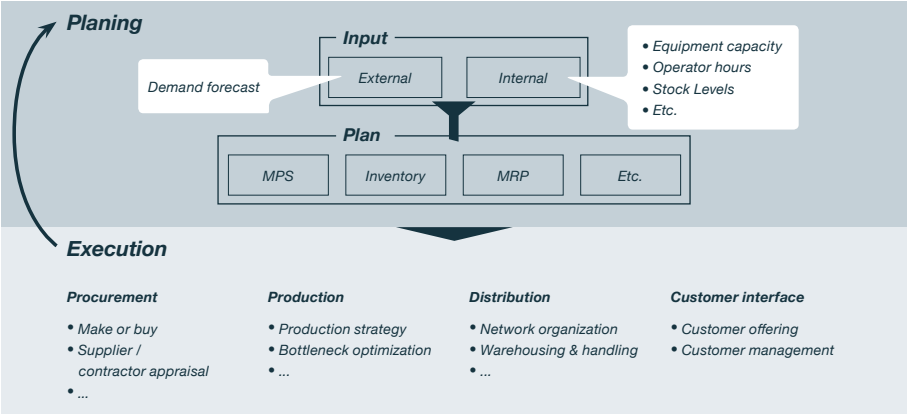

Figure 3. *Framework representing role of planning within an organization. Planning is the coordination point.*

taking this variability into account (e.g., target equipment occupancy).

The first course of action is more focused on levers devoted to minimizing root causes of variability (e.g., process or equipment failures). The second leverages on planning levers to establish an environment that foresees risks and sets actions to mitigate and cope with risk-realization impact.

As the focus of this article is planning levers, we will look at the second course of action.

Integrating variability (supply and demand) into planning means all the planning tasks mentioned (MPS, requirement planning, scheduling) can be integrated with tools and processes to manage risks.

The risk management process can be broken down into four phases:

1. Variability baseline measurement
2. Risks identification and potential mitigation actions
3. Definition of scenarios
4. Prioritization and development of a mitigation plan

Variability baseline measurement

The baseline is the measure of variability, which is defined as the distance between the plan and produced goods over a certain period of time. A measure such as "plan attainment" defines this timeframe as a quarter. Comparing the plan three months before, one month before, one week before, and at actual production date indicates the number of changes in the plan that occur regularly throughout the supply chain. This visualization often presents a compelling case for taking action because it exposes changes/losses to the plan and allows for the introduction of expected output as a "forecasted plan attainment."

Risk identification and potential mitigation actions

The establishment of a data-gathering system, such as tracking changes to the plan and attributing root causes based on a categorization system, allows for creating a database for further analysis and continuous improvement using Six Sigma tools. The development of such a system requires prior identification of risks, defined as the sources of variability (and therefore threats) to the realization of the desired outcome. A risk tree is built that clusters sources of variability by main

categories and develops into second- or third-level root causes.

Each risk has an associated frequency of realization and a level of potential impact on the plan. Historical data analysis (or when unavailable, a structured qualitative estimation system) allows estimation of the distribution of impacts to the plan for every risk factor.

For every risk, there are four possible paths, depending on the current and potential impact of that risk:

1. Avoidance (eliminate – withdraw from or not become involved)
2. Reduction (optimize – mitigate)
3. Sharing (transfer – outsource or insure)
4. Retention (accept and budget)

Definition of scenarios

Development of scenarios represents a critical step, whereby the combination of the realization of a number of events leads to forecasted production. Scenarios allow stress-testing the plan. Each scenario is based on the realization of a number of values for each risk variable (The Monte Carlo simulation is an analytical method to determine different outcomes based on generated scenarios). Based on the created scenarios, decisions can be taken to mitigate risks to ensure the expected level of output.

Prioritization and development of a mitigation plan

The decision of which lever to activate depends on a number of factors (e.g., potential risk impact, timing, and the cost to pursue a certain path). Therefore, a risk factor analysis (based on the Pareto principle) allows prioritizing the critical risks to address and develop a mitigation plan.

Developing such a plan must consider that planning levers are timeframe-dependent:

- **Over the longer term.** Some options: outsourcing or reshuffling the product mix in production sites on the same network, making safety stock adjustment, or setting a different target equipment occupancy. Resupply strategies can be adjusted by estimating reorder stock levels based on historical performance and considering future expectations (e.g., expected higher volatility during certain months for a specific reason).
- **Over the shorter term.** Schedules can absorb variances and disturbances to the system by adjusting non-bottleneck cycle times or introducing less-aggressive standards.

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