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How Does Strategic Planning Help to Mitigate Risks in the Pharmaceutical Supply Chain

by Agnes Trouchaud

This article presents the implementation of a key strategic planning process to mitigate risks in GSK's API supply chain; it was adapted from an ISPE France presentation held in June 2013.

Because of the quick evolution of its portfolio, including a significant number of new product launches, molecules going off-patent, and increasing financial constraints, GSK has to manage a more complex supply chain making it even more critical to optimally manage its primary API supply.

In an effort to better manage risk, GSK has implemented a key strategic planning process to help identify the risks associated with the product lifecycle, their market, and the global supply chain, enabling them to successfully study and launch projects.

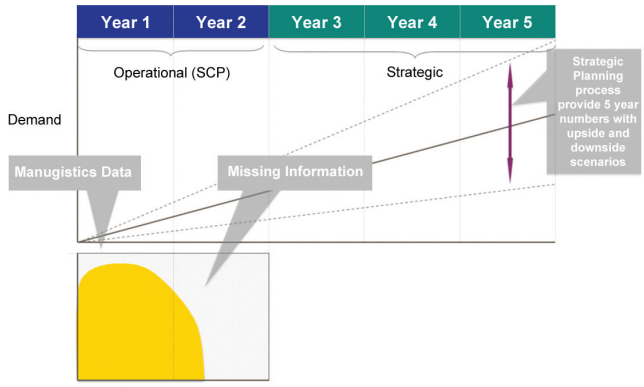

Figure 1. API planning levels.

With the implementation of robust planning processes, GSK is able to work toward its goal to have continuous control over the proper size of the network – an important part of its program of excellence.

To put it in context, GSK has 37 secondary sites which produce a large variety of drugs, including oncology, respiratory, infectious diseases, HIV, neurosciences, cardiovascular, metabolic, etc. It has eight internal sites and approximately 200 external sub-contractors that supply more than 300 APIs. Among those, 80 are managed by the Primary Business Planning (PBP) team responsible for either revenue or medically critical drug products, including New Chemical Entities (NCE).

Main Characteristics of the Primary Supply Chain

GSK follows a "Make to Forecast" model based on commercial forecasts to determine when to manufacture primary (API); while the decision to move forward with secondary manufacturing is based on a "Make to Order" model. The focus of this article is on GSK's strategy for mitigating risks in its primary pharmaceuticals supply chain; secondary manufacturing is not discussed.

The "Make to Forecast" model is mainly driven by the long manufacturing lead times for APIs (some are more than 12 months) due to:

- Multi-stage processes with a multiplication of the number of chemical steps to obtain an API

Figure 2. Key supply chain processes.

- Campaign effect of batch processing
- Capacity limitation due to interaction of processes on multi-purpose plant
- Labor restricted use of plant
- Long lead time to implement extra capacity

The "Make to Forecast" model is also driven by raw materials, intermediates, and API's procurement constraints with:

- Long procuring raw material processes (some up to nine months)
- Growing expenditures and use of external suppliers requiring longer lead times
- Contractual obligations with the suppliers (some requiring firm order 3 years in advance) with few "Take or Buy" contracts in place
- "Turn on and off" impossible at short notice without losing credibility and flexibility with the suppliers

Today, API facilities are manufacturing what was decided two to three years ago. As a result, under forecasting can lead to supply constraints, which may take years to recover from, making it even more critical to have robust planning processes in place to understand and anticipate forecasts variability.

Two levels of API planning: operational/tactical and strategic – each one having its own process and data are depicted in Figure 1.

The purpose of operational/tactical planning is to manage firm sensitivities and operational changes within a 2 year timeframe. This is done through a site based monthly process (Supply Chain Planning process) and is made up of a number of sub process steps: demand review, capacity review and consolidation and scenario planning. Purpose of this SCP process to first ensure that supply meet demand with maintaining the appropriate stock level but also to highlight any demand sensitivities and derived capacity constraints through scenario planning. A monthly Above Site SCP review is then held, purpose of which is to endorse production/supply plans and to make decisions on option/recommendation to mitigate notably risk of supply interruptions.

Strategic planning focuses on year 3 + timeframe. Strategic planning consists of two main sub processes: long term demand review (carried out through Product Review Forum process) and long term capacity review that followed the demand review. Strategic planning leads to more strategic decisions, such as investment on site, introduction of new API sources.

Risks on the Primary Supply Chain

GSK used a set of standard Ishikawa diagrams to define the type of risks that could possibly impact its supply chain. In parallel to using Ishikawa diagrams, GSK performed a SWOT analysis (strength/weakness – opportunity/threat) as well conducted audits, specific studies, and operational measurements. Figure 2 presents the model used by GSK's Global Manufacturing System.

More details are provided in the Ishikawa (fishbone) diagrams located at www.pharmaceuticalengineering.org.

Planning and Risk Management Processes and Tools

There are Two Key Principles to Supply Risk Management

- Consider risk to supply situations (catastrophic loss, step

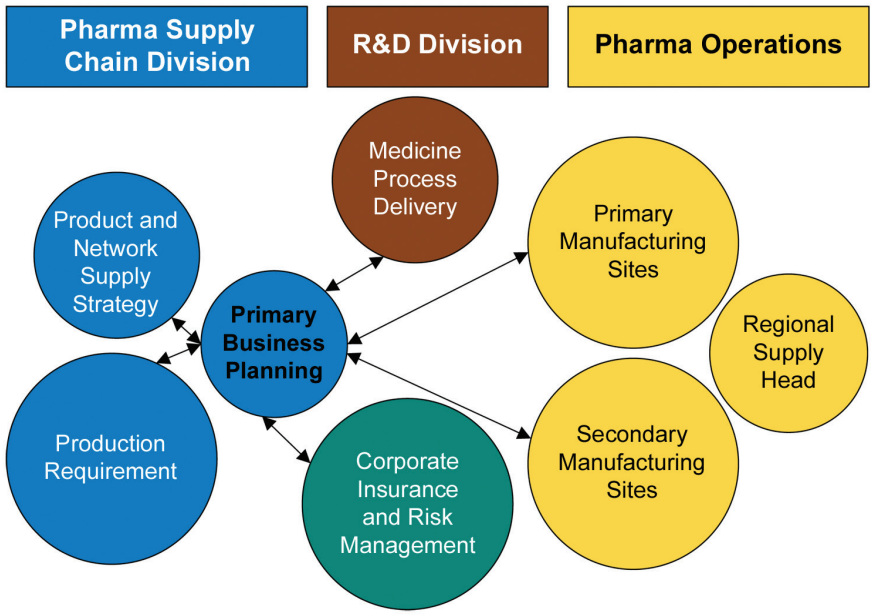

Figure 3. The key roles of PBP and its relationships in the whole structure.

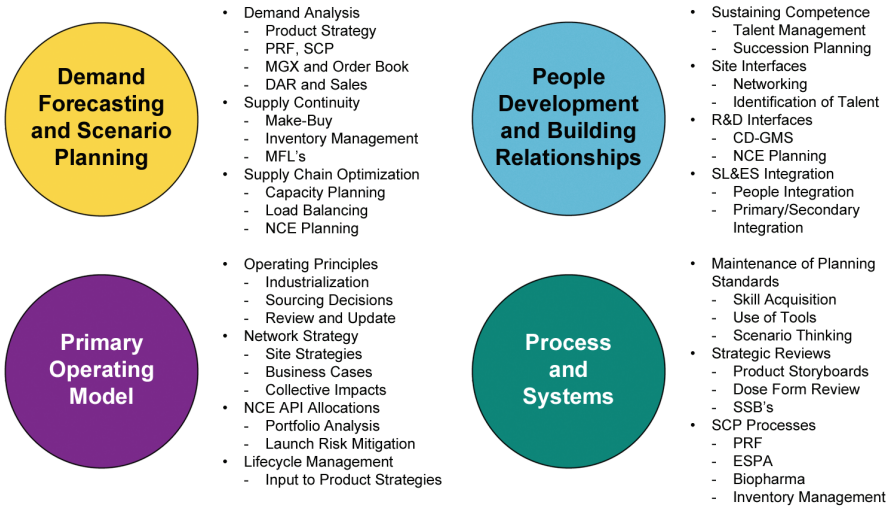

Figure 4. The four main competencies of PBP.

increase in demand, etc.)

- Organize workshops involving the sites, the Primary Business Planning (PBP) team, and the Procurement and Strategy teams to review the risks for the critical internal sites and third parties; review and agree on what to do to mitigate the risks - *Figure 3 and Figure 4*.

Product Review Forum (PRF), the Strategic Planning Process

The Product Review Forum (PRF) is at the cornerstone of API demand forecasting and scenario planning. This annual process consists of a 5 years demand review and of the supply plan to meet this demand. The key competence for this process is the ability to understand the long term business requirements to ensure what we make/buy today will maintain appropriate inventory levels. The purpose of the demand review is to agree the best view of the demand but also to understand all possible demand scenarios.

The PRF must review and identify drivers of upside and downside demand, what will be impacted as a result, particularly the external supply chain, develop responses to all scenarios with timeframe and costs, consider any technical difficulties and resolution time, and finally understand when to implement a response. The commercial group will conduct this review once a year or more often depending on the urgency.

The PRF is an event that is organized once a year. It supports the Supply Chain Planning (SCP) demand review process (0 to 2 years), but does not replace it. The PRF identifies what drives the sensitivities that then need to be tracked through the SCP process - *Figure 5*.

The PRF provides a five year demand which allows capacity utilization to be forecasted for commercialized products using standard templates and definitions. A forecast for new products based on a standard model (developed by R&D) of likely launch success and upside launch success is overlaid on the commercialized products. Site and network capacity utilization graphs are then developed for capacity of various types of internal and external manufacturing resources – large, medium, small or special. Scenario planning will allow decisions to be made in the long term around sourcing strategies and tactical use of plant for the retention of capability.

It is important to ensure that tactical use of a plant will align with the long term strategy for the site and the external supply chain. It is too easy to be focused on short-term operational benefits without understanding what this will mean in the long term – particularly the loss of flexibility and potential increased costs.

It is common in many companies to analyze risks continuously by updating the risk management process map and the resulting score matrix (probability of occurrence multiplied by impact). An exception to this scenario is when there is no way to mitigate the risk, which leads to a plan aimed at eliminating the root cause of the risks, minimizing their impact, decreasing their probability of occurrence, or transferring or sharing the risks.

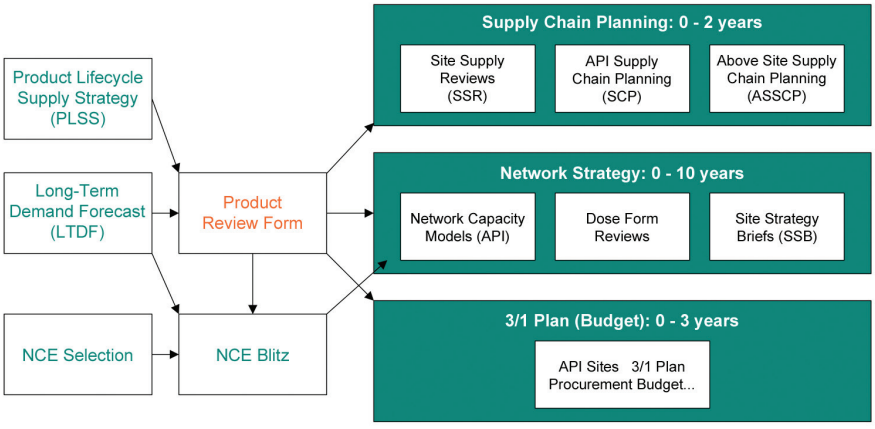

Figure 5. Key strategic and tactical planning processes.

Focus on Outsourcing

Shortages in the supply chain may actually occur at suppliers and subcontractors sites; therefore, the same risk management rules must be applied

to external sites. Those risks must be mitigated by implementing a robust Business Continuity Plan and processes to ensure that those sites do not add additional risk to the supply chain. Three key axes are taken into considering: security of supply, quality/regulatory, and performance as seen in Table A.

Security of Supply
• Understand the Supply Market Size, Importance of pharma supply as well as GSK in the market
• Stockholding/Safety Stock (quantity/time/money) *Raw intermediates plus final product to GSK safety stock at GSK and Suppliers. Is it all located in one place or multiple? Last time checked/covered by contract?*
• Sole supplier/multi-sourced?
• Capacity constraints *Industry as a whole and individual suppliers*
• Lead-times
• BCP Supplier Disaster Recover plans in place?
• EHS Audit Status
• Logicstics and distribution plans/methodologies
• Geography *Lead times implication, areas of natural risk*
Regulatory
• Annual Updates
• Registered Supplier/Site/Commodity
• Time taken to approve alternative suppliers/site of manufacture
• Number of regulatory events that GSK will have to manage as a result of change
• Supplier willingness to be audited by regulatory bodies
• Supplier performance in regulatory audits, e.g., FDA
• Stability testing required to change supplier
Quality
• Last audit status? (full approved/conditionally approved/not approved)
• Critical findings?
Performance History
• Customer feedback
• Relationship management – proactive/reactive

Table A. Three axes: security of supply, quality/regulatory and performance.

GSK has implemented a process to help evaluate the threat every supplier potentially poses to the product supply chain by completing an internal questionnaire dedicated to risk scoring and by submitting it to an internal expert. This API supplier questionnaire may be developed using elements from a standard survey and a Q7-GxP survey.

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Depending on the result, this may trigger a Loss Prevention Audit by the Insurance and Risk Management (IRM) Department, which could result in the Supply Chain Manager, the Procurement Manager, and IRM generating an action plan. This action plan or realistic risk improvement strategy should be implemented over an agreed timeframe with the supplier. If an audit is not triggered, the Supply Chain Managers involved must make sure that Business Continuity Plans issued by Corporate Insurance and Risk Management group are in place at an appropriate level.

Conclusion

There are three main benefits of developing a process for API strategic planning:

- A better alignment between the long term business strategy and the order management process
- A better consistency between the plans built to meet the markets requirements at the best cost
- An implementation of protection measures and risk management rules which secure continuously the appropriate stock levels

About the Author

Agnes Trouchaud is a Senior Analyst working at the Supply Chain Strategic Division of GSK Pharmaceuticals in London. She had worked for more than six years at the API Strategic and Tactical Planning department of GSK Pharmaceuticals. After completing her studies at Rennes Business School and Ecole des Mines de Paris, she worked successively for Leo Animal Health and Ipsen Laboratories on Supply Chain projects. She can be contacted by email: agnes.x.trouchard@gsk.com.