Insuring success by implementing a pragmatic Demand & Supply decision support for start-ups and product launches.

This White Paper provides an overview on supply chain integrated planning solutions developed by Supply Chain Operations SA.

Authors:

- Laurent Foetisch, Supply Chain Operations SA
- María Luz Monterrubio, Supply Chain Operations SA

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Within the pharmaceutical and biotech supply chain, many small to medium start-up companies struggle to design and implement a planning, scenario building and inventory monitoring tool. Based on the Demand data and the Supply configuration and constraints, a planning engine is proposed to compute Finished Product, Drug Product and Drug Substance requirements. The engine should allow what-if scenario analysis evaluating changes in the Demand or the Supply patterns or in the value chain operational parameters. A risk assessment method, based on Monte Carlo simulation, may be also integrated.

1. Introduction

Supply Chain practitioners in small to medium start-up companies in the pharmaceutical sector face a number of specific challenges; a small but dynamic demand base, outsourced supply networks, frequent changes to launch programmes. Effective planning decisions are hampered by the lack of visibility over the supply network inventories and access to intuitive planning support tools. This White Paper describes how a pragmatic planning engine, making use of existing demand and supply information, can address the growth ambitions of start-ups and provide valuable support during the critical product launch phases.

Demand-Driven forecasting and quantitative forecasting methods have been known and used for decades. The main objective is always to bring together all elements required to support demand forecasting from a fact-based perspective. Demand forecasting includes commercial products as well as clinical material and/or Early Access Program (EAP) quantities. Once demand data are consolidated and reorganised in an appropriate format and granularity, and upon completion of the supply chain network definition and parametrization, the engine computes the Finished Product (FP) requirements, the Drug Product (DP) requirements, the Drug Substance (DS) requirements and also any critical starting materials which may be needed in the manufacturing recipe of the DS.

The Demand and Supply Engine enables the company to simulate as many scenarios as required (base line, optimistic, pessimistic, …) and project inventory levels and coverages accordingly. Volume figures, as well as financial numbers, can be easily extracted and sent to internal or external functions to help them build their own sets of data.

A Monte Carlo risk assessment can be integrated into the planning engine in order to evaluate the robustness of the results.

The planning solution is particularly relevant for a company which does not have yet an ERP system (Enterprise Resource Planning) and is moving from a development stage to a commercial stage. Between 18 and 12 months prior to the first commercial product launch, inventory build-up needs to take place to secure product availability, taking into account all the manufacturing constraints as well as all the various lead-times (manufacturing, release, distribution, incoming, transportation, etc.).

The management of remaining shelf-life at any product stage and along the end-to-end supply chain has always be difficult to manage and to anticipate. With the Demand and Supply Engine, the company can model shelf-life requirements and constraints, and the engine will simulate inventory levels and show predictive obsolescence resulting from shelf-life limitations.

The Demand and Supply Engine provides a single set of data across the company and external partners in a consistent format over time. It is able to accommodate any planning horizon (usually minimum 24 months) in the required time buckets.

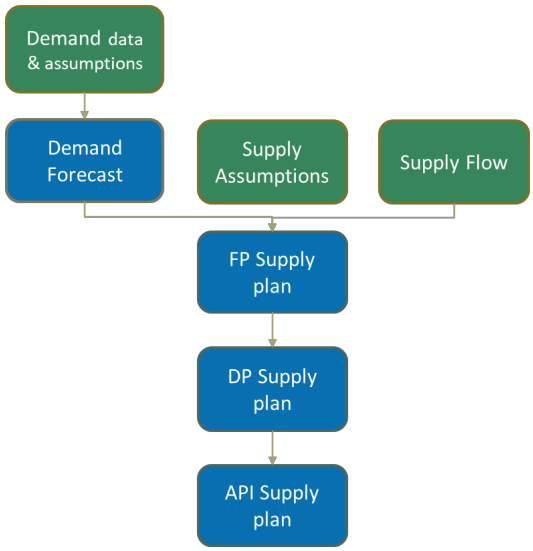
Typically, implementable in a few days depending on the availability of reliable data, it normally takes several iterations to reach a level of maturity which reflects as close as possible the company supply chain specificities and includes all the parameters which influence the planning cycles.

2. The Supply Chain flows and parametrization

A company's revenue predictions are only as strong as the supply chain management system, regardless of the size and complexity of the organization.

The supply chain flows and parameters must be captured and maintained dynamically. It is essential to keep full transparency over the supply chain "nuts and bolts" since they will be used for each forecast computation.

The supply chain network hierarchy and the Demand & Supply planning assumptions form the backbone of the Demand and Supply Engine. While the flows and the assumptions are essentially static data, the Demand data are the key dynamic inputs to the process.



The updated and integrated FP, DP and API (or DS) Supply plans are the main outputs of the process.

3. Demand Forecasting

In all business, in all industry sectors, there is no supply without Demand Forecasting.

The primary purpose of the Demand and Supply Engine is not to perform *Demand Sensing or Shaping* but rather to collect Demand data and assumptions over given time horizons, geographies and business units and convert it into a consolidated Demand Forecast with the appropriate format.

Demand Forecasting data should be comparable over consecutive submissions, quantifiable in both volume (units, containers, grams, boxes, cartons, etc.) and value (currencies, selling prices, standard prices, standard costs, etc.).

Should there be the need to have a sophisticated algorithm to help build the Demand, for example Bass diffusion models for new product penetration, bottom up or top down, the engine is easily adapted to match the company requirements for Demand Forecasting.

4. Supply Planning

Supply Planning is all about determining how to best fulfil the requirements created from the demand plan. The objective is to balance supply and demand in a manner that achieves the financial and service objectives of the enterprise.

The supply engine will calculate supply plans for all product stages (FP, DP, DS or API) each time the demand forecast is updated or each time there is a change in the upstream manufacturing structure and constraints. The result of the plan will be shown in a graphical way highlighting the various values that are normally displayed in the production plan.

The manufacturing contract with a Contract Manufacturing Organisation (CMO or “toll” manufacturer) always have frozen horizons which the toll will take into account and place additional requirements only for the first open period.

At any time within the planning process, the users can interact with the engine and develop scenarios based on alternative sets of assumptions. Each scenario can be saved for comparison purposes.

5. Manufacturing and distribution parametrization

The upstream manufacturing parametrization includes, for example, the following parameters which can be adjusted based on the specific manufacturing constraints and specifications:

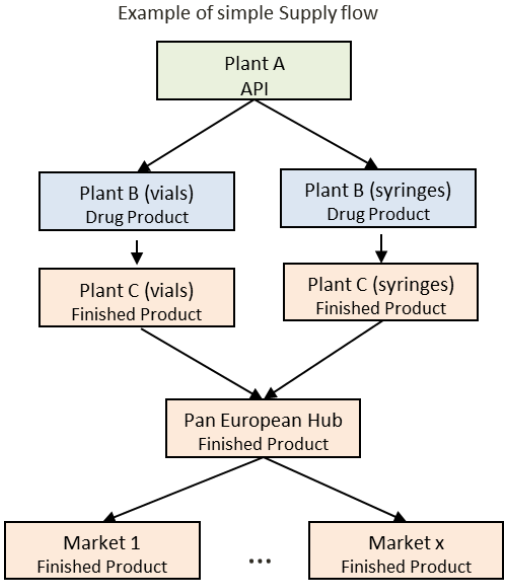
Drug Substance (API)	Drug Product (DP)	Finished product (FP)
Formulation	Packaging	Packaging
Concentration (e.g.: gr/l)	Dosage	Units DP per FP
Shelf-life or re-test date	Shelf-life	Shelf-life
Batch size	Use-by shelf-life for DP	Remaining shelf-life for FP
Min/max campaign size	Min/max batch size	Min/max batch size
Success rate	Incremental batch size	Min/max order qty
Purification yields	Fix and variable production losses (gr or units)	Fix and variable packaging losses
Container capacity	Overfill quantity	Packs per box/layer/pallet
Container filling rate	Units per box/layer/pallet	
…	…	…

The downstream distribution parametrization includes a combination of parameters which define features linked to the warehousing, distribution and transportation of the products up to the final customers. Some of the parameters are listed in the table attached below:

Downstream Distribution parametization
SKUs (Stock Keeping Units)
Country grouping and launch dates
Stock holding point(s) and safety stocks
Transportation set-up and constraints
Distribution set-up and constraints
Etc.

6. The Supply flows

The material flows are modelled through a table that maps the different steps from the API production to the final locations with the related lead-times (production time, release time, distribution duration, etc).



Site	Product	Packaging	Origin	Distribution from Origin	Income release	Production/ packaging	…
Plant A	API	Bag	NA	In days	In days	In days	…
Plant B	DP	Vial	Plant A	In days	In days	In days	…
Plant C	FP	Vial	Plant B	In days	In days	In days	…
…	…	…	…	…	…	…	…

The tables above are examples for illustrative purposes and can be adapted as required during the modelling phase of the engine.

7. The Simulation feature

One of the main purposes of the Demand and Supply Engine is to perform simulations across the supply chain. The objectives of such a simulation capability are:

1) To organise the timely manufacture of enough inventory in anticipation of the launch of a product in a given geography.
2) To decide on production activities: When? What? Why? and adapt in case of changes.
3) To draw and play “what if scenarios” to stress-test the plan and confirm robustness in case of upside potential or downside risks.
4) To evaluate the risks associated with production and/or supply uncertainty

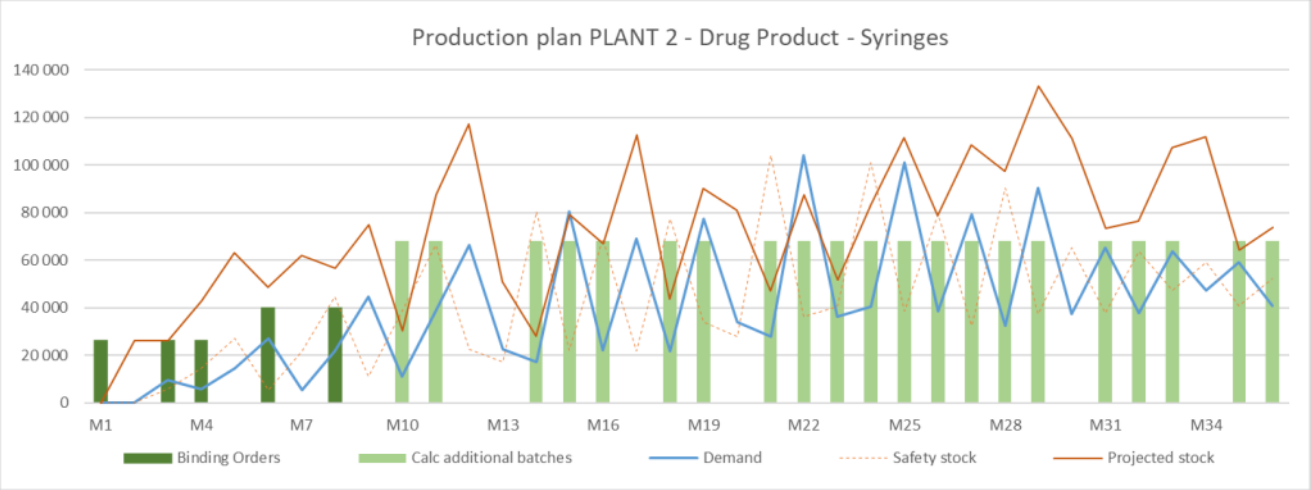
5) To communicate the production plan across manufacturing and distribution partners.
6) To minimize risk of inventory obsolescence in case of demand changes.
7) To simulate shelf-life requirements of the various product stages (DS, API, DP, FP) across the entire value chain.

The real power of the feature lies in its flexibility to simulate any adverse event which can potentially hit the value chain and to understand the operational and financial impacts.

8. Inventory projection and management

The Demand and Supply Engine includes graphical views which project inventory level in volume, value and coverage at any level of the supply planning hierarchy. All the parameters are visible and easily understandable which make it simple to disseminate and discuss tactics across the extended organization.

An example of the graphics which illustrate a typical inventory projection is shown below.



9. Risk assessment with Monte Carlo Simulations

Uncertainty may come from multiple sources, both external to and within the supply chain: supply shortages of key components, transportation disruptions, failures during the production process, market volatility, etc. Rather than just replacing the random variables with a single average number, a Monte Carlo approach may bring significant value when evaluating the overall risk faced by the process. Monte Carlo simulation is a technique used to understand the impact of risk and uncertainty in forecasting models by replacing a single estimate by best-case / worst case values and selecting representative statistical profiles to provide a range and probability of expected outcomes.

The Monte Carlo Simulation feature may be activated within the Demand and Supply Engine allowing:

- sensitivity analysis: how do variables impact the outcome? which are the most cost-efficient adjustments that may be brought to the design?

- scenario analysis: risks and outcomes evaluation (stock-outs, write-offs, expected costs, …) for each scenario given the uncertainties within the process.

10. Summary

Small to medium start-ups planning to launch a new bio-pharmaceutical product will need to perform advance production planning to anticipate manufacturing activities which secure product availability at launch time. The Demand and Supply Engine serves the following purposes:

1) To capture the Demand Forecast, aggregate figures and compare periodic submissions.
2) To define, store and track your demand and supply chain parameters.
3) To compute production plans at DS, API, DP and FP levels.
4) To simulate and stress-test your plans across the extended value chain.
5) To project inventory levels within your supply network.
6) To communicate production plans to manufacturing and distribution partners.
7) To address any type of change in a consistent manner over time.
8) To optimize and secure supply launch readiness

With proven records of operational efficiency, the Demand and Supply Engine is a “must have” feature and a key strategic capability to support any launch team program and to serve the ongoing planning needs of small to medium start-ups during the critical growth phase.

Integrated launch program without integrated supply chain planning tool cannot sustain launch readiness and secure product availability.

Supply Chain Operations SA, based in Switzerland, is a specialized healthcare supply chain consultancy firm created in 2011 to serve the bio-pharmaceutical and medtech industry. We bring more than 120 years of end-to-end supply chain expertise to our valued customers.

Laurent Foetisch of Supply Chain Operations SA has extensive experience as a supply chain executive responsible for managing a global bio-pharmaceutical company in Switzerland for more than 20 years. In 2007 Laurent managed the supply chain integration between Merck and Serono with the responsibility to create one central supply chain structure using common processes and tools.
Mobile: +41 79 205 23 32
Email: laurent.foetisch@supplychainoperations.ch
Website: www.supplychainoperations.ch

María Luz Monterrubio of Supply Chain Operations SA holds a master's degree in Mathematical Sciences and an executive master in Global Supply Chain Management both from Ecole Polytechnique Fédérale de Lausanne. She has many years' experience in developing tools aimed to automate and optimize processes.
Mobile: +41 79 462 27 05
Email : ml.monterrubio@supplychainoperations.ch
Website: www.supplychainoperations.ch