E-BOOK | **BIOPHARMA**

OMP.

Addressing the biopharma supply chain challenge

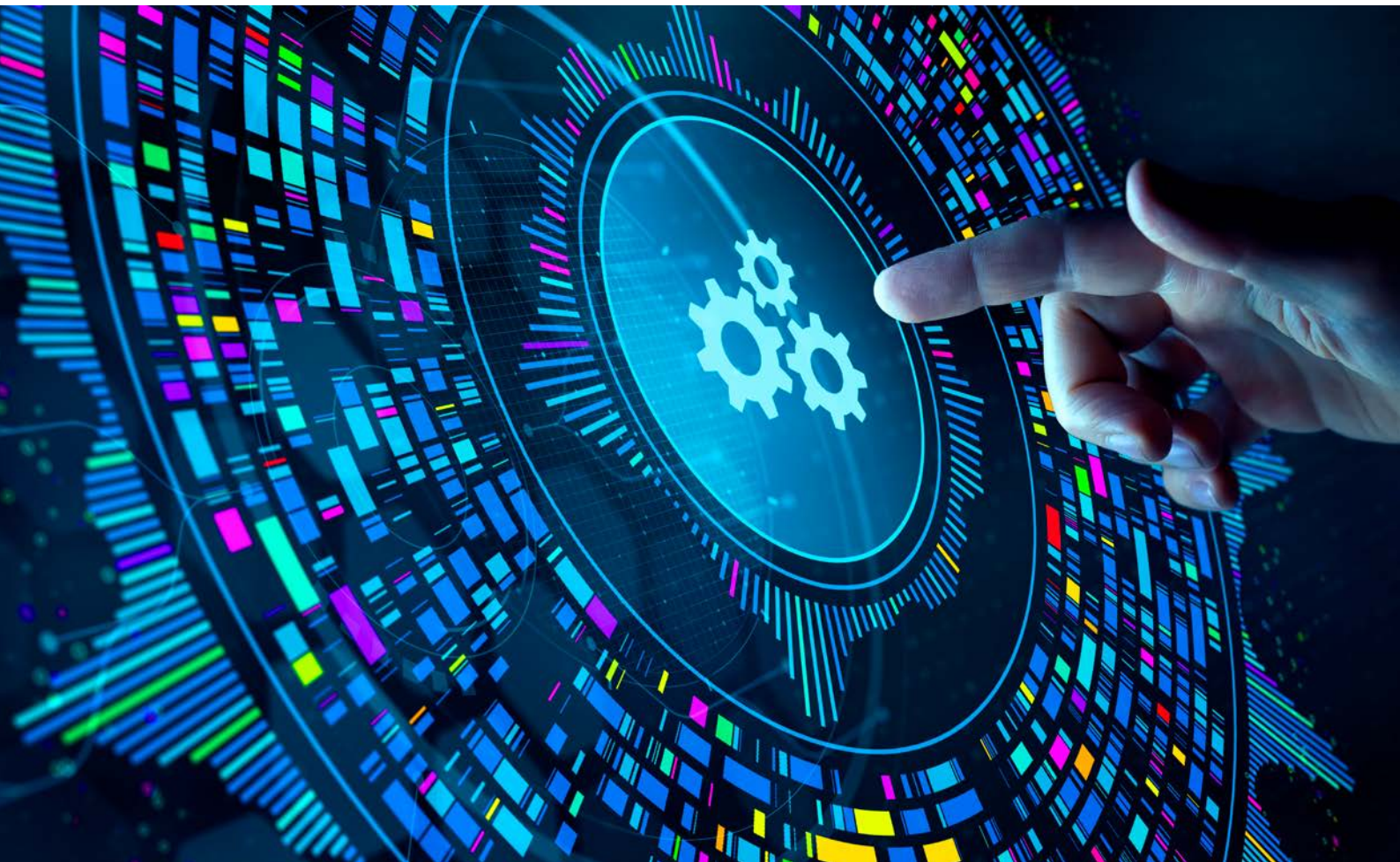


Table of contents

Introduction

As the biopharma industry continues to grow, accurately planning **active ingredient manufacturing** becomes a major challenge. You must adapt to the **ever-changing demand for drug products** while keeping your operations running efficiently.

Unlike traditional pharma, the **complexities of upstream processes** in biopharma are far more complex. Relying on **outdated spreadsheet-based planning** is risky and can lead to slow responses and failure to meet demand.

How can advanced planning help? **Unison Planning for Life Sciences** offers a game-changing solution.

Drawing on deep industry **expertise**, we've developed practical **solutions** that streamline your planning process. This e-book reveals how an end-to-end approach can turn complexity into your competitive advantage, delivering **real business results**.

1

Biopharma is a different race against the clock

1.1 Complex and sensitive active ingredient manufacturing

The biopharma industry is quite different from traditional pharma, mainly because of the entirely different method of producing the active pharmaceutical ingredient (API). While traditional pharmaceuticals are manufactured using chemical synthesis processes, biopharmaceuticals are produced in living organisms such as bacteria, yeast, and mammalian cells.

The need to rely on living organisms has far-reaching consequences for the biopharma supply chain. The upstream processes are especially complex compared to traditional pharma because multiple intricate steps are needed to create just one API batch ready to be used in a bulk formulation:

- **Cell culture:** cells are developed starting from frozen cells in a master cell bank. Cell development is in itself a multistep process involving multiple bioreactors in which the cell culture is cultivated to achieve industry-scale volumes.
- **Harvesting and isolation:** active ingredient cells are harvested and separated using centrifugation or filtration processes.
- **Purification:** the harvested cells are refined to remove impurities, involving multiple possible purification steps such as precipitation, liquid-liquid extraction, several types of chromatography, virus inactivation, virus filtration, pH adjustment, and many more, depending on what they're going to be used for.

The entire manufacturing process becomes extremely complex, easily involving hundreds of activities and intermediate steps to be synchronized depending on factors such as the product's nature and the type of production platform (for example, a mammalian cell culture or a microbial fermentation). Regulatory requirements need to be factored in as well, especially in sourcing and usage decisions. And the very short expiration periods limit the storage times of intermediate products, meaning that allocation decisions need to follow fundamentally different rules from those in other parts of the supply chain.

In addition, intermediate steps in this complex manufacturing process can be very sensitive to variations in ambient temperature, pressure, and humidity, much more than the highly controlled chemical processes of traditional pharma. The resulting outputs may therefore vary significantly in grade or potency.

1.2 Current planning practices lead to high risks

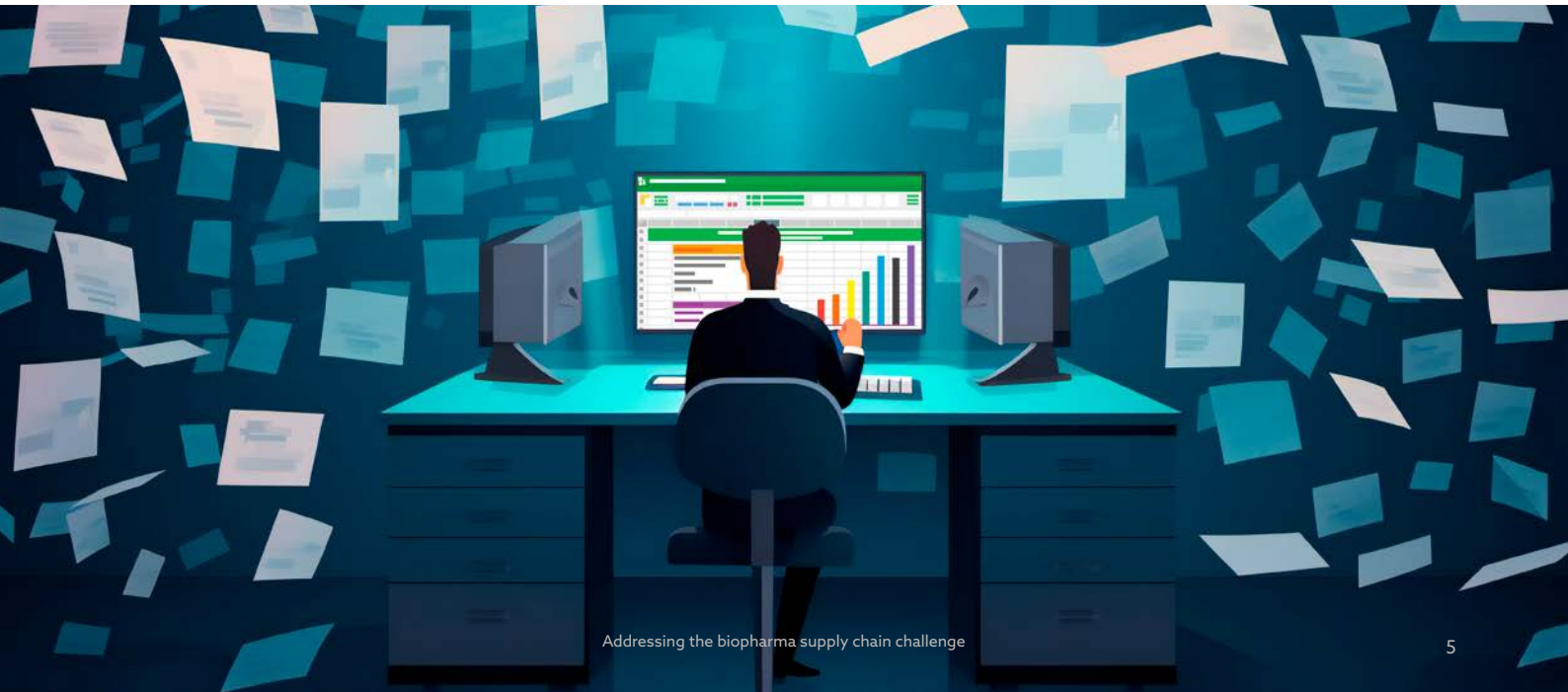
At present, most biopharma producers plan their API manufacturing on a manual basis in tailor-made spreadsheets, most likely because they believe there's no workable alternative available. Yet manual planning takes a lot of time and requires significant effort when dealing with multiple intermediate steps, varying process parameters, and numerous batches or production runs. A lot of data needs to be gathered, highly specific calculations need to be made by experts, and manual adjustments need to be made to the spreadsheets, with all of these activities prone to errors and inefficiencies.

Now that biopharmaceutical manufacturing is facing increasing demand, manual planning is becoming a huge challenge to the necessary upscaling. The complexity of the process and the large data volumes can quickly overwhelm planners, who are stuck with the cumbersome spreadsheets.

In addition, the manual planning process creates a huge disconnect between API manufacturing on the one hand and the downstream fill-finishing processes on the other.

All this leads to significant risks in a sector that's in a continuous race against the clock to provide drugs and treatment to patients at the right time and place. The following risks are particularly high, even more so when biopharma products are getting higher in demand:

- Slow response to peaks in demand leading to shortages. If there's a manufacturing issue, shortages may even occur in periods of normal demand and may impact supply for relatively long periods.
- Limited capability to re-route production in the event of changes or issues. The complex cascades of constraints for a particular drug mean that planners are not able to quickly find alternative production routes.
- Infringements to regulatory constraints and other errors due to production complexity. Such errors, in turn, increase the risk of drug shortages.
- Limited capabilities to optimize production. It is difficult to improve manufacturing efficiency if the entire process is planned manually.



2

Unison Planning for Life Sciences: a game-changing solution

OMP has developed a unique solution specifically for the biopharma industry, integrated into Unison Planning for Life Sciences. It provides a workable and much more effective alternative to manual spreadsheet-based planning.

2.1 What is it?

Built on a digital supply chain twin of the biopharma manufacturing and handling apparatus and logic, Unison Planning for Life Sciences allows companies to accurately plan the entire API manufacturing process with all its complexities.

With this solution, planners create workable API manufacturing plans much faster than with the manual process while considering all the key planning constraints. This is a major benefit because the planning activity itself is of course part of the lead time and a significant one in the case of manual planning.

In addition, the solution effectively integrates the planning of biopharma API manufacturing with the planning of fill-finish activities. As a result, fill-finish planners have real-time visibility on the API manufacturing plan, which again means a significant gain in time and accuracy. And the API planners are at all times aware of what is happening downstream in the supply chain.

2.2 How does it work?

With the Unison Planning for Life Sciences biopharma solution, planners have full visibility over all API manufacturing subprocesses to be launched and synchronized. In-built AI solvers tailored to the biopharma industry automatically make the necessary calculations while checking with regulatory requirements and product expiration constraints.

The integration of API production planning with the planning and scheduling of downstream fill-finish activities is a real game-changer in this industry. It effectively addresses the challenges resulting from a fundamental difference between both processes:

- API manufacturing is **a push process**. The long lead times and big changeovers require campaigning, which means that API production has a slower pace than what the market requests. For this reason, API is pushed downstream to ensure a consistent and sufficient supply.
- Fill-finish, on the other hand, is **a pull process**, designed to minimize excess inventory of finished drug products and respond flexibly to fluctuations in demand.

It is crucial to effectively coordinate these two processes with accurate two-way communication so that a seamless supply chain can be maintained and drug products are available when needed in the market. In Unison Planning's end-to-end digital supply chain twin for the life sciences industry, this communication happens through **a smart order allocation process**.

Firstly, the system calculates **a consolidated overview of demand for each API** based on the planning cycle at the finished goods and drug product levels. The end-to-end pegging solution embedded in Unison Planning ensures that this consolidated demand **contains the necessary destination market regulatory characteristics** so that the right decisions can be made at the API level.

Secondly, the solution provides an array of AI solvers that can **automatically calibrate the API manufacturing schedule** to the latest demand, taking into account target inventory levels and process-specific factors such as campaigning rules, harvesting pace, and storage constraints.

Additionally, users can model yield curves to predict and monitor variations in active ingredient potency. Based on this, Unison Planning for Life Sciences will recommend optimal blends to create a more **consistent and homogeneous feedstock** for downstream purification.

The solution also provides scenario planning, meaning that planners can develop a series of alternative scenarios and evaluate them against selected criteria.

The great advantage of this solution, beyond all the automation and optimization, is that API planners have **a clear view of market demand and priorities at any time**. Unlike manual planners in offline systems, they don't work in the dark and their planning aligns with what's happening in the market.

2.3 A responsive, efficient, and resilient biopharma supply chain

Unison Planning for Life Sciences reduces biopharma lead times and risks and improves overall efficiency and service levels while making the supply chain more resilient.

- Faster planning (and re-planning) accelerates the decision-making process and contributes significantly to making lead times shorter.
- Alternative plans can be developed quickly if needed, making the supply chain more resilient.
- Scenario planning further improves the quality of decision-making.
- Plan optimizations make for a more efficient production and lower production costs. Yields can be optimized by blending batches with different potencies.
- The solution eliminates costly planning errors and optimally matches supply and demand to reduce changeover times and avoid rejected batches.
- This also results in higher service levels.

3
Conclusion

For end-to-end biopharma planning to work effectively, it is essential to establish a flexible connection between the complex active pharmaceutical ingredient (API) push process and the fill-finish pull process. That's exactly what Unison Planning for Life Sciences does with its smart order allocation process tailored to the biopharma industry. As a result, a seamless supply chain can be maintained, and drug products are available when needed in the market.

About the author

Philip Verhulst

With an educational background in business management and operations research, and close to a decade of experience in delivering OMP as a planning solution within the life sciences industry, Philip focuses on designing solutions to optimize and efficiently orchestrate customers' supply chains for both operational and strategic decision making.

An enthusiast for innovation, user-friendly solutions, and promoting best practice within the industry, he is a powerful advocate and contributor to developing the standard product offering in the life sciences industry.

About OMP

Hundreds of customers in a **wide range of industries** — consumer goods, life sciences, chemicals, metals, paper, plastics &packaging, tires & building products — benefit from OMP's unique **Unison Planning™**, an open, cloud-native, and AI-driven platform that embeds our deep **industry expertise** and offers real solutions for the challenges your industry faces.

A proven platform for **all your supply chain planning needs**, from demand to supply, from the strategic to the operational levels. A **real solution** that supports your journey toward autonomous, decision-centric planning. Built on 40 years of expertise.

Recognized by **Gartner®** for its leadership and vision, OMP helps you navigate supply chain challenges with data-driven insights, dynamic optimization, and sustainable decision-making, delivering **real business value**

Also want to master your supply chain from end to end?
Contact us

OMP.

Antwerp - Atlanta - Barcelona -
Cologne - Mumbai - Paris -
Rotterdam - São Paulo - Shanghai

info@omp.com
omp.com