Integrating Safety Stock Policies into Roche's S&OP Process

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ABSTRACT

Globalization, demand uncertainty, and shorter life cycles have increased the risks in pharmaceutical supply chains. To mitigate these risks, firms can carry safety stock. Classic theory on stochastic safety stock strategies assume that demand forecast errors are normally distributed with no bias or, in other words, have an expected value equal to zero. This assumption does not hold when considering over-optimistic, or positively biased, demand forecast, which is a common issue, as indicated by the prevalence of Sales and Operations Planning (S&OP) efforts. We began exploration of the biased forecast impact on safety stock for our sponsor company by understanding the managerial situation. To better frame the problem, we developed a conceptual model of the overall S&OP process based on responses to interviews with the company teams that influence the safety stock target definition. The conceptual model informed a formal model that we used to test the impact of a new safety stock formula that addresses forecast bias. Our results show that even though safety stock can be adjusted with this new approach, there are still many opportunities for improvement along this process. We conclude that in order to make the best informed decision about safety stock levels, Roche's team should better integrate safety stock decisions into their S&OP process. Also, effort should be allocated to understanding which data is being used, what it means, and whether it is appropriately informing inventory decisions made explicitly by managers or implicitly in information systems. Finally, further analysis shows there is much greater potential to reduce inventory beyond that dictated by safety stock policy. Roche should continue working towards understanding the root causes behind their excess of inventory to achieve long-term substantial impact.

Capstone Advisor: Dr. Jarrod Goentzel Title: Director, MIT Humanitarian Supply Chain Lab

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1 INTRODUCTION

1.1 Company background

Our partner for this capstone is F. Hoffmann-La Roche (Roche), a pharmaceutical corporation with 125 years of history as a leader in this industry. Roche is one of the world's largest biotech companies and the biggest investor in research and development. The company is divided into two groups, the Pharma Division and Diagnostic Division. The Pharma Division focuses on finding new medicines. Its vision is to deliver 3-5 times the benefit to society for half the cost. The Diagnostic Division develops solutions to identify illness in advance (F. Hoffmann-La Roche Ltd, 2021). This capstone will focus on demand planning and replenishment in the US Pharma Division.

The Roche Pharma Division produces two types of products: small molecule and biologics. The production process for small molecule drugs starts by manufacturing the Active Pharmaceutical Ingredient (API). This API is later made into a bulk drug product, then into a drug product, and finally labeled and packaged into a finished good product. The finished good product is then distributed to channel partners. On the biologics side, a liquid drug substance is manufactured first. This substance is filled into a drug product, labeled, and packaged into a finished product that is then distributed to the channel partners. The lead time for this whole process can vary from 18 to 24 months, depending on whether it is Roche or its contract manufacturers who produce the product. Figure 1 summarizes the different operations for both type of products.

Note: This figure shows types of products manufactured by Roche and various manufacturing operations and terminology (F. Hoffmann-La Roche Ltd, 2021)

The Pharma Technical Supply Chain (PTS) Team, is comprised of more than 400 employees across 8 locations, segments the product portfolio into the following categories based on the product life cycle stage:

- New Pre-Launch: a product that has not yet been launched. It requires early PTS attention/involvement.
- New Launch: a product that is commercially launched in one market and obtains a critical market share. It is expected to have strong growth.
- Resilient: a product that is launched in major markets.
- Established: a product launched in all major markets. There are no major promotions from affiliates and demand volume starts to decline.
- Established Late Life Cycle: the product has been identified for divestment or discontinuation.

Roche currently works with a ten-year planning horizon to develop three different demand forecasts for their products: most likely, low, and high. The high forecast takes the upper limit of the confidential boundaries, a conservative approach that will be most likely above real sales. During the monthly Sales and Operations Planning (S&OP) process, the team creates a new estimate for the next three years' time horizon: the manufacturing or S&OP forecast. This new prediction generally surpasses the high demand forecast and contemplates other factors to protect against, such as regulatory approvals, market fluctuations, and results of new studies on the drug.

1.2 Motivation

Globalization, demand uncertainty, and shorter life cycles have increased the uncertainty and risks in pharmaceutical supply chains (Wang & Jie, 2020). To mitigate these risks, firms can carry safety stock or plan for excess capacity (Chaturvedi & Martínez-De-Albéniz, 2016). Due to high invested capital requirements and fixed costs, idle capacity is expensive and surplus stock ties up significant capital, especially in the pharmaceutical industry. Thus, managers face increasing pressure to reduce inventories across the supply chain and minimize the risk of write-offs. Therefore, companies need to develop safety stock methods that balance the cost of stock out against the holding costs (Graves & Willems, 2000). This method considers expected demand, expected lead times for product replenishment, the variability of both, and desired service level to protect against uncertainty.

In the case of Roche, the PTS team decides the amount of safety stock to hold at each supply chain node: at the drug substance, drug product, and finished good stagesin varying amounts, as well as at the channel or partner level. They base their decision on the previous year's information and set a target at the beginning of each year for every product. This target is set in weeks of demand, which is later translated into units through the manufacturing forecast that is updated every month.

1.3 Problem statement

As mentioned, the manufacturing demand forecast at Roche is meant to protect against various demand uncertainties. The purpose of safety stock is to protect against uncertainty and assure a desire service level. Therefore, this practice has led to a double buffering against uncertainties in a policy that is reviewed only once a year (though it depends on each period forecast, as it will be explained in the following sections). The Roche PTS team believes these are the major contributors to the company's working capital and tackling them would help reduce the write-offs.

The purpose of this project is to develop a new approach for safety stock targets for the finished products. We also estimate the financial impact and future overall inventory changes. The scope is limited to products in the launch and resilient phases since pre-launch products do not have historical data to challenge existent policies and established products have a predictable demand.

2 LITERATURE REVIEW

As mentioned in the previous chapter, this project proposes a more dynamic and integrated approach for Roche safety stock target settings in the US market.

2.1 Introduction

Safety stock literature focuses on its dimensioning, positioning, management, and placement (Gonçalves et al., 2020). Two types of models could be adapted for this purpose: deterministic and stochastic. Deterministic models are selected when every variable is uniquely defined by the parameters of the model. It is cost-effective to do deterministic inventory optimization when large quantities are ordered, as it is easier to predict end inventory position. Stochastic inventory models consider the uncertainty of demand (demand variability) and supply (lead time variability). Even though the different variables may be considered deterministic in some settings, in most cases demand and lead time are uncertain and should be factored in the safety stock models (Küçükyavuz, 2011).

Classic theory in stochastic safety stock strategies considers that demand forecast errors are normally distributed with no bias or, in other words, an expected value equal to zero (Silver et al., 2016). This assumption does not hold when considering over-optimistic demand forecasts as in the problem we are trying to solve. Moreover, demand is considered a random variable, meaning these strategies fail to consider the presence of trends over time. Therefore, this literature review first summarizes the traditional approach for safety stock dimensioning.

Following, we will focus on understanding how this approach could be adapted to incorporate the effect of trends and biased forecasts. As it is presented in this literature review, forecasts and inventory decisions are linked. The Sales and Operations Planning (S&OP) process is generally in place to better help teams working in alignment towards the company general goals understand the impact of each decision in the whole SC. This is why this literature review includes a section summarizing how this process is generally structured. Finally, we will summarize our conclusions on the literature analyzed and how it relates to our capstone project.

2.2 The traditional approach for safety stock dimensioning

Safety stock dimensioning strategies are commonly built upon a single echelon model comprised of a single inbound and outbound flow of materials. Even though supply chains have many linked stages, and the best results are achieved when considering inventory strategies holistically, all information and decisions would need to be managed centrally. In most organizations, management responsibilities are

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assigned to each echelon, and therefore decentralized systems are generally in place (Hausman & Erkip, 1994). Under this approach, the demand for each echelon is forecasted separately, and safety stocks are independently determined at each unit level.

An example of a single echelon is a warehouse that orders parts from suppliers and fulfills demand from external customers. Warehouses at the lowest echelons are responsible for their own stocking policies. Once all warehouses determine their individual stocking policies, their combined operations will create a demand for orders to be placed upstream (Hausman & Erkip, 1994).

The most traditional approach to determine safety stock levels in the single echelon model assumes that the lead time (L) and the demand (D) are independent, random, and normally distributed variables, and forecast errors are normally distributed with no bias. Under this assumption, the expected demand $E(x)$ of units in a replenishment lead time, and its standard deviation σ_x , could be calculated using the following expressions:

$$
E(x) = E(L)(D) \tag{2.1}
$$

$$
\sigma_x = \sqrt{E(L)\sigma_D + [E(D)]^2 \sigma_L} \tag{2.2}
$$

where L is the replenishment lead time, with mean $E(L)$ and standard deviation σ_L , and D is the demand with mean $E(D)$ and standard deviation σ_D . PRINTDATE \searrow MERGEFORMAT Then, the safety stock SS could be calculated as:

$$
SS = k\sigma_x \tag{2.3}
$$

where k is the safety factor (Silver et al., 2016). Due to the hypothesis behind this model, the demand variance and the forecast root mean square error (RMSE) are interchangeable. Therefore, Equation 2.2 can also be found in the literature associated with the forecast RMSE.

2.3 Impact of trends and seasonality in safety stock

Based on Equation 2.3, the safety stock formula will result in the number of units needed to protect the single echelon under consideration against uncertainty. This quantity is often incorporated in the planning process as fixed and is updated over a long period (e.g., yearly). This stock will be applicable for all future planning periods, and thus, it fails to respond to demand trends or seasonality (Krupp, 1997).). When the demand trend is negative (e.g., at the end of the life cycle of a product), this limitation could lead to an excess inventory. On the other hand, when there is a positive trend, the approach described in section 2.2 could result in inadequate service to the customers.

Equation 2.2 could be adapted to incorporate these fluctuations in demand and protect companies against potential adverse outcomes. Instead of expressing the demand variance in demand units, it could be expressed in time units, dividing the equation by the forecast for that period. The result will be multiplied at each period by the demand and will adapt to variations over time (Krupp, 1997). Nevertheless, which demand is considered for this multiplication can lead to an inappropriated policy, as we will describe below.

The most common approach in industries is generally the forward coverage, where the safety stock is converted to units by simply summing the forecast of each to the following days until the policy expressed in time units is met (Neale & Willems, 2015). Therefore, with this approach, the safety stock in time units is the expected time it will take to consume the safety stock in production units if the forecast materializes.

Even though the forward coverage approach is widely used and looks appropriate at first glance, it can create the "landslide effect" under a trend or seasonality in demand scenario (Neale & Willems, 2015). In moving from a high demand season to a lower demand one, the forward coverage will begin to decrease the target while still on the high demand season (Neale & Willems, 2015). The safety stock is not the total amount of units a company needs during a certain time span to protect against uncertainty, it is the level of units that should be kept in the inventory at all times as a buffer for the variability that exists every day. Lowering the number of units prematurely will lead to lower service level in the peak season. Intuitively, the opposite effect happens when moving from a low demand season to a high one: the forward coverage approach will create higher inventories than needed during this season (Neale & Willems, 2015).

Neale and Willems (2015) proposed the following simple way to mitigate the impact of this approach, which requires less effort than continuously running a complex mathematical approach: as a first step, calculating the average forecast from time $t + 1$ to $t + T$ (t is an arbitrary time period and T represents the replenishment lead time). Then, use this average forecast to convert the safety stock target expressed in days into a safety stock unit target for time t + T.

2.4 Impact of biased forecasts

As mentioned before, the manufacturing demand forecast at Roche is meant to protect against various demand uncertainties. But the purpose of safety stock is to protect against uncertainty and assure a desire service level; thus, these two effects combined lead to over buffering against uncertainty. The

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recommended approach for biased forecast would be removing the bias from the source data, though this is not always easy due to how responsibilities are allocated in the supply chain. The Planning teams are responsible for setting the inventory targets; however, they have no control over the demand forecast that the Sales and Marketing teams create (Manary & Willems, 2008a). Therefore, a strategy needs to be implemented to fix the safety stock expression against biased forecasts objectively.

One technique found in the literature proposes using a forecast error tracking signal (FETS) (Krupp, 1997). The FETS can be calculated by dividing the mean deviation (MD) by the mean absolute deviation (MAD):

$$
FETS = \frac{ME}{MAD} \tag{2.4}
$$

Its value will range from -1 to +1, depending on the degree of bias (+1 would represent that the forecast has been consistently overoptimistic). This approach proposes to incorporate statistical control theory to safety stock dimensioning: when the signal shows that it is out of control and exceeds certain control limits, the forecast needs to be reassessed. This could be incorporated into planning meetings in order to manually adjust the levels according to behavior. However, this approach is not robust and could lead to lower service levels than desired.

On the other hand, Manary and Willems (2008b) recommended a different approach. According to their methodology, first the bias in the demand forecast should be examined by calculating the relative forecast accuracy for each SKU:

$$
\theta_i = \frac{Fi - k - 1}{Fi - k - 1 + Di} \tag{2.5}
$$

Fi-k-1 denotes the forecast for demand in period *i* and made in the period *i-k-1* if *k* is the number of frozen periods. *Di* denotes the actual demand in period *i.*

For each SKU, if the q*i* is 0.5 then it indicates that Forecast *Fi-k-1* and Demand *Di* are equal. If the q*i* is greater than 0.5 then the SKU is over-forecasted, with Forecast $F_{i,k-1}$ being greater than Demand D_i And, if the θ_i is less than 0.5 then the SKU is under-forecasted, with Forecast *Fi-k-1* being less than Demand *Di.*

To net out the forecast bias from the data, Manary & Willems (2008b) propose, as a next step, to calculate a modified standard deviation of forecasted demand to substitute it in Equation 2.2:

$$
\sigma_D^{Modified} = max \left\{ \frac{E(D)}{Z_{\alpha}} + \sigma_D, 0 \right\}
$$
 (2.6)

The foundation for Equation 2.6, a revised approximation is based on the relative forecast accuracy from a product's sample history (Manary & Willems, 2008b):

$$
\hat{\sigma}_D{}^{Modified} = max \left\{ \frac{(1 - \theta_\beta) / \theta_{\beta} - 1}{t_{\beta, df}} \mu, 0 \right\}
$$
 (2.7)

If $\theta's$ distribution is unbiased, then $\sigma_D{}^\text{Modified}$ and $\sigma_D{}^\text{would}$ converge. Hence, since the forecast accuracy increases, Equation 2.5 will still be valid.

2.5 S&OP, forecast and inventory decisions

S&OP is one of the key strategies companies are using to respond to uncertainties in their supply chain, by fostering the alignment of business strategy and operational planning, and the alignment of demand and supply plans (Tuomikangas & Kaipia, 2014). S&OP is a set of processes that aim to mitigate the effects of demand and supply variability with the goal of helping companies take timely decisions (Muzumdar & Fontanella, 2006). Accomplishing this goal requires the right coordination mechanisms that guarantee all actors who perform tasks are aligned towards the common goals (Tuomikangas & Kaipia, 2014).

According to Lapide (2011) and Wagner et al. (2014), S&OP consists of five global steps, as shown in Figure 2.

	Data Gathering	Demand Planning	Supply Planning	Pre Meeting	Executive Meeting
	Step 1	Step 2	Step 3	Step 4	Step 5
٠	Update last month data Generate KPI to asses company performance Share new data to be used as input in the other steps	Analyze of previous forecast error Understand demand ٠ influencing factor Generate new forecast	Analyze previous month deviations Develop new supply plan (based on new forecast, inventory and backlog and capacities)	Jointly generate one set of plans Review previous gaps Reconciliate with Finance plan Prepare next meeting	Evaluate new plan Approve pending decisions (outside authority of previous meeting) Review current business performance

Figure 2 *Various steps of Sales & Operations Planning*

Note: This figure shows the various steps of S&OP

The first sept in the S&OP structure is Data Gathering. This activity is generally supported by automatic IT systems and encompasses the preparation, consolidation and sharing of this data to be used as input in the other steps (Wagner et al. 2014). Typical data needed includes actual sales, production and inventory of the month that just closed, which will allow the generation of key performance indicators and reports to be disseminated.

In the next step, the Demand Planning phase, sales-related teams jointly discuss the data gathered regarding past customer demand and agree on a new demand forecast for the next 12 months (Wagner et al. 2014). In this phase, forecast errors, as well as any assumptions made that did not materialize, should be reviewed.

In the Supply Planning stage, the deviations from the previous month are analyzed, which means understanding the root causes behind the difference in the actual versus planned performance in terms of inventory levels, capacity utilization, and so forth (Wagner et al. 2014). This information, with the input from the previous phase as well as order backlogs, inventory levels, material and capacity availability, and lead times, is needed to modify the supply plans (Wagner et al. 2014).

Afterwards, in the Pre-Meeting phase, representatives from all the previous stages, as well as development and finance delegates, discuss and validate the supply and demand plans. When the desired plans cannot materialize due to constrains, the team needs to reach a set of aligned recommendations to be presented to the executive meeting alongside an updated financial report of the current situation against the business planned (Wagner et al. 2014).

Finally, in the executive meetings, top management meets the S&OP process owners to review all decisions and recommendations made up to this point (Wagner et al. 2014). If the company objectives are clear and the different teams' work is aligned towards those goals, there shouldn't be many modifications in the decisions previously made, and the discussion should focus on the points where the previous teams couldn't reach a consensus. Moreover, in this meeting the crucial key performance indicators are analyzed, the financial deviations from the business plan being one of the most relevant ones (Wagner et al. 2014).

2.6 Robust Inventory Approach

Another way to look at this overall problem is by addressing the inventory. A simplified rule of thumb is that safety stock held to cover forecast error should roughly equal the worst under forecast in an SKU's history. This result makes it easy for management to interpret and understand inventory target setting (Manary & Willems, 2008b):

Robust Inventory = Minimum Inventory Maximum realized demand Opportunity on Hand over net replenishment time

The robust inventory opportunity is more heuristic, but intriguing. The minimum inventory on hand is simply the lowest inventory on hand for the product in the period, and the maximum realized demand over net replenishment time is calculated by taking the maximum over the summation of all the consecutive months' shipments over the lead time and frozen period in the data set.

2.7 Conclusion

Safety stock is one of the most important levers to protect companies against uncertainty. Even though managing safety stocks levels in a centralized way and selecting its positioning holistically can result in the best outcomes, many companies, like Roche, do single stage inventory planning. The reason for the gap between existing research and low adoption in industry with advanced planning is twofold: the research done does not account for real-world supply chain scenarios and focuses on being mathematically tractable; and many companies do not fully understand the complexity of inventory management and prefer to rely on the experience of planners rather than mathematically sound inventory management methods (Cattani et al., 2011). Moreover, moving from a decentralized to a centralized approach would require a transformation in how companies operate and how incentives are allocated (Hausman & Erkip, 1994).

The literature review identified different strategies that could help the Planning team at Roche better manage their safety stocks and prevent double buffering due to a biased forecast. Moreover, literature supports that forecast and inventory decisions should be linked inside the S&OP framework, allowing the different teams to jointly make decisions that improve the overall performance rather than isolated goals.

3 METHODOLOGY

As mentioned in the previous chapter, this project proposes a more dynamic and integrated approach for Roche safety stock target settings in the US market to lower both the cost of capital allocated to this inventory and the risk of write-offs. This approach needs to consider demand uncertainty, life cycle, market events, and forecast bias without introducing more risk or jeopardizing the desired level of service.

The problem we are trying to solve falls into the category of an unstructured problem, due to the existence of multiple actors with multiple perspectives, conflicting interests, and key uncertainties (Mingers & Rosenhead, 2001). In order to guarantee that all the complexity is understood, and that the solution or formal model proposed has a positive impact from a holistic perspective, a traditional approach is not sufficient.

To develop our methodology, we built on the work of Oral & Kettani (1993). They propose that an operational research project should start from a managerial situation or problem that needs to be solved. This problem will lead to a conceptual model, which will be the input needed to develop a formal model. This formal model will give a company the necessary insights to make decisions, which, if implemented, should solve the managerial situation. Since the managerial situation is already defined, and the scope of our project does not include implementing our recommendations, our methodology mainly focuses on developing a conceptual and a formal model. This approach will provide insights that the Roche team could use to solve the problem. Our methodology is summarized in Figure 3.

Figure 3 Capstone Methodology

Note: This figure shows capstone methodology adapted from Oral & Kettani (1993)

Each of the steps is described below.

3.1 Develop a conceptual model

Developing a conceptual model requires forming a holistic and cohesive image of the problem or managerial situation that needs solving (Oral & Kettani, 1993). In our case, many teams are making decisions that have an impact on the safety stock target setting and on the guarantee that the target service level is met. When different teams, with different goals and different perceptions, individually impact the same result, their decisions are generally biased by the problems each of them experienced and may not be aligned with the global company strategy. This is why incorporating the vision of the different stakeholders and creating a single point of truth to jointly understand the complexity behind setting safety stock targets is extremely valuable as a starting point.

To incorporate the vision of the many stakeholders, a combination of multiple approaches was selected. We decided to conduct unstructured interviews with all the teams involved to better understand their process and pain points. After that, we shadowed the different team meetings where they made decisions that affect the safety stock target setting. The different steps were mapped in a SIPOC diagram (suppliers, inputs, processes, outputs, customers) as presented in Figure 4.1. SIPOC is a map that divides a process into small steps and, for each of those steps, lays out the inputs required, the suppliers of those inputs, the outcomes of those smaller processes, and finally, the customers expecting those outcomes.

3.2 Creating a formal model

We proposed a list of recommendations that Roche could apply in the short and medium term to create a more integrated process and better allocate their working capital, as well as eliminate redundancy in the process. These recommendations are mainly supported by methods from the literature review.

For those measures where the potential impact can be assessed, we created scenarios representative of Roche product behavior and numerically compared the differences between the process as it is and the new proposed process, in a formal model. In other words, the conceptual model was then translated into a testable model, such as a mathematical or simulation model (Oral & Kettani, 1993). This comparison not only focused on the number units but also on the financial implications of holding stock, which could help the improved process be accepted by the different teams.

The final list of recommendations that Roche could apply in the short and medium term and the reasoning behind them should be considered as an input for the company decision makers. Choosing whether to follow said recommendations, and their implementation itself, is beyond our scope.

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4 RESULTS AND ANALYSIS

This chapter summarizes the results of implementing the two steps of this capstone methodology: the conceptual model and the formal model.

4.1 Step 1: Develop a conceptual model

Various teams across Roche are involved in setting the safety stock target. Due to the company's riskaverse behavior, each team adds an inherent buffer for many products, which leads to high inventory. In this section, we look at the four teams involved in the safety stock setting process at Roche:

- US Commercial Team: This team is responsible for developing a demand forecast each month. This forecast is protected against uncertainties in the market.
- Global Target Assessment Consolidation Tool (TACT) Team: Every year, this team works with historical data to propose parameters for a safety stock target. They use the previous 12 months' demand and lead time data to determine the variability in demand and lead times, average lead time, and service level.
- Affiliate Team/Demand Planners: Annually, this team evaluates the safety stock proposed based on the parameters set by the TACT Team and the monthly demand forecast from the US Commercial team.
- Supply Planners: This team takes the safety stock proposed by the affiliates and converts it into the production plan. They identify any upcoming challenges in supply and production schedules. Each of the teams is detailed in the following subsections.

4.1.1 US Commercial team

The US Commercial team does long-term and short-term forecasting. For the purposes of S&OP (Sales & Operations Planning), we consider short-term forecasting, which spans across 25 forecasters. Products are allocated by therapeutic area: some forecasters will do forecasting for multiple products that target a similar disease, while some of the therapeutic areas have single forecasters. Forecasting is done on gStarr, an Excel application which queries data from a TM1 Database. The gStarr tool queries actual historical demand, price of the product, and other assumptions that do not change from a forecaster's perspective.

The forecasters can refresh the forecast every month; they have from the start of the month until a lock date to review the forecast. Once the forecast is refreshed, the latest numbers are published in the TM1 database and are later shared with the demand affiliate team during the DRM (Demand Review Meeting). Every month, the prediction is done for the following month and the 36 months after that. In the forecasting process, there is no standard one-size-fits-all solution, and the process is directly influenced by the risk appetite of each forecaster.

Historically, the main intent of this team has been to ensure that Roche has enough product to guarantee that all market demand will be met. To achieve this goal, forecasters contemplated multiple scenarios, resulting in a forecast that was positively biased. However, in the past 2-3 years, there has been a shift towards being efficient and lean, which means they need to ensure that Roche has enough product while working within capacity constraints and being closer to true actuals. This shift toward efficient forecasting has shrunk the difference between the S&OP forecast and financial forecast (closer to the actual demand), but the bias still exists.

Even though the demand forecast and its variability are key for the safety stock definition, as explained in the literature review, this team is not accountable for the safety stock decisions.

4.1.2 Global TACT Team

The Global TACT (Target Assessment Consolidation Tool) team in Basel, Switzerland, proposes the safety stock target for each product based on the historical demand and lead time. This activity is typically conducted once a year in October and adjusted in ad hoc scenarios such as changes in regulatory requirements. The Global TACT team handles several SKUs across the US and Canada. Using the historical demand for each SKU, the global TACT team decides the parameters of lead time variability and demand variability. The output of this activity is the number of safety days, and it is obtained with the same method explained in formula 2.3.

The average demand and lead time, and the variability of demand and lead time are set based on the past 12 months' actual data. This method determines the safety stock target measured in number of units. Given the long horizon of 12 months, the target does not incorporate the latest market trends and supply chain uncertainties at a monthly level.

The products with supply constraint are excluded from this review. Success in setting the right number of safety days depends on the right lead time and replenishment data from the packaging sites. "Frozen period" is defined as the period in which no changes to the production plan can be made. In the current state, frozen periods or any other exceptions are not factored into the stock transfer horizon. The lead time considered here is the time it takes the product to go from the manufacturing site to the distribution center. Activities before or after this period are not included in the safety stock calculations.

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The issue of forecast bias exists across Roche and is not limited to North America. In the European region, the global TACT team has been tackling the issue of reducing safety stock by reducing the safety days from 30 days to 25 days. However, they soon realized that convincing the planners to stock for less than 20 days is a challenge because fear of being out of stock prevents planners from accepting the TACT team's safety stock target recommendations.

4.1.3 Affiliates Team

The various forecasts predicted by the Commercial Team are then passed on to the Affiliates, who look at the S&OP (Sales & Operations Planning) forecast data for individual products every month. They also review the safety stock target in days set by the Global TACT Team. They speak with the Affiliate planners and Supply planners to understand upcoming uncertainties, such as longer lead times, reasons for variability in demand, product launches, FDA approvals, etc. Using all this information and the historical safety stock target, they decide to either accept the safety stock target or reject it and propose a new one. They update the reason for the change in safety stock as well.

Upon analyzing few SKUs on the TACT tool for the US, we found that 92% of the safety stock targets recommended by the TACT tool were rejected. The Affiliate planners team accepted the safety stock target for only 8%. Out of the 92% SKUs with rejected safety stock targets, 80% were rejected by the Affiliates planner because they thought the proposed safety stock target was too low. From this observation, we conclude that the Affiliates Team has very little confidence in the safety stock targets proposed by the tool; they prefer to manually change the safety stock target.

Upon further analysis of these 197 SKUs whose safety stock target was rejected, we found that planners reject the target due to the following reasons:

- 1. The TACT tool works with the formula presented in Equations 2.2 and 2.3, where one input is the lead time, understood as the time it would take suppliers to make a replenishment if we place an order today. Lead time cannot be easily traced in ERP systems. For many of Roche's SKUs, there is a "frozen period" agreed upon with the suppliers. During this period, no changes to the production plan can be made. The TACT tool does not consider the frozen period when calculating safety stock days. Hence, in such scenarios, planners would propose a safety stock target that is far greater than the recommended amount. This approach is not optimal and leads to high inventory.
- 2. Affiliate planners round the target up.
- 3. If the Affiliate planners have additional knowledge about upcoming uncertainties, such as an expected bottle neck in packaging, a scheduled factory shutdown due to system upgrade, longer supplier lead times, an expected drop in sales, etc., they might increase the safety stock target recommended by the system.
- 4. Planners might also decrease the safety stock target when it is a sample SKU (a product being tested out and not yet launched).

The first reason was the most common in the sample analyzed. Instead of recalculating the safety stock levels with a more appropriate lead time, the modifications are done based on experience and there is no traceability of the previous decision made.

4.1.4 Supply planners

Once the Affiliate planners propose the safety stock days, the supply planners check for any concerns. If there is an increase in safety stock days, then the Supply planners check whether they have enough capacity and raw materials to ramp up production. If there is a decrease in safety stock days, the Supply planners try to evaluate how this situation could affect the production frequency. Once they finalize the safety stock days, Affiliate planners update the APO tool. The tool now creates a production plan ready to be used by the Supply planners. Affiliates act as liaisons between the commercial planning team and the Supply planners. However, the demand and the safety stock days are set by the Commercial and Affiliates teams.

The Supply planners are accountable for inventory targets. The Commercial Team forecasts to satisfy 100% of the forecasted demand and include a buffer to mitigate upside risk, which could lead to stock out. The resulting forecast has a bullwhip effect on safety stock days, which increases capacity utilization and leads to increase in inventory.

4.1.5 Buffering of Safety Stock

As stated in the methodology chapter, all the previous work was consolidated into a SIPOC diagram. This diagram, shown in Figure 4, also highlights the different situations in which a buffer is added.

Figure 4 *Current state process to set safety stock process*

Note: Figure shows the current state process to set safety stock targets. Various numbers indicate the opportunities of improvement in the current process.

As can be seen in the diagram, we identified the following five buffer sources:

- 1) Forecasters consider various inputs before they finalize the forecast numbers each month, which could lead to upside forecasting:
	- Actual historical demand: any seasonality or trend in demand.
	- Unintended usage: They look at the market to identify situations in which the specific product is used for any unintended therapeutic area, something that it was not made for, but which could lead to a spike in demand. This situation is not included in the financial forecast, but will be considered by the S&OP Team to ensure the supply planning can meet their demand.
	- FDA approvals: If the drug is approved for a new application, a spike in demand would be expected.
- Competitor erosion: If the competitor launches a product in the same therapeutic area, the launch might take away Roche's market share, creating a drop in the demand.
- Competitor supply issues: If a competitor has supply issues, this could lead to an increase in Roche's product demand.

● Introduction of new SKU: A new product launch could mean cannibalization of other brands. Adding extra units to the most likely forecast to protect against uncertainty in demand pushes production orders that, when demand is less than expected, will remain as extra inventory.

- 2) The Global TACT team level sets the factor Z, which reflects the service level, too high. Safety stock increases exponentially as a function of the cycle service level.
- 3) The Global TACT team assumes the demand forecast errors to be normally distributed with no bias, i.e., with an expected value of zero, which aligns with classical theory. However, in an upside demand forecast, this assumption does not hold. As summarized in the literature review, this results in more units of safety stock than required for the same level of service.
- 4) The affiliate, upon receiving the TACT safety stock recommendation, looks at feasibility and other supply planning issues and adds an additional buffer to ensure they have sufficient product for patients.
- 5) The translation of the safety stock target from time units into physical units inappropriately reflects past trends. As presented in the literature review (Neale & Willems, 2015), when facing an upper trend in the forecast, translating days of inventory into units but looking for the forecast demand for those next days results in more units than needed. Similarly, when there is a lower trend, the safety stock could result in more units than actually needed.

4.1.6 Conceptual recommendations

Based on our understanding of Roche's US supply chain, we offer the following safety stock policy:

- 1. Documenting the reason for buffer. The 25 forecasters for various therapeutic drugs forecast the demand based on their personal risk tolerance levels and intuition. In the existing process, we cannot trace back and explain the historical demand forecast. A sudden spike or drop in demand has a bullwhip effect on the upstream planning. Hence, there is a need for standardizing and documenting the intuition of demand forecasting.
- 2. Develop a metric to track impact of manual corrections of safety stock. Once the TACT tool recommends the safety stock level, the Affiliate planners make appropriate changes to the safety stock target days due to expected supply chain disruptions. Tracking the number of those changes every month, documenting the reasons for these manual interventions, and validating them in the upcoming months would help the Affiliate planners understand their bias. These steps will help the planners understand the impact of manually correcting the safety stock proposed by the TACT tool.
- 3. Account for frozen periods. In the existing process, due to the frozen period of suppliers, the Affiliate planners increase the safety stock days. These frozen periods are standard operating procedure for the suppliers and hence should be accounted for in the TACT and not be an afterthought.
- 4. Review safety stock values more frequently. Safety stocks are determined once a year by the TACT tool and then updated based on experience according to situations that occur, such as lifecycle events. We believe this frequency should be changed from yearly to quarterly/half yearly. Recent changes in demand and the product lead time have a bigger influence on the product than 12 month-old data.
- 5. Improve communication channels among the supply chain planners. In the existing process, the ideas between Supply planners and the Commercial Team are not well translated by the Affiliate planners. The commercial team could attend the SRM (Supply Review Meeting) to explain the reasoning behind the increase in demand forecast, and Supply planners should be able to freely challenge any underlying bias behind such decisions. Affiliate planners should act as liaisons by bringing the teams together and discussing the uncertainties across the supply chain. Any change made to the safety stock should be based on a consensus across the commercial, demand and supply planners.
- 6. Align inventory planning across echelons and regions. In the existing process, Affiliate planners determine safety stock for individual regions without considering interdependencies between regions. Although this strategy provides opportunities to streamline operations while maintaining service level, it is not the most effective way to optimize total inventory for the product. MEIO (Multi-Echelon Inventory Optimization) would enable setting the optimal safety stock throughout the supply chain network. It would also help in setting the right mix of drug products and finished goods.
- 7. Improve translations from days to units of inventory. Working with a safety stock policy in days can help make safety stock more dynamic and dependent on the forecast for each period. Nevertheless, we found out it was not clear how to translate this number into units and it was in fact done by a forward coverage approach. As presented in the literature review, for products with trends or seasonality, Roche could be negatively impacted by the *landslide effect*. We recommend following Neale and Willems' (2015) proposals to mitigate this risk.

4.1.7 Conclusions from the Conceptual Model

The conceptual model allowed us to understand the interactions between the different teams and how the different decisions that each of them makes buffer against uncertainty. It is important to highlight that, of the five buffering sources identified, the only place where there should be one is in the safety stock, by fixing the desired service level.

4.2 Step 2: Creating a formal model

In this section we summarize the results of the second step of our methodology, creating a formal model with made-up data that represents the different pain points we gathered in the previous section. Our aim was to understand what could be done with a representative example, and then validate the results with real data in section 4.3.

4.2.1 Scientific recommendations

High inventory levels and large amounts of product write-offs within the Roche North American team have led the planning organization to explore new techniques to set safety stock targets. Although the planning tools were in line with the academic recommendations (the TACT tool, which is shown in Equation 1.1 and 2.2) to define the safety stock level, planners often rejected them. These counterintuitive results led to a thorough examination of various processes involved in determining the safety stock (Figure 4). First, the S&OP demand forecast for most of the SKUs exhibited significant bias. Second, this biased

forecast was loaded into the Starr tool in the form of planned demand for future weeks. Third, the TACT tool, which is used to determine the safety stock, assumed this planned future demand was unbiased.

One way to address forecast bias is to remove the bias from the S&OP forecast provided by the Commercial Team. However, removing the bias is not feasible at Roche, as this forecast data is entered into the Starr tool, which is used by multiple teams. Hence, the planning team needs to find a way to use the biased forecast to determine the right safety stock target level.

As an illustrative example, consider a hypothetical SKU with the following actual monthly demand and forecast for the year 2020, as shown in Figure 5. This SKU has a two-month lead time with a service level of 99% and a frozen period of zero. The corresponding average demand is 45,829 and standard deviation is 34,023. The expected safety stock, based on the formula above, is 111,934.

Figure 5 *Actual demand and forecast data for a sample SKU*

Note: Figure shows demand and forecast data for an SKU per month from January 2020 to December

2020

As a first step, we examine the bias in the demand forecast by calculating the relative forecast accuracy for each SKU (Manary & Willems, 2008b):

$$
\theta i = \frac{F i - k - 1}{F i - k - 1 + D i} \tag{4.1}
$$

Fi-k-1 denotes the forecast for demand in period *i* and made in the period *i-k-1* if *k* is the number of frozen periods. D_i denotes the actual demand in period *i*. For each SKU, if the θ_i is 0.5, then it indicates that Forecast $F_{i,k-1}$ and Demand D_i are equal. If the θ_i is greater than 0.5, then the SKU is over-forecasted with Forecast $F_{i,k-1}$ being greater than Demand D_i . Additionally, if the θ_i is less than 0.5, then the SKU is underforecasted and Forecast *Fi-k-1* is less than Demand *Di.*

Note: Figure shows θ distribution and bias in forecast for a 12-month period.

To net out the forecast bias from the data, we calculate a modified standard deviation of forecasted demand (Manary & Willems, 2008b):

$$
\sigma_D \text{ Modified} = \frac{E(D)}{Z_{\alpha}} + \sigma_D \tag{4.2}
$$

The modified standard deviation is

$$
\sigma_D^{\text{Modified}} = \frac{45,829}{-2.33} + 34,023 = 14,322 \tag{4.3}
$$

Then,

$$
\sigma_x = \sqrt{E(L)\sigma_D^{Modified} + [E(D)]^2 \sigma_L}
$$
\n(4.4)

Therefore, the updated safety stock is

$$
SS = k\sigma_x \tag{4.5}
$$

The safety stock with this standard deviation is 47,121 units of SKU. Before removing the bias, the safety stock was greater than 100,000, so we see a significant decrease with this method. As we can see in Figure 7, even after reducing the safety stock, we are not running out of stock.

Initial Safety Stock and Modified Safety Stock relative to Error

Note: Figure shows initial and modified safety stock target with respect to error. The second figure shows the actual demand, initial and modified inventory target for the sample SKU.

4.3 Application to Roche's products

In this section, we present the impact of applying our formal model to different Roche SKUs that are representative of their product portfolio.

4.3.1 SKU 1

This SKU has 30 days of theoretical lead time with 4w 6d 21h 0m (35 days) of frozen period and is in its launch phase with cycle service level of 99% and actual lead time of 32 days. The actual forecasted demand and inventory from September 2020 to February 2022 (18 months) can be seen in Figure 8. The number of days during this period is 548 and total actual demand during this period is 13,975 units, hence the average units sold each day in this 18-month horizon is 26. The safety stock in the system during this period is 65 days. See Appendix 7.1 SKU 1 for further details.

Actual & Forecasted Demand against Inventory

Note: Figure shows actual demand, forecasted demand, and inventory for SKU 1.

Upon visualizing the safety stock days, actual lead time, frozen period, and days of inventory, we get Figure 9. The minimum Inventory on Hand for the past 12 months is 9,400 units. The net replenishment time is the sum of frozen period (38 days) and average lead time (33 days). The net replenishment time for this product is therefore 68 days. The maximum demand over the net replenishment time in the last 12 months is 2,108 units.

Note: Figure shows safety stock days, actual lead time + safety stock days, frozen period + actual lead time + safety stock days, and days of inventory for SKU 1.

Upon examining the bias for this product, we see that the product is over forecasted ($\theta > 0.5$) for 15 months and under forecasted for 3 months (θ < 0.5) (see Figure 10). From the figure, we conclude that the data has a positive bias. The mean actual demand for the September 2020 to August 2021 period is 655, and standard deviation of actual demand for the training set is 300.

Note: Figure shows Error and θ Distribution for the 18-month period for SKU 1.

Upon calculating the modified standard deviation of actual demand as per Equation 4.4, we get 282 units, and the updated safety stock days is 60. Hence, there is a drop of close to 5 days in safety stock days, which can be seen in Figure 11. Assuming the cost of goods sold (COGS) for this product is \$100, the inventory investment without the bias adjustment is 65*26*100 = \$169,000. The inventory investment with the bias adjustment is $60*26*100 = 156,000$. Thus, the working capital reduction is \$169,000 -\$156,000 = \$13,000. Assuming, out of the \$100 only 10% is variable cost and the remaining 90% is fixed cost, the financial impact of removing bias from safety stock would be \$13,000*10% = \$1,300.

Note: Figure shows modified safety stock days, actual lead time + safety stock days, frozen period + actual lead time + safety stock days, and days of inventory for SKU 1.

4.3.2 SKU 2

This SKU has 67 days of theoretical lead time with 6w 0d 6h 0m 0s (48 days) of frozen period and is in its launch phase with cycle service level of 99% and actual lead time of 12 days. The actual forecasted demand and inventory from May 2021 to March 2022 (9 months) can be seen in Figure 12. The number of days during this period is 274 and the total actual demand during this period is 161,506 units, making the average units sold each day in this 9-month horizon 590. The safety stock in the system during this period is 60 days. See Appendix 7.2 SKU 2 for further details.

Figure 12 *SKU 2 demand and inventory*

Actual & Forecasted Demand with Inventory for 9 months

Note: Figure shows actual demand, forecasted demand, and inventory for SKU 2.

Upon visualizing the safety stock days, actual lead time, frozen period, and days of inventory, we get Figure 13. The minimum Inventory on Hand for the past 9 months is 50 units. The net replenishment time is the sum of the frozen period (48 days) and average lead time (12 days). The net replenishment time for this product is, therefore, 60 days. The maximum demand over the net replenishment time in the last 12 months is 38,202 units.

Figure 13 *SKU 2 Comparison of days of inventory*

Note: Figure shows safety stock days, actual lead time + safety stock days, frozen period + actual lead time + safety stock days, and days of inventory for SKU 2.

Upon examining the bias for this product, we see that the product is over forecasted ($\theta > 0.5$) for 9 months and under forecasted for 3 months (θ < 0.5) (see Figure 14). From the figure, we conclude that the data has a positive bias.

Figure 14 *SKU 2 Error and Distribution*

Note: Figure shows Error and θ Distribution for the 18-month period for SKU 2.

We notice the product had a stock out scenario, i.e., inventory was less than actual demand (seen in Figure 12). When we verified with Roche, they mentioned the inventory data has discrepancies, so we did not proceed with any further analysis.

4.3.3 SKU 3

This SKU has 68 days of theoretical lead time with 6w 0d 6h 0m 0s (48 days) of frozen period and is in its launch phase with a cycle service level of 99% and an actual lead time of 18 days. The actual forecasted demand and inventory from April 2020 to March 2022 (23 months) can be seen in Figure 15. The number of days during this period is 700 and the total actual demand during this period is 108,132 units, hence, the average units sold each day in this 23-month horizon is 154. The safety stock in the system during this period is 60 days. See Appendix 7.3 SKU 3 for further details.

Note: Figure shows actual demand, forecasted demand, and inventory for SKU 3.

Upon visualizing the safety stock days, actual lead time, frozen period, and days of inventory, we get Figure 16. The minimum Inventory on Hand for the past 12 months is 1,929 units. The net replenishment time is the sum of the frozen period (48 days) and average lead time (18 days). The net replenishment time for this product is, therefore, 66 days. The maximum demand over the net replenishment time in the recent 12 months is 10,286 units.

Figure 16 *SKU 3 Comparison of days of inventory*

Note: Figure shows safety stock days, actual lead time + safety stock days, frozen period + actual lead time + safety stock days, and days of inventory for SKU 3.

Upon examining the bias for this product, we see that the product is over forecasted ($\theta > 0.5$) for 23 months and under forecasted for 5 months (θ < 0.5) (see Figure 17). From the figure, we conclude that the data has a positive bias.

Note: Figure shows Error and θ Distribution for the 18-month period for SKU 3.

We notice the product had a stock out scenario, i.e., inventory was less than actual demand (seen in Figure 15). When we verified with Roche, they mentioned the inventory data had discrepancies, so we did not proceed with any further analysis.

4.3.4 SKU 4

This SKU has 31 days of theoretical lead time with 4w 6d 21h 0m (35 days) of frozen period and is in its resilient phase with a cycle service level of 99% and an actual lead time of 32 days. The actual forecasted demand and inventory from March 2020 to February 2022 (24 months) can be seen in Figure 18. The number of days during this period is 730 and the total actual demand during this period is 126,818 units, hence, the average units sold each day in this 24-month horizon is 174. The safety stock in the system during this period is 35 days. See Appendix 7.4 SKU 4 for further details.

Figure 18 *SKU 4 demand and inventory*

Note: Figure shows actual demand, forecasted demand, and inventory for SKU 4.

Upon visualizing the safety stock days, actual lead time, frozen period, and days of inventory, we get Figure 19. The minimum Inventory on Hand for the past 12 months is 15,685 units. The net replenishment time is the sum of the frozen period (35 days) and average lead time (32 days). The net replenishment time for this product is, therefore, 67 days. The maximum demand over the net replenishment time in the last 12 months is 12,184 units.

Figure 19 *SKU 4 Comparison of days of inventory*

Note: Figure shows the safety stock days, actual lead time + safety stock days, frozen period + actual lead time + safety stock days, and days of inventory for SKU 4.

The mean actual demand for the March 2020 to February 2021 period is 5,104, and the standard deviation of actual demand for the training set is 666. Upon examining the bias, we see that the product is over forecasted ($\theta > 0.5$) for 10 months and under forecasted for 2 months ($\theta < 0.5$) (see Figure 20). In this example, we observe the bias is much closer to the 0.5 region. This product seems to be slightly over forecasted. From the figure, we conclude that the data has a positive bias.

Note: Figure shows the Error and θ Distribution for the 12-month period for SKU 4.

Upon calculating the modified standard deviation of the actual demand per Equation 4.4, we get 668 units, and the updated safety stock days is 33. Hence, there is a drop of close to 2 days in safety stock days, which can be seen in Figure 21. Assuming the cost of goods sold (COGS) for this product is \$100, the inventory investment without the bias adjustment is 35*174*100 = \$609,000. The inventory investment with the bias adjustment is 33*174*100 = \$574,200. Thus, the working capital reduction is \$609,000 -\$574,200 = \$34,800. Assuming that out of the \$100 only 10% is variable cost and the remaining 90% is fixed cost, the financial impact of removing bias from safety stock would be \$34,800*10% = \$3,480.

Note: Figures shows modified safety stock days, actual lead time + safety stock days, frozen period + actual lead time + safety stock days, and days of inventory for SKU 4.

4.3.5 SKU 5

This SKU has 0 days of theoretical lead time with 3w 0d 0h 0m 0s (21 days) of frozen period and is in its launch phase with a cycle service level of 99% and an actual lead time of 12 days. The actual forecasted demand and inventory from November 2021 to February 2022 (4 months) can be seen in Figure 22. The number of days during this period is 122, and total actual demand during this period is 252 units, making the average units sold each day in this 4-month horizon 2. The safety stock in the system during this period is 80 days. See Appendix 7.5 SKU 5 for further details.

Figure 22 *SKU 5 demand and inventory*

Note: Figure shows actual demand, forecasted demand, and inventory for SKU 5.

Upon visualizing the safety stock days, actual lead time, frozen period, and days of inventory, we get Figure 23. Here we notice that the days of inventory value is significantly higher than the safety stock days. The minimum Inventory on Hand for the past 12 months is 743 units. The net replenishment time is the sum of the frozen period (21 days) and average lead time (12 days). The net replenishment time for this product is, therefore, 33 days. The maximum demand over the net replenishment time in the last 12 months is 131 units.

Figure 23 *SKU 5 Comparison of days of inventory*

Note: Figure shows safety stock days, actual lead time + safety stock days, frozen period + actual lead time + safety stock days, and days of inventory for SKU 5.

The mean actual demand for the period of November 2021 to January 2022 is 74, and standard deviation of actual demand for the training set is 51. Upon examining the bias for this product, we see that the product is over forecasted ($\theta > 0.5$) for 4 months (See Figure 24). In this example, we can say that the product is highly over forecasted.

Note: Figure shows error and θ distribution for the 12-month period for SKU 5.

Upon calculating the modified standard deviation of actual demand per Equation 4.4, we get 50 units, and the updated safety stock days is 50. Hence, there is a drop of close to 30 days in safety stock days, which

can be seen in Figure 25. Assuming the cost of goods sold (COGS) for this product is \$100, the inventory investment without the bias adjustment is $80*2*100 = $16,000$. The inventory investment with the bias adjustment is $50*2*100 = $10,000$. Thus, the working capital reduction is $$16,000 - $10,000 = $6,000$. Assuming that out of the \$100 only 10% is variable cost and the remaining 90% is fixed cost, the financial impact of removing bias from safety stock would be \$6,000*10% = \$600.

Figure 25 *SKU 5 Comparison of days of inventory after removing bias*

Note: Figure shows modified safety stock days, actual lead time + safety stock days, frozen period + actual lead time + safety stock days, and days of inventory for SKU 5.

4.3.6 SKU 6

This SKU has 30 days of theoretical lead time with 7w 2d 6h 0m 0s (51 days) of frozen period and is in its launch phase with a cycle service level of 99% and an actual lead time of 36 days. The actual forecasted demand and inventory from March 2020 to February 2022 (24 months) can be seen in Figure 26. The number of days during this period is 730, and the total actual demand during this period is 15,477 units, hence, the average units sold each day in this 24-month horizon is 21. The safety stock in the system during this period is 75 days. See Appendix 7.6 SKU 6 for further details.

Note: Figure shows safety stock days, actual lead time + safety stock days, frozen period + actual lead time + safety stock days, and days of inventory for SKU 6.

Upon visualizing the safety stock days, actual lead time, frozen period, and days of inventory, we get Figure 27. Here we notice that the days of inventory value is significantly higher than the safety stock days. The minimum Inventory on Hand for the past 12 months is 3,925 units. The net replenishment time is the sum of the frozen period (51 days) and average lead time (36 days). The net replenishment time for this product is, therefore, 87 days. The maximum demand over the net replenishment time in the last 12 months is 1,765 units.

Figure 27 *SKU 6 Comparison of days of inventory*

Note: Figure shows safety stock days, actual lead time + safety stock days, frozen period + actual lead time + safety stock days, and days of inventory for SKU 6.

Upon examining the bias for this product, we see that the product is over forecasted ($\theta > 0.5$) for 12 months (see Figure 28). In this example, we can say the product is frequently over forecasted. The mean actual demand for the March 2020 to February 2021 period is 725, and the standard deviation of actual demand for the training set is 227.

Note: Figure shows the Error and Distribution for the 12-month period for SKU 6.

Upon calculating the modified standard deviation of actual demand per Equation 4.4, we get -84 units, which due to the upper bound of max function, we take it as 0. The modified safety stock days is 64. Hence, there is a drop of close to 11 days in safety stock days, which can be seen in Figure 29. Assuming the cost of goods sold (COGS) for this product is \$100, the inventory investment without the bias adjustment is 75*21*100 = \$157,500. The inventory investment with the bias adjustment is 64*21*100 = \$134,400. Thus, the working capital reduction is \$609,000 - \$574,200 = \$23,100. Assuming that out of the \$100 only 10% is variable cost and the remaining 90% is fixed cost, the financial impact of removing bias from safety stock would be $$23,100*10% = $2,300$.

Figure 29 *SKU 6 Comparison of days of inventory after removing bias*

Note: Figure shows modified safety stock days, actual lead time + safety stock days, frozen period + actual lead time + safety stock days, and days of inventory for SKU 6.

4.4 Inferences

First, if we analyze the bias across the products, we notice that not all products are positively biased with a large forecast as compared to the actual demand. SKU 6, SKU 1, and SKU 5 have large θ and are further away from 0.5. However, SKU 2, SKU 3, SKU 4 are around 0.5 and have occasionally been under forecasted, as seen in Figure 30.

Note: Figure shows bias θ across various products.

Second, despite the high safety stock target in the system, we noticed a few products might have a stockout situation, that is, inventory is less than actual demand. From Figure 31, we can infer products like SKU 2 & 3 have a stock-out situation. For SKU 3 in March 2021 and September 2021, the inventory on hand was below the actual demand. For SKU 2 in January 2022, we see that the inventory was below actual demand. The out-of-stock situation indicates that the safety stock target set in the system, which should have avoided the stockout, is not implemented. There is a gap between the target set in the system and the actual inventory levels; therefore, we did not conduct any financial analysis for SKU 3 and SKU 2.

Note: Figure shows actual demand, forecasted demand, and inventory across various products.

4.5 Discussion

4.5.1. Bias and safety stock

We can conclude from Table 1 that removing bias in safety stock leads to two percent overall reduction of inventory for all four products. We observe that across all products analyzed in this paper, safety stock reduction due to bias is a small fraction of the overall average inventory per month. For example, in Table 1 we can see the safety stock units for SKU 4 are reduced by 347 units, which is less than two percent of the average inventory per month (around 21,042). However, this is not significant enough, we need to learn more about other factors contributing to high inventory levels. Per our analysis, buffering of safety stock is not the biggest contributor to inventory. Instead, we suggest that Roche invest in understanding their existing inventory policy and identifying the major cause of high inventory levels.

Table 1 Summary statistics of buffer in safety stock

Product	Total Months	Total Days	Total Demand (units)	Average Inventory/ month	Average Demand/day	Average IOH/day	Safety Stock in the system (days)	Safety stock after removina Bias (days)	Safety Stock Reduced (units)	Financial Impact	% of reduction in Inventory due to Bias
SKU ₄	24	730	126,818	21.042	174	29	35	33	347	3,480	1.7%
SKU ₆	24	730	15.447	4,767	21		75	64	231	2,310	4.8%
SKU ₁	18	548	13,975	11,891	26	22	65	60	128	1,300	1.1%
SKU ₅		122	252	1,385		11	80	50	60	600	4.3%
Total				39,085					766		2.0%

Note: Table shows summary statistics across products.

4.5.2. Root cause of Inventory Investment

In understanding the magnitude of the gap between safety stock reduction due to buffer and Average Inventory per month, we did further analysis to understand the inventory policy. The affiliate planners mentioned that inventory is defined by minimum and maximum range and is not defined by the safety stock target in the system. We did not have access to how the range for inventory is set.

Given that safety stock is a small part of the inventory, we did a quick analysis to identify potential for broader inventory research. As mentioned in the literature review, section 2.6, another robust approach is to set inventory to a sufficient level to cover risk.

Table 2 Summary of potential inventory reduction

Note: Table shows minimum inventory on hand, maximum demand over net replenishment time in units, and difference is indicated as the potential inventory reduction.

For example, in the case of SKU 4, minimum inventory on hand in the last 12 months is 15,685, and the maximum demand over a net replenishment time of 3 month is 12,184. The potential inventory reduction is around 3,500, that is, a 16% reduction in inventory. As mentioned earlier, removing safety stock bias leads to 2% drop in inventory for SKU 4, whereas there is room for reducing the inventory by 16%.

Table 3 Comparison of inventory reduction due to removal of buffer and total inventory reduction

Note: Table compares the two methods of inventory reduction. It shows the percentage of inventory reduction due to removal of buffer from safety stock and percentage of overall inventory reduction for each product.

When we look at the products, the average inventory on hand per month is 39,085 units. The potential reduction of safety stock due to bias across products is 2% (770 units), and the potential reduction of overall inventory using the robust method is 35% (13,565 units), which can be seen in Table 3. This analysis helps us understand that bias in safety stock is only part of the reason for high inventory levels. There is a need for further investigation to identify the root cause of the remaining 33%. To understand this gap, we need to investigate the inventory policy, question how frequently an order is placed with the supplier, understand how the reorder point is defined, and investigate if there is a minimum lot size for upstream orders.

Inferring from Table 3, we recommend that Roche examine the reason for high inventory levels instead of implementing the modified safety stock targets, as it is a small portion of a larger problem. Implementing the modified safety stock targets will take quite some time and make the existing system more complex.

First, Roche could start by monitoring its actual inventory levels during their monthly DRM (Demand review meeting) and SRM (Supply review meeting). Second, they need to start tracking safety stock and actual inventory in the same units, whether that be in units or days of safety stock and days of inventory. Third, planners need to fully understand and explain the inventory levels; they should question the gap between safety stock and actual inventory.

5 CONCLUSION

Globalization, demand uncertainty, and shorter life cycles have increased the uncertainty and risks in pharmaceutical supply chains. To mitigate these risks, firms can carry safety stock. Classic theory in stochastic safety stock strategies considers that demand forecast errors are normally distributed with no bias or, in other words, an expected value equal to zero. This assumption does not hold when considering over-optimistic demand forecasts like in our sponsor company, F. Hoffmann-La Roche (Roche).

As an operational research project, we started by understanding the managerial situation or problem that needs to be solved. Then, we developed a conceptual model by interviewing the different teams that have an impact on the safety stock target definition. By doing so, we were able to understand not only the decisions they make but also the motivation behind them. Contrary to our initial hypothesis, we found out that a buffer is included in many points of their supply and demand processes, not only at a safety stock calculation stage. This is due to an overoptimistic forecast.

The first buffer is that forecasters consider various inputs before they finalize the forecast numbers each month, which could lead to upside forecasting. Adding extra units to the most likely forecast to protect against uncertainty in demand pushes production orders that, when demand is less than expected, will remain as extra inventory but not as safety stock. The second buffer is the Global TACT team setting the safety factor Z based on the service level to protect the company from stock-outs. Safety stock increases exponentially as a function of the cycle service level. If the selected desire level is too high, the safety stock level must also be high to fulfill that aim. Third, buffering of safety stock happens when Affiliate planners, engaged in the S&OP process, further consider feasibility and other supply planning issues and add an additional buffer to the TACT safety stock recommendation. Finally, there is the buffer that motivated this project, when the Global TACT team, in alignment with most textbook approaches for safety stock calculation, considers the demand forecast errors to be normally distributed with no bias, i.e., with an expected value of zero. However, the demand forecast in this planning process consistently has a positive bias. As summarized in the literature review, this results in more units of safety stock than required for the same level of service.

To tackle the multi-buffering problem, many organizational measures could be taken. We propose a better documented procedure for the 25 forecasters that leverage their personal experience and intuition, along with variable risk tolerance levels. Monitoring of these individual forecasts along with a frequent review of the manual edits to the forecast would enable bias measurement and assessment of the value added from subsequent intervention. Additionally, if bias persists in demand forecast, appropriate changes need

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to be made to remove it before determining the safety stock, following a process such as the one proposed earlier. Next, a sincere debate regarding frozen periods needs to be carried out. if Roche has better control over their suppliers and can avoid such agreements, then frozen period need not complicate the inventory planning process. If the frozen period is retained, then it should be part of the lead time calculations and, thus, affect the safety stock. Finally, safety stocks are currently determined once a year by the TACT tool and then updated situationally based on experiences and events. We believe this frequency should be changed to a quarterly/biannual review.

More generally, proper communication channels across the supply chain are needed. The S&OP process, even though it is structured according to the literature, still retains independent discussions among demand and supply teams. The Affiliate demand planners should act as liaisons by bringing the teams together to discuss the uncertainties across the supply chain. Any change made to the safety stock and inventory policies should reflect consensus across the commercial, demand, and supply planners.

We developed a conceptual model that was the foundation for our formal model, which uses a new safety stock formula to address bias in the forecast. Along with the conceptual model, we also need to make changes in the formal model where we identify bias using the θ distribution. If the $\theta > 0.5$, this would indicate forecast is greater than actual demand for the product. Then, we calculate the modified standard deviation of demand and modified safety stock once bias is removed. However, in the case of Roche, for the products we analyzed, we notice that inventory is higher than safety stock. We concluded that Roche needs to investigate its inventory policy to make a bigger impact on reducing safety stock. Results show that, even though safety stock can be adjusted with this new approach, there are still many opportunities for improvement that goes beyond this process.

The products taken as examples show there is an even bigger potential to reduce inventory that goes beyond the safety stock. Roche should continue working towards understanding its root causes to achieve long-term substantial impact. We conclude that, to make the best informed decision, further efforts should be allocated to understand the source of the data, its configuration in the system, what it means, and whether it is appropriate to make certain decisions based on it. Also, there is a need to understand the inventory management policies for each product, that includes safety stocks but also reorder points, economic and minimal order quantities, and so forth. All this should be visualized in a single point of truth, where all teams can understand how inventory, demand, forecast, and lead times affect inventory.

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7 APPENDIX

7.1 SKU 1

Table 4 *Information on SKU 1*

Note: Table shows various metrics for SKU 1.

Table 5 *Demand and Inventory for SKU 1*

Note: Table shows actual demand, forecasted demand, inventory, error, bias term, and demand over net replenishment time (2 months) for SKU 1.

7.2 SKU 2

Table 6 *Information on SKU 2*

Note: Table shows various metrics for SKU 2.

Table 7 *Demand and Inventory for SKU 2*

Metrics	Actual Demand	Forecasted Demand	Inventory	Error	Tetha
$May-21$	16,115	19,019	17,817	2,904	0.54
Jun-21	20,438	21,897	52,762	1,459	0.52
Jul-21	17,025	20,777	35,737	3,752	0.55
$Aug-21$	16,441	19,786	19,296	3,345	0.55
Sep-21	21,851	23,750	50	1,899	0.52
Oct-21	15,876	20,437	50	4,561	0.56
$Nov-21$	16,544	19,896	10,857	3,352	0.55
Dec-21	20,322	20,430	10,854	108	0.50
$Jan-22$	16,894	15,015	88,698	(1,879)	0.47

Note: Table shows actual demand, forecasted demand, inventory, error, bias term, and demand over net replenishment time (2 months) for SKU 2.

7.3 SKU 3

Table 8 *Information on SKU 3*

Note: Table shows various metrics for SKU 3.

Table 9 *Demand and Inventory for SKU 3*

Note: Table shows actual demand, forecasted demand, inventory, error, bias term, and demand over net replenishment time (2 months) for SKU 3.

7.4 SKU 4

Table 10 *Information on SKU 4*

Note: Table shows various metrics for SKU 4

Table 11 *Demand and Inventory for SKU 4*

Note: Tables shows, actual demand, forecasted demand, inventory, error, bias term, and demand over net replenishment time (2 months) for SKU 4

7.5 SKU 5

Table 12 *Information on SKU 5*

Note: Table shows various metrics for SKU 5.

Table 13 *Demand and Inventory for SKU 5*

Note: Table shows actual demand, forecasted demand, inventory, error, bias term, and demand over net replenishment time (2 months) for SKU 5.

7.6 SKU 6

Table 14 *Information on SKU 6*

Note: Table shows various metrics for SKU 6.

Table 15 *Demand and Inventory for SKU 6*

Note: Table shows actual demand, forecasted demand, inventory, error, bias term, and demand over net replenishment time (2 months) for SKU 6.