

### COMMUNICATION IS THE FOUNDATION FOR EFFECTIVE PHARMACEUTICAL SUPPLY CHAIN STRATEGY

A conversation with Joe Shedlawski

#### ABOUT

Joe Shedlawski is a pharmaceutical manufacturing and logistics expert with experience in the vaccines sector as director of supply chain for a major global producer. Ben Locwin is a healthcare executive with quantitative and qualitative analytics expertise. He works with senior managers at biopharmaceutical, vaccine, and medical device companies to market at higher velocity and with higher quality.





Joe Shedlawski APICS master instructor

Ben Locwin Evaluating Biopharma

BL: It is widely acknowledged that pharmaceutical production and distribution is a highly complex activity, requiring the co-ordination of multiple processes, separate organisations and materials.

### But what are some of the less well known supply chain management challenges you see in the pharmaceutical industry?

JS: Well I would say rapid growth is one of the major challenges because it can put pressure on the supply chain and reveal weaknesses.

To give you an example, at one point in my career we experienced a period of rapid growth, both domestically and internationally. While this was initially positive, the additional pressure on our supply chain meant we were actually starting to over promise and under deliver on a too frequent basis.

We had a regulatory team that was good at getting approvals and more bids on vaccination programs in various states in the United States as well as internationally. But it was tough to keep supply and demand in balance not only in the short term but in our longer term plans and projections.



JS: And as a result, different constraints and bottlenecks appeared. For example, until that period of rapid growth things like manufacturing equipment downtime, lunch breaks and different shifts and so forth were not so much of an issue.

A lack of vial filling capacity was another issue. Who would think that a company that could develop brilliant vaccine production processes could run into a bottleneck in the vial filling process? But we did.

## *BL*: So how did you successfully overcome these challenges and reconfigure your supply chain?

JS: We had to be a little bit resourceful in our use of capacity. The easy answer would have been to get more filling capacity buy that's a long-term proposition. So we took a look at our hand and said we've got a couple options, one of which was to divert some of the demand into syringes.

I did a study on that and we get more doses out of a batch of product when we looked at all of the losses in process and all the overfills and so forth.

We also recommended to the federal government and some International governments that they start with a lower dosage so we could extend supply and at least get more individuals immunized. So we started to take control of supply and demand.

### BL: Were there any other measures that you implemented?

JS: We also changed the way we were forecasting. Forecasts are always problematic in any business or industry but particularly in vaccines where there is variability in both production output – you are growing the product rather than manufacturing it - and demand as you enter new markets.

One way of addressing this is to control the demand by saying "this is our upper limit so let's decide how we fill that bucket of demand and what promises we will make."

Demand forecasting in vaccines when I started, when the business was relatively small was based on statistics and history. But this became worse than useless because it was taking us in the wrong direction sometimes.

So we had to get closer to our markets. We had to get closer to some of our International affiliates into the timing of regulatory approvals and so forth to get a better handle on future demand.

And I'm not talking about future meaning the next month or two but further out to see what changes we need to make structurally. What capital investments we need to keep building this business, to keep it on the trajectory that the demand could take us if we were able to handle it.



BL: It seems like a lot of the steps you took - demand control, production planning - are in the realm of lean. To what extent did lean thinking influence efforts to reconfigure your supply chain?

JS: We think about lean as elimination - or a reduction to the extent possible - of waste. In our supply chain we had processes that were not very lean and not very Six Sigma quite honestly.

We also had processes for quality control sampling and testing that had a lot of variability in lead time so we started to shore up on those. We put together a team combining a quality control person, a supply chain person, an operations person and a regulatory person together and asked how can we standardize some of these processes that have multiple links in them? Sometimes simplification was the answer - we took one process for example as I mentioned for sampling and testing down from a 14-step to a four-step handoff.

Lean was also critical to helping solve the vial filling issue I mentioned. Partly there was a need for better predictive maintenance in place so we're not subject to the line going down or we're filling in a way that is out of spec.

But our solutions were not purely about lean, we also used idea taken from the "theory of constraints" approach. We had sent some folks to a theory of constraints lecture a few years before and we realized we may not have been focusing on the right things.

For example, we had packaging lines that could run faster and faster - and they were making the headlines around the around the plant - but they weren't improving throughput, they weren't improving, ultimately, the ability to sell.

# BL: When you have task a multi-disciplinary team with supply chain management, how best do you ensure everyone is involved who needs to be involved?

JS: The best answer I can give you is that it is something that came out of a structured sales and operations planning process. The president of the division is the ultimate executive, the person who has all of the functional heads reporting. And it is at those structured, monthly meetings that we determined what our true demand, supply and inventory plans would be.

We also used those meeting to look at what our backlogs would be, where we had gaps, and where we needed to put the appropriate people on those teams. And it's not just a case of saying who's got spare time in a department and we'll do the best we can, but those teams have to have some specific goals so they really have to put on the right folks for a certain period of time.

I remember one of the first meetings was pretty tough because we're coming right up to the top of the division and showing graphs indicating that if we kept doing what we're doing with a major new product line, our inventory was going to hit zero in a year. In other words we're planning ourselves into a real disaster in our supply chain. But the use of the meeting allowed us to say "We need to determine how we can systematically close that projection gap."



BL: You mentioned that sales and production meetings were sometimes a tough environment. How important is it that companies have processes where supply chain professionals can share information and interact?

JS: Ninety nine percent of the world's problems are somehow rooted in a communications issue.

We can have the equipment, the knowledge base, the resources, the facilities and the materials but if we don't have a good solid consistent communication process we're not really all working towards the same objectives, same goals and same time frames. We're not going to be as ultimately successful as we can be.

Instead if you use a process that involves top-down sales and operations planning, clear direction, clear priorities and consistent communication of the goals and objectives around the organization you are likely to build more effective, more robust supply chains.



This case study was originally presented at Evaluating Biopharma's Supply chain challenges online and interactive event

You can watch Joe's case study in full and on demand here.

Details of future Evaluating Biopharma events can be found here.

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