



Manufacturing Perspective:

Product Delivery Challenges: Beyond the Pandemic

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The recent pandemic has created ingredient supply and manufacturing challenges that neither the Brand Owner or the Contract Manufacturing Organization (CMO) ever envisioned. No one could have foreseen the curtailment of flights between the US and China, the stopping of shipments from India for one month, employees self-quarantining for 2 weeks due to virus exposure, etc. Even with these conditions and constraints there are things the Brand Owner and CMO can do to minimize their impact. The key is doing the basic things right and having them in place - selecting the right Contract Manufacturing Organization (CMO), setting raw material specifications, working with the CMO on product development, and facility/equipment suitability offered by the CMO. All of these influence the ability of a CMO to deliver product to the Brand Owner - as the Brand Owner must have inventory to

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fill their customer's orders as they are received. In today's fast-paced world, no customer wants to wait 4 to 6 weeks to receive the dietary supplement bottle they have ordered.

Hopefully, the Brand Owner has chosen the correct CMO. However, there are still decisions made by the Brand Owner that can significantly impact the CMO's ability to deliver products in a timely manner despite everyone's best intentions and efforts. This is the ongoing struggle faced by all innovative Brands – the tradeoff between the rapid ability to scale-up an item, and a product/ingredient that is unique and different from the competition.

Often the Brand Owner will engage in research and study various ingredients before choosing a particular one to include in their dietary supplement formula. For example, if this ingredient is a Traditional Chinese or Ayurvedic botanical that is only harvested during certain seasons, or an ingredient which the supplier cannot provide at commercial scale or has stability issues, there may be supply issues that can disrupt production independent of the pandemic. Further, due to the scope of sourcing and world-wide demand, there also are a number of ingredients that suffer from spot shortages and may not always be available at any price. Most importantly, as the Brand Owner's business grows, will any of these issues cause them to lose sales or credibility because they cannot deliver product? While forecasting is required and is helpful, very rarely will it offer a guarantee the materials are going to be available when needed.

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When setting raw material specifications with the CMO, the Brand Owner has to factor in ingredient availability along with their desire for unique materials. If possible, there needs to be sufficient flexibility to enable the CMO to establish multiple sources for an ingredient, and to prime the supply chain for growth. From experience, Branded Ingredients offer the most stable supply, but this is no guarantee that spot shortages still won't

occur. It is imperative that the Brand Owner and the CMO speak with the key raw material suppliers, inform them of their business plans, and work to secure an open relationship where supply disappointments can be mitigated. From there, the Brand Owner should reach an agreement with the CMO as to what, if any, raw materials need to be inventoried by the CMO for rapid response to orders and who bears the financial responsibility for these materials. Having this understanding up front or covered in a Supply Agreement can go a long way to ensuring the Brand Owner receives product in a timely fashion.

Along with availability of the raw material, there is another potential delay factor that can significantly impact the CMO's ability to supply product on time – Customs/FDA hold at the border. This is becoming more prevalent, especially with new or unique ingredients, as more suppliers are looking to avoid inventorying materials in the US and provide just-in-time (JIT) service. This hold time can be a few days to as much as a month as the wheels of government spin to review and release the product.

After a raw material is received by the CMO, there may be required testing that can take up to 10 days to complete. A robust Quality program will prohibit the processing of the material until such

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testing is complete, especially because of the disturbing trend of raw materials failing identity testing. This has been widely reported by industry trade groups as well as our own experience.

While yet unclear as to its root cause – whether increased demand is causing intentionally adulterated materials to reach the market or the prevalence of improved, robust testing techniques or substituting cheaper raw materials that may test close to the raw material actually ordered or poor vetting of up-stream practices by suppliers or all of the previously mentioned items, these can and do cause a multitude of issues which cascade through the entire production process. A failing a raw material lot from an approved vendor can set the CMO back weeks in their manufacturing cycle as they try to obtain an acceptable replacement.

Once the raw materials are approved, now the ability of the CMO to produce the product in a timely manner comes into play. The ability to blend the correct size batch and to quickly make and package the product without compromising quality are paramount considerations. These factors should be checked by the Brand Owner before engaging with the CMO. Flexibility and scalability need to be at the core of the CMO's operational practices. The CMO should have the ability to address current and future opportunities so as not to impact the timely delivery of product to the Brand Owner.

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For example, the Brand Owner orders 10,000 bottles of a 90 count capsule supplement. If the CMO only can run the product on a semi-automatic machine at a rate of 18,000 capsules per hour, it will take a 6 or 7 days running one shift a day to make the order. However, if the formula was designed to run on an automatic machine at 90,000 capsules per hour, the product would be through encapsulation 1 ½ days. While speed is usually king, the CMO should also have smaller equipment to help with sample production, clinical testing, and opening orders so the growth of the Brand can be supported throughout its life cycle.

The most critical area which may significantly impact the finished product delivery is quality testing. While 21CFR Part 111 does not require each and every ingredient be tested each time the finished product is made, significant planning is required to ensure that testing is done on time and complies both with regulations and product specifications. A CMO who has a fully equipped and staffed laboratory has a significant advantage over the CMO who utilizes third party laboratories. With proper scheduling, finished product testing, ie the active components and potential contaminants, can be accomplished in a day or two. If any of these assays have to be sent to an outside lab, the turn-

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around time for results can easily reach 10 to 15 days. A CMO who can perform the assays using an in-house lab can save 5 to 7 days in finished product delivery time (with microbiological testing completed), as opposed to a manufacturer with only a basic quality lab.

As can be seen by the examples above, there are numerous things affecting the delivery of the finished product. Some are controlled by the Brand Owners, some are controlled by the CMO, others are shared responsibilities and some are out of everyone's control, ie a pandemic. It is extremely important for the Brand Owner to understand all of these potential pitfalls in their desire to receive a quality product in a timely manner. It is clearer than ever that cooperation and partnership between the CMO and the Brand Owner is an imperative to allow the Brand Owner to grow their company to its fullest potential.

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