

Table 21: Raw Materials Procurement Challenges: Lessons from the Pandemic

Facilitators-

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Scope:

The Pandemic has put a focus on Supply Chains - even before, there were several concerns over the availability of key raw materials going into cell culture media, key consumables used in Single Use Systems, and container closure components. The Pandemic has worsened the supply situation - from initial disruption in supply chains through manufacturing under the pandemic conditions. Finally, the impact of the preparation for and the production of the vaccine candidates - this has shock loaded the supply base with important levels of demand for materials and prioritization schemes which impact supply chain dynamics. The situation has not yet resolved itself into the new normal level of demand and it will be a while before we do have longer term clarity on the impact of the Pandemic on global supply chains, especially for key materials; that Planning Forecast, Demand and Production is more important now than ever and building resilience into supply chains at a global level across an enterprise (and not just a site level plan) is key to proper Risk & Business Continuity Management.

Questions for Discussion:

1. How have you been impacted by the Pandemic - in what areas of operations of the supply chain have you seen be affected as the course of the Pandemic has evolved ?
2. What has the Pandemic made you do different with regards to your supply chain management practices?
3. What are your major concerns for the future over the next 2–3-year horizon? What is your long-term approach to building resilience into your global supply chains? What are your thoughts on the need to collaborate and share best practices as an industry so that we can make best use of the limited availability of key raw materials and consumables?

Discussion Notes:

January 26 and 28 –

Issues with raw material scarceness during the pandemic are multiple: consumables, bags, stoppers, various single use systems components. Issue was also difficult from the point of view of suppliers who saw a massive surge in demand for certain chemicals, reagents, and other raw materials. How are you supposed to prioritize? The situation happened from the start of the pandemic, and the IS FDA guidelines for prioritization were published in September, so there was a good 6 months when tough decisions had to be made.

Nobody in the industry had planned for a global pandemic; there were some contingency plans for a site going down or even a region. But nobody had planned for the whole world to be impacted.

Biomanufacturers and suppliers have been tackling the issues in multiple manners:

- Change commercial scale of manufacture when single-use components for large scale manufacturing were unavailable but smaller ones were
- Scale-up manufacture for raw materials in high demand as quickly as possible
- Qualifying and validating alternative source materials at record speed, especially for those consumables that are not registered (detergents, masks, gloves etc)
- Changing their processes to account for limited number of staff present on site, such as replacing paper signatures by electronic ones (quality)
- Adapting stocks – from just in time (very risky approach now), to stock piling of either raw materials or finished products (both very inefficient in a supply chain, through immobilization of capital and unavailable storage space)
- Re-use and clean single use components, validate a cleaning method, taking into account potential extractables and Leachables
- Considering extensions of shelf-life for raw materials, DS (especially if frozen) and DPs

February 1 –

COVID programs are impacted by raw materials scarcity.

- All aspects impacted by the pandemic:
- Manufacturing of raw materials slowed/stalled
- Transport of materials locally and internationally impacted by border closures, regional requirements for quarantine, limited staffing at transport companies
- Increased orders due to acceleration / new products causing inventory depletion

Non-COVID programs impacted by prioritization of COVID programs by (1) raw materials vendors, and (2) CMO firms that are prioritizing manufacture of COVID programs and diverting raw materials from traditional programs.

Process filters, HPLC columns and vials were provided as specific examples. Lack of availability has impacted timelines. Strategies for mitigation in non-COVID programs have included careful management and prioritization of materials already in house taking into account supply chain needs when making manufacturing decisions.

For COVID vaccine programs being supported by Project Warp Speed, government officials dialogued with raw materials vendors on behalf of sponsors to ensure that COVID programs were prioritized

For container closure changes, changes may have been required to minimize requirements for eaches. Eg, shift from single dose vials to multidose vials.

February 3 –

Examples:

Raw materials vendors have had to prioritize raw materials orders for production of COVID vaccines and treatments under the Defensive Production Act (Manufacturing act requiring US suppliers to prioritize emergent manufacturing for specified purposes). In some cases sponsors have been given very short notice that long standing orders may not be fulfilled according to expected timelines because of this prioritization.

The Round Table Session focused on immediate and long term impact of strategies that might be employed in the event that critical raw materials might become limited.

- Agreement that commercial products must be prioritized over development products when there is competition for critical raw materials.

Strategy 1: When materials are scarce, manufacturing scheduling should take into account clinical supply needs on a batch to batch basis to minimize/prevent impact to patient treatment. Requires careful coordination between clinical supply planning and scheduling (if the schedule is flexible and in the hands of the sponsor).

- CMO manufacturing schedules are very tight and often not flexible, nor within the control of sponsors.
- Partnerships between sponsors\suppliers\CMOs key to ensuring the most beneficial schema
- Shared responsibilities across internal teams required in assessing priorities
- Consider leveraging commercial manufacturing facilities for clinical \development programs

- o This strategy has tradeoffs as there are differing facility requirements based on different phases of development, eg, tradeoffs in flexibility typically allowed in the clinical space

Strategy 2: Risk Mitigation Inventory - sponsors resorting to large orders and maintenance of inventory of critical raw materials over the long term.

- Raw materials may have shelf life that needs to be considered

Strategy 3: Dual / triple sourcing of raw materials to ensure supply continuity for critical raw materials.

- Long term strategy due to the time it takes for identification of raw materials vendors and any potential development work that might be required to assess impact of new source. Especially for commercial products

- Thorough understanding of product / process attributes and potential impact of raws is beneficial when Identifying raw materials sources and equivalency

- Mitigations:

- o File flexible information?

- o Where there is regulatory impact for changes in raw materials, can dual sourcing be established as a protocol in the MA (protocols)?

- Can new manufacturers be identified to make custom raw materials?

- o Sponsors proactively approaching potential suppliers for feasibility of manufacturing using historical raws as baselines.

Strategy 4: Nimble organizations and sponsorships that are capable of making decisions and acting upon them in dynamic scenarios. Organizations need to focus on

- (1) Early identification of risk to product supply

- (2) Having supportive leadership/governance is critical

- Roadblocks need to be removed and teams empowered to act once a problem has been identified

- Once identified, small, technically saavy, dedicated, and empowered individuals should then be dedicate to risk mitigation and solutions to raw materials constraints (sponsorship support)