# STREAMLINING PHARMA OPERATIONS IN THE WAKE OF COVID-19

by Jim Morris

COVID-19 is shedding further light on pharmaceutical sourcing strategies and their inherent complexity. Consider the example of Gilead's ramp-up of remdesivir manufacture under FDA Emergency Use Authorization. Behind the scenes, Gilead is managing the production of an API in Canada, sourcing key starting materials from across the globe, and finishing the injectable product at a facility in La Verne, CA. The enormity of the task when the product is early in its lifecycle is substantial. And, consider the efforts of so many companies racing to bring vaccines and therapeutics for COVID-19 through clinical development, demonstrating safety and efficacy at speeds rarely seen in the past.

As these organizations source starting materials, active ingredients, excipients and other components, they will face pressure to reduce timelines and find ways to accelerate development, testing and launch. And they will do so against a background of regulatory agencies across the globe having to scale back their inspection oversight due to COVID-19. This does not mean regulatory and GMP compliance is not expected, on the contrary, it's incumbent on all companies to tighten internal oversight. This requires creativity and unleashing new ways of managing suppliers, scaling-up production, accelerating regulatory review cycles, and managing changes.

The following issues will undoubtedly take on added meaning and call for leadership's attention.

## PRODUCT SUPPLY SHORTAGES

Finished product supply shortages in the pharmaceutical sector were already an issue and have been a significant source of concern for regulatory agencies. U.S. companies like CivicRx and the Phlow Corporation have stepped in to fill the void. And regulatory warning letters continue to require notice to the FDA of a potential supply disruption. COVID-19 has only exacerbated the situation.

This is the time to sharpen the focus on supplier risk assessment and supply chain strategy. Companies need to go beyond which components are single-sourced and those suppliers that have had a poor quality record, to concerns around the logistics of shipment and possible trade barriers that might prevent shipment from a country. This requires a careful review of supplier risk of the entire supply chain. As indicated above, regulatory bodies are sensitive to drug shortages and will work with manufacturers to facilitate the registration and approval of alternate sources.

## SUPPLIER OVERSIGHT

The on-site supplier audit may become a thing of the past. Forward-thinking companies will look to substitute the on-site audit with data which provides confidence in their suppliers' systems and performance.

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However, data about a supplier's performance cannot be downloaded or purchased. The data must relate to the supplier and the customer's relationship with that supplier. For instance, suppose your company is purchasing valsartan from a supplier in China. The data you require should be relevant to that API: batches manufactured, batches rejected, deviations, change controls issued and importantly how they are testing for nitrosamine impurities upstream in the production process. The data must be granular enough to establish confidence in the source of supply and/or raise concerns which warrant further evaluation.

Moving towards a more proactive, data-centric approach to managing supply chain risk is a welcome change. There will always be a need for an on-site audit, however COVID-19 is demonstrating supplier oversight can be accomplished remotely if you ask the right questions and the relationship with the supplier is built around transparency.

## PERSONNEL IMPACT

The virus is an invisible foe, as is the unseen stress on people in the workplace. I have heard the term "COVID vacation" used to describe working from home. For managers on the frontline leading unit operations where people are undoubtedly concerned about their well-being and that of their families there is no rest. They are managing higher levels of absenteeism, onboarding new employees virtually, and triaging issues to keep production schedules on track.

Every crisis breeds opportunity. If there's a silver lining it will lie with those employees who stepped forward for their colleagues and found creative ways to get things done. Or it may lie in the cross-training of employees for new or expanded roles. Key decisions around product quality may be delegated closer to the unit operation which should result in efficiency gains. However, employee knowledge gaps will become more apparent when a key subject matter expert (SME) is not available.

Knowledge and skill shortfalls should be tracked as this will inform training curricula. If someone has stepped into a new role and/or interim role, additional check points or huddles will be warranted.

## TRIAGE MANAGEMENT

Risk-based decision-making during a time of crisis takes on new meaning. Quality systems (deviations, change controls, product complaints) are categorized on the basis of risk. The degree of effort required to investigate and document findings is commensurate with the degree of patient safety risk. Under COVID-19 two things will happen: A) resources will become more scarce and B) the number of issues and severity of those issues will increase. Thus, organizations need to rely on their most competent managers to triage and focus their effort on those issues which will make the most significant difference to the organization. And they must do so with excellent understanding of their products, processes and regulatory requirements.

## INSPECTION READINESS

The first inspection post COVID-19 requires special preparation. It's important to keep in mind that your organization or unit is only as good as its last inspection. Therefore, it's incumbent on each organization to treat its upcoming regulatory inspection as its first inspection. The list of issues will undoubtedly be unique and include conditional release of components, shipments under quarantine, deviations in transit, and a number of challenges which had to be managed under the stress of fewer people, newer people and people working at a distance.

Good companies emerge stronger after a crisis and we can predict that their regulatory inspections post COVID-19 will go well. Other companies will struggle and have difficulty explaining the rationale for the decisions taken during a period of intense pressure. We recommend starting your inspection planning now as opposed to a few months or weeks before an anticipated inspection.

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## TAKEAWAY MESSAGE

Companies are adjusting to new ways of working under COVID-19. In pharma operations, these adjustments range from identifying alternative suppliers, conducting supplier audits remotely, expediting prior approval manufacturing changes, and shifting teams and roles as needed to keep product moving. Furthermore, regulatory agencies are adjusting their activities, from application review to compliance oversight.

We recommend taking stock of these adjustments and determining which changes should be embedded into operations. Operational efficiency gains in the short term due to handling COVID-19 could represent long term efficiency gains for individual companies and for the industry.

## ABOUT THE AUTHOR

Jim Morris has over 25 years of pharmaceutical management experience in both plant operations and corporate offices, working with Pfizer, Cilag AG and Mass Biologics in the U.S. and Europe. He has held positions as Deputy Director QA/QC and Regulatory Affairs while at Mass Biologics, Director of QA/QC for the Biologics business unit of Cilag AG and a number of quality assurance and manufacturing roles with Pfizer over a 16-year timeframe, culminating as the head of Quality Assurance for Pfizer in Latina, Italy.

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