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REMOTE WORKING

HOW THE CLINICAL TRIALS INDUSTRY MOVED AWAY FROM TRADITIONAL WORKING METHODS DURING THE PANDEMIC TO GO REMOTE.

FROM QUALITY CONTROL TO COLD CHAIN

– WHAT THE PANDEMIC TAUGHT US

The impact of Covid-19 on the pharma supply chain and the lessons learned in the race to a vaccine.

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In the wake of the Covid-19 pandemic, the pharmaceutical industry and its suppliers had to mobilise overnight in order to implement a healthcare solution as quickly as possible. Although the world had seen pandemics as recent as the spread of H1N1, the severity and impact of Covid-19 presented a global challenge due to how easily transmittable the disease is and the number of deaths worldwide.

Capacity reservation and emergency protocols are not a new concept but following H1N1, the industry seemingly moved away from a preventative approach to emergency response planning. The current pandemic is a testament to this shift, with the industry taking a reactive approach by drawing on past experiences with a certain level of preparedness and planning. As the pandemic continues to unfold and unprecedented demands for drug delivery components and packaging continue to arise, it is imperative that we prepare for future occurrences and move closer to a proactive approach.

TRANSPARENCY IS KEY

Drug manufacturers faced exponential volume increases as mass vaccination plans progressed in 2021. These demands rippled out to their suppliers of packaging components like vials and stoppers. What became clear from the outset is that communication channels needed to be as clear and transparent as possible to deliver what was realistic in a short timeframe. Prior to the pandemic, pharmaceutical companies were less inclined to share challenges with their production, especially since competing manufacturers can use that information to their advantage. However, the pandemic opened communication channels beyond what we would generally see across the board.

The pandemic forced the industry from a norm of closely guarded planning to a more open and communicative industry as all players involved had to work closely to resolve major supply chain challenges, anticipate potential personnel and raw material shortages, and navigate planning amid a global crisis. It forged the most united front this industry has seen in decades.

THE CORE TO AN EFFECTIVE RESPONSE: RISK MANAGEMENT AND QUALITY

Just as supply chains were impacted, so was the ability to mitigate packaging supply chain risk with the lack of necessary materials and machinery to meet demands. Across the industry, the impact varied as countries reacted based on the severity of the situation that unfolded domestically. Moreover, in addition to supply chain challenges as well as impacted labor and difficulty sourcing equipment such as PPE, expanding capacity in terms of machinery and materials was also difficult.

As the industry moves forward, it will benefit from being better prepared for any interruption in supply of materials, lockdowns, both locally and nationally, as well as a hugely reduced labor force. In the short-term, it is critical to build significant safety stocks to mitigate the impact of disruption.

In terms of cold chains, formulators and drug development experts continue to work on 2-8 Celsius options or even vaccines that can be stored at room temperature. During the pandemic, initial storage conditions were reexamined to see if less severe storage conditions could be used. As supported by stability data, the next generation of vaccines and boosters will likely have storage conditions optimised for the best possible global distribution. That said, the industry continues to work to simplify the cold chain by increasing the temperatures at which drugs need to be stored.

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QUALITY CONTROL IS PARAMOUNT

Quality is codified by global authorities. It is not optional, nor is it flexible – and rightly so. The pharma industry is incredibly stringent and holds itself to the highest standards and with the goal to disseminate vaccines to every person on the globe, this is more important than ever before. It is critical that even when volume is increased, quality standards are still met.

There are certain standards to which manufacturers must adhere to in this industry. All involved in the response to Covid-19 have been acutely aware of this fact from the outset. Even prior to the pandemic, the industry has operated with the understanding that cutting corners could have potentially life-threatening consequences. Sacrificing quality and safety is not an option.

With so much pressure to meet unprecedented demand, flexibility became paramount for drug manufacturers. If minor changes were required, they were allowed some latitude to get things done more quickly. Datwyler for example, proactively streamlined the pathway to qualification, and qualified components in the greatest volume in the shortest time. The authorities were a bit more flexible in their approach to the production of pharmaceuticals, but only up to a point. For the packaging and distribution elements there was no change.

RISK REDUCTION IS KEY

Whether it's a Covid-19 vaccine or any other critical drug, risk reduction is a vital element throughout the entire drug delivery process. As such, packaging suppliers are evolving to take already stringent manufacturing practices to another level. FirstLine manufacturing, for example, is based on ultra-modern cleanroom technology, automated production cells, automated camera inspection, and a unique validated washing process. Designed and operated under a zero-defect philosophy, FirstLine manufacturing facilities keeps particulate extremely low to avoid contamination once the vaccine is packaged and ensures that what reaches the end user is of the highest quality.

These strategies combined with a fluoropolymer spray coating, can significantly reduce risk of contamination. As a result, particulates or unanticipated interactions between the vaccine or drug and the closure are greatly reduced or eliminated, lowering overall risk in the production of the vaccine. Further automation capabilities like those used in FirstLine facilities allow for increased production with the exact same world-class quality levels without having to add labor.

Before the pandemic compromised employees' safety and, in most cases, prevented people from going to work, interruptions in labor were not fully considered. The industry had already been moving towards greater levels of automation to ensure quality, but reduced labor only reinforced the need for solutions that address capacity limits and prevent disruptions. The pandemic highlighted the fact that in addition to reducing human error and increasing efficiency, automation tackles unexpected interruptions to labor. In the event of a global pandemic, demand can still be met when automation tools are in place.

MANY LESSONS HAVE BEEN LEARNED

Just as any pandemic before it, Covid-19 brought core lessons to be learned that helped push the industry forward and improve global health. For one, transparency is vital and embracing greater communication helps the industry better plan and tackle unanticipated occurrences.

An industry-wide proactive approach towards preparing for something like another global healthcare crisis will be the rule going forward. It is imperative to have a formal pandemic plan in place with protocols that identify the types of closures, the overall packaging and better ensure immediate capacities along with scale up plans.

The pharma industry is one of the most impactful in the world and it has risen to the challenge of the Covid-19 pandemic in ways few would have thought possible. With a continued focus on collaboration, cooperation, and transparency, that impact can be harnessed even further to tackle challenges in the future and contribute to better and healthier communities all around the world.