Shoring up Diagnostics Manufacturing for the Next Pandemic

As the global response to COVID-19 continues to move from a state of national lockdowns to the re-opening of societies, diagnostic assay developers are confronting two major challenges. Firstly, how to handle manufacturing volumes when level of demand is so uncertain. Secondly, where to invest in non-COVID diagnostics innovation and for which disease areas. Both essentially come back to the same question: "What does a world now somewhat accustomed to being in a pandemic need from diagnostic testing next?" While we at Cytiva cannot answer this broad question with certainty, I do believe it is vital that assay developers reduce their risk in relation to these two central challenges.

Advancing secure supply

As a supplier to the industry, we have seen uncertainty from our customers as to how best to manage their own supply chains. A year ago, the rapid spike in demand for COVID-19 assays led to intensive raw material purchasing, which in turn led to raw material constraints in a variety of areas. In the same way as grocery store shelves were left bare of toilet paper, so too were suppliers of assay components. Demand for COVID-19 assays has settled for the moment but uncertainty as to how to manage the supply chain remains. Should material stock levels be increased to de-risk future demand spikes? Should raw materials on the shelf be drawn down due to a testing plateau or even a decline?

The answer, as it usually is in our industry, is to hedge the risk. Our customers, as they should be, are pushing their pressures further back in the supply chain. We are seeing a high demand for critical components like nitrocellulose and magnetic beads. Even more importantly is the need for transparency and communication. We regularly review demand forecasts with our customers and discuss how and when we can best meet their needs within the context of the overall demand we are seeing. Finally, we are helping our customers structure contracts that give them flexibility to take product when they need it and scale down when they don't.

Accelerating Development

By March 2020 assay developers had diverted their focus towards developing fast, scalable, reliable COVID-19 testing. Now, developers are at a crossroads. They can continue developing better, faster assays or go back to the cutting room floor and pick up one of their pre-COVID projects. I believe this is a false binary. Successful developers will find ways to continue both COVID-19 and non-COVID programs and it is imperative that their suppliers step up as partners to support this way of working.

By providing expertise, access to materials and, most importantly, the increased pace of work that comes with iterating ideas quickly together, we are seeing that our customers can

work on more projects and achieve developmental milestones faster. Moreover, these projects can move to market faster because manufacturing and supply strategy can progress while the prototyping is still ongoing. That's the power of co-development.

Conclusions

This is a tough environment for an assay developer. The frenzied pace of the past 18 months is starting to ebb and is being replaced with an uncertain short-term future. I firmly believe that COVID-19 has created a broad understanding of the power of diagnostic assays in society and as such we are going to see more innovation and assay use in our everyday lives. However, resource allocation, stock levels, and new product development decisions all have to be balanced between caution and ambition. It is critical that component providers and developers work together in these areas to ensure mutual success.

Emmanuel Abate

Emmanuel Abate, Vice President Genomics & Cellular Research and Head of Corporate Social Responsibility, works to bring out the best in his team so they can better serve the scientific community working on the next medical breakthrough. Genomics and Cellular Research comprises lab filtration products, genomics and diagnostics solutions, biomolecular imaging, western blotting consumables and cellular research tools. Emmanuel also leads the companywide Corporate Social Responsibility strategy. Emmanuel's career began in 1999 with GE Healthcare, where he worked in business development and eBusiness. He earned his MBA in 2004 and joined the Boston Consulting Group from 2004–2007, based in Paris. When he returned to GE Healthcare in 2007, he served in product and commercial leadership positions for Interventional Imaging, Women's Health Imaging, and Radiology. In 2018, Emmanuel became the General Manager of Genomics and Cellular Research, when the business was part of GE Healthcare Life Sciences, now Cytiva. Emmanuel, known for his humble leadership, is inspired by the hundreds of scientists, specialists, and technicians working in on the instruments and consumables used to speed up the development of future diagnostics and therapies.