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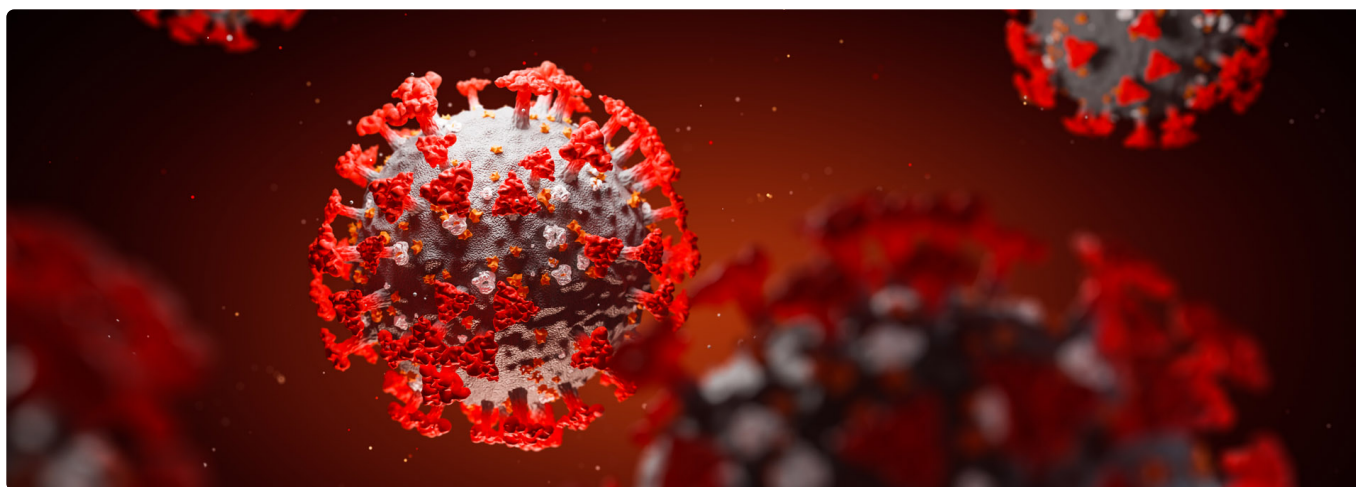
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Guest Editorial: Consulting Firms Can Fill in Missing Pieces

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by Stephanie Gaulding, Pharmatech Associates



As the global health crisis continues to unfold, new realities impact all industries. Within the global life sciences community, pharmaceutical, biotech and medical device companies are dealing with new challenges in protecting employees and vendors while, at the same time, continuing to produce existing therapies. In parallel, the industry is ramping up efforts to find new treatments for COVID-19.

Consulting firms routinely find themselves in a highly valued position during a crisis. Their very business models demonstrate an ability to maintain strategic project performance with distributed teams. Their focus can quickly shift to best meet the evolving needs of a client as they recognize and face the challenges of new realities.

Here are some of the challenges business of all types are facing from COVID-19:

This virus is novel to humans who have no immunity to it. Researchers also do not completely understand how it behaves in the human population. For this reason, current policies limit exposure with social distancing that closes plants, offices and collective spaces. This has resulted in uncertainty about when business will resume, or if it will resume “as usual.”

There are no known treatments for patients once infected, nor existing vaccines to prevent infection. The global regulatory landscape is responding to meet the needs of patients, healthcare workers and the general public.

Scientific collaboration is essential and fundamental. Although drug discovery can result from proprietary ventures within academic institutions and pharmaceutical/biotech companies, combating COVID-19 requires that data be shared rapidly and publicly for the benefit of those working on effective treatments and vaccine development.

This is the first time that so many people around the world have had to rely on technology to work remotely at the same time. For some, this means working at a significant distance from their teams. Many organizations are rapidly implementing technologies to enable remote work, while others do not know where to begin.

How Can Consulting Firms Help?

Consulting firms bring decades of experience and expertise to serve clients, and some bring the ability to step right into a program to retool processes or adapt to remote operations. They can help find new ways to keep vital supplies of medicine and devices moving to patients and healthcare providers, and work with companies to develop effective treatments and vaccines for COVID-19.

A consulting firm’s infrastructure is set up to provide remote support, host virtual meetings and provide secure exchange portals for document collaboration and knowledge-sharing and a secure means to approve documents electronically with geographically diverse approvers. Remote capabilities mean a consulting firm can start new projects seamlessly and keep critical projects moving forward.

In a time of extreme urgency, the life science community is engaged in open and public collaboration. Scientific sponsors are seizing the opportunities to begin projects for which support is required to complete the development vision and objectives. Consulting firms, with their broad-based and interconnected networks, afford these innovative sponsors access to known subject-matter experts, who can effectively bridge with immediacy and extremely limited learning curves deep understanding the knowledge gaps that exist within a project team. As trusted advisors, these consultants can accelerate the development of novel products for companies where critical technology gaps had previously existed, ultimately, filling the void in an organizational culture that is familiar with a high rate of collaboration and discussion.

Regulatory Intelligence

Consultants must remain current and hypervigilant in all the global regulatory landscapes. Information specific to COVID-19 is changing at an extremely rapid pace. Every day—sometimes multiple times within a day—various global health authorities issue new guidances, provide new pathways to approval and offer advice on continuing operations. Each change to the current guidance could have a significant impact on a client's projects and the speed of their path to market.

For consultants, this translates to risk reduction while maintaining process velocity. Both will be required to defeat this virus. Consulting networks and their experience bring perspective on what to prioritize in escalating situations, to respond appropriately to questions and to provide information summaries to clients that align with their ongoing projects and initiatives.

Using such infrastructure and regulatory intelligence, consultants work to meet the changing reality of clients: from planning a regulatory strategy for a COVID-19 treatment or vaccine, to assisting with evaluating suppliers using remote assessment methods or technical expertise in bringing more critical medical equipment to the market.

All of these services are valuable to urgently overcome a novel threat to the global human population and, ultimately, satisfy the extraordinary demand of bringing innovative solutions to a world of over seven billion people.

ABOUT THE AUTHOR

Stephanie Gaulding has over 20 years' quality and regulatory compliance experience in the pharma, biotech and medical device industries.



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