Executive Q&A on Driving Digital Transformation in the Pharma Industry

As seen in Pharmaceutical Outsourcing

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Please tell us about the services and technologies PCI Pharma Services offers to the pharmaceutical industry

As a respected industry leader and trusted partner, PCI Pharma Services provides a comprehensive range of pharmaceutical services from the earliest stages of drug development through to commercial launch and ongoing supply.

We combine best-in-class technologies with cutting-edge research support by an exceptional team of people, delivering the highest level of regulatory compliance and quality standards. Equally important is our commitment to providing an industry-leading customer experience, sharing our customers' passion for supplying often lifesaving medicines to patients around the world. We are committed to meeting the evolving needs of our clients by leveraging our experience and expertise to always deliver the best possible pharmaceutical services.

In general, what are some pressing issues facing the pharmaceutical industry and what are some issues facing the clinical trials segment of the industry?

Clinical Trials: The methods for development and delivery of new pharmaceutical entities is constantly evolving to meet the demands of its patient population. This has been more evident than ever over the last 12-18 months as pharmaceutical companies have had to adapt to meet the changing landscape. In the new world accessibility is key, consumers are accustomed to experiencing convenience across all aspects of their day-to-day lives For example, you can virtually meet with your doctor and have a Rx prescribed and delivered to your home almost immediately. We see these pressures for convenience continuing to impact the planning and execution of Clinical Trials globally with a continued focus on patient centricity and convenience.

Looking at the last two years, how has COVID-19 transformed the industry, especially when looking at supply chains and clinical trials?

COVID-19 has transformed the pharmaceutical supply chain and there has been a significant re-thinking and re-engineering of the clinical trial process. There are currently supply chain challenges for every industry. Flights are less frequent, general supplies are in high demand, even basics such as paper, card, plastic and metals. All of which go into packaging. Gas/Petrol

shortages in the UK, full lockdowns in Asia Pacific. As we come out on the other side of the pandemic, we have proved that we can adapt to new ways of working and remain reliable and professional.
The ongoing ramifications of COVID will continue to impact the pharmaceutical supply chain for some time. Materials, staffing and logistic challenges are significant concerns to continuity of drug delivery processes and programs. To address these challenges, pharmaceutical companies will need to diversify their supply chains, bringing in additional countries and distribution networks to ensure ongoing delivery of their medicines to their trials and patient populations.

The digital transformation of the industry has been slow – what do you see now as companies try to become nimbler and more efficient?

We are starting to see a positive movement towards digital transformation and believe this will accelerate with outside influences such as wearable technologies. One of the key differentials will be telemetry and data capture, which today's wearables are headed towards: EKG, Blood Oxygen, could every day, affordable Glucose monitoring be next? There is an acceleration in the demand by the end-user to have a more convenient clinical trial experience. For example, we as a population can have virtually anything delivered to us within 24 hours. I see the pharma industry adopting more technology and hybrid trial designs driven by patient centricity.

Specifically regarding clinical trials, how has the digital revolution permanently changed how companies conduct clinical trials? What are the implications for:

- How patient and hybrid clinical trials can be utilized. Hybrid clinical trials allow a more convenient and patient-centric approach towards the clinical trial experience, delivering a drug directly to the patients doorstep. We see the pharma industry adopting more innovative technologies and a more hybrid trial design that will continue to be driven by the convenience of the patient.
- Increasing speed to market. Speed to Market is a key focus in the entire industry, and can be seen directly with Project Warp Speed and accelerated development/approval/deployment of other COVID treatments.
- Structural and compliance challenges. Generally, Quality/Compliance have been very conservative, and the changing industry and adoption of technology will push for an evolution.

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Looking forward what do you see for the future of the clinical trials segment of the industry and how will your company continue to adapt and provide problem-solving services to current and future clients?

PCI Clinical Services currently supports D2P in the "Site-to- Patient" model using one of our specialty logistics partners and we are exploring taking the next step into D2P by creating a central pharmacy (non-resident, mail-order) at one of our locations to support shipments directly from PCI to a patient's home. There is significant licensing and infrastructure requirements to follow to comply with all states, who unfortunately do not have consistent guidance on D2P central pharmacies.

Supply chain visibility is ensured via the pci | bridge digital solution, which provides real-time supply-chain information, including inventory, production, distribution and shipping data, to customers. This platform technology enables customers to make informed decisions based on real-time insights, collaborate more effectively, speed validations, create customized reports for greater efficiency, and do so knowing their sensitive project information and data is protected in a cyber-secured environment. The pci | bridge platform is suitable for clients of any size and projects at any development stage and has been designed to be effective for very small clinical projects to large-scale commercial products.