Supply Chain Transformation, 503B and Reducing Drug Shortages

By Kurt R. Nielsen, Ph.D., President and CEO, Pharmaceutics International, Inc (Pii)

Currently there are two great forces at work that are disrupting traditional models for advancing drug therapies from discovery to commercial production and distribution. This transformation, when complete, will impact the biopharmaceutical supply chain significantly and potentially achieve outcomes that were considered impossible a short time ago.

The first is scientific innovation which the industry has been talking about for a while. These healthcare innovations, driven by advancements in clinical pharmacology, are being introduced at an unprecedented pace. The quantity and quality of encouraging early phase drug therapies is challenging the traditional pharmaceutical supply chain and demanding far more agility from biopharma companies, contract development and manufacturing organizations (CDMOs), clinical and contract research organizations (CROs), and regulatory bodies like FDA and EMA.

The second is not something we anticipated: the urgency with which treatments and vaccines are being developed to combat the COVID-19 pandemic. If a vaccine is ready by early 2021, as many experts believe, it will be completed in a period of time like nothing we have experienced before. Commercial biopharmaceutical development timelines have always been measured in years, not months. If the anticipated COVID-19 vaccine is delivered to patients as expected, it will be difficult to accept a return to the traditional timelines.

At the same time that these two powerful forces are transforming healthcare and specifically drug therapy development, manufacturing and distribution to patients, FDA has been also improving Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The improvements are intended to advance FDA's public health mission to reduce drug shortages and establish a regulatory environment that helps accelerate innovative therapies reaching the patients that need them most.

Transforming the Role of CDMOs

CDMOs will play a critically important role as healthcare supply chains are transformed and the changes are happening faster than anyone could have predicted. CDMOs have long possessed the agility to quickly re-purpose facilities and production lines for emerging market needs and requirements of specific drug sponsor clients.

At Pii, we were expecting this transformation. We began modernizing our facilities and analytical labs precisely for the kind of transformation underway, one that demands a more responsive biopharmaceutical supply chain. Additionally, we recognized that to deliver a better organizational response we needed some additional skills. We went to work becoming more collaborative, flattening our organization for quicker decision-making, and placed a premium of professional project management to deliver client outcomes on time or even early. These organizational changes also enable us to manage our capacity better and more predictably and be ready to flexibly respond to drug shortages when they are experienced by healthcare providers.

The future of healthcare will increasingly require drug development and manufacturing that is far more agile than it is today and able to reliably produce small batches of highly-complex, potent drug formulations for smaller, but better understood, patient populations.

The transformations underway are more exciting than anything I've experienced before in my career and at Pii we believe we are positioned to make a real difference in how we deliver complex, innovative treatments to patients.

Pharmaceutics International, Inc. (Pii) is a contract development and manufacturing organization (CDMO) located in Hunt Valley, Maryland. The experienced scientists, engineers, and staff at Pii pride themselves on solving difficult problems, it is part of their DNA. In addition to knowing how to innovate for the future needs of the biopharmaceutical industry, Pii has an expertise in developing and manufacturing complex parenteral drugs and possesses a wealth of analytical testing, formulation development, and manufacturing capabilities across a variety of dosage forms. Its Hunt Valley campus has four aseptic suites with lyophilization capabilities. Our talented professionals stand ready to help!

ABOUT THE AUTHOR
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Dr. Kurt Nielsen is the President and CEO at Pharmaceutics International, Inc (Pii) and is available for interviews regarding his views on how the biopharma industry's transformation. Dr. Nielsen is a seasoned pharmaceutical executive with over 20 years of diverse experience, most recently as the President of Lupin Somerset, responsible for all their generic and branded products. Prior to Lupin, he held the post of Vice President, U.S. Development, Portfolio and Launch Management at Sandoz Inc., where he was accountable for the U.S. development of generic, OTC and specialty brand products. Dr. Nielsen has also held positions at Catalent, where he was Senior Vice President of R&D and Chief Technology Officer, and URL Pharma where he was the Executive Vice President, Pharmaceuticals.

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