CDMO Innovation for the Future Pharmaceutical Supply Chain

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

The most impactful innovations are often the result of someone's efforts to solve a problem. Consider the science behind vaccinations, or more specifically immunizations. In the 18th Century, the mortality rate for children under the age of five was a staggering 20%. Spurred by the societal pain around him, Edward Jenner applied his own patient observations and conducted what is believed to be the first-ever clinical trial. He introduced small amounts of an infectious disease, cowpox, into a child attempting to boost their immune systems and protect them from the virus. This radical-for-its-day approach to healthcare remains important today.

At Pii, we have a longstanding mantra, "challenges frame opportunities", and this applies to how we intentionally innovate, modernize, introduce new capabilities, and expand capacity. However, before embarking on something new a typical question we ask ourselves; what problem are we solving and for whom? For us, innovation isn't simply about doing something within the walls of our facilities.

Providing Value in a Complex Supply Chain

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 disrupting the regulatory approval processes with which we've become comfortable.

The direction of healthcare, specifically drug therapies, is driving more patient-customized compounds containing highly potent active pharmaceutical ingredients (API). We will continue to see smaller dosage forms, complex delivery devices, and smaller batches and the current pandemic is calling for pharma supply chains to be more secure and reliable.

Competition is also fueling an expectation among drug developers for a more efficient, accelerated process from discovery through phase 1 along with regulatory approvals done right the first time. Smaller drug developer organizations rely on contract development and manufacturing organizations (CDMOs) for the capabilities they don't have and this is an intentional business model to keep their operations lean and cost-effective.

Beyond Capabilities and Capacity

Our approach to innovation at Pii looks beyond today's capability and capacity requirements and takes a longer view of what the biopharmaceutical supply chain will need in the next decade and beyond. The development pipelines are no longer dominated by drug therapies seeking blockbuster status. Rather, pipelines are described in the following ways: highly potent APIs, complex drugs in custom delivery devices, micro-quantities of API, challenging sterility issues, stability challenges, the proliferation of parenterals, small batches, non-aqueous compounds, and complex regulatory issues.

Modern pipelines will require more aseptic manufacturing and fill-finish capacity. Additionally, they will demand experts with the confidence and capabilities to develop, qualify, manufacture and package these challenging compounds, as well as, the regulatory know how to effectively support FDA approval processes. The growth of these complex drug pipelines is showing no signs of slowing.

At Pii, as we considered the nature of the drug candidates described above, we determined that the best way to support the biopharmaceutical supply chain was to invest in state-of-the-art technology intended for these specific drug therapies and combine it with our experience and expertise.

Technology Solution

As Pii pivoted to become a CDMO more oriented toward supporting the development and manufacturing of modern drug therapies, we made the decision to invest in technology. We understood that there was a growing need for CDMOs to support the specific challenges of developing and manufacturing highly potent drug compounds.

What we sought was an automated, robotic fill-finish line capable of handling small amounts of potent, cytotoxic drug compounds safely. We knew that limiting human interaction with the fill-finish process would deliver better results. These types of compounds also tend to be very costly, so efficiency is critical and state-of-the-art technology can greatly reduce and even eliminate wasting these valuable products. That led us to AST.

Our GENiSYS R Aseptic Filling and Closure System allows us to process these complex drug compounds and convert them to finished products at very high yields. Additionally, it is safe, flexible and delivers with precision.

Adding the Human Component - Expertise and Collaboration

Aseptic manufacturing and specifically complex parenteral drug compounds require a great deal of expertise. We have great scientists, engineers, and regulatory experts at Pii and state-of-the-art technology paired with experience and expertise in developing and manufacturing delivers extraordinary results.

Our expertise with the complex compounds I am describing has been built over years of experience. Not simply experience in developing and manufacturing, but skills established by being immersed in solving some of the most challenging issues the biopharmaceutical industry faces. Additionally, the value of understanding the effects of decisions made at the early development stage when scaling manufacturing is immeasurable.

While drug development is a linear process, characterized by deliberate phases, collaborative communications across functional areas through the process keep projects on their timelines. With effective cross functional coordination, critical regulatory work can happen in a way that is synchronized with the chemistry, manufacturing, and controls (CMC) work. In the end, this synchronized approach will save time and resources.

At Pii, we approach innovation and modernization by looking beyond what the biopharmaceutical industry currently needs and beyond the walls of our facilities. We do our best to envision the future healthcare supply chain and develop ways to best meet the requirements we expect. We pair state-of-the-art technology with the skills and expertise of our scientific, engineering, and regulatory talent. We plan to continue with this innovation and modernization strategy to ensure we bring the best solutions to our clients' most vexing challenges.

We expect our innovations to have an impact now and long into the future.

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
Kurt R. Nielsen, Ph.D.

Dr. Kurt Nielsen is a seasoned pharmaceutical executive with over 20 years of diverse experience, most recently as the President of Lupin Somerset, responsible for all its 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.