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Alternate Paradigms to Pharmaceutical Product Development

Roger Nosal is currently Principal Consultant with Roger Nosal PharmaCMC Regulatory Consultants and serves as Head of Regulatory Strategy for NGT BioPharma Consultants, a consortium of experienced experts and leaders in development of pharmaceutical products. For 12 years prior to September 2022, he was Vice President and Head of Global Chemistry, Manufacturing and Controls at Pfizer where he was accountable for all global regulatory CMC strategies and applications for innovative products and medical devices.

Roger led the development of the CMC regulatory strategy and was responsible for negotiating clinical and commercial requirements with global regulatory authorities for authorization/ approval of the first mRNA vaccines to effectively address the COVID-19 virus. From 2018 – 2023 Roger served as Rapporteur for the ICH Quality Discussion Group. He has been a representative to several ICH Expert and Implementation Working Groups since 1994. Roger was instrumental in development and implementation of Quality by Design and, in 2013, was awarded the Pharmaceutical Discovery, Development and Manufacturing Forum Award from AIChE for outstanding contributions to advancing QbD. Roger's 41 years of experience at G. D. Searle, Monsanto, Pharmacia and Pfizer includes 28 years in regulatory CMC and 13 years as a Medicinal and Process Chemist. He is co-author of 24 patents and has publicly presented and published on a wide variety of regulatory and pharmaceutical policy initiatives and topics.

Abstract: The development of pharmaceutical products, in particular, the transition from late discovery research to initiation of human clinical studies, has adhered to relatively standard scientific & regulatory expectations for the last 40 years. The threshold for a new medicinal entity is demonstration of requisite safety & viable pharmacological activity to effectively justify administration to humans. These criteria tenaciously rely on surrogate animal studies but do not guarantee human efficacy. Expanding toxicological databases & the emergence of increasingly robust pharmacokinetic/ pharmacodynamic models offer the prospect of improving human, in vivo predictability.

Perhaps more significantly, opportunities to accelerate product development have emerged from recent experience in response to the COVID-19 pandemic. While

alternative approaches did not preclude the need for compelling & robust demonstration of product quality, safety or efficacy, they did establish groundbreaking development & regulatory paradigms that expedited global access to COVID-19 vaccines.

This presentation focuses on how leveraging the paradigms from the pandemic experience, in conjunction with steadily improving preclinical models & digital data can expedite the pharmaceutical development timeline.