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Accelerating Drug Development: How QbD, Regulatory Partnerships, and Pandemic Learning Can Further Expedite Meeting Patient Needs



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Diane I. Blumenthal is currently serving as President of Dianthus Biopharma Consulting, LLC, a consulting firm providing CMC strategy and technical support to the biopharmaceutical industry. Prior to starting Dianthus Biopharma Consulting, Diane was SVP/Head of Technical Operations at Spark Therapeutics where from 2014-2020 she led the CMC efforts that resulted in the first US approval of a gene therapy product including the approval of the first US manufacturing facility to produce a gene therapy product. Diane has extensive expertise in building and transitioning companies from a start-up research and development organization to a fully integrated biopharmaceutical company with approved commercial manufacturing operations and products. Throughout her career, Diane has played a key role in the development and commercialization of six pharmaceutical products, including Erbitux® and Cyramza® and Luxturna®. Prior to joining Spark Therapeutics, she served as Vice President of Manufacturing Sciences and Technology for Eli Lilly and Company, following the acquisition of ImClone Systems. While in this role, Diane was responsible for leading a multi-disciplinary team of scientists, statisticians and engineers tasked with providing technical support to manufacturing, development, quality control, quality assurance and regulatory teams. During her time at ImClone Systems, Diane and her team were responsible for the implementation of novel methodologies used for the demonstration process and product comparability. Diane has extensive experience in the transfer and scale-up of processes from the laboratory bench to commercial scale manufacturing with expertise in both microbial and mammalian cell culture expression systems and the corresponding downstream purification processes. Prior to her time at Lilly, Diane served as a scientific and manufacturing consultant to multiple start-up biotechnology companies and held scientific leadership positions at Zymquest, Inc., Scios, Inc. (formally California Biotechnology) and the Eastman Kodak Company. Member of the Board of Directors for ValSource a Philadelphia based company that specializes in validation services. She received her M.S.E. in Chemical Engineering from Lehigh University and a B.S.E. in Bioengineering at the University of Pennsylvania.

