

Successful translation from academic research to GMP-compliant, scalable manufacturing remains a major challenge and is often the reason promising discoveries fail to reach the clinic. This seminar explores real-world challenges scientists face on the path from research to commercialization. Using an mRNA/LNP case study, we will demonstrate how Quality by Design (QbD) principles can be applied to overcome these challenges and enable the development of robust, scalable, and stable drug products.