Historically, 3D Printing (3DP) and Additive Manufacturing (AM) have been used as both a replacement for and supplement to traditional manufacturing methods for small machine parts, engine parts, and custom tools. In the last decade, AM/3DP has emerged as a key concept in custom-designed orthopedic implants and prototyping of new medical devices. The most recent advancements in AM/3DP focus on technical applications in drug discovery, drug dosage form development and manufacturing, and bioprinting of cells, tissues, and organs. While other submission categories, mainly 510(k), have been used as a pathway to approval, the first NDA using 3DP principles was approved by the FDA in 2015. The AM/3DP market reached $4.1 billion in 2014 and industry analysts project it will reach over $21 billion by 2020 – an estimate inclusive of only currently known AM/3DP applications and exclusive of new innovations.

This discussion will address emerging uses of AM/3DP in the drug discovery and pharmaceutical development processes.