From the identification of a molecule as a potential preclinical candidate, there is a long road to get to an approved medicine. Pharmaceutical Sciences are a big part of that journey. An introduction will be provided with some of the considerations used to design a drug product formulation and process, such as the target population, disease and the physicochemical properties of the active pharmaceutical ingredient. Two case studies will be presented. The first one is an example of formulation and process development for a pediatric product, focusing on some of the unique challenges with pediatric populations. The second one is an example of a continuous manufacturing platform for drug product and the risk based approach taken to transfer processes from batch to continuous production. The examples will provide some insight to the types of challenges and opportunities encountered during drug development.

**BIO**

Eleni Dokou is the Vice-President of Formulation and Analytical Development at Vertex Pharmaceuticals Inc. Eleni has a diploma in Chemical Engineering from the Aristotle University of Thessaloniki in Greece and a Ph.D. in Chemical Engineering from the University of Delaware. She has more than 20 years of experience in Pharmaceutical Development, including formulation and process development from preclinical stages to commercialization and life cycle management. She has also been responsible for the creation and operation of the Vertex clinical and commercial drug product manufacturing facility in Boston and the launch of the first fully integrated continuous tablet manufacturing production line with real time release testing. She has extensive expertise in bioavailability enhancing approaches and drug deliver. Eleni also has a keen interest in pediatric drug development and patient focused drug design and has spent several years focusing on line extensions and pediatric formulations.