New Regulatory guidelines together with increasing demand for patient self-management have dramatically increased the competency required to produce, manufacture and support [Drug+Device] combination products within the pharmaceutical industry. The quality requirements for these combination products are stringent and extend beyond the familiar drug product considerations to include assurance that all intended users of the product will be able to readily, reliably, and safely use the product to achieve the intended dosing. To successfully achieve such quality, many details regarding the product in development are needed to guide device design decisions including: the characteristics of the user population, the characteristics of the drug formulation, and the critical features of the device mechanism that ensure safe operation, complete dosing, and mitigation of failures due to un-intended modes of use.

A key implication of these high demands is that the device design development relies on an iterative process where key attributes are incorporated into prototypes for testing to assess compatibility of the device with the formulation as it evolves and with the user population as it becomes clarified. To keep the device component manufacturing off the critical path during clinical development, device designs which are broadly useful by divergent populations of patients and that can accommodate formulations having a variety of characteristics and volumes are highly desirable and valuable to pharmaceutical innovator companies.

The crux of the challenge is the requirement to ready the intended commercial design in time to incorporate it into clinical supplies for quantitative assessment of its safety, usability, appropriateness, and dosing efficacy within the context of pivotal studies. A device development approach which anticipates changes and tests them as thoroughly as possible reduces delays in the clinical program.

This presentation will describe a novel self-injection device solution and associated manufacturing partnership that fits the needs of pharmaceutical innovators, supply chains, regulators, and patients.