OBJECTIVES

To review applicable regulatory standards and current expectations of the FDA for filing an ANDA of a tablet dosage form for US market. The study will cover the following areas considering an example dosage form (tablet) and/or a drug product

- To study applicable FDA guidance for successful filing of an ANDA.
- To study dosage form specific regulatory requirements including inactive ingredients for each route of administration under solid oral dosage form category, i.e. Buccal, Sublingual, Oral.
- To study shape, size and functionality related specific study requirements for solid oral dosage forms including split tablets studies, physical dimensions etc.
- To study BA/BE studies requirements and dissolution profile studies requirements
- To study product development studies covering photo stability, compatibility studies, and process understanding utilizing QbD principles
- To study drug substance DMF requirements including correct designation of starting material for the synthesis of the API
- To study cGMP compliance requirements of the sites involved in the manufacture of drug substance intermediates, API and Drug Product
- To study documents required for the construction of the ANDA (CMC, Micro, Disso, Bio, Stability, batch size etc.) and associated write-ups in each module.
- To study compilation and publishing standards using eCTD software including file naming convention, inherent zoom, hyperlinks, placement of the documents etc.
- To study final QC of the published ANDA to meet the FDA checklist to secure the acceptance of the ANDA.

To provide regulatory strategic recommendations to lower the quantum of work within the regulatory framework, where possible.

To provide regulatory strategic recommendations for successful ANDA submissions.