THEORY: (3 hours per week)

1. Process Validation — Differences and similarities between process qualification and process validation protocols, Methodology & Interpretation of data, validation of process like mixing, granulation, drying, compression, filling and water process system.

2. Validation of equipments: Installment qualification and operational qualification for sterilization equipment like autoclave, oven & membrane filler.

3. Cleaning methods Validation of effective cleaning.

4. Validation of purified water system distilled water & water for injection.

5. Validation of air handling system, sterile & non-sterile.

6. Introduction to validation of computer assisted processor- software validation methodology.

7. Validation of vendor and services

8. Documentation related to Pharmaceutical Industries:
   a. New application: NDA, ANDA requirements, Data presentation, verification and grant by FDA.
   b. Manufacturing documents: BMR, routine records, downtime records, calibration and validation records.
   d. Quality Assurance documents internal audits, SOP documents, security and related issues.
   e. Store management documents: Stock reconciliation records for raw material, finished products and packaging materials.
   f. Maintenance and environment control related documents.
   g. Consumer related documents: Product recall, complaint traceability, printed packing, preventive maintenance records.
BOOKS RECOMMENDED: