

Gujarat Technological University

Master of Pharmacy

Semester – II

Paper code -2920202

Specialization paper - IV

Global Regulatory Requirements

Theory

(Six hours per week, 8 credits)

1. Validation of Pharmaceutical Processes, equipments/apparatus, basic concept in analytical method development for dosage forms., Computer System validation, ERP and SAP systems.
2. Basics in Drug approval process with reference to: Orange book, Freedom of information, IIG, DMF, Historical aspects with Various phases of drug development and approval.
3. IND, NDA, ANDA , Concept of para I to IV, exclusivity: Content, format and Application.
4. Brief and comparative introduction to various regulatory agencies: USFDA, MCA, TGA, MHRA, ANVISA, CTD, WHO, ICH, SUPAC etc.

Reference Book:

The guidance documents shall be procured from the website of the respective Government.