Gujarat Technological University
Master of Pharmacy
Semester – II

Specialization paper - IV
Global Regulatory Requirements

Theory
(Four hours per week, 6 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.

References Books:

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