THEORY: (3 hours per week)

1. Organization and personnel, responsibilities, training, hygiene, personnel, records.
2. Premises: Location, design, Plant lay out. Construction maintenance and sanitation environmental control, utilities and services like gas, water maintenance of sterile areas control of contamination.
3. equipment: selection, purchase specifications, maintenance, clean in place and sterilize in place, methods (TP and STP)
4. Raw materials: purchase, specifications, stores selection of venders, control of raw materials
6. In process quality controls on various dosage form sterile & non sterile, Standard operating procedure for various operations like cleaning, filling, compression,drying.
9. Warehousing, good warehousing practices, materials management.
11. Waste disposal, scrap disposal procedures and records.
12. Regulatory aspects of pharmaceutical and bulk drug manufacturing.
13. Loan licenses (contract manufacture)

PRACTICALS : (4 hours per week)

Practical exercises will be based on theory syllabus
BOOKS RECOMMENDED:

1. The Internal Quality Audit by Monica Girmaldi and Janet Gough Davis Harwood international Publishing.
2. Validation Master Plan by Terveeks or Deeks, Davis Harwood international Publishing.
4. Statistical Design and Analysis in Pharmaceutical Science, by Chow (Marcel Dekker).
5. Automation and Validation of Information in Pharmaceutical Processing, by deSPAUTZ,(Marcel Dekker).
7. Pharmaceutical Experimental Design by Lewis (Marcel Dekker).