GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMCEUTICAL REGULATORY AFFAIRS

SEMESTER: II

Subject Name: REGULATORY AFFAIRS PRACTICAL - II
Subject Code: MRA205P

List of Practicals:

1. Case studies on
2. Change Management/Change control. Deviations
3. Corrective & Preventive Actions(CAPA)
4. Documentation of raw materials analysisas per official monographs
5. Preparation of audit checklist for various agencies
6. Preparation of submission to FDAusing Ectd software
7. Preparation of submission to EMA using eCTD software
8. Preparation of submission to MHRA using eCTD software
9. Preparation of Biologics License Applications(BLA)
10. Preparation of documents required for Vaccine Product Approval
11. Comparison of clinical trial application requirements of US, EU and India of Biologics
12. Preparation of Checklist for Registration of Blood and BloodProducts
13. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
14. Registration requirement comparison study in emerging markets (BRICS) and preparing check l list for market authorization
15. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
16. Registration requirement comparison study in emerging markets (ASEAN) and preparing check l list for market authorization
17. Registration requirement comparison study in emerging markets(GCC) and preparing check l list for market authorization
18. Checklistsfor510kand PMA forUS market
19. Checklistfor CE marking for various classes of devices for EU
20. STED Application for Class III Devices
21. Audit Checklist for Medical Device Facility
22. Clinical Investigation Plan for Medical Devices