| Course Type | Course Code | Name of Course | L | T | P | Credit |
|---|---|---|---|---|---|---|
| DP | NCYC508 | Pharmaceutical Documentation Lab | 0 | 0 | 3 | 1.5 |

| **Course Objective** |
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| • Documentation is highly important in Pharma industry. The objective of this course is to give hands-on experience to students on how documentation is done in pharma industry |
| **Learning Outcomes** |
| • Students will learn various types of documentation involved in manufacturing, regulatory affairs, pharmacovigilance and intellectual property. |

| Unit No. | Topics to be Covered | Lecture Hours | Learning Outcome |
|---|---|---|---|
| 1 | General Instructions | 3 | General instructions for the lab |
| 2 | Preparation of monographs for a new chemical entity | 3 | Students will learn about pharrmacoepieas of various countries |
| 3 | Preparation of material safety data sheets for a new chemical | 3 | Students will learn the various safety protocols and considerations associated with chemicals |
| 4 | Preparation of IPQA checklist for various drug formulations | 3 | Students will learn the aspects of in-process quality control |
| 5 | Preparation of SOPs for given instrument | 3 | Students will learn to how to prepare standard operating procudures for given instrument |
| 6 | Preparation of Batch manufacturing records | 3 | Students will learn to how BMRs are prepared and maintained to ensure quality |
| 7 | Preparation of Master formula records | 3 | Students will learn to how MFRs are prepared and maintained to ensure quality |
| 8 | Pharmacovigilance mining | 3 | Students will learn to search PV databases to explore various adverse drug reactions associated with given therapy |
| 9 | Patent searching and mining | 3 | Students will learn to search various databases to search the existing/expired patents on given branded or generic products |
| 10 | Drafting patent claims for new chemical entity | 3 | Students will learn how to write a patent for a new chemical entity |
| 11 | Drafting patent claims for new drug formulation | 3 | Students will learn how to write a patent for new drug formulation |
| 12-13 | IND and NDA applications | 3 | Students will learn how to file various types of IND and NDA application with the FDA |
| 14 | Six sigma principles | 6 | Students will learn how six sigma principles are employed in industry for problem solving and improving efficiency. |
| | **Total** | **42L** | |

**Text Books:**


1) Pharmaceutical Production Facilities: Design and Applications G.C.Cole
2) Mann's Pharmacovigilance, E.B. Andrews, N. Moore, Wiley, 2014.

**References:**

1) US FDA website
2) USPTO, WIPO websites