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Department of Pharmacy

Faculty of Allied Health Science

**Course Name:** Pharmaceutical Regulatory Affairs **Course Code:** BPH-425

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| **Lecture no.** |  | **Lecture topics (sub-topic)** | **Credit hours** |
| L-1 | 1. **Introduction to regulatory affairs**
 | Definition, scope & Goals for Regulatory Affairs. | 1hr 20 mins |
| L-2 | Function of regulatory professionals. | 1hr 20 mins |
| L-3 | 1. **Drug controlling authority of Bangladesh and pharmacy council.**
 | Functions and activities of DGDA, Drug Control committee (DCC) and related technical committees. | 1hr 20 mins |
| L-4 | Introduction, Ordinance, different Committees, Scope and functions of Pharmacy Council of Bangladesh. | 1hr 20 mins |
| L-5 | 1. **International regulatory agencies, regulatory requirements & Total quality management (TQM).**
 | FDA, MHRA, TGA, ICH | 1hr 20 mins |
| L -6 | Total quality management system. | 1hr 20 mins |
| L-7 | Role of Quality Assurance, Stability study | 1hr 20 mins |
| L-8 | Dossier, CTD, eCTD | 1hr 20 mins |
| L-9 | 1. **Approval process, format and registration of pharmaceuticals in Bangladesh.**
 | Key processes involved approval of new pharma, Project approval, manufacturing license | 1hr 20 mins |
| L-10 | Recipe approval, Packaging materials approval. | 1hr 20 mins |
| L-11 | Product registration, Block list approval | 1hr 20 mins |
| L-12 | Promotional materials, vendor and source approval,  | 1hr 20 mins |
|  L-13 | GMPcertification, Free sale certificate | 1hr 20 mins |
| L-14 | 1. **Regulations and laws governing the practices of pharmacy in Bangladesh.**
 | The Pharmacy Ordinance1976, Drug Ordinance 1982, The Narcotics (Control) Act 1990 | 1hr 20 mins |
| L-15 | 1. **Good pharmacy practice in Bangladesh.**
 | Introduction of model pharmacy and GPP in Bangladesh. | 1hr 20 mins |
| L-16 | 1. **Regulation of cosmetics and poison control.**
 | Schedules of drugs and poisons. |  |