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Course Module

Regulatory Affairs

Sr No.	Content	Hours
1	**Introduction to Regulatory Affairs** • Definition and scope of regulatory affairs • Role of regulatory affairs in the pharmaceutical industry • Global regulatory guidelines and key regulatory authorities	02
2	**Regulatory Guidelines and Standards** • Overview of international regulatory guidelines and standards • Good Laboratory Practices (GLP) • Good Clinical Practices (GCP) • Good Manufacturing Practices (GMP) • Good Pharmacovigilance Practices (GVP)	02
3	**Drug Development Process** • Preclinical testing and data requirements • Phases of clinical trials and regulatory considerations • Investigational New Drug (IND) application • New Drug Application (NDA) and Biologic License Application (BLA)	04
4	**Regulatory Submissions and Interactions** • Electronic Common Technical Document (eCTD) format • Preparation and submission of regulatory dossiers • Regulatory meetings and communications with Regulatory authorities • Post-submission requirements and updates	04
5	**Pharmacovigilance and Post-Marketing Surveillance** • Adverse drug event reporting and monitoring • Post-marketing safety studies • Risk management plans • Labeling and package inserts	04

6	**Regulatory Compliance and Inspections** • Regulatory inspections and audits • Corrective and preventive actions (CAPA) • Quality management systems • Compliance with regulatory requirements	04
7	**Global Regulatory Harmonization** • International Conference on Harmonisation(ICH) guidelines • Mutual Recognition Agreements (MRAs) • Harmonization initiatives and their impact on Regulatory affairs.	02
8	**Regulatory Affairs in Specialized Areas** • Regulatory considerations for generics and biosimilars • Medical devices and diagnostics regulations • Nutraceuticals and dietary supplements regulations • Regulatory affairs in emerging technologies (e.g.,Gene therapies, cell-based products)	04
9	**Current Trends and Future Developments** • Regulatory challenges and emerging issues • Digital health technologies and regulatory implications • Regulatory affairs careers and professional • Development opportunities**.**	04

Remark by IQAC	Dr. Marina Dsouza
Signature	

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