SANDIP FOUNDATION''s
SANDIP INSTITUTE OF PHARMACEUTICAL SCIENCES,
At Post- Mahiravani, Tal/Dist. Nashik–422213, Maharashtra, India
Web: www.sandipfoundation.org E-mail: info@sandipfoundation.org
Phone: (02594) 222591/92/93/94/95, Fax: (02594) 222555

Medical Coding/ Medical Writing/ Pharmacovigilance

Units	Syllabus	Hours
1	**Medical Coding:** **(CPT, ICD 9-CM, ICD -10 CM, DSM, CDT, APC, and HCPCS)** CPT – Current Procedural Terminology ICD – International Classification of Diseases DSM- Diagnostic and Statistical manual CDT – Code on Dental Procedures and Nomenclature. APC- Ambulatory Payment Categories HCPCS- Healthcare Common Procedure Coding System .	5 Hours
2	Health Insurance Policies Health insurance Portability and Accountability Act Evaluating medical services, procedures, and guidelines Documenting medical records Medical Ethics Anaesthesia	5 Hours
3	**Medical Writing:** 1- Introduction in Healthcare Communication and Medical Writing: • Understanding the term 'Medical Writing' • Types of medical writing • Qualities required in a medical writer • Target audience • Employers and clients 2- The Writing Process • The four steps in the writing process • Prewriting strategies • Drafting	5 Hours

	• Revising • Refining 3- Online and Offline Writing Skills for Media • Reader behaviors • Differences between web and print media • Effective web writing techniques	
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	5 hours
5	□ Basic Rules of Writing • Basic structure of a write-up • Writing the basic components • Grammar basics • General rules of writing	5 Hour
6	Consumer writing • General rules for consumer writing • Types of consumer writing • Consumer news • Consumer reviews • Blogs • Newsletters • Fact sheets • Care guides	5 hours
7	**Pharmacovigilance:** 1. Introduction to Pharmacovigilance • History and development of Pharmacovigilance • Importance of safety monitoring of Medicine • WHO international drug monitoring programme	5 hours

	• Pharmacovigilance Program of India(PvPI) 2. Basic terminologies used in pharmacovigilance • Terminologies of adverse medication related events • Regulatory terminologies 3. Drug dictionaries and coding in pharmacovigilance • WHO adverse reaction terminologies • Med DRA and Standardised MedDRA queries • WHO drug dictionary • Eudravigilance medicinal product dictionary	
8.	4. Information resources in pharmacovigilance • Basic drug information resources • Specialized resources for ADRs 5. Establishing pharmacovigilance programme • Establishing in a hospital • Establishment & operation of drug safety department in industry • Contract Research Organisations(CROs) • Establishing a national programme 6. Pharmacovigilance methods • Passive surveillance–Spontaneous reports and case series • Stimulated reporting • Active surveillance-Sentinel sites, drug event monitoring and registries • Comparative observational studies–Cross sectional study, case control study and cohort study • Targeted clinical investigations	5 hours

Subject In charge:

IQAC In charge	Dr. Atul Bendale
Signature	

Sandip Institute of Pharmaceutical Science SIPS Nashik

Principal
Sandip Foundation's
Sandip Institute of
Pharmaceutical Sciences
Mahiravani, Nashik-422 213