SRI VENKATESWARA COLLEGE OF ENGINEERING

COURSE DELIVERY PLAN - THEORY

Department of Biotechnology	LP: VD22202 Rev. No: 00 Date: 21.01.2025
B.E/**B.Tech**/M.E/M.Tech : **Biotechnology** Regulation: **2022** PG Specialisation : **NA** Sub. Code / Sub. Name : **VD22202 / Introduction to Regulatory Practices in Pharmaceutical Industries** Unit 1 : **Regulatory Concepts**	

Unit Syllabus: **Regulatory Concepts (6 h)**

Practice of cGMP, Quality control and quality assurance in pharma industries.

Objective : To impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals

Session No *	Topics to be covered	Ref	Teaching Aids
1	Introduction to cGMP	T1 (pg. 1-34), R1 (pg. 534-536)	LCD/GCR
2	Regulatory Agencies and cGMP Guidelines	T1 (pg. 35-60), R1 (pg. 538-540), R2 (pg. 210-212)	LCD/GCR
3	cGMP in Manufacturing and Controls	T1 (pg. 61-85), R3 (pg. 145-150)	LCD/GCR
4	Quality Control Systems	T1 (pg. 86-110), R2 (pg. 115-120)	LCD/GCR
5	Quality Assurance Practices	T1 (pg. 111-130), R3 (pg. 159-161)	LCD/GCR
6	Compliance and Audits in GMP	T1 (pg. 131-150), R1 (pg. 545-550), R4 (pg. 70-75)	LCD/GCR
Content beyond syllabus covered (if any): -			

* Session duration: 50 minutes

Sub. Code / Sub. Name: **VD22202 / Introduction to Regulatory Practices in Pharmaceutical Industries**

Unit : **II - Regulatory Aspects**

Unit Syllabus: **Regulatory Aspects (6 h)**

Study plans: Study protocols, Master schedule: Responsibility of study directors, Multisite management and principles, investigators responsibility, Reporting of study results, Storage and retention of records and materials.

Objective: To provide the pharmaceutical industry manufacturing practices and regulatory aspects of pharmacy products..

Session No *	Topics to be covered	Ref	Teaching Aids
7	Study Plans and Study Protocols	T1 (pg. 151-175), R2 (pg. 189-192)	LCD/GCR
8	Master Schedule and Project Management	T1 (pg. 176-200), R1 (pg. 540-545)	LCD/GCR
9	Role of Study Directors	T1 (pg. 201-225), R3 (pg. 88-90)	LCD/GCR
10	Multisite Management and Principles	T1 (pg. 226-245), R2 (pg. 230-235)	LCD/GCR
11	Investigator's Responsibility	T1 (pg. 246-265), R4 (pg. 95-100)	LCD/GCR
12	Reporting of Study Results and Data	T1 (pg. 266-285), R3 (pg. 107-110), R2 (pg. 220-230)	LCD/GCR
Content beyond syllabus covered (if any): -			

* Session duration: 50 mins

Sub. Code / Sub. Name: **VD22202 / Introduction to Regulatory Practices in Pharmaceutical Industries**

Unit : **III - Intellectual Property Rights**

Unit Syllabus : **Intellectual Property Rights (6 h)**

Patent system, Different types of patents, Filing process of application for patent, The patent rules 2003 as amended by the patents (amendment) rules 2016.

Objective : To know the process of patenting activities.

Session No *	Topics to be covered	Ref	Teaching Aids
13	Introduction to Patent System	T2 (pg. 51-75), R1 (pg. 44-46)	LCD/GCR
14	Different Types of Patents	T2 (pg. 76-100), R2 (pg. 88-90)	LCD/GCR
15	Filing Process for Patent Applications	T2 (pg. 101-125), R1 (pg. 47-50), R4 (pg. 120-125)	LCD/GCR
16	Patent Rules 2003 and Amendments 2016	T2 (pg. 126-145), R3 (pg. 10-15)	LCD/GCR
17	Patentability and Novelty Requirements	T2 (pg. 146-160), R1 (pg. 51-55)	LCD/GCR
18	Patent Enforcement and Infringement	T2 (pg. 161-180), R4 (pg. 135-140)	LCD/GCR
Content beyond syllabus covered (if any): -			

* Session duration: 50 mins

Sub. Code / Sub. Name: **VD22202 / Introduction to Regulatory Practices in Pharmaceutical Industries**

Unit : **IV - Quality Audit And Self Inspections**

Unit Syllabus : **Quality Audit And Self Inspection (6 h)**

SOP writing and implementation: GLP establishment, Cost benefit comparisons in regulatory set ups, GLP audits and inspections.

Objective: To know the quality guidelines followed for pharmaceutical products and few of the aspects involved in document preparation for pharmaceutical product registration.

Session No *	Topics to be covered	Ref	Teaching Aids
19	Introduction to SOP Writing	T3 (pg. 50-75), R3 (pg. 67-70), R4 (pg. 200-205)	LCD/GCR
20	GLP Establishment in Laboratories	T3 (pg. 76-100), R2 (pg. 193-195)	LCD/GCR
21	Cost-Benefit Analysis in Regulatory Setup	T3 (pg. 101-120), R1 (pg. 12-15)	LCD/GCR
22	GLP Audits and Inspections	T3 (pg. 121-140), R5 (pg. 95-100)	LCD/GCR
23	Key Elements of GLP Compliance	T3 (pg. 141-160), R5 (pg. 135-140)	LCD/GCR
24	Best Practices in SOP Implementation	T3 (pg. 161-180), R5 (pg. 55-59)	LCD/GCR
Content beyond syllabus covered (if any): -			

* Session duration: 50 mins

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Unit : **V - Role of BIS and ISO in Pharmaceutical Products**

Unit Syllabus: **Role of BIS and ISO in Pharmaceutical Products (6 h)**

Bureau of Indian Standards (BIS) and International Organization for Standardization (ISO) perspectives. Overview of BIS Standards for Medical Devices, Indian Standard specification for pharmaceutical glass containers, Standardization in AYUSH systems DA.

Objective: To create the awareness about the Indian standards for pharmaceutical products.

Session No *	Topics to be covered	Ref	Teaching Aids
25	Overview of Bureau of Indian Standards (BIS)	T4 (pg. 12-35), R2 (pg. 233-235), R4 (pg. 188-190)	LCD/GCR
26	Introduction to ISO Standards	T4 (pg. 36-50), R3 (pg. 101-105)	LCD/GCR
27	BIS Standards for Medical Devices	T4 (pg. 51-75), R2 (pg. 45-47)	LCD/GCR
28	Indian Standard Specification for Pharmaceutical Glass Containers	T4 (pg. 76-95), R3 (pg. 192-195)	LCD/GCR
29	Standardization in AYUSH Systems	T4 (pg. 96-110), R2 (pg. 120-125)	LCD/GCR
30	ISO 13485:2016 and Quality Management Systems	T4 (pg. 111-130), R4 (pg. 50-60)	LCD/GCR
Content beyond syllabus covered (if any): -			

* Session duration: 50 mins

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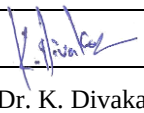
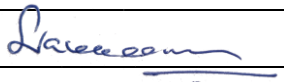
TEXT BOOKS

1. Subbrahmanyam C. V & Thimmasetty J, "Pharmaceutical regulatory affairs", 1st Edition, vallabhprakashan, 2012.
2. Willig H, Tuckeman M.M & Hitchings W.S, "Good Manufacturing Practices for Pharmaceuticals", 5th Edition, Marcel Dekker Drugs and the Pharmaceutical Sciences, CRC Press, 2000.
3. Udupa N, Krishnamurthy Bhat, "A Concise Textbook of Drug Regulatory Affairs", Manipal University Press (MUP), 1st Edition, 2015.
4. IS 23485 Medical Devices – Quality Management System requirements and Essential Principles of safety & performance for Medical Devices ISO 13485 : 2016, 16142-1 : 2016 & 16142-2:2017.

REFERENCE BOOKS

1. Mindy J. Allport-Settle, "Current Good Manufacturing Practices: Pharmaceutical, Biologics and Medical Device Regulations and Guidance Documents Concise Reference", Pharmalogika, 2009.
2. Ira R. Berry, "The Pharmaceutical Regulatory Process", Marcel dekker Series: Drugs and the Pharmaceutical Sciences, CRC Press, Newyork, 2004.
3. Jurg P. Seiler, "Good Laboratory Practice", 2nd Edition, Springer, 2014.
4. WHO/TDR Manual for Good Laboratory Practice, WHO/TDR, Geneva, Switzerland, 2nd Edition, 2008.
5. Sharma P.P, "How to Practice GMPs", 3rd Edition, Vandana, 2006.

	Prepared by	Approved by
Signature		
Name	Dr. K. Divakar	Dr. E. Nakkeeran
Designation	Associate Professor	Professor and Head
Date	21.01.2025	21.01.2025
Remarks *: -		
Remarks *: -		

* If the same lesson plan is followed in the subsequent semester/year it should be mentioned and signed by the Faculty and the HOD