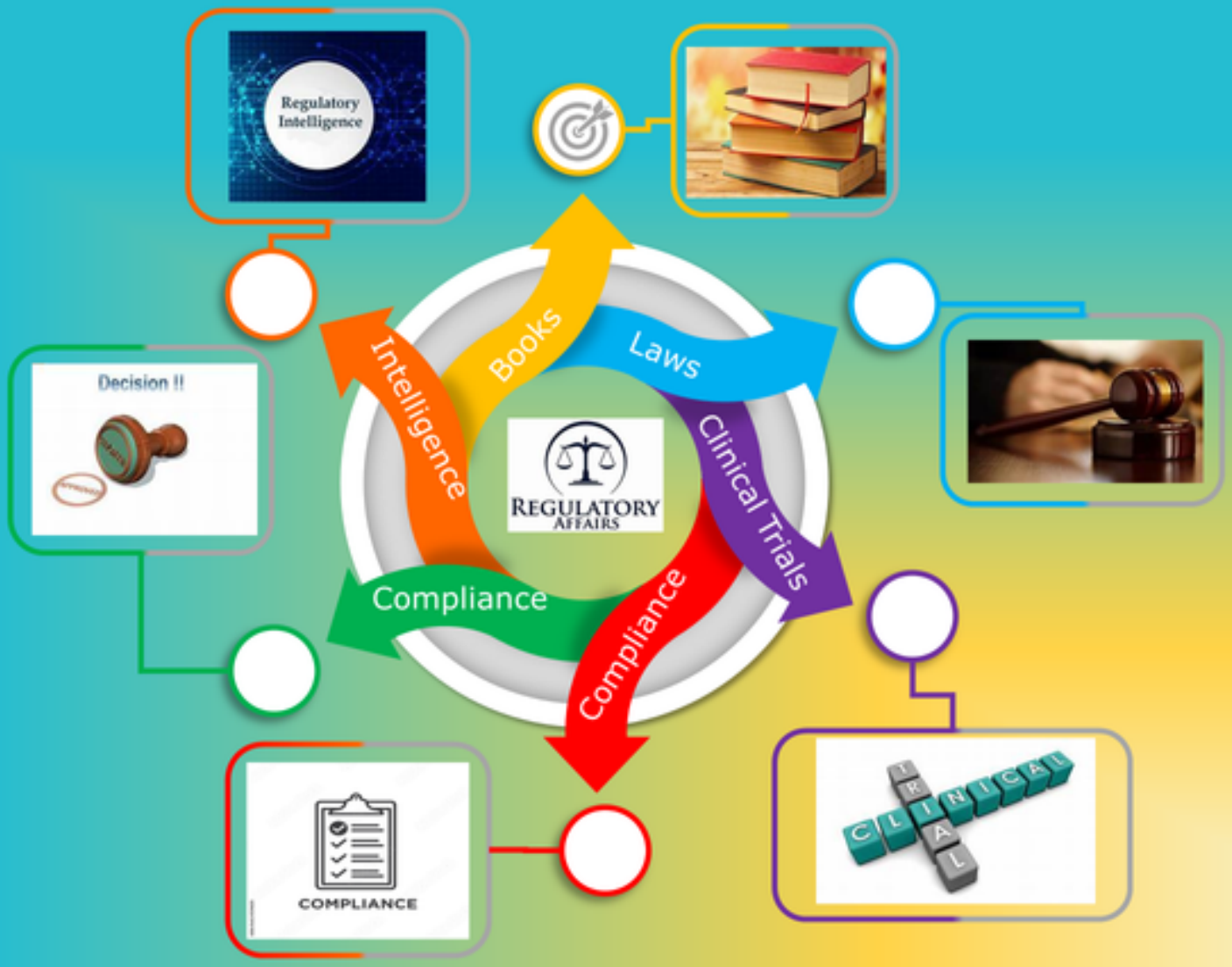
KLE ACADEMY OF HIGHER EDUCATION & RESEARCH
BELAGAVI
[DEEMED-TO-BE-UNIVERSITY]
REACCREDITED AT THE 'A+' LEVEL BY NAAC (THIRD CYCLE).
PLACED IN 'A+' CATEGORY BY MHRD (GoI)



VALUE ADDED COURSE ON

REGULATORY GUIDELINES FOR PHARMACEUTICAL PRODUCTS:

An e-Governance Perspective

Offered By:

Dept of Pharmaceutics

KLE College of Pharmacy, 2nd Block, Rajaji Nagar,
Bengaluru, Karnataka-560010
Contact: 080 2332 4529

Course Preamble:

Regulatory Affairs is an integral part of the organizational structure of the company. It liaises at the interphase of drug development, manufacturing, marketing and clinical research and is the key interface between the company and the national or international regulatory authorities. The course covers basics of regulatory industry, through vital documentation with perspective hands-on in addressing regulatory registrations.

Course Objective:

1. To provide an overview of global pharmaceutical market and regulatory concepts
2. To know the importance of documentation and various report generation
3. To understand the regulatory provisions & licensing conditions in cosmetic & medical device sale & manufacturing
4. To introduce an e-governance tool from the Government of India named SUGAM for ease of application and approval process

Course Outcomes:

Upon completion of this course, participants will be able to:

CO1: Understand the key concepts of NDA, ANDA, Clinical research & tech transfer

CO2: Comprehend the importance of audits, inspections, validation and calibration reports

CO3: Know the principles of medical devices and cosmetic sale and manufacturing

CO4: Use SUGAM portal for regulatory applications and approvals in India

Modules:

Module 1: Basics of the regulatory industry

Sl No	Value added Topic	Duration
1.	Overview of Pharmaceutical markets and global Drug Regulatory Bodies 1.1 Drug regulation History 1.2 Role of regulatory Affairs 1.3 Indian & US FDA guidelines	01 Hour
2.	Regulatory concepts 2.1. Investigational New drug Application (IND) 2.2 New Drug Application (NDA) 2.3 Abbreviated New Drug Application (ANDA) 2.4 FDA approval process	02 Hours
3.	Clinical Research-Related Guidelines 3.1 Stages of Clinical trials 3.2 Regulation of clinical trials	01 Hour
4.	ICH Q8 stability studies 4.1 Global Harmonization Initiatives 4.2 ICH for better health and accelerated stability testing 4.3 Q8 stability guidelines	01 Hour
5.	Tech Transfer stages with WHO guidelines 5.1 Tech transfer process and team 5.2 WHO guidelines for Technology Transfer 5.3 TT agencies in India	02 Hours
	Total Hours	**07 Hours**

Upon completion of this module students will able to

- **MO1:** Discuss the functions of global regulatory bodies & importance of clinical research
- **MO2:** Describe the concepts of NDA, ANDA & ICH
- **MO3:** Understand the stages of tech transfer in industrial innovations

Module 2: Vital Documentation

Sl No	Value added Topic	Duration
1.	Product lifecycle management 1.1 Pre-formulation aspects 1.2 Development stages 1.3 Pre-submission Auditing 1.4 Validation batches	02 Hours
2.	Calibration & Validation reports 2.1. ICH & WHO guidelines for calibration of equipments 2.2 ICH & WHO guidelines for validation of equipments 2.3 Validation Master Plan (VMP)	03 Hours
3.	Audits & Inspections 3.1 Types of audits in Pharmaceutical Industry 3.2 Classes of inspections 3.3 Preparation and management criteria	02 Hours
	Total Hours	**07 Hours**

Upon completion of this module students will able to:

- **MO1:** Comprehend the stages of product development guide
- **MO2:** Understand the calibration and validation of equipment
- **MO3:** Admire the importance of audits and inspections for industries

Module 3: Regulatory aspects of Medical Devices and cosmetics

Sl No	Value added Topic	Duration
1.	Essential principles of medical devices 1.1 CDSCO FAQs for Medical Devices 1.2 Medical Devices sector and components 1.3 Regulatory pathway from development to commercialization	03 Hours
2.	Regulatory provisions & licensing conditions in cosmetic sale & manufacturing 2.1 Requirements of factory premises 2.2 Conditions for obtaining license	01 Hour
3.	COSMOS Standards 3.1 Objectives of COSMOS – standard 3.2 Origin and processing of ingredients	02 Hours
	Total Hours	**07 Hours**

Upon completion of this module students will able to

- **MO1:** Visualise the development of medical device as a commercial product
- **MO2:** Know the requirements to obtain cosmetic manufacturing and exports

Module 4: e-Governance for regulations in India

Sr No	Value added Topic	Duration
1.	Introduction to the SUGAM Portal - An e-Governance solution for CDSCO 1.1 Cosmetic registrations, Blood bank licenses, State FDA manufacturing site approval, BA/BE application, clinical trial registration, drug/device approvals, with medical device and diagnostics approval US (FDA- Food and Drug Administration) 1.2 Steps for registration and online payment of fees & fines to the CDSCO for various purposes. 1.3 An introduction to the User Manual for Post Approval Change (BA/BE Export Division) at CDSCO 1.4 Online Process demonstration for Import of drugs for Personal Use - Form12A 1.5 Method to upload manufacturing sites, formulation Data & State FDA	09 Hours
	Total Hours	**09 Hours**

Upon completion of this module students will able to

- **MO1:** Use SUGAM portal for registration and license activities in India

Total Course Duration: 30 Hours

TEACHING METHODOLOGY & EVALUATION

- **Professional Activities, Learning Resources and Assessment**
- **Suggested Class Room Activities**
    - FAQs, Case studies, Assignment, Group Discussions
- ***25% Formative assessment:***
    - 20% marks will be awarded on the basis of an average of two assignments given in the course (05 Marks)
    - 40% marks will be given on the basis of discussion (10 Marks)
    - 40% marks will be awarded on the basis of an objective / subjective test (10 Marks)

***75% summative assessment*:**

- End term exam of 75 marks will be conducted to award 75% of the total exam score. Exam Score: 40% passing criterion will be based on Formative assessment plus Summative assessment scores.
- Attendance: 80% attendance is compulsory to complete this course.

ELIGIBILITY & OTHER RELEVANT INFORMATION

- **Eligibility: Students pursuing B. Pharm 6th semester**
- **Duration:** 30hrs of lectures spread over 3 Months
- **Fees/Charges:** The course is offered to the students free of cost
- **Added Benefits for the Participating Students:**
    - Attain transferable skills needed to build successful careers in a variety of sectors requiring regulatory affairs expertise and training

- Nurture dedication to safeguard public health while ensuring the safety and effectiveness of various products
- Learn group discussion skill

CAREER OPPORTUNITIES

- Regulatory Affairs Officer
- Junior Regulatory Associate
- Clinical research Co-ordinator
- Drug Safety Specialist

REGULATORY GUIDELINES FOR PHARMACEUTICAL PRODUCTS: An e-governance perspective

Recommended Books and E-References:

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics. Edited By Douglas J. Pisano, David Mantus
2. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
3. Medical Devices Division, Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Govt. of India; Doc No.: CDSCO/FAQ/MD/01/2024
4. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
5. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185, Informa Health care Publishers
6. http://www.fda.gov/
7. http://www.cdsco.nic.in/
8. https://www.tga.gov.au/tga-basics
9. https://www.canada.ca/
10. The Basics of Pharmaceutical Regulatory Affairs, Aman Kumar Subudhi

11. Journal of Applied Pharmaceutical Science 02 (03); 2012: 129-138; Stability Testing of Pharmaceutical Products - Sanjay Bajaj, Dinesh Singla and Neha Sakhuja
12. Handbook of Pharmaceutical Sect:2. 15 Generic Development; Chapter2, Product Development Guide
13. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-second report. Geneva, World Health Organization, 2008 (WHO Technical Report Series, No. 948)
14. ICH Draft Consensus Guideline. Pharmaceutical Quality System. Q10. Geneva, ICH Secretariat, 2008 (http://www.ich.org/LOB/media/MEDIA3917. pdf, last accessed 27 July 2010)