Krishna Vishwa Vidyapeeth, (Deemed To Be University), Karad.

Krishna Institute of Pharmacy, Karad.

Programme Name: Master of Pharmacy (M. Pharmacy)

(Pharmaceutical Regulatory Affairs)

Programme code: 6203

CourseRegulation2014

BasedonNotificationInTheGazetteOfIndiaNo.362, Dated December 11, 2014.

VISION

To be recognized as a premier academic institution imparting excellent pharmaceutical education and research

MISSION

To offer quality pharmaceutical education, to create healthcare professionals with requisite skills, knowledge, research aptitude, values and ethics ensuring rewarding careers.

- **M1.** Quality Pharmaceutical Education: To offer outcome based pharmaceutical education to produce qualified and competent pharmacists of International standards
- **M2.** CompetentPharmacist:Tocreatecompetentpharmacistwithrequisiteskills, knowledge, innovative thinking, Research aptitude and having professional excellence
- **M3.** Rewarding Career: To impart strong ethical values and good Professional behavior,soastoundertakerewardingcareerinapharmacyprofession,tailor-made to meet stringent requirements of pharmaceutical industry

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PHARMACY COUNCIL OF INDIA

NOTIFICATION

New Delhi, the 10th December, 2014

The Master of Pharmacy (M.Pharm) Course Regulations, 2014

No. 14-136/ 2014-PCI.—In exercise of the powers conferred by Sections 10 and 18 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government hereby makes the following regulations: namely–

CHAPTER–I: REGULATIONS

1. Short T i t l e and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program-Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55% of the maximum marks (aggregate of 4years of B. Pharm.)

b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of

his/her admission, failing which the admission of the candidate shall be cancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B.Pharm.)

3. Duration of the program

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years).The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of n the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

Credit assignment

Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one

(1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a c credit of 2.

The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by1.

Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration off our semesters. The credits are

distributed semester-wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

9. Course of study

The specializations in M. Pharm program is given in Table1.

Table–1:List of M. Pharm. Specializations and their Code

Sr .No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Industrial Pharmacy	MIP
3.	Pharmaceutical Chemistry	MPC
4.	Pharmaceutical Analysis	MPA
5.	Pharmaceutical Quality Assurance	MQA
6.	Pharmaceutical Regulatory Affairs	MRA
7.	Pharmaceutical Biotechnology	MPB
8.	Pharmacy Practice	MPP
9.	Pharmacology	MPL
10.	Pharmacognosy	MPG

The course of study for M. Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2 to 11. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table– 2to11.

Table-2:Course of study for M. Pharm.(Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
6201-11T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
6201-12T	Drug Delivery System	4	4	4	100
6201-13T	Modern Pharmaceutics	4	4	4	100
6201-14T	Regulatory Affair	4	4	4	100
6201-15P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
6201-16T	Molecular Pharmaceutics (Nano Tech and Targeted D DS)	4	4	4	100
6201-17T	Advanced Biopharmaceutics & pharmacokinetics	4	4	4	100
6201-18T	Computer Aided Drug Delivery System	4	4	4	100
6201-19T	Cosmetic and Cosmeceuticals	4	4	4	100
6201-20P	Pharmaceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table-3:Course of study for M. Pharm.(Pharmaceutical Quality Assurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
6202-11T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
6202-12T	Quality Management System	4	4	4	100
6202-13T	Quality Control and Quality Assurance	4	4	4	100
6202-14T	Product Development and Technology Transfer	4	4	4	100
6202-15P	Pharmaceutical Quality Assurance Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
6202-16T	Hazards and Safety Management	4	4	4	100
6202-17T	Pharmaceutical Validation	4	4	4	100
6202-18T	Audits and Regulatory Compliance	4	4	4	100
6202-19T	Pharmaceutical Manufacturing Technology	4	4	4	100
6202-20P	Pharmaceutical Quality Assurance PracticalII	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table-4:Course of study for M. Pharm.(Pharmaceutical Regulatory Affairs)

Course Code	Course	Credit Hours	Credit Points	Hrs./ wk	Marks
Semester I					
6203-11T	Good Regulatory Practices	4	4	4	100
6203-12T	Documentation and Regulatory Writing	4	4	4	100
6203-13T	Clinical Research Regulations	4	4	4	100
6203-14T	Regulations and Legislation For Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	4	4	4	100
6203-15P	Regulatory Affairs Practical I	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
6203-16T	Regulatory Aspects of Drugs & Cosmetics	4	4	4	100
6203-17T	Regulatory Aspects of Herbal & Biologicals	4	4	4	100
6203-18T	Regulatory Aspects of Medical Devices	4	4	4	100
6203-19T	Regulatory Aspects of Food & Nutraceuticals	4	4	4	100
6203-20P	Regulatory Affairs Practical II	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table-5: Course of study for M. Pharm. III Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion/Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
Total		35	21

*Non University Exam

Table-6:Course of study for M. Pharm. IV Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion/Final Presentation	3	3
Total		35	20

Table-6: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

*Credit Points for Co-curricular Activities

Table-7: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points Eligible/Activity
Participation in National Level Seminar/Conference/Workshop/Symposium/Training Programs(related to the specialization of the student)	01
Participation in international Level Seminar/Conference/Workshop/Symposium/Training Programs(related to the specialization of the student)	02
Academic Award/Research Award from State Level/National Agencies	01
Academic Award/Research Award from International Agencies	02
Research/Review Publication in National Journals (Indexed in Scopus/Web of Science)	01
Research/Review Publication in International Journals (Indexed in Scopus/Web of Science)	02

Note: International Conference: Held Outside India

International Journal: The Editorial Board Outside India

*The credit points as signed for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

10. Program Committee

1. The M. Pharm. Programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:

A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

3. Duties of the Programme Committee:

i. Periodically reviewing the progress of the classes.
ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.

iv. Communicating its recommendation to the Head of the institution on academic matters.
v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table-16.

End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the respective university except for the subject with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Tables-8: Schemes for internal assessments and end semester (Pharmaceutics-MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTERI								
6201-11T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
6201-12T	Drug Delivery System	10	15	1Hr	25	75	3Hrs	100
6201-13T	Modern Pharmaceutics	10	15	1Hr	25	75	3Hrs	100
6201-14T	Regulatory Affair	10	15	1Hr	25	75	3Hrs	100
6201-15P	Pharmaceutics PracticalI	20	30	6Hrs	50	100	6Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTERII								
6201-16T	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	10	15	1Hr	25	75	3Hrs	100
6201-17T	Advanced Biopharmaceutics &Pharmacokinetics	10	15	1Hr	25	75	3Hrs	100
6201-18T	Computer Aided Drug Delivery System	10	15	1Hr	25	75	3Hrs	100

6201-19T	and Cosmeceuticals							
6201-20P	Pharmaceutics Practicall	20	30	6Hrs	50	100	6Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables -9: Schemes for internal assessments and end semester examinations (Pharmaceutical Quality Assurance-MQA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTERI								
6202-11T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
6202-12T	Quality Management System	10	15	1Hr	25	75	3Hrs	100
6202-13T	Quality Control and Quality Assurance	10	15	1Hr	25	75	3Hrs	100
6202-14T	Product Development and Technology Transfer	10	15	1Hr	25	75	3Hrs	100
6202-15P	Pharmaceutical Quality Assurance Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTERII								
6202-16T	Hazards and Safety Management	10	15	1Hr	25	75	3Hrs	100
6202-17T	Pharmaceutical Validation	10	15	1Hr	25	75	3Hrs	100
6202-18T	Audits and Regulatory Compliance	10	15	1Hr	25	75	3Hrs	100
6202-19T	Pharmaceutical Manufacturing Technology	10	15	1Hr	25	75	3Hrs	100
6202-20P	Pharmaceutical Quality Assurance Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100

Tables -10: Schemes for internal assessments and end semester examinations (Pharmaceutical Regulatory Affairs-MRA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTERI								
6203-11T	Good Pharmaceutical Practices	10	15	1Hr	25	75	3Hrs	100
6203-12T	Documentation and Regulatory Writing	10	15	1Hr	25	75	3Hrs	100
6203-13T	Clinical Research Regulations	10	15	1Hr	25	75	3Hrs	100
6203-14T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & NutraceuticalsIn India and Intellectual Property Rights	10	15	1Hr	25	75	3Hrs	100
6203-15P	Pharmaceutical Regulatory Affairs Practicall	20	30	6Hrs	50	100	6Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTERII								
6203-16T	Regulatory Aspects of Drugs & Cosmetics	10	15	1Hr	25	75	3Hrs	100

6203-17T	Regulatory Aspects of Herbal & Biologicals	10	15	1Hr	25	75	3Hrs	100
6203-18T	Regulatory Aspects of Medical Devices	10	15	1Hr	25	75	3Hrs	100
6203-19T	Regulatory As pects of Food &Nutraceuticals	10	15	1Hr	25	75	3Hrs	100
6203-20P	Pharmaceutical Regulatory Affairs Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables -11: Schemes for internal assessments and end semester examinations (Semester III & IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTERIII								
MRM301T	Research Methodology and Biostatistics*	10	15	1Hr	25	75	3Hrs	100
-	Journal club	-	-	-	25	-	-	25
-	Discussion /Presentation (Proposal Presentation)	-	-	-	50	-	-	50
-	Research work*	-	-	-	-	350	1Hr	350
Total								525
SEMESTERIV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion /Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	1Hr	400
Total								500

*Non University Examination

Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table-12: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	Maximum Marks
Attendance (Refer Table–28)	8
Student–Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table–28	10
Based on Practical Records, Regular viva voce,etc.	10
Total	20

Table-28: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95–100	8	10
90–94	6	7.5
85–89	4	5
80–84	2	2.5
Lessthan80	0	0

11.2.1. Sessional Exams

Two sessional exams shall be conducted for each theory /practical course as per the schedule fixed by the college(s).The scheme of question paper for theory and practical sessional examinations is given in the table. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

12. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M. Pharm. programme if he/she secures at least 50% marks in that particular course including internal assessment.

13. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

14. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 29. The exact dates of examinations shall be notified from time to time.

Table-13: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November/December	May/June
II and IV	May/June	November/December

16. Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

17. Grading of performances

Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table-30.

Table –14: Letter grades and grade points equivalent toPercentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00–100	O	10	Outstanding
80.00–89.99	A	9	Excellent
70.00–79.99	B	8	Good
60.00–69.99	C	7	Fair
50.00–59.99	D	6	Average
Lessthan50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero.He/sheshouldreappearforthesaidevaluation/examinationinduecourse.

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA).The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses(Theory/Practical) in a semester with credits C1,C2, C3 and C4 and the student's grade points in these courses areG1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1+C_2+C_3+C_4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$ZEROSGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4*}{C_1+C_2+C_3+C_4}$$

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed

by obtaining a pass grade on subsequent examination(s) the CGPA

Shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

$$CGPA = \frac{C_1S_1+C_2S_2+C_3S_3+C_4S_4}{C_1+C_2+C_3+C_4}$$

Where C_1, C_2,C_3,.... is the total number of credits for semester I,II,III,.... And S_1,S_2,S_3,....is the SGPA of semester I,II,III,.....

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

FirstClass with Distinction	= CGPAof.7.50 and above
First Class	=CGPA of 6.00to7.49
Second Class	= CGPA of 5.00to5.99

21. Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report.4 copies of the project report shall be submitted (typed &bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	50Marks
Methodology adopted	150Marks
Results and Discussions	250Marks
Conclusions and Outcomes	50 Marks
Total	500Marks

Evaluation of Presentation:

Presentation of work	100Marks
Communication skills	50Marks
Question and answer skills	100Marks
Total	250Marks

22. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

23. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

24. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

25. Revaluation I Retotaling of answer papers

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

26. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

GOOD REGULATORY PRACTICES (6203-11T)

Scope

This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements and will propose ways and means of complying with them.

Objectives

At completion of this course it is expected that students will be able to understand,

- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
- Prepare and implement the check lists and SOPs for various Good Regulatory Practices
- Implement Good Regulatory Practices in the Healthcare and related Industries
- Prepare for the readiness and conduct of audits and inspections.

THEORY 60Hrs

1.	Current Good Manufacturing Practices: Introduction, US cGMP Part210 and Part211. EC Principles of GMP (Directive91/356/EEC)Article6toArticle14andWHOcGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization TaskForce(GHTF)Guidancedocs.	12 Hrs
2	Good Laboratory Practices: ntroduction, USFDA GLP Regulations (Subpart At o SubpartK),Controlling the GLP inspection process, Documentation, Audit,goalsofLaboratoryQualityAudit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India(QCI)Standards	12 Hrs
3	Good Automated Laboratory Practices: Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP,TrainingDocumentation,21CFRPart11,Generalchecklist	12 Hrs

of21CFRPart11,SoftwareEvaluationchecklist,relevantISOand QCIStandards.

4	Good Distribution Practices: Introduction to GDP, Legal GD Prequirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USPGDP (Supply chain integrity), relevant CDSCO guidance and ISO standards	12 Hrs
5	Quality management systems: Concept of Quality, Total QualityManagement,Qualityby design,Six Sigmaconcept,Out ofSpecifications (OOS),Change control.Validation: Types ofValidation, Types of Qualification,Validation master plan (VMP),Analytical Method Validation. Validation of utilities, [Compressedair,steam,watersystems,HeatVentilationandAir conditioning(HVAC)]andCleaningValidation.TheInternational ConferenceonHarmonization(ICH)process,ICHguidelinesto establish quality,safety and efficacy of drug substances and products, ISO 13485,SchMIIIand other relevant CDSCO regulatory guidance documents.	12 Hrs

REFERENCES

1. Good Laboratory PracticeRegulations,by Sandy Weinberg, FourthEditionDrugsandthePharmaceuticalSciences,Vol.168
2. GoodPharmaceuticalManufacturingpractice,RationalandcompliancebyJohnSharp,CRCPress
3. EstablishingacGMPLaboratoryAuditSystem,ApracticalGuidebyDavidM.Bleisner,WileyPublication.
4. HowtopracticeGLPbyPPSharma,VandanaPublications.
5. LaboratoryAuditingforQualityandRegulatorycompliancebuDonaldC.Singer,DrugsandthePharmaceuticalSciences,Vol.150.
6. Drugs&CosmeticsAct,Rules&Amendments

DOCUMENTATIONANDREGULATORYWRITING

(6203-12T)

Scope

This course is designed to impart fundamental knowledge ondocumentation andgeneralprinciplesinvolvedinregulatorywritingandsubmissiontoagencies.

Objectives

Upon completion of the course the student shall be able to,

- Know the various documents per taining todrugs in pharmaceutical industry
- Understand the basicsofregulatorycompilation
- Create and assemble the regulation submission as per the requirements of agencies
- Follow up the submissions andpostapprovaldocumentrequirements

THEORY		60Hrs
1.	Documentation in pharmaceutical industry: Exploratory Product Development Brief(EPDB)for DrugsubstanceandDrugproduct, Product Development Plan (PDP),Product Development Report(PDR),MasterFormulaRecord,Batch Manufactu ring Record and its calculations ,Batch Reconciliation, BatchPacka ging Records,Printpack specifications,Distribution records, Certificate of Analysis (CoA), Site Master File and DrugMasterFiles(DMF).	12 Hrs
2	Dossier preparation and submission :Introduction andoverview ofdossiers,contentsandorganizationofdossier,bindersand sections, compilation and review of dossier. Papersubmissions,overview and modulesof CTD, electronicCTDsubmissions;Electronicsubmission:Planningelectr onicsubmission,requirements for submission,regulatorybindingsandrequirements,ToolandTechnolog ies,electronicdossiersubmissionprocessandvalidatingthe submission,ElectronicSubmissionGateway(ESG).NoneCTD electronic submissions(NeeS),AsianCTDformats(ACTD)submission.Organiz ing,process and validationof submission.Submission in SugamsystemofCDSCO.	12 Hrs

3	Audits: Introduction,Definition, Summary, Types of audits, GMPcomplianceaudit, Audit policy,Internal and External Audits,SecondPartyAudits,Externalthirdpartyaudits,Auditingstrategies,Preparationandconductingaudit,Auditingstrategies,audit analysis, audit report, audit follow up. Auditing/inspection ofmanufacturingfacilitiesbyregulatoryagencies.Timelinesforaudits/ inspection.GHTF study group 4 guidance document.ISO13485.	12 Hrs
4	Inspections: Pre-approval inspections, Inspection of pharmaceuticalmanufacturers,Inspectionofdrugdistribution channels, Quality systems requirements for national good manufacturing practiceinspectorates,inspection report,model certificate of good manufacturing practices, Root cause analysis,CorrectiveandPreventiveaction(CAPA).	12 Hrs
5	Productlifecyclemanagement:Prior Approval Supplement(PAS),PostApprovalChanges[SUPAC],ChangesBeing Effectedin30Days (CBE-30),AnnualReport,PostmarketingReportingRequirements,PostapprovalLabelingChanges,Lifecycle Management,FDAInspectionandEnforcement,Establishment Inspection Report (EIR), Warning Letters, Recalls,SeizureandInjunctions.ISORiskManagementStandard	12 Hrs

REFERENCES

1. ComplianceauditingforPharmaceuticalManufacturers.KarenGinsburyandGilBismuth,Interpharm/CRC,BocaRaton,LondonNew York,WashingtonD.C.
2. PharmaceuticalManufacturingHandbook,RegulationsandQuality byShayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc.,Publications.
3. Handbook ofmicrobiologicalQualitycontrol.Rosamund M.Baird,NormanA.Hodges,StephenP.Denyar.CRCPress.2000.
4. Laboratoryauditingforqualityandregulatorycompliance.Donald C.Singer, Raluca-Ioana Stefan, Jacobus F. Van Staden. Taylor andFrancis(2005).
5. ImplementingJuran'sRoadMap forQualityLeadership:Benchmarks andResults,ByAlEndres,Wiley,2000
6. Understanding,ManagingandImplementingQuality:Frameworks,TechniquesandCases,ByJijuAntony;DavidPreece,Routledge,2002

7. Organizingfor HighPerformance: EmployeeInvolvement, TQM,Reengineering, and Knowledge Management in the Fortune 1000: TheCEO Report By Edward E. Lawler; Susan Albers Mohrman; GeorgeBenson,Jossey-Bass,2001
8. CorporateCulture and the Quality Organization By James W. Fairfield-Sonn,QuorumBooks,2001
9. The QualityManagementSourcebook:An InternationalGuidetoMaterials and Resources By Christine Avery; Diane Zabel, Routledge,1997
10. TheQualityToolbox,SecondEdition,NancyR.Tague, ASQPublications
11. Juran'sQualityHandbook,SixthEdition,JosephM.JuranandJoseph A.DeFeo,ASQPublications
12. Root Cause Analysis, The Coreof Problem Solving and CorrectiveAction,DukeOkes,2009,ASQPublications
13. International MedicalDeviceRegulatorsForum(IMDRF)MedicalDeviceSingleAuditProgram(MDSAP)

CLINICALRESEARCHREGULATIONS

(6203-13T)

Scope

Thiscourseisdesignedtoimpartthefundamentalknowledgeontheclinical developmentprocessofdrugs,pharmaceuticalsandMedicalDevices,phasesand conduct of clinicaltrials and research, regulations and guidance governingtheconductof clinicalresearchinIndia,USAand EU.It preparesthestudentsto learnin detail on various laws, legislations and guidance related to safety,efficacy,ethicalconductandregulatoryapprovalof clinicalresearch.

Objectives

Uponcompletionofthecourse,thestudentshallbeableto(know,doandappreciate)

- History,originandethicsofclinicalandbiomedicalresearchand evaluation
- Clinicaldrug,medicaldevicedevelopmenttprocess and differenttypes and phases of clinical trials
- Regulatoryrequirementsand guidanceforconductofclinicaltrials and research

Theory — 60Hrs

1. Clinical — 12 Hrs
   - DrugDevelopmentProcessDifferenttypesof
   - ClinicalStudies
   - Phasesofclinicaltrials,ClinicalTrialprotocol
   - Phase0studies

   Phase I and subtype studies (single ascending, multipleascending,dose escalation, methods,foodeffect studies,drug-druginteraction,PKendpoints

   - Phase II studies (proof of concept or principle studies toestablishefficacy)
   - PhaseIIIstudies(Multiethnicity,globalclinicaltrial,registration studies)
   - PhaseIV studies(PostMarketingStudies;PSUR)

   ClinicalInvestigationandEvaluation of Medical Devices&IVDs

   DifferentTypesofStudies

   KeyConceptsofMedicalDeviceClinicalEvaluationKeyconc eptsofClinicalInvestigation

2 EthicsinClinicalResearch: 12 Hrs

- HistoricalPerspectives:NurembergCode,Thalidomidestudy ,NazisTrials,TuskegeeSyphilisStudy,TheBelmont Report,The declaration of Helsinki
- OriginofInternationalConferenceonHarmonization–Good Clinical Practice (ICH–GCP) guidelines.
- Theethicsofrandomizedclinicaltrials
- Theroleofplacebo inclinicaltrials
- Ethicsofclinicalresearchinspecialpopulation
- Institutional Review Board /Independent Ethics Committee/EthicsCommittee– composition,roles, responsibilities, review and approval process and ongoingmonitoringofsafetydata
- Datasafetymonitoringboards.
- Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research
  - Ethicalprinciplesgoverninginformedconsentprocess
  - PatientInformationSheetandInformedConsentForm
  - Theinformedconsentprocessanddocumentation

3 RegulationsgoverningClinicalTrials 12 Hrs

India: Clinical Research regulations in India – Schedule Y &MedicalDeviceGuidance

USA:RegulationstoconductdrugstudiesinUSA(FDA)

- NDA505 (b)(1)oftheFD&C Act(Application forapprovalof anewdrug)
- NDA505(b)(2)oftheFD&CAct(Applicationforapprovalofanew drugthatrelies,atleastinpart,ondatanotdevelopedbythe applicant)
- ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)
- FDAGuidanceforIndustry–AcceptanceofForeignClinical Studies
- FDAClinicalTrialsGuidanceDocument:GoodClinical PracticeEU:ClinicalResearchregulationsinEuropeanUnion(EMA)

4	Clinical Research ' RelatedGuidelinesGoodClinicalPracticeGui ' delines(ICHGCPE6) IndianGCPGuidelines ' ICMREthicalGuidelinesforBiomedicalResearch ' CDSCOguidelines GHTFstudygroup5guidancedocuments RegulatoryGuidanceonEfficacyandSafetyICHGuidance's ' E4- DoseResponseInformation tosupportDrugRegistration ' E7-StudiesinsupportofGeneralPopulation:Geriatrics E8- ' GeneralConsiderationsofClinicalTrials ' E10-ChoiceofControlGroupsandRelatedIssuesin ClinicalTrials, ' E11-ClinicalInvestigationofMedicinalProductsinthe Pediatric Population ' Generalbiostaticsprincipleappliedinclinicalresearch	12 Hrs
5	USA&EUGuidanceU SA:FDAGuidance ' CFR21Part50: Protection ofHumanSubjects ' CFR21Part54:FinancialDisclosurebyClinicalInvestigators ' CFR21Part312:INDApplication ' CFR21Part314:Application for FDA Approvalto Market a New Drug ' CFR 21 Part320:Bioavailability and bioequivalence requirements ' CFR21Part812:InvestigationalDeviceExemptions ' CFR21Part822: Post-marketsurveillance ' FDA Safety Reporting Requirements for INDs andBA/BE Studies ' FDAMedWatch ' GuidanceforIndustry:Good Pharmacovigilance Practices and PharmacoepidemiologicAssessment EuropeanUnion:EMAGuidance ' EUDirectives2001 ' EudraLex(EMEA)Volume3- Scientificguidelinesformedicinalproductsforhumanuse ' EU Annual Safety Report(ASR) ' Volume9A- PharmacovigilanceforMedicinalProductsforHumanUse ' EUMDDwithrespecttoclinicalresearch ' ISO14155	12 Hrs

REFERENCES

1. Clinical Trials and Human Research:A Practical Guide to RegulatoryComplianceByFayA.RozovskyandRodneyK.Adams
2. HIPAA and Human Subjects Research: A Question and AnswerReferenceGuideByMarkBarnes,JD,LLMandJenniferKulynych,JD,PhD
3. PrinciplesandPracticesofClinicalResearch,SecondEditionEdited byJohnI.GallinandFrederickP.Ognibene
4. ReviewingClinicalTrials:AGuidefortheEthicsCommittee;Johan PEKarlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, HongKong.
5. International Pharmaceutical Product Registration: Aspects of Quality,SafetyandEfficacy;AnthonyC.Cartwright;Taylor&FrancisInc.,USA.
6. New DrugApprovalProcess: The Global Challenge; Guarino,RichardA;MarcelDekkerInc.,NY.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices,andbiologics;DouglasJ.Pisano,DavidMantus;CRCPress,USA
8. CountrySpecificGuidelinesfromofficialwebsites.
9. Drugs&CosmeticsAct&RulesandAmendments

RECOMMENDEDWEBSITES:

1. EUClinicalResearchDirective2001:http://www.eortc.be/services/doc /clinical-eudirective-04-april-01.pdf
2. Code of Federal Regulations, FDA:http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
3. GuidelinesofInternationalConferenceonHarmonization:http://www.ich.org/products/guidelines.html
4. EudralexGuidelines:http://www.gmpcompliance.info/euguide.htm
5. FDANewDrugApplication:
6. http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm
7. MedicinesandHealthcareproductsRegulatoryAgency:http://www .mhra.gov.uk
8. CentralDrugsStandardControlOrganizationGuidanceforIndustry:http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf
9. ICMREthicalGuidelinesforBiomedicalResearch:http://icmr.nic.in /ethical_guidelines.pdf

REGULATIONSANDLEGISLATIONFORDRUGS&COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS

(6203-14T)

Scope

This course is designed to impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals &Herbals, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs& Cosmetics, Medical Devices, Biologicals &Herbals, and Food & Nutraceuticals. For manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

Objectives

Upon the completion of the course the student shall be able to:

- Know different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.
- Understand the approval processandregulatoryrequirementsfor Drugs&Cosmetics,MedicalDevices,Biologicals&Herbals,andFood&Nutraceuticals

THEORY 60Hrs

1. Biologicals&Herbals,andFood&Nutraceuticals Acts and Rules(withlatestamendments): 12 Hrs
    1. Drugs and Cosmetics Act 1940 and Rules 1945: DPCOandNPPA
    2. Otherrelevantprovisions(rulesschedulesandguidelinesfor approvalof Drugs & Cosmetics, Medical Devices,Biologicals & Herbals, and Food & Nutraceuticals in India

    OtherrelevantActs:NarcoticsDrugsandPsychotropic Substances Act; Medicinal and Toilet Preparations (ExciseDuties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act,1955;PreventionofCrueltytoAnimalsAct.

2	Regulatory requirements and approval proceduresforDrugs& Cosmetics Medical Devices, Biologicals & Herbals,and Food&Nutraceuticals CDSCO(Central Drug Standard Control Organization) and State LicensingAuthority:Organization,Responsibilities ▯ Rules, regulations, guidelines and standards for regulatoryfilingofDrugs&Cosmetics,MedicalDevices, Biologicals&Herbals,andFood&Nutraceuticals ▯ Format and contents of Regulatory dossier filing Clinical trial/investigations	12 Hrs
3	Indian Pharmacopoeial Standards, BISstandards and ISO andotherrelevantstandards	12 Hrs
4	Bioavailability and Bioequivalence data (BA&BE), BCS Classification of Drugs,Regulatory Requirements for Bioequivalencestudy Stability requirements: ICH and WHO GuidelinesforDrugtestinginanimals/PreclinicalStudies Animaltesting:Rationaleforconductingstudies,CPCSEA Guidelines Ethicalguidelinesforhumanparticipants ICMR-DBTGuidelinesforStemCellResearch	12 Hrs
5	Intellectual Property Rights: Patent,Trademark,Copyright, Industrial Designs and Geographical Indications, Indian PatentScenario.IPRvsRegulatoryAffairs	12 Hrs

REFERENCES

1. ManualofPatentPractice&Procedure,3rdEdition,byThePatentOfficeofIndia
2. PatentFailureHow Judges,Bureaucrats,and LawyersputinnovatorsatriskbyJamesBessenandMichaelJ.Meurer
3. PrinciplesandPracticeofClinicalTrialMedicinebyRichardChinandBruceY.Le e
4. EthicalGuidelinesforBiomedicalResearchonHumanParticipantsbyIndianC ouncilofMedicalResearchNewdelhi2006.
5. CPCSEAGuidelinesforLaboratoryAnimalFacilitybyCommitteeforthepurpos eofcontrol andsupervisiononexperimentson animals(CPCSEA)

6. ICHE6Guideline—GoodClinicalPractice· byICHHarmonisedTripartite
7. Guidance for Industry on Submission of Clinical Trial Application forEvaluating Safety and Efficacy by CDSCO(Central Drug Standard ControlOrganisation)
8. Guidance for Industry on Requirement of Chemical &Pharmaceutical Information including Stability Study Data before approval of clinical trials/BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices byCDSCO
10. Guidelines from official website of CDSCO

REGULATORYAFFAIRSPRACTICAL-I

(6203-15P)

1. Casestudies(4Nos.)ofeachofGoodPharmaceuticalPractices.
2. Documentation for inprocess andfinishedproductsQualitycontroltestsforSolid, liquid,SemisolidandSterilepreparations.
3. PreparationofSOPs,Analyticalreports(Stabilityandvalidation)
4. Protocolpreparationfordocumentationofvarioustypesofrecords (BMR,MFR,DR)
5. Labelingcomparisonbetweenbrand&generics.
6. Preparationofclinicaltrialprotocolforregisteringtrialin India
7. RegistrationforconductingBA/BEstudiesinIndia
8. Importofdrugsforresearchanddevelopmentalactivities
9. PreparationofregulatorydossierasperIndianCTD formatandsubmissioninSUGAM
10. RegisteringfordifferentIntellectualPropertyRightsinIndia
11. GMPAuditRequirementsasperCDSCO
12. PreparationanddocumentationforIndianPatentapplication.
13. PreparationofchecklistforregistrationofINDasperICHCTDformat.
14. PreparationofchecklistforregistrationofNDAasperICHCTDformat.
15. PreparationofchecklistforregistrationofANDAasperICHCTDformat.
16. CasestudiesonresponsewithscientificrationaletoUSFDAWarningLetter
17. PreparationofsubmissionchecklistofIMPDforEUsubmission.
18. ComparisonstudyofmarketingauthorizationproceduresinEU.
19. ComparativestudyofDMFsysteminUS,EUandJapan
20. PreparationofregulatorysubmissionusingeCTDsoftware
21. PreparationofClinicalTrialApplication(CTA)forUSsubmission
22. PreparationofClinicalTrialApplication(CTA)forEUsubmission
23. Comparisonof ClinicalTrialApplicationrequirementsofUS,EUandJapanofadosageform.
24. Regulatoryrequirementschecklistforconductingclinicaltrialsin India.
25. Regulatoryrequirementschecklistforconductingclinicaltrialsin Europe.
26. Regulatoryrequirementschecklistforconductingclinicaltrialsin USA

SEMESTERII

REGULATORYASPECTSOFDRUGS&COSMETICS

(6203-16T)

Scope

This course is designed to impart the fundamental knowledge on the drugdevelopmentprocess,regulatory requirementsfor approval of new drugs,drugproductsandcosmeticsinregulatedandsemi-regulatedcountriesIt preparesthe students to learnin detail on the regulatory requirements, documentationrequirements,and registrationproceduresfor marketingthedrugproductsandcosmeticsinregulatedandsemi-regulatedcountries.

Objectives

Uponcompletionofthecourse,thestudentshallbeableto know

- processofdrugdiscoveryanddevelopmentandgenericproduct development
- Regulatoryapprovalprocess andregistrationproceduresfor APIanddrugproductsinUS,EU
- Cosmeticsregulationsinregulatedandsemi-regulatedcountries
- AcomparativestudyofIndiawithotherglobalregulatedmarkets

Theory 60Hrs

1. USA &CANADA:Organization structure and functions of FDA.Federal registerand Code of Federal Regulations (CFR),HistoryandevolutionofUnitedStatesFederal,Food,Drug andCosmeticAct(FFDCA),HatchWaxmanactandOrangebook, Purple book,DrugMasterFiles(DMF)systeminUS,RegulatoryApproval ProcessforInvestigationalNewDrug(IND),NewDrug Application(NDA),AbbreviatedNewDrugApplication(ANDA), SupplementalNewDrugApplication(SNDA);Regulatory requirements for Orphan drugs and CombinationProducts,ChangestoanapprovedNDA/ANDA. Regulatory considerationsfor manufacturing, packagingand labelingofpharmaceuticalsinUSA.Legislationandregulationsforimp ort, manufacture,distributionandsale of cosmeticsin USA and Canada. 12 Hrs

2 EuropeanUnion&Australia:OrganizationandstructureofEMA& EDQM,Generalguidelines,ActiveSubstanceMasterFiles(ASMF) system in EU, Content and approval process of IMPD,MarketingAuthorizationproceduresinEU(Centralizedprocedure, 12 Hrs

Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labelingofpharmaceuticalsinEU, Eudralexdirectives for human medicines, Variations& extensions,Compliance of European Pharmacopoeia (CEP)/Certificateof Suitability (CoS), Marketing Authorization (MA) transfers, QualifiedPerson (QP) in EU. Legislation and regulations for import, manufacture, distributionand saleof cosmeticsinEuropeanUnion&Australia.

3 Japan: Organization of the PMDA, Pharmaceutical Laws andregulations,typesofregistrationapplications,DMFsystem inJapan,drugregulatoryapprovalprocess,Regulatoryconsiderations for manufacturing,packagingand labeling ofpharmaceuticals in Japan, Post marketing surveillancein Japan.Legislation and regulations for import,manufacture, distributionandsaleofcosmeticsinJapan

EmergingMarket:Introduction, Countries covered, Study of theworld map,study of various committees across the globe (ASEAN,APEC,EAC,GCC,PANDRH,SADC)

WHO:WHO, GMP, Regulatory Requirements for registration ofdrugsandpostapprovalrequirementsinWHOthroughprequalification programme,CertificateofPharmaceuticalProduct(CoPP)- General and Country Specific (South Africa,Egypt,Algeriaand Morocco,Nigeria,KenyaandBotswana)

1. Brazil,ASEAN,CISandGCCCountries:

ASIANCountries: IntroductiontoACTD, Regulatory Requirementsforregistrationofdrugsand postapprovalrequirementsinChinaandSouthKorea&Association fSoutheast Asian Nations(ASEAN)Regioni.e.Vietnam,Malaysia,Philippines,Singaporeand Thailand.

CIS (Common wealth Independent States): Regulatory pre-requisitesrelatedtoMarketingauthorizationrequirementsfor drugsandpostapprovalrequirementsinCIScountries i.e.Russia,KazakhstanandUkraineGCC(GulfCooperation Council)forArabstates:Regulatorypre-requisitesrelatedto Marketingauthorizationrequirementsfordrugsandpostapprovalrequirements in Saudi Arabia and UAE

Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN,

12
Hrs

12
Hrs

12

CISandGCCCountries.

REFERENCES:

1. Generic Drug Product Development, Solid Oral Dosage forms, LeonShargelandIsaderKaufer,MarcelDekkerseries,Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry MarcelDekkerSeries,Vol.144
3. ThePharmaceuticalRegulatoryProcess,SecondEditionEditedbyIra R.Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185InformaHealthcarePublishers.
4. NewDrugApprovalProcess:AcceleratingGlobalRegistrationsBy RichardAGuarino,MD,5th edition,DrugsandthePharmaceutical ences,Vol.190.
5. Guidebookfordrugregulatorysubmissions/SandyWeinberg.ByJohnWiley&S ons.Inc.
6. Drugs:FromDiscoverytoApproval,SecondEditionByRickNg
7. NewDrugDevelopment:ARegulatoryOverview, EighthEditionByMarkMathieu
8. PharmaceuticalRiskManagementBy JeffreyE. Fetterman,WayneL. PinesandGaryH.Slatko
9. PreparationandMaintenanceoftheINDApplicationineCTDFormatByWilliam K.Sietsema
10. CountrySpecificGuidelinesfromofficialwebsites.
11. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListM RAWebsites.pdf
12. RoadmaptoanASEANeconomiccommunityEditedbyDenisHew.ISEAS Publications,Singapore2005,ISBN981-230-347-2
13. ASEAN, Rodolfo C. Severino, ISEASPublications, Singapore 2005,ISBN978-981-230-750-7
14. Building a Future with Brics: The Next Decade for Offshoring,MarkKobayashi-Hillary,Springer
15. OutsourcingtoIndia:TheOffshoreAdvantage,MarkKobayashi-Hillary,SpringerTradeperformanceand RegionalIntegrationoftheCISCountries,LevFreinkman,
16. TheworldBank,Washington,DC,ISBN:0-8212-5896-0
17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow'sWorldByFrederick M. Abbott, GrahamDukes,Maurice Nelson Graham Dukes139
18. The GulfCooperationCouncil:A RisingPowerand Lessons forASEANbyLindaLowandLorraineCarlosSalazar(Nov22,2010)
19. Doing Business in the Asean Countries, Balbir Bhasin, Business ExpertPressISBN:13:978-1-60649-108-9
20. RealizingtheASEANEconomicCommunity:AComprehensiveAssessm ent, Michael G Plummer (Editor), Chia Siow Yue (Editor),InstuteofSoutheastasianstudies,Singapore

REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (6203-17T)

Scope

This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe
It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products

Objectives

Upon the completion of the course the students shall be able to:

- Know the regulatory Requirements for Biologics and Vaccines
- Understand the regulation for newly developed biologics and biosimilars
- Know the pre-clinical and clinical development considerations of biologics
- Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

Theory	60 Hrs
1. India: Introduction, Applicable Regulations and Guidelines, Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.	12 Hrs
2 USA: Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics	12 Hrs
3 European Union: Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/biosimilarity assessment, Plasma master file, TSE/BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical	12 Hrs

	And clinical developmentconsiderations;stability,safety, advertising,labeling andpackingofbiologics in EU	
4	Vaccine regulations in India,US and European Union: Clinical evaluation,Marketingauthorisation,Registrationorlicensing, Qualityassessment, Pharmacovigilance, Addition al requirements BloodandBloodProductsRegulationsin India,USandEuropeanUnion:RegulatoryRequirementsofBloodand/or ItsComponents Includin Blood Products, Label Requirements, ISBT(InternationalSocietyof BloodTransfusion)andIHN (InternationalHaemovigilenceNetwork)	12 Hrs
5	HerbalProducts:Quality,safetyandlegislationforherbal productsinIndia,USAandEuropeanUnion.	12 Hrs

REFERENCES

1. FDARegulatoryAffairs:AGuideforPrescriptionDrugs,MedicalDevices,andBiologics,DouglasJ.Pisano,DavidS.Mantus;Informa,2008
2. BiologicalDrug Products:Development and Strategies; WeiWang,ManmohanSingh;wiley,2013
3. Developmentof Vaccines:FromDiscovery to ClinicalTesting;ManmohanSingh,IndreshK.Srivastava;Wiley,2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelineson SimilarBiologics:RegulatoryRequirementsforMarketingAuthorizationinIndia
9. www.cdsco.nic.in
10. www.ema.europa.eu›scientificguidelines›Biologicals
11. www.fda.gov/biologicsbloodVaccines/GuidanceComplianceRegulatoryInformation (Biologics)

REGULATORY ASPECTS OF MEDICAL DEVICES

(6203-18T)

Scope

This course is designed to impart the fundamental knowledge on the medical devices and invitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.

Objectives

Upon completion of the course, the students shall be able to know

- basics of medical devices and IVDs, process of development, ethical and quality considerations
- harmonization initiatives for approval and marketing of medical devices and IVDs
- regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN
- clinical evaluation and investigation of medical devices and IVDs

Theory — 60Hrs

1. Medical Devices: Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Life cycle of Medical Devices and Classification of Medical Devices. IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN). — 12 Hrs

2. Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155: 2011) Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device — 12 Hrs

3	USA:Introduction,Classification,Regulatoryapprovalprocess forMedicalDevices(510k) PremarketNotification,Pre-Market Approval(PMA),InvestigationalDeviceExemption(IDE)and InvitroDiagnostics,QualitySystemRequirements21CFRPart820,La belingrequirements21 CFRPart 801, Post marketingsurveillanceofMDandUniqueDeviceIdentification (UDI). BasicsofInvitrodiagnostics,classification and approvalprocess.	12 Hrs
4	EuropeanUnion:Introduction,Classification,Regulatoryapprovalp rocessforMedicalDevices (MedicalDeviceDirective, ActiveImplantableMedical DeviceDirective) and In vitro Diagnostics (In Vitro Diagnostics Directive),CEcertification process. BasicsofInvitrodiagnostics,classificationandapprovalprocess.	12 Hrs
5	ASEAN,China & Japan: Medical Devices and IVDs, Regulatoryregistrationprocedures,QualitySystemrequirements and clinicalevaluationandinvestigation. IMDRFstudygroupsandguidancedocuments.	12 Hrs

REFERENCES

1. FDAregulatoryaffairs:a guidefor prescriptiondrugs,medicaldevices,andbiologicsbyDouglasJ.Pisano,DavidMan tus.
2. MedicalDeviceDevelopment:ARegulatoryOverviewbyJonathanS. Kahan
3. MedicalProductRegulatoryAffairs:Pharmaceuticals,Diagnostics,MedicalDevic esbyJohnJ.TobinandGaryWalsh
4. ComplianceHandbookforPharmaceuticals,MedicalDevicesandBiologic sbyCarmenMedina
5. CountrySpecificGuidelinesfromofficialwebsites.

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS

(6203-19T)

Scope

This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA and Europe. It prepares the students to learn in detail on Regulatory Aspects for Nutraceuticals and food supplements.

Objectives

Upon completion of the course, the students shall be able to

- Know the regulatory Requirements for nutraceuticals
- Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe.

Theory 60Hrs

1.	Nutraceuticals: Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.	12 Hrs
2	Global Aspects: WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals	12 Hrs
3	India: Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.	12 Hrs
4	USA: USFDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S	12 Hrs

5	EuropeanUnion: European Food Safety Authority (EFSA):Organization and Functions. EUDirectives and regulationsformanufactureandsaleofnutraceuticalsanddietary supplements.Nutritionlabelling.EuropeanRegulationonNovel Foods andNovelFoodIngredients.Recommended DietaryAllowances(RDA) inEurope.	12 Hrs

REFERENCES

1. RegulationofFunctionalFoodsandNutraceuticals:A GlobalPerspectivebyClareM.Hasler(Wiley OnlineLibrary)
2. NutraceuticalandFunctionalFood RegulationsintheUnitedStatesandAroundtheWorldbyDebasisBagchi(Academic Press,Elsevier)
3. http://www.who.int/publications/guidelines/nutrition/en/
4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324_EN.pdf
5. HandbookofNutraceuticalsbyYashwantPathak(CRCPress)
6. FoodRegulation:Law,Science,PolicyandPracticebyNealD.Fortin(Wiley)
7. CountrySpecificGuidelinesfromofficialwebsites.

REGULATORYAFFAIRSPRACTICAL-II

(6203-20P)

1. Casestudieson
2. ChangeManagement/Changecontrol.Deviations
3. Corrective&PreventiveActions(CAPA)
4. Documentationofrawmaterialsanalysisasperofficialmonographs
5. Preparationofauditchecklistforvariousagencies
6. PreparationofsubmissionoFDAusingeCTDsoftware
7. PreparationofsubmissiontoEMAusingeCTDsoftware
8. PreparationofsubmissiontoMHRAusingeCTDsoftware
9. PreparationofBiologicsLicenseApplications(BLA)
10. PreparationofdocumentsrequiredforVaccineProductApproval
11. ComparisonofclinicaltrialapplicationrequirementsofUS,EUandIndiaofBiologics
12. PreparationofChecklistforRegistrationofBloodandBloodProducts
13. Registrationrequirementcomparisonstudyin5 emergingmarkets(WHO)andpreparingchecklistformarketauthorization
14. Registrationrequirementcomparisonstudyinemergingmarkets(BRICS)and preparingchecklistformarketauthorization
15. Registrationrequirementcomparisonstudyinemergingmarkets(China and South Korea) and preparing check list formarketauthorization
16. Registrationrequirementcomparisonstudyinemergingmarkets(ASEAN)and preparingchecklistformarketauthorization
17. Registrationrequirementcomparisonstudyinemergingmarkets (GCC)andpreparingchecklistformarketauthorization
18. Checklistsfor510kandPMAforUSmarket
19. ChecklistforCEmarkingforvariousclassesofdevicesforEU
20. STEDApplicationforClassIIIDevices
21. AuditChecklistforMedicalDeviceFacility
22. ClinicalInvestigationPlanforMedicalDevices

SemesterIII

ResearchMethodology&Biostatistics

UNIT-I

General Research Methodology: Research, objective, requirements, practical difficulties, reviewof literature,studydesign,types ofstudies,strategies toeliminateerrors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT-II

Biostatistics:Definition,application,samplesize,importanceofsamplesize, factors influencingsamplesize,dropouts,statisticaltestsofsignificance,typeof significance tests,parametrictests(students"t"test,ANOVA,Correlation coefficient,regression), non-parametrictests(wilcoxanranktests,analysisofvariance,correlation,chisquare test), null hypothesis, Pvalues, degree offreedom,interpretationofPvalues.

UNIT-III

MedicalResearch:History,valuesinmedicalethics,autonomy,beneficence,non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informedconsent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees,culturalconcerns,truthtelling, onlinebusinesspractices,conflictsof interest, referral, vendor relationships, treatment of family members, sexual relationships,fatality.

UNIT-IV

CPCSEAguidelinesforlaboratoryanimalfacility:Goals,veterinarycare,quarantine, surveillance,diagnosis,treatmentandcontrolofdisease,personalhygiene,locationof animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animalhusbandry,recordkeeping,SOPs,personnelandtraining,transportoflab animals.

UNIT-V

DeclarationofHelsinki:History,introduction,basicprinciplesforallmedicalresearch, and additional principles for medical research combined with medical care.