SARDAR PATEL UNIVERSITY
Vallabh Vidyanagar, Gujarat
(Reaccredited with 'A' Grade by NAAC (CGPA 3.25)
Syllabus with effect from the Academic Year 2022-2023

PROGRAMME STRUCTURE
Master of Pharmacy in Pharmaceutical Quality Assurance
M. Pharm (Pharmaceutical Quality Assurance) Semester: III

Programme Outcome (PO) - For M. Pharm (PQA) Programme	At the end of Master of Pharmacy (M. Pharm) program, the students will be able to: 1. Acquire knowledge and comprehension of the advancements in the core and specialization area of pharmacy. 2. Demonstrate a degree of expertise in laboratory practices, analytical techniques and scientific tools. 3. Independently carry out research/investigation and development work to solve problem. 4. Write and present a substantial scientific document and technical report. 5. Apply reasoning by contextual knowledge to assess societal impact, environmental impact, health, safety and legal issues and the consequent responsibilities relevant to the pharmacy profession.
Programme Specific Outcome (PSO) - For M. Pharm (PQA) Semester - III	After completion of the program students are able to: 1. Understand the Quality Assurance, Total Quality Management, and Quality Management concepts, Hazard Management system and technology transfer system. 2. Adopt GMP, Schedule M, ISO 9000 and 14000 standards, NABL accreditation, ICH, USFDA, WHO and other regulatory guidelines and common requirement for product registration and product development. 3. Dealing with different quality concept and use modern pharmaceutical tools, software and equipment to analyze & solve problems with the help of GLP, GCP, QbD, PAT and their documentation. 4. Doing various pharmaceutical product development interaction such as calibration, validation, product complain and recall, corrective and preventive action, documentation and their regulatory requirement. 5. Dealing with various advanced instrumental techniques for identification, characterization, and quantification of drugs and pharmaceuticals. 6. To generate validation protocol for all pharmaceutical operations starting from drug research to development to formulation.

To Pass	At least 50% Marks in the University Examination in each paper and 50% Marks in the aggregate of University and Internal examination in each course of Theory, Practical & Research work

Course Type	Course Code	Name of Course	Theory/ Practical	Credit	Exam Duration in hrs	Component of Marks		
						Internal	External	Total
Employability, Entrepreneurship	MRM301T	Research Methodology and Biostatistics	T	4	3	25	75	100/50
Employability, Skill Development	MQA302J	Journal club	-	1	-	25	-	25/13
Employability, Skill Development	MQA303D	Discussion / Presentation (Proposal Presentation)	-	2	-	50	-	50/25
Employability, Skill Development	MQA304R	Research work	-	14	1		350	350/175
				21				**525/263**

Master of Pharmacy
M. Pharm, Pharmaceutical Quality Assurance, Semester - III

Course Code	MQA301T	Title of the Course	Research Methodology & Biostatistics
Total Credits of the Course	4	Hours per Week	4

Course Objective: Upon completion of the course student shall be able to understand	
1.	Learn general research methodology and the basic concepts of biostatistics
2.	Understand the functions of ethics committees in medical research

Course Content

Unit	Description	Hrs.
I	**General Research Methodology:** Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques	**15**
II	**Biostatistics:** Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values	**15**
III	**Medical Research:** History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality	**15**
IV	**CPCSEA guidelines for laboratory animal facility:** Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals	**12**
V	**Declaration of Helsinki:** History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	**03**

Teaching-Learning Methodology	1. Students will be oriented about the course content in the first session of the course 2. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Power Point presentations, audio-visual presentations. 3. Virtual teaching and examination will also utilized for the learners of the course. 4. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 5. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 6. Internal theory test will be conducted as a part of regular curriculum. 7. Attendance will be marked for each session as a part of overall evaluation. 8. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern		
Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes: Students will be able to	
1.	Theorize the elements of research methodology
2.	Apply statistical methodology for data analysis
3.	Practice ethical principles and regulatory considerations in medical research
4.	Acquire requirements for laboratory animal facility

Suggested References:	
Sr. No	**References**
1	Research in Education- John V. Best, John V. Kahn 7th edition
2	Thesis & Assignment – Jonathan Anderson
3	Writing a technical paper- Donald Menzel
4	Pharmaceutical Statistics , Practical and Clinical Applications, Fifth Edition, Sanford Bolton, Charles Bon
5	ICMR guidelines for medical research
6	Principle and Practice of Clinical Trial Medicine, Richard Chin, Bruce Y. Lee, Academic Press
7	CPCSEA guideline for laboratory animal care and handling

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PROGRAMME STRUCTURE
Master of Pharmacy in Pharmaceutical Quality Assurance
M. Pharm (Pharmaceutical Quality Assurance) Semester: IV

Programme Outcome (PO) - For M. Pharm (PQA) Programme	At the end of Master of Pharmacy (M. Pharm) program, the students will be able to: 1. Acquire knowledge and comprehension of the advancements in the core and specialization area of pharmacy. 2. Demonstrate a degree of expertise in laboratory practices, analytical techniques and scientific tools. 3. Independently carry out research/investigation and development work to solve problem. 4. Write and present a substantial scientific document and technical report. 5. Apply reasoning by contextual knowledge to assess societal impact, environmental impact, health, safety and legal issues and the consequent responsibilities relevant to the pharmacy profession.
Programme Specific Outcome (PSO) - For M. Pharm (PQA) Semester - IV	After completion of the program students are able to: 1. Understand the Quality Assurance, Total Quality Management, and Quality Management concepts, Hazard Management system and technology transfer system. 2. Adopt GMP, Schedule M, ISO 9000 and 14000 standards, NABL accreditation, ICH, USFDA, WHO and other regulatory guidelines and common requirement for product registration and product development. 3. Dealing with different quality concept and use modern pharmaceutical tools, software and equipment to analyze & solve problems with the help of GLP, GCP, QbD, PAT and their documentation. 4. Doing various pharmaceutical product development interaction such as calibration, validation, product complain and recall, corrective and preventive action, documentation and their regulatory requirement. 5. Dealing with various advanced instrumental techniques for identification, characterization, and quantification of drugs and pharmaceuticals. 6. To generate validation protocol for all pharmaceutical operations starting from drug research to development to formulation.

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	Course Code	**Name of Course**	**Theory/ Practical**	**Credit**	**Exam Duration in hrs**	**Component of Marks**		
						Internal	**External**	**Total**
Employability, Skill development	MQA401J	Journal club	-	1	-	25	-	25/13
Employability, Skill development	MQA402D	Discussion / Presentation	-	3	-	75	-	75/38
Employability, Skill development	MQA403R	Research work and Colloquium	-	16	1	-	400	400/200
				20		100	400	**500/250**