



Gyanmanjari
Innovative University

Course Syllabus
Gyanmanjari Science College
Semester-1(M.Sc.)

Subject: QA & QC in IVF laboratory-MSCSEM11505

Type of course: Major

Prerequisite: Basic knowledge of IVF and aspects of QA & QC laboratory design for IVF

Rationale: Embryology provides a fundamental understanding of how life begins and develops. This knowledge has far-reaching implications for medicine, evolutionary biology, biotechnology, and our overall appreciation of the natural world.

Teaching and Examination Scheme:

Teaching Scheme			Credits	Examination Marks					Total Marks
CI	T	P		C	Theory Marks		Practical Marks		
			ESE		MSE	V	P	ALA	
3	0	0	3	60	30	10	00	50	150

Legends: CI-Class Room Instructions; T – Tutorial; P - Practical; C – Credit; ESE - End Semester Examination; MSE- Mid Semester Examination; V – Viva; CA - Continuous Assessment; ALA- Active Learning Activities.

Continuous Assessment:

Sr. No	Active Learning Activities	Marks
1	Survey of PCOD in women Students have to survey the report regarding PCOD phasing women and survey report will be upload on GMIU web Portal.	10
2	Study of adverse effect of smoking and drinking Students have to survey the effect of smoking and drinking addiction in male, which adversely affect the sperm development and submit report on GMIU web portal.	10



3	Continuous Improvement and Innovation Students has to get aware about emerging tools and techniques for quality improvement of Lab and tool photo has to upload on GMIU web Portal.	10
4	Self manage and alleviate stress Student need to perform activity which can reduce his/her stress leading healthy reproductive system and photo need to upload on GMIU web portal.	10
5	Paper Review Faculty will provide a particular portion of the research paper and a group of students will review it and prepare a conclusion in 100 words and upload it to GMIU web Portal.	10
Total		50

CourseContent:

Unit No	Course content	Hrs	% Weightage
1	<p>Chapter-1 Introduction to Quality Assurance and Quality Control</p> <ol style="list-style-type: none"> <u>Basic Concepts of QA & QC</u> <ul style="list-style-type: none"> Definitions and differences between QA and QC. Importance of QA and QC in embryology. Historical development of quality systems in healthcare. <u>Quality Management Systems</u> <ul style="list-style-type: none"> Components of a quality management system (QMS). ISO standards relevant to ART laboratories (e.g., ISO 15189). Implementation of QMS in an ART setting. <p>Chapter-2 Regulatory and Accreditation Standards</p> <ol style="list-style-type: none"> <u>Regulatory Bodies and Guidelines</u> <ul style="list-style-type: none"> Overview of regulatory bodies (e.g., FDA, ESHRE, ASRM). Key guidelines and standards for ART laboratories. Compliance with local and international regulations. <u>Accreditation and Certification</u> <ul style="list-style-type: none"> Accreditation processes for ART laboratories. Certification programs and their importance. Steps to achieve and maintain accreditation. 	15	25%



2	<p>Chapter-3 Laboratory Quality Control</p> <ol style="list-style-type: none"> <u>Internal Quality Control (IQC)*</u> - Daily, weekly, and monthly QC checks. - Use of control materials and standards. - Documentation and record-keeping for IQC. <u>External Quality Assurance (EQA)</u> <ul style="list-style-type: none"> • Participation in EQA programs. • Proficiency testing and inter-laboratory comparisons. • Analyzing and responding to EQA results. <p>Chapter-4 Standard Operating Procedures (SOPs)</p> <ol style="list-style-type: none"> <u>Development of SOPs</u> <ul style="list-style-type: none"> • Importance of SOPs in maintaining quality. • Writing and updating SOPs for laboratory procedures. • Ensuring compliance with SOPs. <u>Implementation and Training</u> <ul style="list-style-type: none"> • Training staff on SOPs and QC protocols. • Monitoring adherence to SOPs. • Addressing non-compliance and implementing corrective actions. 	10	25%
3	<p>Chapter-5 Risk Management and Troubleshooting</p> <ol style="list-style-type: none"> <u>Risk Assessment</u> <ul style="list-style-type: none"> • Identifying potential risks in ART procedures. • Risk mitigation strategies. • Use of Failure Mode and Effects Analysis (FMEA). <u>Troubleshooting and Problem-Solving</u> <ul style="list-style-type: none"> • Common issues in ART laboratories. • Systematic approach to troubleshooting. • Case studies and real-world examples. 	10	25%
4	<p>Chapter-6 Data Management and Quality Audits</p> <ol style="list-style-type: none"> <u>Data Management</u> <ul style="list-style-type: none"> • Laboratory Information Management Systems (LIMS). • Ensuring data accuracy and integrity. • Data security and confidentiality. <u>Quality Audits</u> <ul style="list-style-type: none"> • Types of audits: Internal and external. • Preparing for and conducting audits. • Responding to audit findings and implementing improvements. <u>Continuous Quality Improvement (COI)</u> <ul style="list-style-type: none"> • Principles of COI in an ART laboratory. • Emerging technologies for quality improvement (e.g., Six Sigma, Lean). 	10	25%



Suggested Specification table with Marks (Theory):60

Distribution of Theory Marks (Revised Bloom's Taxonomy)						
Level	Remembrance (R)	Understanding (U)	Application (A)	Analyze (N)	Evaluate (E)	Create (C)
Weightage	20%	40%	30%	10%	-	-

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Course Outcome:

After learning the course, the students should be able to:	
CO1	Apply quality assurance and quality control principles in embryology.
CO2	Pursue skills in implementing and maintaining QA and QC programs in ART laboratories.
CO3	Understand regulatory requirements and best practices for ensuring high standards in embryological procedures.
CO4	Develop skill of the data management in the laboratories and get aware about emerging tools in ART.

Instructional Method:

The course delivery method will depend upon the requirement of content and need of students. The teacher in addition to conventional teaching method by black board, may also use any of tools such as demonstration, role play, Quiz, brainstorming, MOOCs etc.

From the content 10% topics are suggested for flipped mode instruction.

Students will use supplementary resources such as online videos, NPTEL/SWAYAM videos, e-courses, Virtual Laboratory

The internal evaluation will be done on the basis of Active Learning Assignment

Practical/Viva examination will be conducted at the end of semester for evaluation of performance of students in laboratory.



Reference Books:

- [1] Quality and Risk Management in the IVF Laboratory by David Mortimer, Sharon T. Mortimer, and David S. Mortimer.
- [2] Manual of Quality Assurance in Assisted Reproduction by Kamini A. Rao and Alper T. Tekin.
- [3] Clinical Laboratory Quality Management by Lynne S. Garcia.
- [4] Handbook of Quality Assurance in Laboratory Medicine by Shubangi Tambwekar
- [5] Langman's Medical Embryology by T.W. Sadler
- [6] The Developing Human: Clinically Oriented Embryology by Keith L. Moore, T.V.N. Persaud, and Mark G. Torchia.
- [7] Human Embryology and Developmental Biology by Bruce M. Carlson.
- [8] Medical Embryology by Jan Langman.

