

**Course Title: Quality Control, Medico Legal, Regulatory and Ethical Aspects****Course Code:****Credit Units: 4****Level: PG Diploma**

L	T	P/S	SW/F W	TOTAL CREDIT UNITS
2	0	2	2	4

**Course Objectives:**

- To provide structured training program in QC & medico legal aspects of the ART procedures

**Prerequisites:**

- MBBS /MSc (Reproductive Biology/Genetics/life sciences(mammalian))

**Course Contents/ Syllabus**

<b>Module I: Quality assurance &amp; Quality controls</b>	<b>Weightage %</b>
<ul style="list-style-type: none"> <li>How to set up a laboratory – detailing of equipment, layout, cleaning etc.</li> <li>Accreditation</li> </ul>	20
<b>Module II: Third Party Reproduction</b>	<b>Weightage %</b>

14

<ul style="list-style-type: none"> <li>Oocyte donation</li> <li>Embryo donation</li> <li>Surrogacy</li> </ul>	20
<b>Module III: Ethical &amp; medico-legal aspects of infertility management</b>	<b>Weightage %</b>
<ul style="list-style-type: none"> <li>Ethical &amp; medico-legal aspects of infertility management- ICMR guidelines</li> <li>MTP, PNDT</li> </ul>	30
<b>Module IV: Data analysis and management</b>	<b>Weightage %</b>
<ul style="list-style-type: none"> <li>Biostatics &amp; Online data management.</li> <li>Fertility preservation – Social &amp; Onco- fertility.</li> <li>Monitoring &amp; treatment of early pregnancy after ART treatment</li> </ul>	30
<b>Practical</b>	<b>Weightage %</b>
<ul style="list-style-type: none"> <li>Biostatistics</li> <li>Data management</li> </ul>	

**Student Learning Outcomes:**

- At the end of this course, the students will be able to develop:  
Comprehensive knowledge of various aspects QC medico legal aspects of ART procedures

**Pedagogy for Course Delivery:**

The course pedagogy will include lectures , practical, as well as self -work having rigorous application .

**Assessment/ Examination Scheme:**

Theory L/T (%)	Lab/Practical/Studio (%)	End Term Examination
75	25	100

**Theory Assessment (L&T):**

	Continuous Assessment/Internal Assessment			End Term Examination	Total
Components (Drop down)	Class Test	Presentation	Attendance		
Weightage (%)	15	10	5	70	100

**Laboratory Assessment:**

	Continuous Assessment/Internal Assessment			End Term Examination	Total
Components (Drop down)	Class Test (Practical)	Lab Record	Attendance	Viva	
Weightage (%)	20	5	5	70	100

**Text / Reference Books:**

- ESHRE Guideline Group on good practice in IVF labs: Revised guidelines for good practice in IVF laboratories (2015)
- ICMR, MINISTRY OF HEALTH & FAMILY WELFARE, INDIA| regulations for THE ASSISTED REPRODUCTIVE TECHNOLOGIES
- Organization and Management of IVF Units: A Practical Guide for the Clinician 1st ed. 2016 Edition by Steven D. Fleming (Editor), Alex C. Varghese (Editor)
- Clean Room Technology in ART Clinics: A Practical Guide by Sandro C. Esteves, Alex C. Varghese, Kathryn C. Worrilow

<ul style="list-style-type: none"> <li>• Window of implantation – factors governing implantation</li> <li>• Physiology &amp; Endocrinology of the menstrual cycle</li> <li>• Neuroendocrine control of menstrual cycle</li> <li>• Endometrial changes during MC</li> <li>• Window of implantation – factors governing implantation.</li> </ul>	
<b>Module III: Anatomy &amp; Physiology of male reproduction</b>	<b>Weightage%</b>
<ul style="list-style-type: none"> <li>• Anatomy &amp; anatomical abnormalities – testes, epididymis, vas</li> <li>• Spermatogenesis</li> <li>• Hormonal control of spermatogenesis</li> <li>• Fertilization – sperm changes leading to fertilization, contribution of male genome to the embryo.</li> <li>• Ejaculation – physiology and abnormality</li> </ul>	<b>20</b>
<b>Module IV: Molecular Biology and genetics</b>	<b>Weightage%</b>
<ul style="list-style-type: none"> <li>• Genetics and epigenetics in infertility</li> <li>• Basics of genetics and transmission of genetic diseases</li> <li>• Role of ART in genetic disease</li> </ul>	<b>20</b>
<b>Module V: Genetic disorders and counselling</b>	<b>Weightage %</b>
<ul style="list-style-type: none"> <li>• Single gene disorders: recessive and dominant</li> <li>• Sex-linked disorders</li> <li>• Late-onset disorders and disease susceptibilities</li> <li>• Chromosome rearrangements: Robertsonian reciprocal translocations and their consequences</li> <li>• Aneuploidy, sporadic aneuploidy and important aneuploidy syndromes (e.g. Edwards, Turner Patau).</li> <li>• Counselling for inherited disorders</li> </ul>	<b>20</b>
<b>Practical:</b>	
<ul style="list-style-type: none"> <li>• LectuMicroscopic structure of human sperm from different clinic-pathological conditions</li> <li>• Microscopic structure of oocyte from different clinic-pathological conditions</li> <li>• Microscopic structure of embryo from different clinic-pathological conditions</li> </ul>	

**Student Learning Outcomes:**

- At the end of this course, the students will be able to develop:  
Comprehensive knowledge of various aspects of reproductive biology.

**Pedagogy for Course Delivery:**

- The course pedagogy will include lectures, tutorials, as well practical and self-work having rigorous application .

**Assessment/ Examination Scheme:**

Theory L/T (%)	Lab/Practical/Studio (%)	End Term Examination
50	50	100

**Theory Assessment (L&T):**

	Continuous Assessment/Internal Assessment			End Term Examination	Total
Components (Drop down)	Class Test	Presentation	Attendance		
Weightage (%)	15	10	5	70	100

**Laboratory Assessment:**

	Continuous Assessment/Internal Assessment			End Term Examination	Total
Components (Drop down)	Class Test (Practical)	Lab Record	Attendance	Viva	
Weightage (%)	20	5	5	70	100

**Text / Reference Books:**

- Human Reproductive Biology (Fourth Edition) *Author(s): Richard E. Jones and Kristin H. Lopez; ISBN: 978-0-12-382184-3.*
- A Textbook of In Vitro Fertilization and Assisted Reproduction: The Bourn Hall Guide to Clinical and Laboratory Practice: Includes Bourn Hall Protocols on CD-ROM, Third Edition by Peter R. Brinsden