Program Academic Information

Master of Business Administration
Medical Device Regulatory Affairs
2025-27

Table of Contents

Section 1: Program General Information

Program	**Medical Device Regulatory Affairs**
Level	**Postgraduate**
Course Duration	**2 years (4 Semester)**

Section 2: Program Educational Objectives (PEOs)

Broad goals that address institutional and program mission statements and are responsive to the expressed interests of various groups of program stakeholders.

PEO-1 :	Graduates will be able to enhance their skills in regulatory compliance, supply chain management, and strategic operations within the medical device industry.
PEO-2 :	Graduates will be able to understand and handle medical device regulations, certifications, and accreditation worldwide.
PEO-3 :	Graduates will be able to exhibit leadership in medical device regulatory processes by initiating and managing successful ventures.
PEO-4 :	Graduates will be able to understand best practices in global regulatory audits.
PEO-5 :	Graduates will be able to pursue career opportunities in research and development.

Section 3: Program Outcomes

The program must then formulate a set of program outcomes (knowledge, skills, and attitudes the program graduates should have) that directly address the educational objectives and encompass certain specified outcomes.

PO-1	Apply knowledge of management theories and practice to solve business problems.
PO-2	Foster analytical and critical thinking abilities for data-based decision making.
PO-3	Ability to develop a strong leadership, promoting ethical practices within the medical device industry.
PO-4	Ability to understand, analyze and communicate global economic, legal & ethical concepts of business.
PO-5	Ability to lead themselves and others in the achievement of organizational goals, contributing effectively to a team environment.

Program Specific Outcomes :

By the end of the program, students should be able to develop the following specific skills and accomplishments

PSO-1	Graduates will be able to interpret and apply regulatory frameworks and guidelines for medical devices across different regions, ensuring compliance with global regulatory standards.
PSO-2	Graduates will be proficient in managing and coordinating regulatory submissions, audits, and documentation processes to facilitate product approvals and lifecycle management in the medical device industry.

Section 4: Program Benchmarking

Details of the international standards / subject benchmark statements referred and web link for the same.

International standards / benchmarks statements referred	**URL**
The Quality Assurance Agency for Higher Education (QAA), UK	https://www.qaa.ac.uk/docs/qaa/sbs/subject-benchmark-statement-business-and-management-masters-23.pdf?sfvrsn=3570a881_18
Southeast Technological University (SETU)	https://www.setu.ie/courses/msc-in-medical-device-regulatory-affairs
Trinity College Dublin, The University of Dublin, Ireland	https://www.tcd.ie/courses/postgraduate/courses/regulatory-affairs-for-medical-devices-mscpgraddip/
Northeastern University's College of Professional Studies, Boston	https://cps.northeastern.edu/program/master-of-science-in-regulatory-affairs-toronto/?_gl=1*1xkrhum*_gcl_au*NDA3NzU1MDUzLjE3MjM0NDM2NTk
TOPRA	https://www.topra.org/TOPRA/TOPRA_Member/Events/Event_Display.aspx?EventKey=MSC1224
Yale University	https://www.mastersportal.com/studies/320970/regulatory-affairs.html?ref=search_card#content:contents

Section 5: Program Structure

CL	Classroom Interaction	**TU**	Tutorials	**PR**	Practical
CC	Core Course	**FE**	Free Elective	**DE**	Specialization Sequence with Directed Electives

Semester - 01								Total Credits:21
S. No	Course Code	Course Title	Course Type	Credits	Weekly Contact Hours			
					CL	TU	PR	Total
1		Overview of Standards, Conformity Assessment and Accreditations	CC	4	3	1	0	4
2		Fundamentals of Medical Devices	CC	4	3	1	0	4
3		Design Thinking for Medical Innovation	DE	3	2	1	0	3
4		Leadership Communication and Change Management	DE	4	3	1	0	4
5		Introduction to Regulatory Affairs	DE	4	3	1	0	4
6		Research Methodology and Medical Ethics	CC	2	2	0	0	2
7		Seminar and Technical Writing - I	CC	0	0	0	2	2

Semester - 02								Total Credits:21
S. 2No	Course Code	Course Title	Course Type	Credits	Weekly Contact Hours			
					CL	TU	PR	Total
1		Medical Devices Quality Management Systems	CC	3	2	1	0	3
2		Medical Device Manufacturing Operation Management	CC	4	3	1	0	4
3		Medical Device Regulatory Strategy and Life cycle Management	DE	2	2	0	0	2
4		Global Medical Device Regulation	DE	3	2	1	0	3
5		Risk management of Medical Devices	DE	3	3	1	0	4

6		Cost-Effectiveness Analysis and Decision Making	FE	4	3	1	0	4
		Macro-Economics for Healthcare		4	3	1	0	4
7		Seminar and Technical Writing - II	CC	0	0	0	2	2
8		Industrial Internship / Certification	CC	2	0	0	0	0

Semester - 03								**Total Credits: 22**
S. No	**Course Code**	**Course Title**	**Course Type**	**Credits**	**Weekly Contact Hours**			
					CL	**TU**	**PR**	**Total**
1		Medical Device Registration	CC	3	2	1	0	3
2		Clinical Trials	CC	3	2	1	0	3
3		Capstone Project-I	CC	5	0	0	10	10
4		Medical Device Regulatory Preparation and Submission	DE	4	3	1	0	4
5		Post Market Surveillance of Medical Devices	DE	3	2	1	0	3
6		Financial Management for Medical Device	FE	4	4	0	0	4
		Software Quality Management			4	0	0	4

Semester - 04								Total Credits: 18
S. No	Course Code	Course Title	Course Type	Credits	Weekly Contact Hours			
					CL	TU	PR	Total
1		Industrial internship/Certification	CC	3	0	0	0	0
2		Capstone Project-II	CC	15	0	0	0	0

Total Program Course Distribution		
Course Category	**Credits**	**Courses**
CC: Core Courses	50	13
DE: Specialization Sequence with Directed Electives	24	08
FE: Free Electives	08	02

Total Program Credit Distribution			
SN	**Year**	**Semester**	**Credits Assigned**
1	First	I	21
2		II	21
3	Second	III	22
4		IV	18
	Total Semester	**4**	**82**

Section 6: Course Sequence

Sequence of courses attaining a particular curriculum outcome or a sequence of courses attaining a particular specialization. Courses sequences could be more than 3 also. Courses to be mentioned in a sequential manner.

Sequence I	Sequence II	Sequence III	Sequence IV	Sequence V
Management Fundamentals	**Medical Device Regulatory Affairs**	**Medical Device Quality Management Systems**	**Regulations, Certification, Accreditation**	**Research**
Design Thinking for Medical Innovation	Fundamentals of Medical Devices	Medical Devices Quality Management Systems	Overview of Standards, Conformity Assessment and Accreditations	Research Methodology and Medical Ethics
Leadership Communication & Change Management	Introduction to Regulatory Affairs	Global Medical Device Regulation	Medical Device Registration	Seminar and Technical Writing - I
Medical Device Manufacturing Operation Management	Risk management of Medical Devices			Seminar and Technical Writing - II
Cost-Effectiveness Analysis and Decision Making	Clinical Trials			Industrial Internship / Certification
~~Project Management~~	Medical Device Regulatory Preparation and Submission			Capstone Project-I

Financial Management for Medical Device	Post Market Surveillance of Medical Devices		Capstone Project-II
Macro-Economics for Healthcare	Medical Device Regulatory Strategy and Life cycle Management		
Software Quality Management			

Specialization Sequence

Management Fundamentals
Medical Device Regulatory Affairs
Medical Device Quality Management Systems
Regulations, Certification, Accreditation
Research

List of Textbooks and Reference Books	
Course name	**Textbooks/ Reference Books/ Study Materials**
Medical Device Business Management	• **"Healthcare Disrupted: Next Generation Business Models and Strategies Hardcover", Anne O'Riordan, 2016** • **"Medical Device Regulations: Global Overview and Guiding Principles"** by World Health Organization • **"MEDICAL DEVICE - Concept to Commercialisation: India Perspective"** Hardcover, Sudhakar Bangera, 2020 • **"The Innovation and Evolution of Medical Devices",** Vaginal Mesh Kits 2018 • **"Inventing Medical Devices: A Perspective from India"**, Hardcover, Dr. Jagdish Chaturvedi, 2016 • **"Strategic Management of Regulatory Compliance: A Business Approach"** by Sherry A. Smith • **"Managing the Regulatory Process: A Strategic Approach"** by Robert L. Brown • **"Regulatory Compliance Management: An Overview of the Business and Legal Aspects"** by William D. Miller • **"Global Regulatory Issues for Medical Devices and Pharmaceuticals"** by Steven D. L. Simmons • **"The Role of Regulatory Affairs in a Business Environment"** by Susan R. Brown
Medical Device Regulatory Affairs	• **"Regulatory Affairs for Biomaterials and Medical Devices"** edited by Stephen F. Amato and Robert M. Ezzell Jr. • **"Medical Device Innovation Handbook"** Paperback , by William Durfee (Author), Paul Iaizzo, 2014

	• **"Combination Products: Regulatory Challenges and Successful Product Development"** edited by Smita Gopalaswamy and Siddhartha Ghosh • **"Managing the Regulatory Affairs for Medical Devices"** by Vera Mihajlovic-Madzarevic • **"Global Medical Device Regulatory Strategy"** by Gloria Hall and Anne J. Daley • **"Medical Device Development: A Regulatory Overview"** by Jonathan S. Kahan • **"Global Medical Device Regulatory Strategy"**, Second Edition by Various Authors and Gloria Hall • **"Risk Management for Medical Device Manufacturers: [MD and IVD]"**, Paperback – Import, 20 January 2022 by Joe W Simon • **"Digital Marketing: Strategy and Tactics - 2 ed",** Hardcover , by Jeremy Kagan, 2020 • **"Medical Regulatory Affairs An International Handbook for Medical Devices and Healthcare Products",** Jack Wong, Raymond Tong, 2022
Medical Device Quality Management Systems	• **"Medical Device Quality Management Systems: Strategy and Techniques for Improving Efficiency and Effectiveness",** by Susanne Manz • **"Developing an ISO 13485-Certified Quality Management System An Implementation Guide for the Medical-Device Industry"** By Ilkka Juuso, 2022

	• **"Developing an ISO 13485-Certified Quality Management System An Implementation Guide for the Medical-Device Industry",** By Ilkka Juuso • **"Medical Device Quality Management Systems: Strategies and Techniques for Compliance",** by Chris Hart • **"The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices", by Amiram Daniel** • **"Medical Device Quality Assurance and Regulatory Compliance", by Peter J. Ogrodnik**
Regulations, **Certification, Accreditation**	• **"Fundamentals of US Regulatory Affairs"** by RAPS (Regulatory Affairs Professionals Society) • **"Medical Devices: Regulations, Standards and Practices"** "(Woodhead Publishing Series in Biomaterials) , by Charlene Wang (Author), Lingling Tian (Author), Seeram Ramakrishna (Author), Susan Liao (Author), Wee Eong Teo, 2015 • **"Handbook of Medical Device Regulatory Affairs in Asia"** Second Edition, 2018 • **"Global Medical Device Regulations: A Guide for the International Regulatory Affairs Professional"** by V. Kumar • **"ISO 13485:2016 – A Complete Guide for the Medical Device Industry"** by Robert J. Russell • **"The ISO 13485:2016 Implementation Guide: A Practical Approach to Achieving Compliance with ISO 13485:2016"** by Dave H. J. Elkins • **"Understanding ISO 13485:2016: A Practical Guide for Medical Device Professionals"** by Ben R. Kromhout

	• **"ISO 13485:2016 - A Complete Guide to Quality Management in the Medical Device Industry"** by Amritha J. George • **"Accreditation and Certification for Medical Devices: A Comprehensive Guide"** by Claire J. Metzger • **"Quality Assurance and Accreditation for Medical Devices: A Practical Guide"** by Anne-Marie Gabel • **"The Guide to Medical Device Regulations and Accreditation"** by Robert D. Smith • **"The Medical Device Industry: Regulations and Quality Assurance"** by Ian G. White
Research Methodology	• **"The Medical Device R&D Handbook"** by Theodore R. Kucklick • **"Medical Device Innovation Handbook",** Paperback by William Durfee, 2014