Code	IIN303	Prerequisites	180 approved credits
Name	Standards and regulations for the pharmaceutical and medical device industry	Co-requisites	None

Credits	Contact Hours
04	44
Categorization of credits	
Math and basic science	
Engineering topic	X
Other	

Coordinator's name	Gerle Peña

Textbook
Ramakrishna S., Tian L. (2015). Medical Devices: Regulations, Standards and Practices. Woodhead Publishing.
Other supplemental materials
Abuhav, I (2011). ISO 13485: A Complete Guide to Quality Management in the Medical Device Industry. CRC Press. Dennis, R. A. (2012). How to Audit the Process Based QMS. Quality Press. Glenn G., Richardson W., & Wortman B. (2012). Certified Quality Auditor Primer. Quality Council of Indiana. Jhonson, J. A. (2012). FDA Regulation of Medical Devices. Create Space. Rodriguez, P. J. (2014). The FDA and Worldwide Current Good Manufacturing Practices and Quality System Requirements Guidebook for Finished Pharmaceuticals. Quality Press.

Description	
Standards and Regulations for the Pharmaceutical and Medical Devices industry is a theoretical-practical subject focused on learning and applying the regulatory concepts, norms and standards applicable to the industry. The course provides an updated approach to the global regulatory framework for the Pharmaceutical and Medical Device manufacturing sector, showing the strategies for compliance with regulatory requirements, which aim to ensure that manufacturers consistently design, produce and place on the market safe, fit-for-purpose medical devices. Through this subject, the student will be able to learn about the entire process and regulatory requirements for the manufacture and distribution of Medical and Pharmaceutical Devices in the different geographies. The course analyzes the relationship between regulations such as: ISO-13485, ISO-9001 and CFR-21 part 820 of the FDA, showing a comprehensive approach to the Audit process for quality systems and the mechanisms to guarantee preparation Of the same.	
Type of course	☐ Required ☒ Elective

Specific goals for the course	
Outcomes of instruction	1. Identify emerging trends and challenges in the medical device industry, to provide optimal solutions
Student outcomes	SO1. Identify, formulate, and solve complex engineering problems by applying the principles of engineering, science, and mathematics.

Topics
Unit I. Introduction to regulations in the Medical Devices industry
Unit II. Development and manufacturing of medical devices
Unit III. Quality systems for medical devices
Unit IV. Introduction to the Code of Federal Regulations CFR-21 Part 820 (cGMP)
Unit V. Design of a regulatory program for medical devices
Unit VI. Quality system audits
Unit VII. Emerging trends and challenges in the medical device industry