| Code | IIN311 | Prerequisites | None |
|---|---|---|---|
| Name | Validation in the Manufacturing of Medical Devices | Co-requisites | None |

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

| Coordinator's name | César Tejeda |
|---|---|

| Textbook |
|---|
| American Society for Testing and Materials (2013) Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment (ASTM E2500 - 13).<br>American Society for Testing and Materials (2013) Standard Guide for Application of Continuous Quality Verification to Pharmaceutical and Biopharmaceutical Manufacturing (ASTM E2537 - 08).<br>Brook, Q. (2017). Lean Six Sigma & Minitab: The complete toolbox guide for business improvement. Winchester: OPEX Resources. |
| Other supplemental materials |
| European Commission (2015). Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use (Volume 4, Annex 15: Qualification and Validation)<br>Ferryanto, L. (2015, May 06) Statistical Sampling Plan for Design Verification and Validation of Medical Devices. Retrieved July 30, 2018, from http://www.ivtnetwork.com/article/statistical-sampling-plan-design-verification-and-validation-medical-devices<br>Food and Drug Administration (2004). Pharmaceutical CGMPs For The 21ST Century — A Risk-Based Approach.<br>Food and Drug Administration (2011). Guidance for Industry Process Validation: General Principles and Practices. Retrieved from: https://www.fda.gov/downloads/Drugs/Guidances/UCM070336.pdf<br>Food and Drug Administration. Quality Systems Regulation, 21 C.R.F. § 820 (2017)<br>Food and Drug Administration. Electronic Records; Electronic Signatures, 21 C.R.F. § 11 (2017)<br>Hojo, T. (2004). Quality Management Systems - Process Validation Guidance (2nd ed.). GHTF. Retrieved July 30, 2018, from http://www.imdrf.org/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n99-10-2004-qms-process-guidance-04010.pdf |

International Organization for Standardization. (2016). Medical devices -- Quality management systems -- Requirements for regulatory purposes (ISO 13485:2016).
Katz, P & Campbell, C. (2012). FDA 2011 Process Validation Guidance: Process Validation Revisited. Journal of GXP, 16(4), 18-29. Retrieved from: https://www.niras.com/media/1486/process_validation_guidance.pdf

| Description | |
|---|---|
| Validation in the Manufacturing of Medical Devices is a theoretical-practical subject focused on learning and applying the concepts and tools used in validations for the medical industries.<br><br>Through this subject the student will be able to know and widely apply the requirements used for the implementation of a validation program and system in the medical industries. They will analyze the types of validations required towards achieving process improvement and ensuring regulatory compliance.<br><br>In addition to this, the student will know the necessary tools to verify that the previously validated process remains within said state; as well as what is expected of a revalidation program in case the process does not comply. | |
| Type of course | ☐ Required<br>☒ Elective |

| Specific goals for the course | |
|---|---|
| Outcomes of instruction | 1. Ensure collaboration with all members of the work team in the planning of the validation / qualification project, achieving good management of time and resources. |
| Student outcomes | SO5. Function effectively in a team whose members together provide leadership, create a collaborative and inclusive environment, set goals, plan tasks, and meet objectives. |

| Topics |
|---|
| Unit I. Introduction to validation<br>Unit II. Administration of a validation program/master plan<br>Unit III. Risk assessment approach for the qualification process<br>Unit IV. Studies and validation protocols<br>Unit V. Statistics applied to the validation process<br>Unit VI. Management of deviations and non-conformities in the validation process<br>Unit VII. Continuous verification of the validated process<br>Unit VIII. Revalidation |