CDRH Learn (Spanish): 510(k) Third Party Review Online Video Presentation and Printable Slide Presentation

U.S. Food & Drug Administration

Listed below are the courses CDRH currently offers in Spanish. Additional online courses are being developed and will be posted upon completion.

Course List

- Quality System Regulation 21 CFR Part 820 Basic Introduction [1]
- Export Certificates for Medical Devices [2]
- Overview of the Premarket Notification Process - 510(k) [3] [**New!** 5/18]
- Bioresearch Monitoring (BIMO) [4] [**New!** 7/25]
- Medical Device Reporting [5] [**New!** 5/18]

Quality System Regulation 21 CFR Part 820 Basic Introduction

- Online Video Presentation [6]
- Transcript [7]

Export Certificates for Medical Devices

- Online Video Presentation [8]
- Printable Slide Presentation [9]
- Transcript [10]

Overview of the Premarket Notification Process - 510(k)

510(k) Overview
Heather Rosecrans - Director, 510(k) Staff - Office of Device Evaluation, CDRH, FDA

- Online Video Presentation [11]

510(k) Product Codes Making the Connection...
Julie "Brandi" Stuart - Center Product Code Coordinator - Consumer Safety Officer - Office of Device Evaluation, CDRH, FDA

- Online Video Presentation [12]

510(k) Format Guidance, Including Standards Form, Extensions/Clinical Trial Form and 510(k)

Marjorie Shulman - Consumer Safety Officer - Premarket Notification (510(k)) Staff - Office of Device Evaluation, CDRH, FDA

- Online Video Presentation [13]

510(k) User Fees
(510(k)) Staff - Office of Device Evaluation, CDRH, FDA

- Online Video Presentation [14]

510(k) Third Party Review

- Online Video Presentation [15]
- Printable Slide Presentation [16]

"513(g)s"...including 513(g) User Fees
Lawrence "Jake" Romanell - Regulatory Affairs and Special Interests Network - Office of the Center Director – CDRH, FDA

- Online Video Presentation [17]

Bioresearch Monitoring (BIMO)

BIMO Part 1b - Introduction to the Bioresearch Monitoring Program
Janet Cooper, MT, MFS, Consumer Safety Officer

- Online Video Presentation [18]

BIMO Part 2a - The Sponsor: Responsibilities in Medical Device Clinical Trials
Catherine Parker, RN - Consumer Safety Officer - CDRH

- Online Video Presentation [19]

BIMO Part 2b - The Clinical Investigator: Responsibilities in Medical Device Trials
Catherine Parker, RN - Consumer Safety Officer - CDRH

- Online Video Presentation [20]

BIMO Part 3a - Institutional Review Board: Responsibilities in Making the Significant Risk and Non-significant Risk Device Determination

Janette Collins-Mitchell, MS, RN, Nurse Consultant

- Online Video Presentation [21]

BIMO Part 3b - Institutional Review Board: Humanitarian Use Devices (HUDs)
Fabienne Santel, MD, Medical Officer

This module defines HUDs and the device regulations that govern these types of devices.

- Online Video Presentation [22]

BIMO Part 3c - Institutional Review Board: Compassionate and Emergency Use
Fabienne Santel, MD, Medical Officer

This module explains compassionate and emergency use for device research and expands upon the requirements for reporting.

- Online Video Presentation [23]

BIMO Part 4a - Preparing for an FDA Sponsor Inspection
Allen Lou, Consumer Safety Officer

This module explains unique techniques on how to prepare for an FDA sponsor inspection and outlines what records will be inspected. It also explains the FDA regulations requirements for sponsors.

- Online Video Presentation [24]

BIMO Part 5a - Strategies for Sponsors to Build Quality into Device Research
Donna Headlee, RN, BSN, CCRP, Consumer Safety Officer

This module identifies the elements of quality throughout the data life cycle of a clinical trial and identifies best practices that a clinical investigator can implement to ensure a quality study.

- Online Video Presentation [25]

BIMO Part 5b - Strategies For Clinical Investigators to Build Quality into Device Research (Spanish Audio Only)
Donna Headlee, RN, BSN, CCRP, Consumer Safety Officer

A clinical investigator's primary responsibilities are the protection of human subjects, supervising the conduct of the investigation, and ensuring the quality and integrity of the data. During this presentation, I will discuss various strategies to assist an investigator to build quality into device research. Some of these strategies include the concepts of: quality data, the data lifecycle, and quality studies; suggestions (what we refer to as helpful hints) for investigators to conduct Quality Studies; and a quality systems approach. Applying the strategies discussed in this presentation will assist an investigator to build quality into every step of device research.

- Online Video Presentation [26]

Medical Device Reporting

MAUDE - Information Available to the Public
Eugene Reilly

This presentation describes the MAUDE and MDR databases.

- Online Video Presentation [27]

Electronic Medical Device Reporting (eMDR)
Eugene Reilly

This presentation will cover the overall process of how to begin submitting electronically, and what you should expect after you begin submitting electronically.

- Online Video Presentation [28]

Medical Device Reporting
Sharon Kapsch

This presentation is devoted to Medical Device Reporting and what that means.

- Online Video Presentation [29]

MDR for User Facilities
Sharon Kapsch

This presentation is devoted to Medical Device Reporting and what that means for device user facilities.

- Online Video Presentation [30]

MDR for Manufacturers and Importers
Sharon Kapsch

This presentation is devoted to Medical Device Reporting and what that means for device manufacturers and importers.

- Online Video Presentation [31]

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