CDRHLearn: Intro to UDI and GUDID Overview

U.S. Food & Drug Administration

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

Course List

- Overview of Regulatory Requirements: Medical Devices [1]
- Guidance Documents and Standard Operating Procedures (SOPs) [2]
- Premarket Notification Process - 510(k) [3]
- Investigational Device Exemption Process - IDE [4] [**Updated!** 12/4/2013]
- Bioresearch Monitoring (BIMO) [5]
- Device Establishment Registration and Listing [6] [**Updated!** 12/6/2013]
- CDRH Regulated Software: An Introduction [7]
- Quality System Regulation 21 CFR Part 820 [8]
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Overview of Medical Device Regulations

Overview of Regulatory Requirements: Medical Devices

- Online Video Presentation (with Captioning) [17]
- Printable Slide Presentation [18]
- Transcript [19]
- Post Test [20] [21]

Medical Device User Fee Amendments 2012 - MDUFA III Overview

- Online Video Presentation (with Captioning) [22]
- Printable Slide Presentation [23]
- Transcript [24]

Guidance Documents and Standard Operating Procedures (SOPs)

Unique Device Identification (UDI) System

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- Printable Slide Presentation [26]
- Transcript [27]

Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications

- Online Video Presentation (with Captioning) [28] [21]
- Printable Slide Presentation [29]
- Transcript [30]

The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications or 510(k)s

- Online Video Presentation (with Captioning) [31] [21]
- Printable Slide Presentation [32]
- Transcript [33]

Premarket Notification Process – 510(k)

The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications or 510(k)s

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- Printable Slide Presentation [32]
- Transcript [33]

510(k) Overview

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- Printable Slide Presentation [35]

Product Codes Making the Connection...

- Online Video Presentation (with Captioning) [36]
- Printable Slide Presentation [37]

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

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- Printable Slide Presentation [39]

510(k) User Fees

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510(k) Third Party Review

- Online Video Presentation (with Captioning) [42]
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"513(g)s".. Including 513(g) User Fees

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Post Test for all 510(k) Modules [46] [21]

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Investigational Device Exemption Process - IDE

What is an Investigational Device Exemption (IDE)?

- Online Video Presentation (with Captioning) [48]
- Printable Slide Presentation [49]
- Transcript [50]

Idea to IDE: A Medical Device in the Making

- Online Video Presentation (with Captioning) [51]

FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations **[DRAFT Guidance]**

- Printable Slide Presentation [52]
- Audio Recording [53]
- Transcript [54]

IDEs for Early Feasibility Medical Device Clinical Studies, Including First in Human (FIH) Studies

- Printable Slide Presentation [55]
- Audio Recording [56]
- Transcript [57]

FDA Guidance: Design Considerations for Pivotal Clinical Investigations for Medical Devices

- Printable Slide Presentation [58]
- Audio Recording [59]
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Bioresearch Monitoring (BIMO)

BIMO Part 1a - Good Clinical Practice 101: An Introduction

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- Printable Slide Presentation [62]
- Post Test [63] [21]

BIMO Part 1b - Introduction to the Bioresearch Monitoring Program

- Online Video Presentation (with Captioning) [64]
- Printable Slide Presentation [65]
- Post Test [66] [21]

BIMO Part 2a - The Sponsor: Responsibilities in Medical Device Clinical Trials

- Online Video Presentation (with Captioning) [67]
- Printable Slide Presentation [68]
- Post Test [69] [21]

BIMO Part 2b - The Clinical Investigator: Responsibilities in Medical Device Trials

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BIMO Part 2c - Computerized Systems Used in Medical Device Clinical Investigations

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- Post Test [75] [21]

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

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BIMO Part 3b - Institutional Review Board: Humanitarian Use Devices (HUDs)

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BIMO Part 3c - Institutional Review Board: Compassionate and Emergency Use

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BIMO Part 4a - Preparing for an FDA Medical Device Sponsor Inspection

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BIMO Part 4b - Preparing for an FDA Clinical Investigator Inspection

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BIMO Part 4c - Preparing for an FDA Institutional Review Board Inspection

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BIMO Part 5a - Strategies for Sponsors to Build Quality into Device Research

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BIMO Part 5b - Strategies For Clinical Investigators to Build Quality into Device Research

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CDER Small Business Webinar on Building Quality into Clinical Trials – an FDA Perspective [102]

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Device Establishment Registration and Listing

Overview of Device Establishment Registration and Listing

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Paying the Annual Registration User Fee via the Device Facility User Fee (DFUF) Website

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- Printable Slide Presentation [107]

FURLS Device Registration and Listing Module Annual Registration

- Interactive Presentation [108]
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CDRH Regulated Software: An Introduction

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Quality System Regulation 21 CFR Part 820

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- Printable Slide Presentation [113]
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Medical Device Recalls

Introduction to Medical Device Recalls: Industry Responsibilities

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Recall Module 21 CFR Part 806: Medical Devices; Reports of Corrections and Removals

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Recall Communication: Medical Device Model Press Release

- Online Video Presentation (with Captioning) [118]
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Recall Communication: Medical Device Model Recall Notification Letter

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Medical Device Recalls: Guidance for Industry

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Medical Device Reporting (MDR)

MAUDE - Information Available to the Public

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Electronic Medical Device Reporting (eMDR)

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Medical Device Reporting

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MDR for User Facilities

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MDR for Manufacturers and Importers

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Export Certificates for Medical Devices

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Regulation of Radiation-Emitting Products

How to Get Your Electronic Product on the U.S. Market

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Phantom Image Scoring (For MQSA Inspectors)

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eSubmitter Tutorial Videos

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Global Initiatives

International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP) Pilot

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ISO 13485:2003 Voluntary Audit Report Submission Pilot Program

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Single Audit Program - Quality Management System Audit Reports (GD211)

GD211 - Welcome and Introduction by Dr. Jeff Shuren and Dr. Surpriya Sharma

- Online Video Presentation (with Captioning) [158]

GD211 - Welcome and Introduction by Dr. Jeff Shuren and Dr. Surpriya Sharma (French audio-only)

- Online Video Presentation (with Captioning) [159]

GD211 - Module 1 - Introduction

- Online Video Presentation (with Captioning) [160]

GD211 - Module 1 - Introduction (French audio-only)

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GD211 - Module 2 - Information about the Manufacturer

- Online Video Presentation (with Captioning) [162]

GD211 - Module 2 - Information about the Manufacturer (French audio-only)

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GD211 - Module 3 - Information about the Audit

- Online Video Presentation (with Captioning) [164]

GD211 - Module 3 - Information about the Audit (French audio-only)

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GD211 - Module 4 - Audit Findings

- Online Video Presentation (with Captioning) [166]

GD211 - Module 4 - Audit Findings (French audio-only)

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GD211 - Module 5 - Conclusions

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Medical Devices in the Home

FDA's Home Use Medical Device Initiative

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Promoting Patient Safety with Home Use Devices

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- Printable Slide Presentation [176]

Home Use Medical Devices: New Risks

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Unique Device Identification (UDI) System

Unique Device Identification (UDI) System - The Final Regulation

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Intro to UDI and GUDID Overview

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Future Course Topics

- Advanced Quality Systems: Corrective and Preventive Actions
- Imports
- Premarket Approvals

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[22] http://fda.yorkcast.com/webcast/Viewer/?peid=072dd831ae74454fb05bbe409458487c1d

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[31] http://fda.yorkcast.com/webcast/Viewer/?peid=f59814465f674e59a19f3b61c6880ea81d
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[35] http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm126288.htm
[36] http://fda.yorkcast.com/webcast/Viewer/?peid=2360fdf6adf7468aaebd0431ffd76ace
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[38] http://fda.yorkcast.com/webcast/Viewer/?peid=7a8fa9b887004ff2b2b72d4035e3916c
[39] http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm127087.htm
[40] http://fda.yorkcast.com/webcast/Viewer/?peid=a7f98ad6e09646fba8b8a2a8c3008849
[41] http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm127105.htm
[42] http://fda.yorkcast.com/webcast/Viewer/?peid=cace6e43f57d47639911944180eb17b3
[43] http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm127127.htm
[44] http://fda.yorkcast.com/webcast/Viewer/?peid=c3f0f2dc62444e07aa5ea7dbc954cea4
[45] http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm127147.htm
[46] http://cdrh.yorkcast.com
[47] http://www.fda.gov/Training/CDRHLearn#top
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[49] http://www.fda.gov/downloads/Training/CDRHLearn/UCM293098.pdf
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[51] http://fda.yorkcast.com/webcast/Viewer/?peid=46344ca5abbb465e88404a92eed542f71d
[52] http://www.fda.gov/downloads/Training/CDRHLearn/UCM359296.pdf
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[58] http://www.fda.gov/downloads/Training/CDRHLearn/UCM377490.pdf
[59] http://www.fda.gov/downloads/Training/CDRHLearn/UCM378759.mp3
[60] http://www.fda.gov/Training/CDRHLearn/ucm378760.htm

[61] http://fda.yorkcast.com/webcast/Viewer/?peid=477af877491747379c36c4ab1c7421b9
[62] http://www.fda.gov/Training/CDRHLearn/ucm176411.htm
[63] http://cdrh.yorkcast.com/startquiz.php?qid=39&from=out
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[66] http://cdrh.yorkcast.com/startquiz.php?qid=36&from=out
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[68] http://www.fda.gov/Training/CDRHLearn/ucm176455.htm
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[91] http://fda.yorkcast.com/webcast/Viewer/?peid=a805008fd1ab4a9c9c2e87641e95a86a
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