CDRHLearn Course List (New Module - Medical Device User Fee Amendments 2012 - MDUFA III 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] [**Updated!** 12/13/2012]
- Guidance Documents and Standard Operating Procedures (SOPs) [2] **[Updated!** 7/12/2012]
- Premarket Notification Process - 510(k) [3]
- Investigational Device Exemption Process - IDE [4]
- Bioresearch Monitoring (BIMO) [5]
- Device Establishment Registration and Listing [6]
- CDRH Regulated Software: An Introduction [7]
- Quality System Regulation 21 CFR Part 820 [8]
- Medical Device Recalls [9] [**Updated!** 5/23/2012]
- Medical Device Reporting (MDR) [10]
- Export Certificates for Medical Devices [11]
- Regulation of Radiation-Emitting Products [12]
- Global Initiatives [13]
- Medical Devices in the Home [14]
- Unique Device Identification (UDI) System [15] [**New!** 7/12/2012]
- Future Course Topics [16]

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

- Online Video Presentation (with Captioning) [25] [21]
- 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

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

510(k) Overview

- Online Video Presentation (with Captioning) [34]
- 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)

- Online Video Presentation (with Captioning) [38]
- Printable Slide Presentation [39]

510(k) User Fees

- Online Video Presentation (with Captioning) [40]
- Printable Slide Presentation [41]

510(k) Third Party Review

- Online Video Presentation (with Captioning) [42]
- Printable Slide Presentation [43]

"513(g)s".. Including 513(g) User Fees

- Online Video Presentation (with Captioning) [44]
- Printable Slide Presentation [45]

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

[Back to Top [47]]

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]

[Back to Top [47]]

Bioresearch Monitoring (BIMO)

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

- Online Video Presentation (with Captioning) [52]
- Printable Slide Presentation [53]
- Post Test [54] [21]

BIMO Part 1b - Introduction to the Bioresearch Monitoring Program

- Online Video Presentation (with Captioning) [55]
- Printable Slide Presentation [56]
- Post Test [57] [21]

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

- Online Video Presentation (with Captioning) [58]
- Printable Slide Presentation [59]
- Post Test [60] [21]

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

- Online Video Presentation (with Captioning) [61]
- Printable Slide Presentation [62]
- Post Test [63] [21]

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

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

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

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

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

- Online Video Presentation (with Captioning) [70]
- Printable Slide Presentation [71]
- Post Test [72] [21]

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

- Online Video Presentation (with Captioning) [73]
- Printable Slide Presentation [74]
- Post Test [75] [21]

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

- Online Video Presentation (with Captioning) [76]
- Printable Slide Presentation [77]
- Post Test [78] [21]

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

- Online Video Presentation (with Captioning) [79]
- Printable Slide Presentation [80]
- Post Test [81] [21]

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

- Online Video Presentation (with Captioning) [82]
- Printable Slide Presentation [83]
- Post Test [84] [21]

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

- Online Video Presentation (with Captioning) [85]
- Printable Slide Presentation [86]
- Post Test [87] [21]

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

- Online Video Presentation (with Captioning) [88]
- Printable Slide Presentation [89]
- Post Test [90] [21]

Preparing for a Clinical Investigator Inspection

- Online Video Presentation (with Captioning) [91]
- Transcript [92]

[Back to Top [47]]

Device Establishment Registration and Listing

- Online Video Presentation (with Captioning) [93]
- Printable Slide Presentation [94]
- Post Test [95] [21]

[Back to Top [47]]

CDRH Regulated Software: An Introduction

- Online Video Presentation (with Captioning) [96]
- Printable Slide Presentation [97]

[Back to Top [47]]

Quality System Regulation 21 CFR Part 820

- Online Video Presentation (with Captioning) [98]
- Printable Slide Presentation [99]
- Post Test [46] [21]

[Back to Top [47]]

Medical Device Recalls

Introduction to Medical Device Recalls: Industry Responsibilities

- Online Video Presentation (with Captioning) [100]
- Printable Slide Presentation [101]

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

- Online Video Presentation (with Captioning) [102]
- Printable Slide Presentation [103]

Recall Communication: Medical Device Model Press Release

- Online Video Presentation (with Captioning) [104]
- Printable Slide Presentation [105]
- Transcript [106]

Recall Communication: Medical Device Model Recall Notification Letter

- Online Video Presentation (with Captioning) [107]
- Printable Slide Presentation [108]
- Transcript [109]

Medical Device Recalls: Guidance for Industry

- Online Video Presentation (with Captioning) [110]
- Post Test [111] [21]

[Back to Top [47]]

Medical Device Reporting (MDR)

MAUDE - Information Available to the Public

- Online Video Presentation (with Captioning) [112]
- Printable Slide Presentation [113]
- Post Test [114] [21]

Electronic Medical Device Reporting (eMDR)

- Online Video Presentation (with Captioning) [115]
- Printable Slide Presentation [116]
- Post Test [117] [21]

Medical Device Reporting

- Online Video Presentation (with Captioning) [118]
- Printable Slide Presentation [119]
- Post Test [120] [21]

MDR for User Facilities

- Online Video Presentation (with Captioning) [121]
- Printable Slide Presentation [122]
- Post Test [123] [21]

MDR for Manufacturers and Importers

- Online Video Presentation (with Captioning) [124]
- Printable Slide Presentation [125]
- Post Test [126] [21]

[Back to Top [47]]

Export Certificates for Medical Devices

- Online Video Presentation (with Captioning) [127]
- Printable Slide Presentation [128]
- Post Test [129] [21]

[Back to Top [47]]

Regulation of Radiation-Emitting Products

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

- Online Video Presentation (with Captioning) [130]
- Printable Slide Presentation [131]
- Post Test [46] [21]

Phantom Image Scoring (For MQSA Inspectors)

- Online Video Presentation (with Captioning) [132]
- Post Test [133] [21]

eSubmitter Tutorial Videos

- eSubmitter Tutorial Videos [134]
- Radiological Health Report Tutorial [135]

[Back to Top [47]]

Global Initiatives

ISO 13485:2003 Voluntary Audit Report Submission Pilot Program

- Online Video Presentation (with Captioning) [136]
- Printable Slide Presentation [137]
- Transcript [138]

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) [139]

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

- Online Video Presentation (with Captioning) [140]

GD211 - Module 1 - Introduction

- Online Video Presentation (with Captioning) [141]

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

- Online Video Presentation (with Captioning) [142]

GD211 - Module 2 - Information about the Manufacturer

- Online Video Presentation (with Captioning) [143]

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

- Online Video Presentation (with Captioning) [144]

GD211 - Module 3 - Information about the Audit

- Online Video Presentation (with Captioning) [145]

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

- Online Video Presentation (with Captioning) [146]

GD211 - Module 4 - Audit Findings

- Online Video Presentation (with Captioning) [147]

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

- Online Video Presentation (with Captioning) [148]

GD211 - Module 5 - Conclusions

- Online Video Presentation (with Captioning) [149]

GD211 - Module 5 - Conclusions (French audio-only)

- Online Video Presentation (with Captioning) [150]

TEST LINK: GD211 Training Course (English) [151] [21]

TEST LINK: GD211 Training Course (French Canadian) [152] [21]

[Back to Top [47]]

Medical Devices in the Home

FDA's Home Use Medical Device Initiative

- Online Video Presentation (with Captioning) [153]
- Printable Slide Presentation [154]
- Post Test [155] [21]

Promoting Patient Safety with Home Use Devices

- Online Video Presentation (with Captioning) [156]
- Printable Slide Presentation [157]

Home Use Medical Devices: New Risks

- Online Video Presentation (with Captioning) [158]
- Printable Slide Presentation [159]

[Back to Top [47]]

Unique Device Identification (UDI) System

- Online Video Presentation (with Captioning) [25] [21]
- Printable Slide Presentation [26]
- Transcript [27]

[Back to Top [47]]

Future Course Topics

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

[Back to Top [47]]

Source URL (retrieved on *12/28/2014 - 4:54am*):
http://www.mdtmag.com/news/2012/12/cdrhlearn-course-list-new-module-medical-device-user-fee-amendments-2012-mdufa-iii-overview

Links:
[1] http://www.fda.gov/Training/CDRHLearn#overview
[2] http://www.fda.gov/Training/CDRHLearn#guidance
[3] http://www.fda.gov/Training/CDRHLearn#510k
[4] http://www.fda.gov/Training/CDRHLearn#ide
[5] http://www.fda.gov/Training/CDRHLearn#bimo
[6] http://www.fda.gov/Training/CDRHLearn#reglist
[7] http://www.fda.gov/Training/CDRHLearn#software
[8] http://www.fda.gov/Training/CDRHLearn#qsr
[9] http://www.fda.gov/Training/CDRHLearn#recalls
[10] http://www.fda.gov/Training/CDRHLearn#mdr
[11] http://www.fda.gov/Training/CDRHLearn#export
[12] http://www.fda.gov/Training/CDRHLearn#rad
[13] http://www.fda.gov/Training/CDRHLearn#gi
[14] http://www.fda.gov/Training/CDRHLearn#home
[15] http://www.fda.gov/Training/CDRHLearn#udi
[16] http://www.fda.gov/Training/CDRHLearn#future
[17] http://fda.yorkcast.com/webcast/Viewer/?peid=040308365ec8405bad39b06de8561bdc1d
[18] http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/ucm126247.pdf
[19] http://www.fda.gov/Training/CDRHLearn/ucm281656.htm
[20] http://cdrh.yorkcast.com.
[21] http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm
[22] http://fda.yorkcast.com/webcast/Viewer/?peid=072dd831ae74454fb05bbe409458487c1d
[23] http://www.fda.gov/downloads/Training/CDRHLearn/UCM332109.pdf
[24] http://www.fda.gov/downloads/Training/CDRHLearn/UCM332110.pdf
[25] http://fda.yorkcast.com/webcast/Viewer/?peid=d93cd41e2c2d495cb8fe11dc1f933a511d
[26] http://www.fda.gov/downloads/Training/CDRHLearn/UCM311629.pdf
[27] http://www.fda.gov/downloads/Training/CDRHLearn/UCM311634.pdf
[28] http://fda.yorkcast.com/webcast/Viewer/?peid=bac3f2698df14fa98388409da5cba6831d
[29] http://www.fda.gov/downloads/Training/CDRHLearn/UCM299514.pdf
[30] http://www.fda.gov/downloads/Training/CDRHLearn/UCM299515.pdf

[31] http://fda.yorkcast.com/webcast/Viewer/?peid=f59814465f674e59a19f3b61c6880ea81d
[32] http://www.fda.gov/downloads/Training/CDRHLearn/UCM285012.pdf
[33] http://www.fda.gov/downloads/Training/CDRHLearn/UCM285014.pdf
[34] http://fda.yorkcast.com/webcast/Viewer/?peid=e0ea02ad4f0c4532a98fa9406caa01d0
[35] http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm126288.htm
[36] http://fda.yorkcast.com/webcast/Viewer/?peid=2360fdf6adf7468aaebd0431ffd76ace
[37] http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm126308.htm
[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
[48] http://fda.yorkcast.com/webcast/Viewer/?peid=8553ad7df9054febb5ef0048e359ad1e1d
[49] http://www.fda.gov/downloads/Training/CDRHLearn/UCM293098.pdf
[50] http://www.fda.gov/downloads/Training/CDRHLearn/UCM293100.pdf
[51] http://fda.yorkcast.com/webcast/Viewer/?peid=46344ca5abbb465e88404a92eed542f71d
[52] http://fda.yorkcast.com/webcast/Viewer/?peid=477af877491747379c36c4ab1c7421b9
[53] http://www.fda.gov/Training/CDRHLearn/ucm176411.htm
[54] http://cdrh.yorkcast.com/startquiz.php?qid=39&from=out
[55] http://fda.yorkcast.com/webcast/Viewer/?peid=96f1ee7896ee4a70876b601f533b4a9c
[56] http://www.fda.gov/Training/CDRHLearn/ucm176437.htm
[57] http://cdrh.yorkcast.com/startquiz.php?qid=36&from=out
[58] http://fda.yorkcast.com/webcast/Viewer/?peid=88f92205e9624bbea1d627126af5360f
[59] http://www.fda.gov/Training/CDRHLearn/ucm176455.htm
[60] http://www.fda.gov/Training/CDRHLearn/ http://cdrh.yorkcast.com/startquiz.php?qid=32&from=out
[61] http://fda.yorkcast.com/webcast/Viewer/?peid=29b55c1dd3f64d8fa74ca2227df14b39
[62] http://www.fda.gov/Training/CDRHLearn/ucm176458.htm
[63] http://cdrh.yorkcast.com/startquiz.php?qid=34&from=out
[64] http://fda.yorkcast.com/webcast/Viewer/?peid=be7b1972ea0e414ea48171d433feadf9

[65] http://www.fda.gov/Training/CDRHLearn/ucm176466.htm
[66] http://cdrh.yorkcast.com/startquiz.php?qid=35&from=out
[67] http://fda.yorkcast.com/webcast/Viewer/?peid=389cda9506134988a1ac3cc5a725ce87
[68] http://www.fda.gov/Training/CDRHLearn/ucm176481.htm
[69] http://cdrh.yorkcast.com/startquiz.php?qid=37&from=out
[70] http://fda.yorkcast.com/webcast/Viewer/?peid=679dff2747964a5c90c7274a7313255f
[71] http://www.fda.gov/Training/CDRHLearn/ucm180875.htm
[72] http://www.fda.gov/Training/CDRHLearn/ http://cdrh.yorkcast.com/startquiz.php?qid=45&from=out
[73] http://fda.yorkcast.com/webcast/Viewer/?peid=d61c521dee6d4ac28eae61c2700f5237
[74] http://www.fda.gov/Training/CDRHLearn/ucm180876.htm
[75] http://cdrh.yorkcast.com/startquiz.php?qid=46&from=out
[76] http://fda.yorkcast.com/webcast/Viewer/?peid=d8cc05eef221470c9cd3f9fcdb5ee722
[77] http://www.fda.gov/Training/CDRHLearn/ucm176841.htm
[78] http://cdrh.yorkcast.com/startquiz.php?qid=40&from=out
[79] http://fda.yorkcast.com/webcast/Viewer/?peid=2c785eeadc754baab704a351a0e5cc19
[80] http://www.fda.gov/Training/CDRHLearn/ucm180878.htm
[81] http://cdrh.yorkcast.com/startquiz.php?qid=41&from=out
[82] http://fda.yorkcast.com/webcast/Viewer/?peid=a805008fd1ab4a9c9c2e87641e95a86a
[83] http://www.fda.gov/Training/CDRHLearn/ucm180891.htm
[84] http://cdrh.yorkcast.com/startquiz.php?qid=42&from=out
[85] http://fda.yorkcast.com/webcast/Viewer/?peid=225ed5f7301b474196b16c8d9b9a20a5
[86] http://www.fda.gov/Training/CDRHLearn/ucm176842.htm
[87] http://cdrh.yorkcast.com/startquiz.php?qid=33&from=out
[88] http://fda.yorkcast.com/webcast/Viewer/?peid=b618186c8c9c488f8d951013adf0b635
[89] http://www.fda.gov/Training/CDRHLearn/ucm176499.htm
[90] http://cdrh.yorkcast.com/startquiz.php?qid=43&from=out
[91] http://fda.yorkcast.com/webcast/Viewer/?peid=e8307dbabea34d30a9fd6a20dead62271d
[92] http://www.fda.gov/downloads/Training/CDRHLearn/UCM293102.pdf
[93] http://fda.yorkcast.com/webcast/Viewer/?peid=84d21e7da6df42f98390f7bdbb1100ba
[94] http://www.fda.gov/Training/CDRHLearn/ucm176506.htm
[95] http://cdrh.yorkcast.com/startquiz.php?qid=38&from=out
[96] http://fda.yorkcast.com/webcast/Viewer/?peid=4dd89d860ce0449e927a0a8bb92be03f
[97] http://www.fda.gov/Training/CDRHLearn/ucm209135.htm
[98] http://fda.yorkcast.com/webcast/Viewer/?peid=dd2d4823b14a4e4ca6d60eae43c5ac9c
[99] http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm126252.htm
[100] http://fda.yorkcast.com/webcast/Viewer/?peid=c830fc5a437d44b384fcefba1a

59747c
[101] http://www.fda.gov/Training/CDRHLearn/ucm209125.htm
[102] http://fda.yorkcast.com/webcast/Viewer/?peid=895f808c834f49bfbc230df241fe64501d
[103] http://www.fda.gov/downloads/Training/CDRHLearn/UCM257476.pdf
[104] http://fda.yorkcast.com/webcast/Viewer/?peid=5cc9c724fd994989a32af7236c0a40711d
[105] http://www.fda.gov/downloads/Training/CDRHLearn/UCM293232.pdf
[106] http://www.fda.gov/downloads/Training/CDRHLearn/UCM293103.pdf
[107] http://fda.yorkcast.com/webcast/Viewer/?peid=c93236b6dd3d46468b9023bb0f6625381d
[108] http://www.fda.gov/downloads/Training/CDRHLearn/UCM293104.pdf
[109] http://www.fda.gov/downloads/Training/CDRHLearn/UCM293105.pdf
[110] http://fda.yorkcast.com/webcast/Viewer/?peid=1b95461f64be40ecbe3415195cb394911d
[111] http://cdrh.yorkcast.com/startquiz.php?qid=67&from=out
[112] http://fda.yorkcast.com/webcast/Viewer/?peid=7ddf5dd1e3d3415b8903dbb7a7426b09
[113] http://www.fda.gov/downloads/Training/CDRHLearn/UCM234355.pdf
[114] http://cdrh.yorkcast.com/startquiz.php?qid=57&from=out
[115] http://fda.yorkcast.com/webcast/Viewer/?peid=52814f93714044deb8c261f4289e5382
[116] http://www.fda.gov/downloads/Training/CDRHLearn/UCM234356.pdf
[117] http://cdrh.yorkcast.com/startquiz.php?qid=56&from=out
[118] http://fda.yorkcast.com/webcast/Viewer/?peid=36d84dd2f83a4afa94a05698617e4343
[119] http://www.fda.gov/downloads/Training/CDRHLearn/UCM234357.pdf
[120] http://cdrh.yorkcast.com/startquiz.php?qid=59&from=out
[121] http://fda.yorkcast.com/webcast/Viewer/?peid=205b5a1afd6b439191dd4063fb7cadc0
[122] http://www.fda.gov/downloads/Training/CDRHLearn/UCM234358.pdf
[123] http://cdrh.yorkcast.com/startquiz.php?qid=58&from=out
[124] http://fda.yorkcast.com/webcast/Viewer/?peid=6d700995f4274271a3dd722ed1c27f56
[125] http://www.fda.gov/downloads/Training/CDRHLearn/UCM234359.pdf
[126] http://cdrh.yorkcast.com/startquiz.php?qid=60&from=out
[127] http://fda.yorkcast.com/webcast/Viewer/?peid=8a0a2d12000a4c3f970d407628db32c3
[128] http://www.fda.gov/downloads/Training/CDRHLearn/UCM234354.pdf
[129] http://cdrh.yorkcast.com/startquiz.php?qid=55&from=out
[130] http://fda.yorkcast.com/webcast/Viewer/?peid=90191244bb324eb3b0062f9eed35c6ae
[131] http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm127161.htm
[132] http://fda.yorkcast.com/webcast/Viewer/?peid=4264a7f01789427a847bc0ce62d587fe
[133] http://cdrh.yorkcast.com/startquiz.php?qid=61&from=out
[134] http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm193862.htm
[135] http://www.fda.gov/downloads/ForIndustry/FDAeSubmitter/UCM247123.wmv

[136] http://fda.yorkcast.com/webcast/Viewer/?peid=d88a49405a434c44800997e4f92f22391d
[137] http://www.fda.gov/downloads/Training/CDRHLearn/UCM297088.pdf
[138] http://www.fda.gov/downloads/Training/CDRHLearn/UCM297089.pdf
[139] http://fda.yorkcast.com/webcast/Viewer/?peid=4dbdd855ae1044a7b8bc817e5182200b1d
[140] http://fda.yorkcast.com/webcast/Viewer/?peid=30d34f1008454a5499562fca049cf3981d
[141] http://fda.yorkcast.com/webcast/Viewer/?peid=4cb12a22229244fbad814a4b9bb514c11d
[142] http://fda.yorkcast.com/webcast/Viewer/?peid=e7ab713026314e70b2e93251620069b61d
[143] http://fda.yorkcast.com/webcast/Viewer/?peid=74fecaded841474582ce35711208c1a31d
[144] http://fda.yorkcast.com/webcast/Viewer/?peid=89fbca1ba92141fd866bad124d75b0851d
[145] http://fda.yorkcast.com/webcast/Viewer/?peid=38df8efd844a48ddbf6c811945f130bd1d
[146] http://fda.yorkcast.com/webcast/Viewer/?peid=4d647bd56c724085a48507385460d0c21d
[147] http://fda.yorkcast.com/webcast/Viewer/?peid=dfccb05506304a30ab2bcc541812d2d51d
[148] http://fda.yorkcast.com/webcast/Viewer/?peid=babb4191babc441ba2d3beb1a5ebf44f1d
[149] http://fda.yorkcast.com/webcast/Viewer/?peid=25579c65cc3142d69627c6ef1cda5fdb1d
[150] http://fda.yorkcast.com/webcast/Viewer/?peid=a75bc9c33a3c4b0284585a94159ebf0c1d
[151] http://cdrh.yorkcast.com/startquiz.php?qid=63&from=out
[152] http://cdrh.yorkcast.com/startquiz.php?qid=64&from=out
[153] http://fda.yorkcast.com/webcast/Viewer/?peid=46b4288ad2a34b71a9d1ff0b9afbd92d1d
[154] http://www.fda.gov/downloads/Training/CDRHLearn/UCM268045.pdf
[155] http://cdrh.yorkcast.com/startquiz.php?qid=62&from=out
[156] http://fda.yorkcast.com/webcast/Viewer/?peid=8c13f3459ca54e84884a78d67a591b3f1d
[157] http://www.fda.gov/downloads/Training/CDRHLearn/UCM268048.pdf
[158] http://fda.yorkcast.com/webcast/Viewer/?peid=a8124bbeb8c34aa4904dbc83bdf4e5771d
[159] http://www.fda.gov/downloads/Training/CDRHLearn/UCM268049.pdf