U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Today (September 15, 2015), the Food and Drug Administration posted 7 new medical device education modules to the CDRH Learn Program website. The CDRH Learn website has also been improved to allow easier navigation to a topic of interest.

What is CDRH Learn?
CDRH Learn is an innovative multimedia catalog of online educational modules intended to provide information about medical device laws, regulations, and policies that is comprehensive, interactive, and easily accessible. The format for each topic is chosen to present the information in the most effective way possible. With the addition of these 7 new modules, the catalog has grown to over 80 educational modules.

New Modules
These 6 new modules may be found in the CDRH Learn Section "How to Study and Market Your Device."

CDRH Learn Module Title	Key Learning Objective(s)
Standards Program Overview	• understand the different type of standards • learn CDRH uses standards during product reviews
Standards Resources	• learn about the FDA-Recognized Standards Database • learn how FDA interprets a standard
Standards Recognition Process	• understand how CDRH recognizes standards • identify different types of recognition • find recognized standards • describe the process to request recognition of a standard

Requests for Feedback: The Pre-Submission Program and Meetings with CDRH Staff	• understand how to obtain feedback from CDRH on regulatory issues • describe the different types of requests for feedback and when they should be used
Early Feasibility Study (EFS) Program (two modules) (1) EFS Overview (2) EFS Process	• understand the overall concepts of the Early Feasibility Study Program • understand the process involved with the review of Early Feasibility Studies

The 7th new module is located under the CDRH Learn Section "Start Here/The Basics!"

CDRH Learn Module Title	**Key Learning Objective(s)**
FURLS Device Registration and Listing Module for Initial Registration: Domestic, Existing Registration in Account	• learn how to register a domestic establishment in an account that has previously been used to register another establishment in the FDA's Unified Registration and Listing System/Device Registration and Listing Module

CDRH Learn Website Improvement
Based on customer feedback, we have added some of the most popular sub-topics under some categories to make the educational modules easier to find. These are:

- "Start Here/The Basics!"
  - Registration and Listing
- "How to Study and Market Your Device"
  - 510k, de novo, IDE, Classification, Bioresearch Monitoring
- Postmarket Activities
  - Quality System, Exporting, Device Recalls, MDR, Inspection - Global Harmonization

Regulatory Education for Industry (REdI) Conference
We would also like to announce the Regulatory Education for Industry (REdI) Conference being held on September 29 – 30 at the Sheraton Hotel in Silver Spring, Maryland. Participants may attend in-person or online.

REdI is an FDA-led forum that brings together the regulatory educators from FDA's Center for Drug Evaluation (CDER) and Center for Devices and Radiological Health (CDRH). Registration for the event is FREE. Register now to hear the latest information on the regulatory requirements for drugs and devices. Event information and registration can be found online at www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm456382.htm.

For More Information about Medical Devices
If you have any questions about CDRH Learn, REdI, or medical devices, contact the Division of Industry and Consumer Education (DICE):

• Phone: (800) 638-2041 or 301-796-7100; 9 am - 12:30 pm and 1:00 pm - 4:30 pm Eastern Time
• Email: DICE@fda.hhs.gov

Please visit us at our website for more information about how we may help you.

Sincerely yours,

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