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Webinar on

Update - FDA Humanitarian Use Device (HUD) / Humanitarian Device Exemption (HDE) Programs

Date : 16 May 2019

Areas Covered

- *Define rare diseases/conditions per 21st Century Cures Act*
- *Review device risk categories, Define HUDs*
- *Present new thresholds for HUD designation*
- *Review 2 step process of HUD/HDE designation*
- *Differentiate clinical versus investigational use of HDE devices*
- *Explain new IRB expectations for oversight of HDEs*

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The passage of the 21st Century Cures Act and the recent release of draft guidance from FDA signal changes ahead for the Humanitarian Use Device and Humanitarian Device Exemption Programs in the US.

PRESENTED BY:

Glenda Guest BS, CCRA, RQAP-GCP, TIACR, FACRP, has an extensive background in the clinical research industry having worked as a monitor, project manager, data management coordinator, database programmer, quality assurance auditor and senior trainer since joining the clinical research profession with Norwich Clinical Research Associates (NCRA) within 1997.

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Date : 16 May 2019

Time : 01 : 00 PM EST

Duration : 60 Minutes

Price: $229

Webinar Description

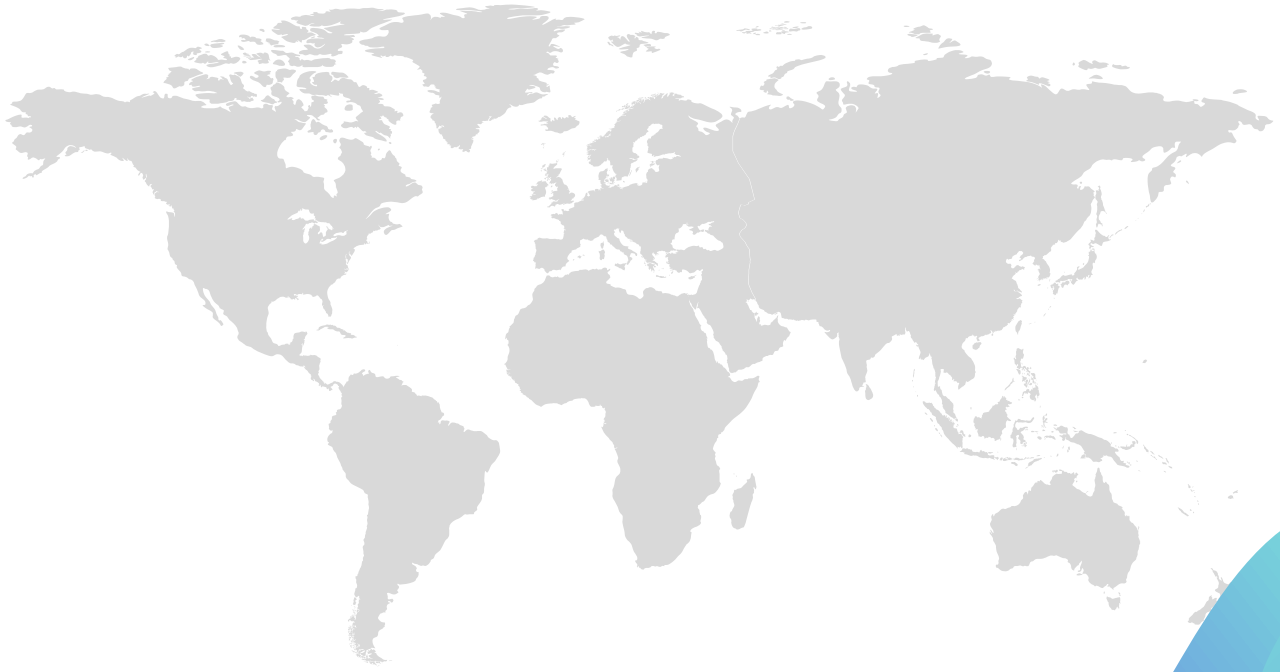
The passage of the 21st Century Cures Act and the recent release of draft guidance from FDA signal changes ahead for the Humanitarian Use Device and Humanitarian Device Exemption Programs in the US.

Whether you work strictly with medical devices, or with device combination products you will not want to miss the opportunities afforded by these changes. The requirements for qualifying for Humanitarian Use Device status have been broadened and there are new insights into IRB oversight of clinical use versus IDE use of such HUD devices.

Be sure you are ready to take advantage of the new opportunities that will become available as a result of these 2 major milestones. An overview of the 2 step process of obtaining HUD and HDE will be provided and IRB oversight expectations reviewed.

Who Should Attend ?

This webinar is appropriate for anyone who needs to understand how to meet the requirements for obtaining HUD designation and obtaining an HDE, including R&D or engineering managers; management representatives; product, project, and program managers; RA/QA managers; internal auditors.



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Why Should Attend ?

Recent changes to FDA requirements resultant from a passage of the 21st Century Cures Act will impact you if you are working in the area of rare diseases or conditions. The FDA Draft Guidance on the Humanitarian Device Exemption (HDE) Program released in June 2018 also contains important changes likely to be implemented upon finalization of the Guidance.

Whether you work strictly with medical devices, or in the area of combination products with medical devices, the changes may positively impact your ability to obtain a HUD designation from FDA, and could open the HDE pathway to market for your product.

Be sure you are ready to take advantage of the new opportunities that will become available as a result of these 2 major milestones. An overview of the 2 step process of obtaining HUD and HDE will be provided and IRB oversight expectations reviewed.

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