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Webinar on

De Novo Classification Process

Learning Objectives

- *Explain when De Novo Process May Be Used*
- *Explain how to gather and submit De Novo Information for FDA Review*
- *Explain the De Novo pathways*
- *Describe the Pre De Novo Submission (PDS) process*
- *Define and explain the purpose of the De Novo Petition*
- *Explain the FDA Review Process for a De Novo application*

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This webinar will examine and define De Novo and discuss the key elements of this classification process.

PRESENTED BY:

Charles H. Paul is the President of C. H. Paul Consulting, Inc. – a regulatory, training, and technical documentation consulting firm. Charles has been a regulatory consultant to the life sciences industry for over 20 years and has published numerous white papers on the subject. The firm works with both domestic and international clients designing solutions for complex human performance problems.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

Today, any new medical device that is found not substantially equivalent for a reason other than performance data not previously classified based on risk is “automatically” or “statutorily” classified as a Class III device. This occurs because, by definition, a new device type would not be equivalent to a device type on the market before the 1976 Medical Device Amendments were placed in force or that has since been classified as a Class I or Class II device. This can have many levels of implication to a manufacturer of a low-risk device that suddenly finds themselves in the position of having their device classified as a Class III.

A device can only be moved out of Class III in this situation only through a reclassification process. The De Novo process provides a possible route to marketing a low-risk device type. Unfortunately, this process remains one of the least utilized routes to the marketing of these devices. This webinar will examine and define De Novo and discuss the key elements of this classification process.

This webinar will follow this pathway explaining the process that must be followed to assure the most potential for a successful outcome.

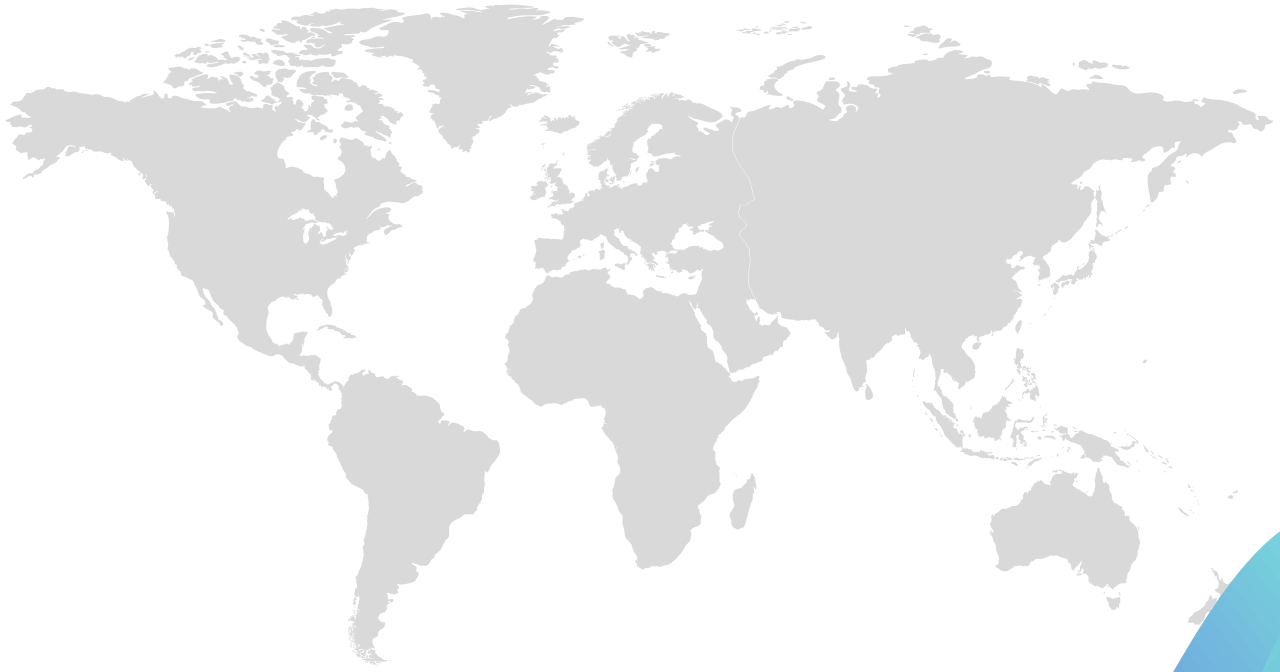
If the petition is denied, the device remains in Class III and may not be marketed.

A new type of device may be eligible for the de novo process if it has received an NSE determination as a result of a 510(k) submission. The submitter of the 510(k), within thirty (30) days of receipt of an NSE determination, submit a De Novo petition requesting that a risk-based classification determination is undertaken. The petition must include a description of the device with detailed information and the reasons for any recommended classification. The FDA must make a classification determination for the device that is the subject of the petition by written order within sixty (60) days of the request.

If FDA grants the de novo petition, the device is reclassified from Class III into Class I or Class II allowing the device to be then marketed and serve as a predicate device.

Who Should Attend ?

Anyone in the medical device industry that has responsibility for the classification of medical devices. Some typical areas and titles include Regulatory Affairs/Compliance, Quality, R & D, Engineering, Marketing, etc.



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