De Novo Classification Process

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PURPLE VERTEX

Unlike other countries in the world, the US uses a predicate-based system to classify its medical devices. For devices that have a predicate device in the marketplace, the classification process is quite straightforward. A predicate device is a legally marketed device, called a preamendments device, that was legally marketed prior to May 28, 1976, a device that has been reclassified from Class III to Class II or I, a device which has been found to be substantially equivalent to such a device through the 510(k) process, or one established through Evaluation of Automatic Class III Definition. The legally marketed device(s) to which equivalence is drawn is known as the "predicate" device(s).

Alternatively, devices of a new type that the FDA has not previously classified based on risk are “automatically” classified into class III regardless of the level of risk they pose. This is because, by definition, a new type of device would not be within a type that was on the market before the 1976 Medical Device Amendments or that has since been classified into Class I or Class II.

For devices that are innovative, when a predicate is found not to exist, The De Novo classification process, also known as “Evaluation of Automatic Class III Designation,” is a device classification process that provides a pathway to either a Class I or Class II classification for medical devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

This webinar will review this De Novo process in conjunction with the recent changes to 21 CFR 860 that pertain to the reclassification of these post amendment devices and the De Novo process in general.

At the completion of this webinar, participants will be able to:

- Describe the De Novo Classification Process
- Explain when the De Novo Process may be used

- Describe the process for submitting a De Novo Request for FDA Review
- Describe each step of the review Process for De Novo Requests
- Explain the implications of the 21 CFR 860 regulation changes to the De Novo process

AREAS COVERED IN THIS WEBINAR

- The De Novo Classification Process
- When the De Novo Process may be used
- Submitting a De Novo Request for FDA Review
- Review Process for De Novo Requests
- 21 CFR 860 regulation changes as they relate to the De Novo process

WHY SHOULD YOU ATTEND

The De Novo process is a complex process that has significant implications for the manufacturer of post amendment devices in terms of how their devices are classified. In addition, the FDA has recently revised the regulations in 21 CFR part 860 that pertain to the reclassification of devices in this category. This webinar will be essential in your continued understanding of this process and in your compliance with the new regulation changes.

INSTRUCTOR PROFILE

CHARLES H. PAUL

Charles H. Paul is the President of C. H. Paul Consulting, Inc. - a regulatory, Lean Manufacturing, training, and technical documentation consulting firm. Charles is a management consultant, instructional designer, and regulatory consultant and has led C. H. Paul Consulting, Inc. since its inception over 25 years ago. He regularly consults with Fortune 500 pharmaceutical, medical device, and biotechnology firms assisting them in achieving human resource, regulatory, and operational excellence. He is a regular presenter of webinars and on-site seminars in a variety of related subjects from documentation development to establishing compliant preventive maintenance systems. The firm works globally completing projects throughout the EU, UK, South America, and Asia.

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