Introduction to Medical Device Approval Pathways

This course introduces participants to the pathways available to acquire permission from FDA to market new medical devices. It provides an overview of the regulations that FDA enforces during the submission of your application. It illustrates how the regulatory status of your invention can radically change the cost and schedule of your project

Who Should Take this Course: Anyone who is involved in developing, designing, testing, or changing any medical device that is intended for sale in the US.

Class Length: 1.5 hours

Course Prerequisites: None

Course Objectives: At the conclusion of the class a participant should have a basic understanding of the following:

- How to distinguish between a PreMarket Notification and a PreMarket Approval
- The components of a 510(k) and PMA submission
- What is meant by the terms 'Clearance' and 'Approval'
- Why the submission regulations are structured as they are
- How to determine whether your new invention is a medical device
- How to determine whether your new invention is a Class I, II, or III device
- The implications of the classification of your invention on the FDA submission pathway
- The implications of the 'Intended Use' of your invention
- How to determine Substantial Equivalence
- What is a Predicate Device
- How a medical device sponsor interacts with the Institutional Review Board
- How to distinguish between a Significant Risk and Non Significant Risk device
- How the Institutional Review Board and FDA interact to approve an Investigational Device Exemption
- How the classification of your invention can cause a dramatic impact on your project's return on investment
- Why you should examine the regulatory pathway for your invention early in the development process

Call 734-274-4680 or email us at Ask VCI to find out how VCI can help you.