Medical Device Regulation USA Seminar

Syllabus, Rev.1

US Regulation	
Module	Topics
Session Kick-Off	• Reflections from the last session, Introduction • Learning objectives
Introduction	• US regulations for medical devices and the role of the FDA • FDA Scope and Code of Federal Regulation
US Regulation Overview	• Regulatory pathways available for medical devices in the US • What Is a Regulated Medical Device? • How to practically use the various FDA tools and databases to determine the required regulatory route
US FDA regulatory pathway	• Device Classification • FDA Pre-Market Notification [510(k)] • 513 (g) mechanism • De Novo Submission • Pre-Market Approval (PMA) • FDA QSR and Post-Submission Requirements • Device Registration and Listing
Session Wrap-Up	• Feedback