

Regulatory Education
for Industry (REdI)
Fall 2016

FDA SMALL BUSINESS AND INDUSTRY ASSISTANCE REdI Conference



CONFERENCE AGENDA
September 27-28, 2016

DAY 1: Tuesday, September 27, 2016

7:15am Registration Opens 4th Floor CYPRESS ROOM	
8:00-8:15am Welcome and Overview, Brenda Stodart, PharmD	
8:15-9:15am Plenary: FDA Insights on Products for Rare Diseases and Pediatrics. <i>Eric Chen, MS, Office of Orphan Product Development</i> <i>Jonathan Goldsmith, MD, FACP, CDER; Vasum Peiris, MD, MPH, CDRH.</i>	
<p>Nearly 7,000 rare diseases are known to affect roughly 30 million Americans. It is estimated that about 80% of rare diseases are genetic and about half of all rare diseases affect children. While manufacturers are developing products (drugs, biologics, devices, or medical foods) to benefit patients with rare diseases, it is important to understand the regulatory considerations available for these products. This presentation will provide a general overview of FDA's regulatory pathways and programs for products that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions with unique perspectives from the Office of Orphan Products Development, Center for Drug Evaluation (CDER) and Research, and Center for Devices and Radiological Health (CDRH).</p>	
9:15-9:30am Break	
DRUG TRACK	DEVICE TRACK
9:30-10:30am Emerging Technology Team: FDA's Tool to Facilitate and Promote Pharmaceutical Innovation <i>Mohan Sapru, PhD</i>	9:30-10:00 am: Overview of CDRH and Basic Submission Process <i>Elias Mallis</i>
<p>Recent advances in different fields of science and technology are at the heart of innovations in pharmaceutical industry. However, despite rapid advances in the form of key biomedical discoveries, there are technological challenges in translating most of these discoveries into viable and cost-effective novel therapeutics. FDA's initiative implemented via the Emerging Technology Team (ETT) is aimed to encourage, facilitate and support the adoption of emerging technologies to modernize all aspects of drug development, including viable innovations in drug designing, effective therapeutic targeting, dosage formulations, drug manufacturing, targeted drug delivery, and product quality control strategies.</p>	<p>Having an overview foundational knowledge is the first step in navigating the medical device regulatory landscape. This presentation will describe the functions of each Office within the Center for Devices and Radiological Health and provide a high-level overview of the overall premarket submission process.</p>
	10:00-10:30 am Resources <i>Diane Nell, PhD.</i>
	<p>The Center for Devices and Radiological Health (CDRH) maintains several resources to help industry stakeholders understand medical device requirements and processes. This presentation will discuss two prime educational resources: Device Advice, a website that contains comprehensive regulatory information and CDRH Learn, a website that houses video modules and presentations regarding key regulatory topics. This presentation will also provide hints about how to navigate the website, including the many FDA databases, to find answers to the most frequently asked questions. The main goal of this presentation is to empower stakeholders to locate answers to routine medical device questions.</p>
10:30-11:15am Prescribing Information: Resources, Review Process, and Guidances Under Development <i>Eric Bradsky, MD</i>	10:30-11:15 am: Design Controls. <i>Stanley Liu</i>
<p>Recent advances in different fields of science and technology are at the heart of innovations in pharmaceutical industry. However, despite rapid advances in the form of key biomedical discoveries, there are technological challenges in translating most of these discoveries into viable and cost-effective novel therapeutics. FDA's initiative implemented via the Emerging Technology Team (ETT) is aimed to encourage, facilitate and support the adoption of emerging technologies to modernize all aspects of drug development, including viable innovations in drug designing, effective therapeutic targeting, dosage formulations, drug manufacturing, targeted drug delivery, and product quality control strategies.</p>	<p>The Quality System (QS) Regulation differ from Good Manufacturing Practices (GMPs) in the key area of Design Controls. This presentation will discuss the regulatory requirements of Design Controls, within FDA's Quality System Regulation, and provide helpful insights into how these requirements can, from start to finish, ensure proper and efficient design and upkeep of medical devices.</p>
11:15 am - 12:15 pm Application of cGMPs to Drug Product Quality Microbiology Laboratory Tests and Manufacturing Process Validation <i>John Metcalfe, PhD</i>	11:15 am-12:15 pm Device Clinical Trials/IDE Program <i>Soma Kalb, PhD</i>
<p>This presentation will provide an overview of the testing regimen and manufacturing process validation activities that are required in the current Good Manufacturing Practice (cGMPs) to demonstrate a drug product's acceptable microbiological quality.</p>	<p>Clinical research is often a critical step along the way for a new medical device to establish its safety and effectiveness profile. This session will address the FDA program, often referred to as the Investigational Device Exemption (IDE) Program, which governs the clinical research of investigational devices, and will provide some insights into what is involved with the evaluation of investigational device studies.</p>
12:15 - 1:30 pm Lunch	
1:30-2:30pm Bioavailability/Bioequivalence (BA/BE) inspections and Surveillance <i>Arindam Dasgupta, PhD</i>	1:30-2:30 pm 510(k) Program <i>CDR Kimberly Piermatteo, MHA</i>
<p>This presentation will describe the Bioavailability/Bioequivalence (BA/BE) Inspection Process of ANDA, NDA and BLA applications by the Office of Study Integrity and Surveillance (OSIS).</p>	<p>The most common pathway for a new medical device to become legally marketed in the United States is through the premarket notification process also known as a 510(k) submission. This session will provide an overview of the 510(k) submission process and will describe how FDA uses a legendary flowchart to evaluate a 510(k) submission.</p>
2:30 - 2:45pm Break	
2:45 - 3:15pm ACE/ITDS: FDA Implementation Update and Tips for Drug Importers <i>Jean E. McCue</i>	2:45-3:30 pm de novo Program <i>Sergio de del Castillo</i>
<p>This session will provide an overview of FDA's efforts to implement the Automated Commercial Environment/International Trade Data System (ACE/ITDS), discuss basic requirements for importing drugs, and provide tips to importers for transmitting drug information in ACE.</p>	<p>Established by Congress in 1998, the <i>de novo</i> process is a reclassification resource that provides a pathway for low-to-moderate risk medical devices to be classified into Class I or II. This presentation will provide regulatory background on the de novo pathway, walk through the process for requesting a de novo reclassification, and identify best practices to optimize the use of this novel regulatory tool when pursuing FDA approval of a novel medical device.</p>
3:15 - 3:45 pm The Drug Supply Chain Security Act (DSCSA): Implementation Updates <i>Connie T. Jung, RPh, PhD</i>	3:30-4:15 pm PMA Program <i>Donna Headlee</i>
<p>This session will provide an overview of the requirements of the Drug Supply Chain Security Act (DSCSA) and agency guidance for industry to help with implementation. FDA implementation updates will be provided.</p>	<p>The Premarket Approval (PMA) review process is a scientific and regulatory review to evaluate the reasonable safety and effectiveness of a class III medical device for a new medical device. This session will provide an overview of the PMA submission process and will describe strategies for a successful submission. In addition, this session will provide an overview of actions after approval including supplements and annual reporting requirements.</p>
3:45 - 4:45 pm Beyond Guidance: Formal Meetings and Requests for Information <i>Kevin B Bugin, MS, RAC</i>	4:15-4:45 pm Wrap Up Q&A
<p>This presentation will cover mechanisms by which industry can communicate with CDER, and specifically, the basic requirements of conducting meetings with CDER, including updates from the recently published March 2015 Draft Guidance for Industry: Formal meetings Between the FDA and Sponsors or Applicants of PDUFA Products, and recommendations for responding to Agency requests for information. The presentation will also offer advice on when and why to request formal meetings, how to successfully respond to request for information, develop relationships with review divisions, and facilitate the receipt adequate and applicable feedback from the review divisions.</p>	
4:30-7:00pm Networking Event	

DAY 2: Wednesday, September 28, 2016

7:15am Registration Opens 4th Floor CYPRESS ROOM

DRUG TRACK		DEVICE TRACK	
8:15 - 8:30am Welcome and Introducing the NEW CDER SBIA webpages <i>Brenda Stodart, PharmD</i> In this short presentation, we will review and navigate through the new and improved CDER SBIA webpage. Our team revamped the webpage based on google analytics data and the most frequently asked questions received by SBIA. We also created the CDER SBIA Learn webpage as a one-stop-shop for all SBIA educational offerings.		8:15-8:30am Welcome and Overview of Day 2 <i>Joseph Tartal</i>	
8:30-9:30am Introduction to Post-marketing Drug Safety Surveillance: Pharmacovigilance in FDA/CDER <i>Suranjan De, MS, MBA</i> <i>Kimberley Swank, PharmD</i>		8:30-9:30 am Quality System Overview <i>Aileen Velez Cabassa, MS</i> The Quality System (QS) Regulation is a must-known for device industry. This presentation will explain the framework of the QS Regulation and its key subsystems. The attendees will learn about document controls, production and process controls, and handling of non-conforming product. Both process validation and personnel requirements will be noted as well.	
9:30-9:45am Break			
9:45-10:45am The PAI/GMP Inspection <i>Details coming soon</i>		9:45-10:45 am Management Controls <i>Tonya Wilbon</i> Management Controls is one of the seven key quality indicators using the subsystem approach and is one of the major subsystems that serve as the basic foundation of a firm's quality system. This presentation will explain the essential elements identified in the Quality System Regulation for Management Controls that ensure adequate resources are provided and that an effective quality system has been implemented and is monitored.	
10:45-11:45am Increasing the Quality and Efficiency of Clinical Trials: The Clinical Trials Transformation Initiative (CTTI) <i>Kristen Miller, PharmD</i> This session will provide an overview of the Clinical Trials Transformation Initiative (CTTI), a public private partnership between the FDA and Duke University that develops projects culminating in recommendations for incremental and transformational changes to clinical trials.		10:45-11:45am Basics of Risk Management for Quality Systems <i>Joseph Tartal</i> What is required in the Quality System Regulation as it pertains to Risk? What is the difference between Risk Analysis and Risk Management? This presentation will answer these questions as well as provide useful information on risk management tools and how to apply them, as well as the use of ISO 14971 Risk Management Standard for Medical Devices.	
11:45am-1:00pm Lunch			
1:00-2:00pm Risk and Team-based Integrated Quality Assessment in the Office of Pharmaceutical Quality <i>M. Scott Furness, PhD</i> This presentation will address the new OPQ CMC review process, and also cover some of the elements used in CMC risk assessment.		1:00-2:00pm FDA Medical Device Inspections <i>Marc Neubauer</i> When FDA visits a medical device manufacturer to conduct an inspection, this can be a very daunting experience for a manufacturer. This presentation will give you the perspective of an FDA investigator on what is involved with medical device inspections.	
2:00 - 2:15pm Break			
2:15 - 3:30pm Best Practices for Communication Between IND Sponsors and FDA during Drug Development <i>Rachel Hartford, BS Physical Sciences</i> Best practices and procedures for timely, transparent, and effective communications between IND sponsors and FDA at critical junctures in drug development, which may facilitate earlier availability of safe and effective drugs to the American public.		2:15-2:45pm Complaints <i>Anike Freeman</i> All complaints must be processed in accordance with the Quality System Regulation and all adverse events must be reported per 21 CFR 803. This presentation will assist you in understanding your FDA regulatory requirements and the importance of effectively gathering, acting upon and communicating this information.	
		2:45-3:30pm Wrap Up Q&A	
3:30pm Conference Adjournment			