Regulatory Education for Industry (REdI)
Fall 2015

FDA SMALL BUSINESS AND INDUSTRY ASSISTANCE

REdI Conference

CONFERENCE AGENDA

September 29-30, 2015

Tuesday September 29

7:15am Registration Opens 4th Floor Cypress Room

8:10am **Welcome** *Brenda Stodart, PharmD*

8:15am - 9:30am PLENARY
Drug / Device Combinations: a Union to Deliver the Best Medical Product to Patients
James Bertram & Kristina J. Lauritsen, Ph.D.

Combination products are comprised of two or more different regulated articles (i.e., combination of drug, device, or biologic). While manufacturers of such products are often focused on developing new and innovative technologies, one should also keep in mind the regulatory considerations associated with each component in the context of the combination product as a whole. The aim of this presentation will be to not only provide stakeholders with a general overview of FDA's regulation of combination products, but also present unique perspectives from both CDER and CDRH during their review of these products

9:00am - 9:15am BREAK

DRUG TRACK	DEVICE TRACK
9:45am - 10:45am **Safety Considerations for Product Design, Container Labels, and Carton Labeling and Best Practices in Developing Proprietary Names for Drugs** *Lubna Merchant, M.S., PharmD* This presentation will discuss the draft guidance on safety considerations for product design, container labels and carton labeling design to minimize medication errors. The guidance provides sponsors with a set of principles and recommendations for ensuring that critical elements of product labels and labeling are designed to promote safe use. The guidance also provides sponsors with a set of principles for developing RX and OTC drug products using a systems approach to minimize medication errors relating to product design. In addition, this presentation provides a brief overview of the Proprietary Name Review guidance that focuses on the safety aspects in the development and selection of proposed proprietary names for all prescription and nonprescription drug products and biological products.	**9:45am - 9:55am Welcome & Overview** *Elias Mallis* **9:55am - 10:45am** **Device Classification Overview** *William M. Sutton* New for 2015! FDA has classified medical devices into Class I, II and III. The class to which your device is assigned determines, among other things, the type of premarketing submission/application required for FDA clearance/approval. This session will discuss the history of device classification, definitions of device classification, the regulatory controls for each class, and why classification is important to you.
10:45am - 11:45am **Good Clinical Practice (GCP) Inspectional Perspective on Use of Electronic Records and Signatures in Clinical Trials** *Kassa Ayalew, M.D., M.P.H.* Discussion about FDA's regulatory requirements that are used to ensure that electronic records used in clinical trials are accurate, complete, and current.	**10:45am - 11:45am** **Device Clinical Trials and the IDE Program** *Soma Kalb, Ph.D.* 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 the current priorities in strengthening the clinical trials enterprise at CDRH.

11:45am - 1:00pm LUNCH

1:00pm - 2:15pm **Comparing Safety Report Requirements for Pre and Post Market** *Chrissy J. Cochran, Ph.D.* This presentation will review Investigational New Drug (IND) safety reporting requirements and Postmarketing Adverse Drug Experience (PADE) reporting requirements. We will explore the similarities and differences between the	**1:00pm - 2:15pm** **The 510(k) Program** *LCDR Kimberly Love Piermatteo* 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.

2:15pm - 2:30pm BREAK

2:30pm - 3:30pm **Pediatric Drug Development: Regulatory Expectations** *Alyson Karesh* This lecture will teach about the pediatric drug development regulatory tools (The Pediatric Research Equity Act, The Best Pharmaceuticals for Children Act). The lecture will cover regulatory expectations for pediatric drug research programs, including pediatric assessments, pediatric study plans, pediatric deferrals, pediatric waivers, and pediatric written requests.	**2:30pm - 3:00pm** **Best Practices & Interactions w/CDRH** *Sergio M. de del Castillo* Sponsor interactions with CDRH often are the key to facilitate a quality submission and FDA review. While there is a wealth of readily-available information on medical device regulations and premarket submissions, sponsors often ask for "the essentials" to ensure a product is cleared/approved for market as quickly and efficiently as possible. This session will outline key information and best practices to facilitate your communications with CDRH staff, to ensure completeness and quality of your premarket submissions, and to minimize delays in the review process. **3:00pm - 3:30pm** **Labeling Overview** *Eric Richardson* Federal Food, Drug, and Cosmetic Act (FD&C) provides the authority to regulate medical device labeling and is implemented under 21 CFR Parts 801, 809, 812, and 820. This presentation provides a basic overview of device labeling requirements for investigational devices and premarket submissions. Topics will include prescription vs. over-the-counter, exemptions of certain requirements, and misbranding.
3:30pm - 4:15pm **Clinical Outcome Assessment Implementation in Clinical Trials** *Jessica Voqui, PharmD, M.S.* Good measurement principles are essential to well-defined and reliable clinical outcome measurement. Development or modification of appropriate clinical outcome assessments requires thoughtful consideration and planning early in medical product development. Establishing the context of use and conceptualization of treatment benefit are critical to a successful clinical trial. This session will provide an overview of the process to establish the context of use, conceptualize treatment benefit, selecting or developing appropriate clinical outcome assessments, and implementing these in clinical trials.	**3:30pm - 4:15pm** **Wrap Up and Q&A** *Elias Mallis; William M. Sutton; Soma Kalb, Ph.D.; LCDR Kimberly Piermatteo; Sergio M. de del Castillo; and Eric Richardson*

4:15pm ADJOURNMENT

4:30pm - 7:00pm Networking Opportunity (Optional Self-Pay Event): Happy Hour at the Mica Lobby Lounge

The Sheraton lobby lounge offers a comfortable atmosphere to network with peers. It features complimentary wifi, onsite dining and bar options at its full service Mica Restaurant, Lobby Bar, and Starbucks Coffee.

Wednesday September 30

7:15am Registration Opens 4th Floor Cypress Room

DRUG TRACK	DEVICE TRACK
8:15am - 8:30am **Welcome & Overview** *Brenda Stodart*	**8:15am - 8:30am** **Welcome & Overview** *William Sutton*
8:30am - 9:30am **Overview of FDA Expedited Programs with a Focus on the Breakthrough Therapy** *Miranda Raggio, BA, BSN, MA* The session will provide an overview of the FDA expedited programs for serious conditions. The session will also provide a focused and more in-depth discussion of the FDASIA 902 Breakthrough Therapy Designation and how this new mandate is being implemented in CDER.	**8:30am - 9:30am** **Overview of Quality Systems Regulation** *Tonya A. Wilbon* 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 management controls, corrective and preventive actions (CAPA), production and process controls, and document controls.
9:30am - 9:45am BREAK	
9:45am - 10:45am **FDA's Pre-Approval Inspection (PAI) Program and How to prepare for a successful outcome** *Denise DiGiulio, R.Ph.* During this presentation you will learn about the FDA's Pre-Approval inspection program and practical tips on how to have a successful outcome. Withhold case studies will be presented to illustrate key points.	**9:45am - 10:15am** **Design Controls** *Stanley Liu* Inadequate design has been cited as one of the main causes for medical device failures and recalls. This presentation will inform you on the regulatory requirements of FDA's Quality System Regulation regarding design controls and provide helpful insight on how these requirements can ensure that you design the right medical device. **10:15am - 10:45am** **Purchasing Controls** *Aileen Velez-Cabassa* In an ever expanding global economy, outsourcing has become the norm, be it for materials, manufacturing or services. This presentation will educate you on both the regulatory requirements, per 21 CFR 820.50, from FDA and the expectations and guidance available so that you may optimally prepared to navigate the vending world and be successful at qualifying your vendors.
10:45am - 11:45am **CDER Regulatory Applications - Investigational New Drug and New Drug Applications** *Balajee Shanmugam* The talk will provide an overview of the new Office, Office of Pharmaceutical Quality (OPQ), and the sub-offices under OPQ with a particular focus on the activities of the Office of New Drug Products and the Office of Process and Facilities. The Quality information (Chemistry, Manufacturing and Controls) required for an Investigational New Drug Application (IND), and for the approval of a New Drug Application (NDA). The talk will also touch upon the requirements for Breakthrough Therapies and Quality by Design approaches.	**10:45am - 11:45am** **Process Validation** *Joseph Tartal* How do you ensure medical devices are manufactured in a consistent and reproducible way so processes result in product that meets specifications? This is where process validation comes in to play. In this presentation you will be provided information on the 21 CFR 820 Quality System regulatory requirements for process validation. Also covered will be suggestions and best practices to determine when and how to perform valuable process validation.
11:45am - 1:00pm LUNCH	
1:00pm - 2:15pm **Lifecycle Management of Drug Products: FDA's Perspective** *Geoffrey Wu, Ph.D.* Provide an overview of the recently established Office of Lifecycle Drug Products (OLDP) within the new Office of Pharmaceutical Quality (OPQ): its roles and responsibilities, with a focus on brand-name drug products. and **Lifecycle Management of Drug Products** *Hasmukh B. Patel, Ph.D.* Share the current thinking and the holistic approach for managing the lifecycle of drug products from the FDA's perspective: how to bridge and manage the knowledge obtained from the various phases (e.g., IND->NDA->sNDA->ANDA->sANDA) of a drug product.	**1:00pm - 1:45pm** **Unique Device Identification (UDI)** *Loretta E. Chi, JD* The Unique Device Identification (UDI) rule became final in September 2013. This presentation provides a basic overview of the UDI regulation and establishing a Global UDI Database (GUDID) System. Attendees will be able to familiarize themselves with the UDI, GUDID and know where to refer to for additional information on the FDA.gov website. **1:45pm - 2:15pm** **Electronic Medical Device Reporting (eMDR)** *Andrew Xiao* The Medical Device Reporting (MDR) regulation (21 CFR 803) contains mandatory requirements for manufacturers, importers, and device user facilities to report certain device-related adverse events and product problems to the FDA. On Feb. 13, 2014, the FDA published a final rule on Electronic Medical Device Reporting (eMDR) that requires manufacturers and importers to submit MDRs in an electronic format.
2:15p - 2:30p BREAK	
2:30pm - 3:30pm **Evidence and Data Requirements for NDA Submissions** *Eileen Navarro, M.D., FACP* The regulatory basis for adequate and well controlled clinical trials and the general principles applied in evaluating adequacy of evidence for labeling claims will be described. Data requirements that facilitate validation of clinical trial data will be discussed.	**2:30pm - 3:30pm** **FDA Medical Device Inspections** *Marc Neubauer, B.S., M.A.* When FDA visits a medical device manufacturer to conduct an inspection, it 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.
3:30pm - 4:15pm **Demystifying Interactions with FDA-CDER: A Primer on Formal Meetings and Best Practices** *Judit Milstein* This presentation will cover the basic requirements of conducting meetings with CDER, including updates from the recently issued revised Draft Guidance for Industry: Formal meetings Between the FDA and Sponsors or Applicants of PDUFA Products, published in March 2015. The presentation will also offer advice on when and why to request formal meetings, and tips for success, such as how frequent to utilize formal meetings, how to develop relationships with review divisions, and how to facilitate the receipt of adequate and applicable feedback from the review divisions.	**3:30pm - 4:15pm** **Wrap Up and Q&A** *Tonya Wilbon; Stanley Liu; Aileen Velez-Cabassa; Joseph Tartal; Andrew Xiao; and Marc Neubauer*