DYNAMIC GLOBAL EVENTS

Basic Drug Development Training 101

May 22-23, 2019 | The Inn at Penn | Philadelphia, PA

- Learn the essentials of FDA structure and organization
- Improve your understanding of current regulations
- Get insights into qualifying requirements for special programs

Agenda

Wednesday, May 22, 2019 | Day 1

8:00 - 8:30 **Registration and Networking Breakfast**

8:30 - 8:45 **Opening Remarks**

8:45 - 10:45 **FDA Scope & Organization**

The scope of the FDA's regulatory authority is very broad. With less than 8,000 employees, FDA regulates approximately 60% of the GDP in the US, including food, drugs, cosmetics, and veterinary products. Learn the full extent and impact of their activities on your life personally and professionally, and how they organize to do so much with so few.

- FDA's mission in its regulation
- FDA's top priorities for regulation
- How they organize to achieve their mission & meet their priorities

10:45 - 11:15 **Networking Break**

11:15 - 12:15 **History of US Regulation**

The regulatory requirements for drug development is complex and intricate; however, it is navigable. This session will explore the historical underpinnings of our current regulatory framework and the current pathways to getting drug approval.

- Learn the submissions required for study and approval for your drug, device, biologic, medical food, or dietary supplement
- Learn the format required for your submissions in an effort to give patients
- Overview of devices regulation for IDE/510(k)/PMA
- Address biologics and biosimilars including IND/BLA
- Touch on dietary supplements and medical foods

12:15 - 1:15 **Networking Lunch**

1:15 - 2:15 **History of US Regulation (Continued)**

2:15 - 3:15 **Special Programs to Consider**

Several special programs that offer different strategic advantages for your product are available for you to consider for your product. Learn about qualifying requirements and considerations you need to make for:

- Orphan drugs
- Breakthrough therapy designation
- Parallel review
- Fast Track
- Exclusivity
- RX to OTC switch
- Pediatric development
- Patient's Right to Try

3:15 - 3:30 **Networking Break**

3:30 - 4:30 **Special Programs to Consider (Continued)**

Thursday, May 23, 2019 | Day 2

8:00 - 9:00 **Continental Breakfast**

9:00 - 9:15 **Recap of Day One Sessions**

9:15 - 10:45 **Meetings with the FDA**

To assist in navigating the intricate web of regulations and requirements, the FDA offer several key points of interaction during the development process.

- Learn what meetings are possible for your products during your development life cycle and what you should aim to get out of them
- Learn how to take advantage of these meetings from scheduling to planning and conducting the meeting to gain full understanding and actionable output
- Review case studies of successful negotiation and communication during meetings
- See lessons learned from less successful meetings and how to manage that during the meeting and recover after the meeting

10:45 - 11:15 **Networking Break**

11:15 - 1:15 **Beginning with the End Target in Mind**

The largest goal of every development program is to help patients and enhance their lives. HoweverContamination of Hand-held Electronic Devices in Healthcare Apr. 10, 2019, that cannot be accomplished philanthropically, so you have to consider what you need to have at the end of the day in order to make money. So how do you ensure that you will hit the target!

- What is a Target Product Profile (TPP) and how do you create it?
- One step beyond the TPP – the claims needed to resonate with customers
- Materializing the development plan from your targets
- Practical application exercise: turn a TPP into a development program

Venue: The Inn at Penn, 3600 Sansom Street, Philadelphia, PA, 19104
(866) 238-8235

Registration: Two - Day Workshop: $1396.00

Group Rate: With every two full price registrations, receive a third registration free!

To Register, Click Here. For groups, or if you just prefer to register by phone, call 201 871 0474