

Dear colleagues:

If any of the following quests fit your career agenda: 1). *Advance your knowledge in the area of regulatory affairs (or its new term "regulatory sciences");* 2). *Explore the possibility being a regulatory scientist;* 3). *Learn how to write a good regulatory dossier (which may or may not be the same as a good scientific report);* 4). *Understand how the regulatory process works in this highly regulated industry;* 5). *Anticipate changes in FDA's new initiatives and industrial responses;* 6). *Network with top regulatory scientists and understand how they become one;* we invite you to join us in this half a day workshop sponsored by SAPA on a leisure Friday June 16, 2006.

This is the pre-conference (SAPA annual conference held June 17) workshop that would definitely allow you to feel the power of "collective bargaining" from the professionals in our community. Please register at www.sapa-gp.org early, as space is limited. We look forward to seeing you there!

Workshop Moderator:

Lee Kang, PhD, MBA, sanofi-aventis

学习研讨班主题: FDA Filing and GMP Compliance

1. 会前研讨班 2006 年六月 16 日 1:00-6:30 PM
2. DoubleTree Hotel, Plymouth Meeting, 640 West Germantown Pike, Plymouth Meeting, PA 19462, (phone 610-879-4122)
3. Moderator: Lee Kang, PhD, MBA (Sanofi-Aventis)

Deliverables

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- Understand filing requirements for API and drug products in general, and specifically for API supplying for generic drug manufacturers.
 - Understand FDA regulations and filing requirements for various types of submissions (DMF, IND, NDA, and ANDA), and familiar with the mechanism and requirements for reporting post-approval changes.
 - Understand regulatory affairs and regulatory requirements - who, what, when, how, and why, and learn how to build regulatory affairs personnel in dealing with FDA and how to develop strategy for filing CMC information to FDA.
 - Understand "post approval change" strategies and how to comply with regulatory commitments and at the same time fulfill the business need.
 - Meet cGMP requirements and understand the system based inspections and customers' expectations in order to seize outsourcing opportunities.
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- 从了解美国食品药品监督管理局对原料药和仿制药制剂的法规要求, 以及从 GMP 认证开始
- 在美国食品药品监督管理局 FDA 注册申请 DMF/CMC/IND 和 NDA/BLA 申报策略
- 美国食品药品监督管理局对新药研发监控管理法规以及在公司研发和生产中的功效和影响
- 新药临床申请(IND)申报前、临床试验中以及新药申请(NDA)申报前和美国食品药品监督管理局的交流讨论会
- 准备美方(FDA or Partner)对(中国)企业在申报前及合同签署前的 GMP 检查

Program Agenda

1:30-2:15 FDA Organization and Medical Review Divisions

(Ruyi He, MD, PhD, FDA)

- FDA organization and division responsibilities
- Filing and communication channels with FDA
- New initiatives and recent changes in FDA

2:15-3:00 Regulatory Affairs' Roles in Pharmaceutical Companies and in Dealing with FDA

(Jiwen Zhang, PhD, Wyeth)

- Cultural differences between industry and FDA
- Effective and constructive interactions
- Manage communication strategies

3:00-3:45 DMF Submission Mechanisms and Overview

(Jane Xiang, PhD, Johnson and Johnson)

- DMF types and submission mechanisms
- Relationship of DMF with other regulatory submissions
- DMF holder's responsibilities and how to handle process changes

3:45-4:30 CMC Information Requirement and Strategy

(Naidong Ye, PhD, Vela Pharmaceuticals)

- IND submissions and data requirements
- NDA and ANDA submissions
- Risk based design and question based review

4:30-5:15 Pre-Approval Inspection and Post Approval Changes and Comparability Protocols

(Lee Kang, PhD, MBA, Sanofi-Aventis)

- Understand FDA's system-based inspections and meet ICH Q7A expectations
- Understand BACPAC and SUPAC for post approval changes
- Report mechanisms Comparability protocol development

5:15-6:00 Panel Discussion and Q/A

培训课题

1:00 主讲致辞，简介讲员

1:30-2:15 美国食品药品监督管理局 FDA 组织机构和职责划分 (Ruyi He, MD, PhD, FDA)

- 美国食品药品监督管理局 FDA 的主要任务和文件审查部门
- 药品申报及审批的一般程序以及和 FDA 联络的方式
- 美国食品药品监督管理局 FDA 最近动态和机构的改组

2:15-3:00 接触 FDA 官员的最佳人员队伍监控管理法规组 Regulatory Affairs 的任务和使命 (Jiwen Zhang, PhD, Wyeth)

- 美国政府和民营企业的文化区别和意识差异
- Regulatory Affairs 主要负责的项目
- 与 FDA 联络的方式、策略和实战技巧

3:00-3:45 美国食品药品监督管理局 FDA 对药物主文件 DMF 的要求和审查程序 (Jane Xiang, PhD, Johnson & Johnson)

- 药物主文件 DMF 的种类和申请审查程序以及提交的 CMC 数据资料要求
- DMF 和其它申请报批文件 (NDA, ANDA, MAA 等) 之间的关系
- 药物主文件 DMF 持有者的责任以及如何申报核准后工艺的变更

3:45-4:30 美国食品药品监督管理局 FDA 对化学制造及控制 (CMC) 数据资料的要求及相应的送审策略 (Naidong Ye, PhD, Vela Pharmaceuticals)

- 新药临床研究申请报批文件 (IND) 的要求
- 新药申请审核批准报批文件 (NDA) 的要求
- 新药申请 NDA 和简略新药申请 (即仿制药申请) ANDA 的 CMC 数据资料要求

4:30-5:15 FDA 对新药申请批准前工厂现场检查 (PAI) 以及批准后工艺变更和申报的要求 (Lee Kang, PhD, MBA, Sanofi-Aventis)

- 了解 FDA 以系统为基准的工厂现场检查
- FDA 核准后的后续事项和相应的补充文件 (合成工艺批准后变更 BACPAC 和制剂批准后变更 SUPAC)
- 如何利用相类似变更协定 comparability protocol 来处理核准后工艺的变更 post-approval change

5:15-6:00 互动交流及问答

6:30 课程总结