FDA REGULATORY COMPLIANCE FOR DRUG AND BIOTECH PRODUCT TRAINING COURSE

2 Day Virtual Instructor led Workshop

COURSE DESCRIPTION

Regulatory Compliance is the level of activity that provides assurance to the sponsor and the regulatory agency that all phases of drug development are conducted in compliance to the good practice regulations as mandated by the Federal Food, Drug, and Cosmetic (FD&C) Act. In this course, you will learn the practical applications for ensuring regulatory compliance as required by FDA regulations for biologics and drug development. You will also examine how a pharmaceutical or biotechnology company can use the graded approach when following the good manufacturing practice (GMP) regulations for manufacturing, testing and control of clinical supplies and commercial products.

FACULTY KARL M. NOBERT

Founder of ReCellerate Inc., a veterinary pharmaceutical company, that develops stem cell-based drug products for dogs, cats and horses. In his role as President and Regulatory Counsel, Karl oversaw the company's FDA Drug Approval Program for six (currently pending) drug applications for products intended to treat and repair various disease conditions and injuries. Some of these investigative drugs are intended for osteoarthritis in dogs, inflammatory bowel disease in cats, and exercise induced pulmonary hemorrhage in horses.

WHO WILL BENEFIT

This course will benefit professionals involved in working with pharmaceutical and Biotech products and management involved in drug development and FDA Regulatory Compliance:

- QA/QC analytical chemists
- QA/QC directors, managers
- Investigators in QA/QC
- Manufacturing/Production
- Research and Development
- Project management
- Manufacturing personnel
- CROs analysts
- Technical liaison
- Regulatory affairs personnel
- CMC specialists
- Senior quality managers
- Quality professionals
- Regulatory professionals
- Compliance professionals
- Quality auditors
- Document control specialists
- New hires, as well as Managers, Directors, and Vice Presidents of Regulatory Affairs and Quality Assurance.

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AGENDA DAY 01

FDA and its Statutory and Regulatory Requirements
FDA's Structure and Purpose

- The Federal Food, Drug and Cosmetic Act
- The Code of Federal Regulations
- Guidane, Policy Documents and Compliance Manuals
- The Evolution of FDA Law
- www.fda.gov

Brief Overview: The Products FDA Regulates and their Pathways to Market

- Drugs
- Medical Devices
- Food & Dietary Supplements
- Cosmetics
- Tobacco
- Veterinary Products

Universal Requirements

- Establishment Registration, Product Listing, User Fees, etc.

FDA Drug Development and Approval Process Considerations

- Statutory and Regulatory Provisions
- Citizen Petitions
- Approvals and Clearances
- The Drug IND, NDA, ANDA and Orphan Designation
- Biologic's BLA
- Medical Device 510(k) and PMA
- Combination Products
- Veterinary INAD, NADA, ANADA, MUMS
- FDA Drug Approval Process
- Case Study # 1: Suitability Petitions
- Case Study #: Paragraph IV Certification
- Post Approval Submissions
- QbD product development and design
- Key elements of IND, NDA/ANDA applications and FDA expectations
- Electronic CTD format and content, most submitted through ESG (Electronic Submissions Gateway
- SPost approval changes to process, methods etc.
- Regulatory Filings
- Risk analysis

Statutory and Regulatory Compliance

- The Concepts of "Adulteration" and "Misbranding"
- Identifying Non-Compliance
- Product Label and Labeling
- The Internet
- Approval and Clearane
- Facility Inspections
- Adverse Events
- Recalls
- Trade Complaints and Anonymous Tips
- FDA's Compliance Options, Historical Case Examples & FDA's Website
- Form 483s
- Untitled Letters
- Warning Letters
- Import Alerts
- Seizures
- Recalls
- Consent Decrees
- Temporary and Permanent Injunctions
- Civil and Criminal Prosecution
- The Park Doctrine
- Other Compliance Bodies
- DOJ, FTC, EPA, the States, NAD

Management's Role and Responsibilities in Compliance

- Communication, Implementation and Decision Making
- Quality Policy and Resourcing
- Personnel Training
- Escalation of issues to upper management

Corrective and Preventive Actions (CAPA)
Gap Analysis
Facility Audits and Inspections

- Internal Company Audits
- Training the Employees
- Use of Third-Party Auditors
- Auditor qualifications understanding.....

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AGENDA DAY 02

Manufacturing and Quality Controls for Drug Products
- Management's Role and Involvement
- Complying with the Good Manufacturing Practices "cGMPs"
- Laboratory Quality Controls
- Standard Operating Procedures
- What Makes a Good SOP
- How to Write an Adequate SOP
- Strategies for Drafting

Recalls and Market Withdrawals
- FDA Jurisdiction and Authority
- Stock Rotations
- Corrections
- Market Withdrawals
- Recalls
- Recall Classifications
- How to Conduct a Product Recall
- Customer Communication
- FDA Communication
- Documentation
- Strategies for Mitigating the Chances of a Recall

Pharmacovigilance
- Definitions of Significant and Serious Adverse Events
- Recording, Investigating and Reporting Compliants
- FDA Communication
- Strategies for Dealing with Complaints

Customs, Detentions and Import Alerts
- The Process
- Holds and Detentions
- Seizure and Destruction
- Remediating
- The Import Alert

Rx Drug Promotion and Advertising
- Risk Considerations
- "Fair Balance"
- Elements & Considerations
- Brief Summary
- Boxed Warning
- Important Safety Information
- False and Misleading Claims
- Fair Balance
- Superiority Claims
- Testimonials
- Market Research
- Quality of Life Data
- Other Considerations
- Enforcement Action Examples

Emerging Compliance Trends
- Counterfeit drug issues and growing concerns
- Drug shortage crisis
- Biosimilar approval pathways
- Others

Other Compliance Issues

Questions & Answers and Closing Thoughts

REGISTRATION FORM

Name **Email**

Organization **Department** **Position**

Phone **Mobile**

Register Online At www.worldcomplianceseminars.com

or by calling our offi ce : 844-267-7299

Terms And Condition

- Registration shall be reconfirmed only once payment has been made prior to the course.
- Cancellation of participant/s shall be submitted in writing to WCS ten days (10 days) before the course. There is a 50% liability on all bookings once made.
- WCS reserves the right to make alterations to the conference/executive briefing content, timing, speakers without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of WCS. If such a situation arises, we will refund your registration fee or we will try to reschedule the event.