8:00-8:30 AM  Registration and Continental Breakfast

8:30-9:30 AM  Welcome and Introduction
Session 1: The FDA Organization & Structure
• FDA’s Mission
• How FDA is organized
• CDER/CBER Role and Responsibility
• Role of FDA Chemistry Reviewer
• Responsibility of Sponsor
• References

Session 2: Introduction to CM&C
• What is CM&C
• FDA Concerns with CM&C
• CM&C Definitions

Session 3: History of FDA
• Drug Law History

Session 4: Laws, Regulations, Guideline
• Laws vs. Regulations
• Regulations vs. Guidance’s FDAMA 116

9:30-10:15 AM  Session 5: Types of Submissions Affected by CM&C
• FDA Briefing Package
• Investigational New Drug Application (IND)
• Investigational Medicinal Product Dossier (IMPD)
• New Drug Application (NDA/CTD)
• Biologics License Application (BLA)
• Common Technical Document (CTD)
• Drug master Files (DMF)
• Abbreviated New Drug Application (ANDA)
• Amendments to an IND
• Supplements to an Approved NDA/ANDA
• IND/NDA Annual Reports

Session 6: Pre-formulation & Formulation Development
• CMC Steps Leading to an IND
• Key API Characteristics
• Development of Analytical Assay
• Pre-Formulation Testing
• Solubility
• Stability
• Pre-Formulation Testing
• Forced Degradation Studies
• Formulation Development
• Formulation Challenges
• GMP Manufacturing
• Requisites for CTM Manufacture
• Stability Testing and Storage

Session 7: FDA Briefing Package
• Contents of an FDA Briefing Package

10:15-10:30 AM  Break

10:30-12:00 PM  Session 8: CMC Requirements for an IND
Part A: Drug Substance
• Contents of an IND
• Quantity of Information for an IND
• Introduction
• Characterization and Description
• Elucidation and Structure
• Name and Address of Manufacturer
• General Method of Manufacture
• The Acceptable Limits and Analytical Methods used to Assure Identity, Structure, Quality and Purity of the Drug Substance
• Validation Data
• Impurities
• Reference Standards
• Batch Analysis
• Container/Closure System
• Stability

Part B: Drug Product
• Components and Composition
• Name and Address of Manufacturer
• Method of manufacture
• In-Process Controls
• Controls and Process Validation
• Specifications and Analytical Methods for Components
• BSE/TSE Certificate
• Novel Excipients
• The Acceptable Limits and Analytical Methods used to Assure Identity, Structure, Quality and Purity of the Drug Substance
• Analytical Procedures
• Impurities
• Batch Analysis Tables
• Container/Closure System
• Stability of the Drug product

Part C: Placebo
• Components and Composition
• Name and Address of Manufacturer
• Method of Manufacture
• In-Process Controls
• Controls and Process Validation
• Specifications and Analytical Methods for Components
• BSE/TSE Certification
• Novel Excipients
• Acceptable Limits and Analytical Methods
• Analytical Procedures
• Batch Analysis Tables
• Container/Closure System
• Stability

12:00-1:00 PM  Luncheon

1:00-2:30 PM  Session 9: The EU Investigational Medicinal Product Dossier
• Scope
• Required Information
• Structure

Session 10: Environmental Impact (IND & NDA)
• Categorical Exclusions
• Contents of a Categorical Exclusion Claim
• Environmental Assessments

Session 11: The CTM Label
• Salient Features of a CTM Label
• Sample CTM Label
• Sample Carton label
• CMC Issues in Finalizing your CTM

Session 12: From Clinical Trial Material to Commercial Product
• Begin with the end in mind
• What is a Target Product Profile
• Design Your Ideal Label
• TOC for a TPP
• Changes to CTMs
• References

Session 13: Special Protocol Assessment
• Purpose and Types of SPAs
• Procedure for request
• Stability Protocol
• Format of an SPA
• Content of an SPA
• Binding Nature of SPAs

2:30-2:45 PM    Break

2:45-5:30 PM    Session 14: Drug Master Files
• Regulatory Basis
• DMF Submissions
• Transmittal Letter
• Administrative Information
• FDA Review of DMFs
• Types of DMFs
• Type I DMFs
• Type II DMFs
• Type III DMFs
• Type IV DMF’s
• Type V DMFs
• General Suggestions
• Letters of Authorization
• Holder Obligations
• Transfer of Ownership
• Potential Issues

Session 15: CMC Requirements for an NDA
• Organization of an NDA
• Labeling
• Application Summary
• Drug Substance
• Drug Product
• Deficiencies that Cause delays
• Investigational Formulations
• Samples for the NDA
• Methods Validation Package
• Patent Information
• Patent Certification
• Field Copy Certification
• Publications
• ANDA requirements for Approval
• ANDA Content

Session 16: Common Technical Document Summaries: Module 2
• Organization and review of Module 2

Session 17: Common Technical Document: Module 3
• Organization of the CTD
• Organization of Module 3
Day Two

8:00- 8:30 AM  Continental Breakfast

8:30-10:00AM  Session 18 : The NDA Labels
   • The NDA Labels
   • Immediate Container Label
   • Carton Label

Session 19: The Global Development Plan
   • Components of a Global Development Plan
   • Manufacturing Strategy (CMC Development Plan)
   • Risks and issues

Session 20: Preparing for CMC Meetings with FDA
   • Why Does a Sponsor Meet with FDA?
   • Early Interactions with FDA
   • Planning
   • Important Documents for a CM&C Meeting
   • Meeting Request Letter
   • Contents of a Meeting request Letter
   • The Briefing Document
   • Contents of a Briefing Document
   • Quality of a Briefing Document
   • Regulatory Mechanism for an FDA Meeting
   • Preparing for the Meeting
   • Rehearsals
   • During the Meeting
   • Pre-IND Meeting
   • Guidance Meeting
   • End-of-Phase 2 Meeting
   • Pre-NDA Meeting
   • Pre-NDA Package

10:00-10:45 AM  Session 21: Manufacturing and GMP Considerations
   • What are GMPs
   • cGMP Regulations
   • Quality Approach to cGMPs
   • FDA’s System-Based Drug Inspection
   • GMP Requirements for Finished products
   • Enforcement Actions by FDA
   • Standards of Performance
   • Audits
   • Standard Operating Procedures
   • Medical Devices
   • References

10:45-11:00 AM  Break

11:00-11:30 AM  Session 22: Designing a Stability Protocol
   • Key Features of a Stability Protocol

Session 23: Contents of a Certificate of Analysis
   • Contents of a COA

11:30-12:30 PM  Session 24: CMC Inspections – the PAI
   • General Considerations
   • What is a PAI
   • Objectives of a PAI
   • Timing of the PAI
   • Preparing for the PAI
   • Documents for an Inspection
   • Beginning the Inspection
• Role of the Facilitator/Escort
• Role of the Scribe
• Role of the War Room
• Areas and Information Subject to Inspection
• FDA Cannot Review or Obtain
• Inspectional Procedures
• General FDA Concerns
• The Exit Meeting
• Post-Inspection

12:30-1:30 PM  Luncheon

1:30-2:00 PM  Session 25: FDA Enforcement Actions-Form FDA 483 & Warning Letters
• Types of Enforcement Actions
• FDA Inspections
• Inspection Documents
• Form FDA 482
• Form FDA 483
• Form FDA 484
• Warning Letters
• Addressing a Warning Letter
• cGMP Deviations

2:00-2:45 PM  Session 26: Beyond Approval – Post Approval Changes
• Reporting Changes to an Approved Application
• Reporting Mechanisms
• Prior Approval Supplements
• Changes Being Effected – 30 Days (CBE-30)
• Changes Being Effected (CBE)
• Annual Report
• Types of Changes
• SUPAC Documents
• Contents of a Prior Approval
• The NDA Annual Report

2:45-3:15 PM  Session 27: Comparability Protocols
• What is a Comparability protocol
• Areas that Utilize Comparability protocols
• Advantages
• Content of a Comparability protocol

3:15 – 3:30PM  Session 28: References
• ICH Guidelines