OVERVIEW – Basics of the FDA Product Approval Process
- History
- The FDA Today
  - Organization
  - Laws/Regulations/Guidance

PRODUCT DEVELOPMENT
- Pre-clinical R&D phase
- Pre-clinical GLP testing phase (pharmacology/toxicology)
- Clinical phases (Phases 1,2,3)
- Market Application (BLA, NDA, PMA)

INTRODUCTION TO THE INVESTIGATIONAL NEW DRUG (IND) APPLICATION
- Definitions/regulations/guidance
- Types of INDs
- When is an IND required?

IND CONTENT/FORMAT
- Section 1 – Form 1571
- Section 2 – TOC
- Section 3 – Introductory Statement
- Section 4 – General Investigational Plan
- Section 5 – Investigator’s Brochure
- Section 6 – Clinical Protocol
- Section 7 – CMC data
- Section 8 – Pharmacology/Toxicology
- Section 9 – Previous Human Experience
- Section 10 – Additional Information

THE IND REVIEW PROCESS
- Timelines
- Clinical Hold
- IND Amendments
- Annual Reports
- Fast Track
- Adverse Event Reporting
- Inactivation/Termination
MARKET APPLICATIONS (BLA/NDA)
- Definitions/regulations/guidance
- The Common Technical Document (CTD) format
- How to file
- Post-Market Requirements

OTHER THINGS YOU NEED TO KNOW
- Interaction with the FDA
- Orphan Drug Applications
- Master Files
- FDA Inspections
- FDA Compliance Actions
  - Inspection findings (FD483)
  - Warning Letters
  - Consent Decrees

FINANCING DRUG DISCOVERY—OVERVIEW OF VENTURE CAPITAL
- Federal government financing
- Venture capital funds
- Term sheets and valuation
- Corporate finance
- Case study

PROTECTING INTELLECTUAL PROPERTY—OVERVIEW OF PATENT PROCESS
- U.S. provisional/patent process
- International patent process
- Tech transfer and licensing
- Looking ahead at the legal issue

Workshop Faculty

James G. Kenimer, Ph.D., is the President of Biologics Consulting Group, Inc., LLC (BCG). His firm was founded in 1993 and consists of 28 consultants and staff, plus additional consultant affiliates. Dr. Kenimer has over 15 years experience at the FDA as researcher, laboratory chief, and inspector. He has been a presenter at numerous professional society meetings and is widely published in the area of biologics. BCG provides regulatory and product development advice to manufacturers of biotechnology products. Its main office is in Alexandria, Virginia, with additional offices in California and North Carolina and an affiliated operation, BCG Europe, with offices in Scotland.

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