QUALITY AND GMP COMPLIANCE

FOR VIRTUAL COMPANIES

March 30-31, 2017
Vancouver, Canada

MEDIA SPONSORS

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AAPS

Branal Scientific
Business Development

EVENT ORGANIZED BY:

International Pharmaceutical Academy
An AAPS Company

About the course:

Today, many companies operate on an outsourcing model. This is very common for companies who are evolving from being mainly development-focused to a point where they are entering latter stages of Phase 2 or Phase 3 clinical trials, and plan to have a product ready for market approval in the coming months. Most such companies are small, and may not have deep expertise in QA and GMP compliance, relying on their partners to cover those areas. Companies who outsource the majority of operations through the use of Contract Manufacturing Organizations (CMOs) and Contract Laboratories, however, remain responsible for the quality and compliance status of the products they send to the clinic or to the marketplace.

In this two day workshop conference you will learn the requirements and expectations of major health care regulators that are applicable to "virtual" companies. You will learn how to diagnose your company's needs based on which GMP-governed operations you retain and which you outsource; what the current expectations and best industry practices are for selecting, qualifying and monitoring your contractors to ensure they are meeting your requirements; and how to build a quality system framework that is not excessive for your current needs, but has the structure and integration to "grow with you" as the scope your operations change in the coming months and years.

You will also learn best practices for managing a regulatory inspection, with emphasis on FDA, EMA and Health Canada, but applicable to most other major agencies as well.

Learning Objectives:

Participants in this seminar will:

- Understand the GMP requirements all virtual companies must meet regardless of the extent of their outsourcing operations
- Understand how to select, qualify and monitor CMOs and Contract Laboratories
- Learn the elements to include in a quality agreement (also known as a technical agreement)
- Understand your obligations under the law for products you release to the clinic or the marketplace
- Appreciate the importance of maintaining data integrity
- Learn how to effectively manage a health regulatory inspection:
    - Inspection logistics
    - Responding effectively to document requests and questions from inspectors
    - Managing the inspection exit discussion
    - How to write an effective response to inspection observations
    - How to find applicable inspection references and procedures of the FDA, EMA and Health Canada

About the speaker:

David L. Chesney
Principal and General Manager
MicroBio Technical Support
DL Chesney Consulting, LLC, Former FDA

Mr. Chesney is the Principal and General Manager of DL Chesney Consulting, LLC. His career includes 23 years with the FDA and over 21 years in GMP and GCP consulting worldwide. In his consulting practice, Mr. Chesney helps clients prevent quality and compliance problems through proactive assessment and planning, and when necessary, with remediation planning and health regulatory authority communications.

Until recently, he served as Vice President, Strategic Compliance Services for PAREXEL Consulting, a business unit of PAREXEL International LLC. Prior to joining PAREXEL Consulting in 1995, Mr. Chesney served 23 years with the FDA, where he advanced from Investigator to Supervisory Investigator and Director, Investigations Branch, working in the Boston, Seattle and Philadelphia District Offices. In 1991, he was appointed the District Director, FDA San Francisco District Office, where he served until joining PAREXEL in 1995. At PAREXEL. Mr. Chesney provided compliance consulting and training services to clients worldwide. For 19 years, he led the Strategic Compliance Consulting group, and also personally provided regulatory enforcement related consulting services to the pharmaceutical, medical device and biologics industries, plus technical assistance to legal counsel in FDA regulatory matters. Mr. Chesney has a bachelor's degree and postgraduate credits in biology from California State University, Northridge and San Diego, and received a Certificate in Health Care Compliance from Seton Hall University School of Law. He is active in PDA, serving as an instructor for the PDA Training and Research Institute, and with the Food and Drug Law Institute where he helps teach the Introduction to Drug Law program of legal continuing education. Mr. Chesney is a charter member of the FDA Alumni Association, where he is presently a member of the Board of Directors.

IPA Speaking Opportunities

Interested in presenting at one of our upcoming events?

We are continually looking for industry experts to present at our international conferences throughout the world and to share their in-depth knowledge of their speciality with our attendees. If you have an interest in becoming one or our select cadre of experts, please contact us at:

Tel: 416-410-7402 or enquiry@ipacanada.com

Course Agenda & Contents

Day 1 Course Agenda

Thursday March 30, 2017
8:30 AM - 9:00 AM Registration and continental breakfast
9:00 AM - 10:30 AM Course begin
10:30 AM - 10:45 AM Mid-Morning break
10:45 AM - 12:15 PM Course continue
12:15 PM - 1:15 PM Networking lunch
1:15 PM - 2:30 PM Course continue
2:30 PM - 2:45 PM Mid-Afternoon refreshment break
2:45 PM - 4:30 PM Course continue
4:30 PM Conclusion of day 1

Day 1 Course Outline

- Introductions and participant expectations for the program
- Fundamentals of Good Manufacturing Practice
  - What is GMP?
  - Purpose of GMP
  - Basis in law: US, Europe, Canada
  - Elements that apply to all virtual companies
  - Elements that depend on how operations are conducted: How to tell what applies to your company
- Data Integrity: What it is and why it is important to GMP
- Postmarketing reporting – small molecule drugs vs biologic drugs (FDA requirements)
- Pharmacovigilance – pre and postmarket – FDA and EMA differences
- Regulatory and business risks: The case for compliance
- Virtual company organizational structure and responsibility for QA/GMP
- Virtual company quality system structure and management
  - Policies, procedures, documentation management
  - Metrics and management review considerations
- Selection, qualification and monitoring of contractors
  - Initial due diligence – public information sources to gage compliance
  - Qualification of vendors
  - Quality agreements – determining and documenting responsibilities for GMP
  - Vendor audit program
- Day One Q&A and recap of progress meeting stated course expectations

Note: Agenda is subject to change without notice. Please check back regularly for updates.

Course Agenda & Contents

Day 2 Course Agenda

Friday March 31, 2017
8:30 AM - 9:00 AM Registration and continental breakfast
9:00 AM - 10:30 AM Course begin
10:30 AM - 10:45 AM Mid-Morning break
10:45 AM - 12:15 PM Course continue
12:15 PM - 1:15 PM Networking lunch
1:15 PM - 2:30 PM Course continue
2:30 PM - 2:45 PM Mid-Afternoon refreshment break
2:45 PM - 4:30 PM Course continue
4:30 PM Conclusion of day 2

Day 2 Course Outline

- Regulatory Inspections
  - Purpose of an inspection
  - Reasons for inspections
  - Inspections at virtual company headquarters locations – purpose and scope
  - Inspections at CMOs and Contract Labs
  - Data Integrity: What it is and why it is important to GMP
  - GMP inspections versus Preapproval inspections – FDA

Course Outline Continued..

  - Pharmacovigilance – pre and postmarket – FDA and EMA differences
  - EMA inspections – contrast with FDA
  - Health Canada inspections
- Logistics for managing inspections at your location
  - Information sources about inspections on agency web sites: What you need and how to find it easily
  - Preparation for inspections
  - Overall process – ready room support
  - Receiving and hosting the inspectors
  - Providing documents
  - Answering questions
  - Interpersonal dos and don'ts for interacting with inspectors
  - Managing the exit discussion at the conclusion of the inspection
- Inspections at your contract organizations
  - Making sure your CMO and contract lab are "PAI ready"
  - Training employees to assure inspection readiness – pitfalls to make sure you avoid
  - Conducting mock inspections effectively
- Post-inspection communications with the inspecting agency
  - How to write an effective response
  - Common mistakes to avoid
  - Following up to ensure the response is satisfactory
  - When to request a meeting, and if granted, how best to handle it
- Enforcement considerations
  - FDA enforcement process – domestic and ex-US
  - EMA enforcement
  - Health Canada
- Final Q&A, discussion, and conclusion

Note: Agenda is subject to change without notice. Please check back regularly for updates.

Who will benefit:

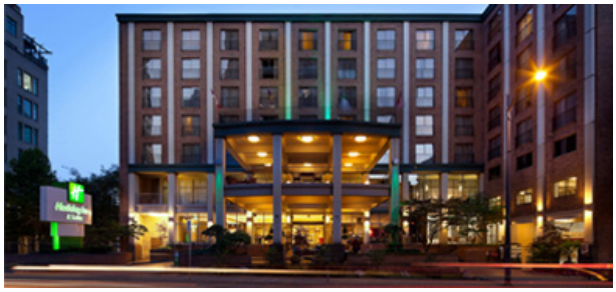
This course is designed for those charged with managing Quality Assurance and Regulatory Affairs for companies in the development or commercial phase of growth who either release investigational drugs to clinical trial sites or send commercial products to the market, but rely to a great extent on the use of Contract Manufacturers and/or Contract Laboratories. The following personnel will benefit from the course:

- Senior quality managers
- Regulatory professionals
- Quality auditors
- Quality professionals
- Compliance professionals
- Document control specialists

Course Venue and Hotel Accommodation

Holiday Inn & Suites Vancouver Downtown
1110 Howe Street
Vancouver, British Columbia, V6Z 1R2
Phone: 1-604-684-2151

Website: http://www.holidayinnvancouverdowntown.com



Sponsorship & Exhibition Opportunities

Interested in Exhibiting or Sponsoring at this event? Contact us at 416-410-7402 or enquiry@ipacanada.com

REGISTRATION FORM

Quality and GMP Compliance for Virtual Companies

March 30-31, 2017 | Vancouver, Canada

Early Bird: Till January 20, 2017	CAD $788 + HST
Discounted Price: January 21, 2017 to February 28, 2017	CAD $888 +HST
Regular Price: March 01, 2017 to March 30, 2017	CAD $988 +HST
Academia / Government at all time (Save Over $250.00)	CAD $688 +HST

Group Discount: Special group rates available for 3 or more registransts. Some restriction applies., please contact us by email: enquiry@ipacanada.com or Call: 416-410-7402

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For registration or any further information, please contact us at:

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Cancellation/Substitutions Policy:

All cancellations are subject to a CAD $150.00/person processing fee. To receive cancellation credits for attendance at an upcoming course, IPA must be notified of the cancellation in writing (by email, mail or fax) up to 3 weeks prior to the program start date. Cancellations submitted less than 3 weeks prior to the event will not be qualified for refund or credit.

Substitution of delegate/s with the member/s of the same organization is permitted at any time with no penalty.

IPA reserves the right to postpone an event, prior to which time all the registered attendees will be notified a minimum of 2 weeks in advance. IPA shall not be responsible for any air fare, hotel or transportation costs incurred by registrant/s.