American Conference Institute's 23rd

# FDA BOOT CAMP

## Basic training in core regulatory concepts for life sciences lawyers, business executives and policy analysts

Earn CLE Credits

September 18 – 19, 2014 | Omni Parker House | Boston, MA

**Our prior delegates say it best:**

*"Comprehensive overviews; invaluable resource; anticipate referencing slides often; good information."*
- Heather S. Brown, Corporate Counsel, Pfizer Inc.

*"Very efficient, effective speakers."*
- Jon Richards, Product Manager, MBL International, Inc.

*"Presentations were relevant & on topic."*
- Rebecca Miller-Larson, Counsel, Sunovion Pharmaceuticals, Inc.

*"This was an excellent CLE. Highly informative!"*
- Matthew Molloy, Attorney, Dinsmore & Shohl LLP

**Preeminent members of the nation's Food and Drug bar will drill you in the basics of FDA law and regulation as they help you:**

- **MASTER** the basics of the **application and approval processes** for drugs, biologics and devices
- **COMPREHEND** the structure of the **FDA** and the roles of the three major agency centers: **CDER**, **CBER**, and **CDRH**
- **DEVELOP** a practical working knowledge of **clinical trials** for drugs and biologics and the **clearance process** for devices
- **LEARN** how **devices** are classified, monitored, and regulated
- **APPRECIATE** the complexities of pharmaceutical **IP** and the regulatory balance between **brand name** and **generic** products
- **RECOGNIZE** the pivotal role of **labeling** in the drug and biologics approval process
- **SEE** the importance of **cGMPs** to the post-approval regulatory process
- **NAVIGATE** the protocols of **adverse events** monitoring, signal detection, product withdrawals, and **recalls**

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| Pre-Conference Workshop | Interactive Post-Conference Master Classes: In depth Hatch-Waxman, BPCIA, and Post-Approval Concerns | |
|---|---|---|
| Workshop A: Fundamentals of FDA Regulatory Law | Master Class B: Hatch-Waxman and BPCIA: Overview of Biosimilars and Life Cycle Planning for Drugs and Biologics | Master Class C: Post-Approval Marketing Guidance and Preemption Protocols |

Register Now | 888-224-2480 | www.AmericanConference.com/FDABootCampBos

## Now in its 23rd iteration, FDA Boot Camp is the premier event that will provide you with the ultimate roadmap to the complicated landscape of FDA regulatory law

**ACI's FDA Boot Camp** has been designed by leading regulatory attorneys to give professionals that work in conjunction with the pharmaceutical, biologics, and medical devices industries — such as products or patent litigators, as well as patent prosecutors, industry in-house counsel, and life sciences investment and securities experts — a strong working knowledge of core FDA competencies.

A distinguished faculty of top FDA regulatory experts — *a "Who's Who of the FDA Bar"* — will share their knowledge and give you critical insights on:

- The organization, jurisdiction, functions, and operations of the FDA
- The essentials of the approval process for drugs, biologics, and devices, including:
  - NDAs
  - INDs
  - BLAs
  - OTC Approval
  - 510(k) submissions
  - PMA process
- Clinical trials for drugs and biologics and the clearance process for devices
- The classification of devices and the concept of "risk-based" classification
- The role of the Hatch-Waxman Act in the patenting of drugs and biologics
- Labeling in the drug and biologics approval process
- cGMPs and other manufacturing concerns relative to products liability
- Proactive adverse events monitoring and signal detection
- Recalls, product withdrawals, and FDA oversight authority

**Attend the pre-conference workshop or post-conference master classes to get the background and/or the in-depth information you need to maximize your learning and networking experience at this event!**

**Workshop A: Fundamentals of FDA Regulatory Law** will address topics to set the stage for the main conference by helping you thoroughly comprehend the structure of the FDA and the essentials of the pre-approval, approval, and post-approval process. Get the background you need to flow seamlessly into the conversations at FDA Boot Camp.

**Master Class B: Hatch-Waxman and BPCIA: Overview of Biosimilars and Life Cycle Planning for Drugs and Biologics** will provide an in-depth overview of biosimilars as well as analyses of bioequivalency and exclusivities and their role in patent and product life cycle management.

**Master Class C: Post-Approval Marketing Guidance and Preemption Protocols** will address issues that arise post-approval, including advertising, promotion, and off-label promotion and enforcement, as well as preemption fundamentals.

Attend this conference and learn to navigate your way through the regulatory maze that plays such a crucial role to your cases and practice areas. *Seats at prior iterations of **ACI's** FDA Boot Camp sold out.* Don't delay — register now by calling **1-888-224-2480**, faxing your registration form to **1-877-927-1563**, or registering online at **www.americanconference.com/FDABootCampBos.**

I look forward to seeing you in Boston this September!

Regards,

Christopher J. Soverow

Christopher J. Soverow, Esq.
Legal Analyst & Conference Director

### Continuing Legal Education Credits

CLE Credits

Accreditation will be sought in those jurisdictions requested by the registrants which have continuing education requirements. This course is identified as transitional as well as non-transitional for the purposes of CLE accreditation.

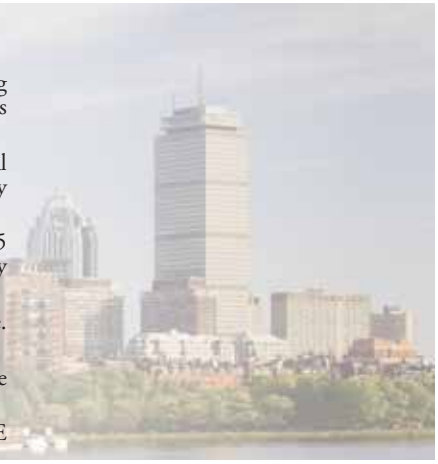
ACI certifies that the activity has been approved for CLE credit by the New York State Continuing Legal Education Board in the amount of 12.5 hours. An additional 4.5 credit hours (1.0 of Ethics) will apply to participation in workshop A. An additional 4.0 credit hours will apply to participation in Master Class B or C.

ACI certifi es that this activity has been approved for CLE credit by the State Bar of California in the amount of 10.5 hours. An additional 4.0 credit hours (1.0 ethics) will apply to workshop A. An additional 3.5 credit hours will apply to participation in Master Class B or C.

You are required to bring your state bar number to complete the appropriate state forms during the conference. CLE credits are processed in 4-8 weeks after a conference is held.

ACI has a dedicated team which processes requests for state approval. Please note that event accreditation varies by state and ACI will make every effort to process your request.

Questions about CLE credits for your state? Visit our online CLE Help Center at www.americanconference.com/CLE



## PRE-CONFERENCE WORKSHOP: WEDNESDAY, SEPTEMBER 17, 2014 | 1:00 P.M. – 5:00 P.M.

### A FDA Regulatory Fundamentals 101 With Ethics Session

*Scott M. Lassman*
Partner
Kleinfeld Kaplan & Becker LLP

1:00 **Fundamentals of FDA Regulatory Law**

Aimed at providing a primer to professionals who have limited or no experience working with FDA on regulatory matters, this workshop will provide you with a basic overview of FDA regulations and will prepare you for the more in-depth discussions that will take place throughout the conference. Topics addressed during this workshop will set the stage for the main conference by helping you thoroughly comprehend the structure of the FDA and walk you through the pre-approval, approval, and post-approval process. Get the background you need to flow seamlessly into the conversations at FDA Boot Camp.

**Topics to include:**

- FDA Mission
- FDA Organization
- History of FDA Laws
- Acronyms and Terminology
- Clinical Trials Process
- Types of New Drug Applications
- The Review Process
- The Hatch Waxman Act
- Legal Barriers to Approval
- Biological Products
- The Basics of Device classification and approval
- Post-marketing issues and enforcement, including recalls

4:00 **Resolving Ethical Challenges Encountered During the Drug Approval Process**

This one hour program will explore ethical issues that may arise in the context of communications with FDA on behalf of clients. The program is based on scenarios involving situations in which FDA requires full disclosure of adverse information and authority. For example:

(1) In the context of citizen petitions FDA requires certification that the petition includes all information and views on which the petition relies as well as data and information known to the petitioner which is unfavorable to the petitioner. 21 CFR 10.30. The discussion will cover the implications of that certification upon an attorney in light of Rules 1.6, 1.7 and 1.8 of the Rules of Professional Responsibility.

(2) In the context of an Advisory Committee meeting at which counsel is present, Committee members ask whether all data regarding adverse events have been reported to FDA. The discussion will cover the implications of the lawyer's participation in light of the requirements of Rules 1.3, 3.4, and 4.1.

(3) Your client has retained a former FDA official and tells you that he will be contacting FDA to discuss a pending NDA. The discussion will cover the implications of Rule 1.11.

5:00 **Workshop Concludes**

## MAIN CONFERENCE: DAY 1, THURSDAY, SEPTEMBER 18, 2014

7:15 **Registration and Continental Breakfast**

8:30 **Co-Chairs' Opening Remarks and Brief Overview of FDA Practice**

*Kurt R. Karst*
Director
Hyman, Phelps & McNamara, P.C.

*Daniel A. Kracov*
Partner
Arnold & Porter LLP

### Preapproval and Approval

9:00 **The Nature of the Approval Process**

*James Czaban*
Partner
Wiley Rein LLP

*Donald Ware*
Partner
Foley Hoag LLP

**Rx Drugs**

- Understanding the difference between "new drugs" and other drugs
- Overview of the research, development, and approval process for new drugs
- The investigational new drug application (IND) — timing, content, and purpose
- The new drug application (NDA) — timing, content, purpose, and review process
- Accelerated approval (fast track)
- Different uses of the REMS process in new drug approvals

**Biological Products**

- What are biological products? What does it mean to say that they are also "drugs"?
- Which "new drugs" require BLAs instead of NDAs?
- How do the research, development, and approval process for biological products differ from the process for new drugs?
- The biologics license application (BLA) — timing, content, purpose, and review process
- Key similarities and differences between the drug and biological product schemes

**OTC Products**

- The concept of "OTC" (OTC-ness)
- The OTC Review — identifying covered drugs and defining a "monograph"
- OTC versus Rx
- Overview of how old and new OTC drugs come to market

10:15 **Morning Coffee Break**

10:30 **Understanding the Clinical Trial Process for Drugs and Biologics**

*David G. Adams*
Partner
Venable LLP

*Daniel A. Kracov*
Partner
Arnold & Porter LLP

- Outlining the phases of clinical trials (I-IV)
- Regulatory requirements (e.g., informed consent, IRBs, sponsor obligations, investigator obligations, etc.)
- FDA authority
- Discussing the roles and obligations surrounding CROs and SMOs
- Identifying major differences between clinical trials for drugs and biologics
- Disclosure of clinical trial information
  - o FDA Amendments Act of 2007
  - o FDAMA § 113
  - o clinicaltrials.gov
  - o PhRMA policies

11:30 **Drugs and Biologics: Labeling**

*Alan G. Minsk*
Partner
Arnall Golden Gregory LLP

*Gary Yingling*
Partner
Morgan, Lewis & Bockius LLP

The labeling of the drug/biological product is the final stage of the approval process. The labeling affects what you can do post-approval. It is the point of transition between the approval process and post-approval world.

- Labeling overview: key regulatory requirements, information, and contents
- Review process for labeling
- How does the final labeling control the scope of post-market activities?
- How can and when should the labeling be amended post-market?
- How is the labeling a defense in products litigation?
- When can punitive damages may be rewarded with respect to labeling
- Assessing the impact of labeling on reimbursement

12:30 **Networking Luncheon**

### Patent and IP Overview for Drugs and Biologics: Understanding The Connection Between FDA Regulation and IP and Related Mechanisms Under Hatch-Waxman and BPCIA

1:45 **Part 1 –Patents, Trademarks and Other IP Protections and Mechanisms**

*Jill K. MacAlpine, Ph.D.*
Partner
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

*Donna M. Meuth*
Associate General Counsel, Intellectual Property
Eisai, Inc.

**Patent Protection for Drugs and Biologics**

- Summarizing the patenting process for drugs and biologics
- Strategies for building patent protection drugs and biologics
- Seeking extension of patent term for time spent in the drug approval process (Patent Term Extension, Supplemental Protection Certificates), and/or time spent obtaining a patent at the United States Patent Office (Patent Term Adjustment)
- 271(e)(1) "safe harbor"
- Identifying the respective roles of the FDA and the PTO in the patenting of drugs and biological products

**Trademarks, Trade Names, and Trade Dress**

- The art and science of selecting a brand name for a proposed drug product
- Understanding the respective roles of the USPTO and FDA in the drug naming process
- Identifying the PTO and FDA clearances necessary for trade name/trademark approval on your product
- Appreciating the use of trade dress as a means of IP protection for drug products

3:00 **Afternoon refreshment break**

3:15 **Part 2- Hatch-Waxman and BPCIA Overview**

*Kurt R. Karst*
Director
Hyman, Phelps & McNamara, P.C.

*Christopher E. Jeffers, Ph.D.*
Attorney at Law
Womble Carlyle Sandridge & Rice, LLP

**Drugs**

- Comparing the NDA, 505(b)(2) and ANDA (Abbreviated New Drug Application) drug approval routes
- ANDA filing: what does the FDA require?
- Showing bioequivalence in an ANDA
- ANDA Paragraph IV Certification, and response to Notice Letters
- The role of the Orange Book in the drug approval process: what is it, why is it Orange, and why is it important?
- Regulatory Exclusivity (FDA)
  - Categories of regulatory (data) exclusivity — NCE (new chemical entity); new indication; NDF (new dosage formulation); ODE (orphan drug exclusivity); PED (pediatric exclusivity)' New antibiotic exclusivity
  - overview of Hatch-Waxman and reforms under MMA
  - the role of Orange Book under Hatch-Waxman vis-à-vis the MMA
    - 30-month stay
    - patent extensions
    - ANDA-filer exclusivity (180 day)

**Biologics**

- Identifying products approved/regulated as biologics
- Overview of biosimilar (FOB) legislation and regulations
- The rationale for safety and efficacy concerns surrounding second generation biologics

**Exclusivity for Combination Products**

- Status and review of Combination Drug Development Incentive Act of 2013 (H.R. 2985)
- Exploring exclusivities for combination products comprised of two new Orange Book listed drugs, two old drugs, a new and an old, a listed drug and device, and a listed drug and biological product

4:45 **The Drug Supply Chain Security Act – Summarizing the Act and Its Effect on FDA Practice**

*Michael A. Walsh*
Partner
Strasburger & Price

- The executive branch's strategy and FDA's pathway for global product supply chain security, safety, and quality
- Overview of the Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act of 2013)
- FDA's Implementation Plan, including timeline for Guidance
- Identifying the scope of the DSCSA
- Outlining the specifics:
  - obligations to create a unique product identifier;
  - establishing tracing and monitoring systems;
  - developing detection and response protocols regarding counterfeit materials;
  - understanding notification obligations;
  - evaluating the effect of the act on the recall process; and
  - penalties.

5:30 **Conference Adjourns to Day Two**

## DAY TWO, FRIDAY, SEPTEMBER 19, 2014

7:15 **Continental Breakfast**

8:00 **Co-Chairs' Opening Remarks and Recap of Day One**

### Post-Approval

8:15 **cGMPs: Drugs and Biologics (current Good Manufacturing Practices)**

*Kirsten Mayer*
Partner
Ropes & Gray

- Examining cGMPs (current Good Manufacturing Practices)and the scope of their importance in pharmaceutical/biological product commercialization
- Looking at how cGMPs factor into the scope of the FDA's authority and history
- Exploring the scope of the FDA's cGMP Initiative and how the concept of "risk-based" cGMPs is defined
- Defining the concept of validation
- How are laboratory investigations in relation to cGMPs conducted?
- Defining the term "quality systems"
- How are cGMPs factoring into products litigation?
- Evaluating the cost of enforcement actions: what happens to company stock when there is an announcement of an enforcement action?

9:00 **Adverse Events Monitoring, Pharmacovigilance and Risk Management**

*Howard L. Dorfman*
Vice President and General Counsel
Ferring Pharmaceuticals, Inc

*David L. Rosen*
Partner
Foley & Lardner LLP

- What is pharmacovigilance?
- How pharmacovigilance uses adverse event reports
  - direct versus indirect reports
  - causality assessments
  - labeling changes
  - pre- and post-market ADE reporting requirements
  - how regulatory agencies use ADE reports
- Risk Evaluation and Minimization Strategies (REMS)
- Risk evaluation in the approval process
- Risk minimization tools
- Enforcement of ADE reporting and REMS requirements
- Examining the relevance to product liability risks

10:00 **Morning Coffee Break**

### Medical Devices

10:15 **Medical Devices: Classifications, the Essentials of the Premarket Review Process, and Post-Market Requirements and Concerns**

*Jennifer L. Bragg*
Partner
Skadden, Arps, Slate, Meager & Flom LLP

*Gael Diane Tisack*
Terumo Cardiovascular Group Vice President of Legal Affairs
& Terumo Americas Vice President of Intellectual Property

**FDA's Risk-Based Classification Scheme**

- Understanding the concept of risk-based classification
- Three main classes of medical devices
- Device reclassification

**The Premarket Review Process**

- Potential changes to 510(k) process and changes to diagnostics
- 510(k) exemptions for low risk devices and the role of the Investigational Device Exemption (IDE)
- Understanding the selection of "predicate" devices when 510(k) submissions are made and the consequences of choosing the wrong predicate
- Premarket approval (PMA) process

**Post-Market Requirements and Concerns**

- What is the scope of the Quality System Regulation (QSR)?
- What are the reporting requirements under the Medical Device Reporting (MDR) and Reports of Corrections and Removals regulations?
- What other types of post-market requirements can FDA impose on medical devices, e.g., tracking?
- What claims can device manufacturers make regarding cleared/approved devices, devices with pending 510(k) notices, and investigational devices?
- What are the consequences of illegal promotion of a device?

### Recalls and Withdrawals

11:30 **Recall Guidance for Drugs, Biologics, and Medical Devices: What You Need to Know**

*Naomi J.L. Halpern*
Senior Regulatory Consulting Attorney
Arent Fox LLP

*Mark Mansour*
Partner
Jones Day

- What is the FDA's recall and oversight authority (overview of 21 CFR Part 7)?
  - guidance versus regulation
  - voluntary recalls versus mandatory recalls
  - market withdrawals and stock recoveries
- What medical device recalls need to be reported to FDA?
- When should a company institute a recall? Can new labeling or a new product warning constitute a recall?
- Working with the FDA versus going it alone
- Interaction between recalls and corrective and preventive action
- FDA seizure and injunction power
- When can product be reintroduced to the market?

12:15 **Conference Concludes***

*** Luncheon will be served for delegates attending the afternoon Master Classes beginning promptly at 12:15**

## POST-CONFERENCE MASTER CLASSES: FRIDAY, SEPTEMBER 19, 2014 | 1:00 P.M. – 5:00 P.M.
## In-Depth Symposia on Hatch-Waxman, BPCIA, and Post-Approval Concerns

These concurrent workshops build on content covered during the main conference relative to Hatch-Waxman, BPCIA, post-approval marketing, and preemption. These detailed master classes will provide enhanced information specific to the intersection of IP and regulatory law, and to litigation and compliance matters, and also help you thoroughly comprehend the complexities and nuances of these areas of regulatory law

- **Master Class B: Hatch-Waxman and BPCIA: Overview of Biosimilars and Life Cycle Planning for Drugs and Biologics** will provide an in-depth overview of biosimilars as well as analyses of bioequivalence and exclusivities and their role in patent and product life cycle management.
- **Master Class C: Post-Approval Marketing Guidance and Preemption Protocols** will address issues that arise post-approval, including advertising, promotion, and off-label promotion and enforcement, as well as preemption fundamentals.

## B Hatch-Waxman and BPCIA: Overview of Biosimilars and Life Cycle Planning for Drugs and Biologics

1:15 **Biosimilars**

*Donald P. Ware*
Partner
Foley Hoag LLP

- Overview of Title VII of the Patient Protection and Affordable Care Act (PPACA, P.L. 111-148), i.e., Biologics Price Competition and Innovation Act of 2009 (BPCIA)
- Biosimilar pathway vs. 505(b)(2) and BLAs
- Defining "biological" and "biosimilars" under BPCIA
- Exploring interchangeability requirements
- Understanding the significance of the methods of making claims in this legislation
- Examining the effect of this abbreviated approval pathway on innovation
- A look at FDA Rule making and guidance relative to biosimilars
- How will biosimilars fit in with life cycle strategies?
  - o targeting R&D efforts
  - o re-examining prosecution efforts
  - o anticipating vulnerable patents and litigation

2:30 **Bioequivalence and the "Same Active Ingredient" vis-à-vis Patentability**

*Adda Gogoris*
Partner
Merchant & Gould

*Clark G. Sullivan*
Partner
Troutman Sanders

- Small molecule patent strategies and their application to biologics
  - o Active ingredient claims
  - o "Purity" claims (impurity profiles, polymorphs
  - o Formulation claims and the Exception Excipient Rule
  - o Analytical method claims and the Supreme Court's Momenta decision
  - o Pharmacokinetic / bioequivalence claims
- Extra hurdles for patenting biologics
  - o Enablement
  - o Written Description
  - o Subject Matter Eligibility
- Bioequivalence v. biosimilarity
  - o What ANDA filers need to show for bioequivalence
  - o Exploring bioequivalence in a BCPIA pathway
  - o Patent opportunities
  - o Relation to doctrine of equivalents and more broadly infringement
    - ▪ Role of "copying"
- What lessons can be applied to biologics from FDA's rating precedent for 505(b)(2) products?
- What lessons can be applied to biologics from FDA's same labeling precedent for small molecules?

3:30 **Afternoon Refreshment Break**

3:45 **Marketing Exclusivities (Non-Patent): Challenges, Opportunities, and Current Controversies**

*David G. Adams*
Partner
Venable LLP

*Jennifer L. Bragg*
Partner
Skadden, Arps, Slate, Meager & Flom LLP

There are a number of different modes and methods of exclusivity (non-patent). This session will outline what they are and what challenges, opportunities, and current controversies arise in relation to them, including the role that the FDA plays in regulating these modes of exclusivity. Modes and methods of exclusivity to be discussed include:

- Orphan Drug Exclusivity (7 years)
- New Chemical Entity Exclusivity (5 years)
- New Clinical Study Exclusivity (3 years)
- Pediatric Exclusivity (6 months)
- First Generic Applicant Exclusivity (180 days)
- New Antibiotic Exclusivity

5:00 **Master Class B Concludes**

## C Post-Approval Marketing Guidance and Preemption Protocols

1:15 **Preemption Fundamentals**

*James Beck*
Partner
Reed Smith LLP

- Defining express and implied preemption
- Recognizing the basis for drug and device preemption
- Uncovering how the presumption against preemption has been applied in drug and device litigation
- Recognizing the interplay between preemption and the FDA regulatory process
- Emerging precedents: *Riegel v. Medtronic* and *Wyeth v. Levine*
- Understanding the "parallel requirements" exception to preemption

2:30 **Advertising and Promotion**

*Dale Cooke*
Vice President/Group Director, Regulatory
Digitas Health LifeBrands

**Advertising and Promotion Overview**

- Overview of laws and regulations controlling the advertising, marketing, and promotion of prescription drugs and biologics
- Office of Prescription Drug Promotion (OPDP) — duties, responsibilities, and enforcement authority
- Evaluating the new guidance on internet promotions and use of social media
- Identifying the role of the FTC in the advertising and promotion of drugs
- Advertising requirements for prescription versus nonprescription products
- Overview of the promotional materials submission and review process
- What constitutes a launch?
- What information must a drug advertisement include?
- Exploring the role of the label in advertising and the perils of off-label promotion

**Special Concerns for DTC Advertising**

- How is direct-to-consumer advertising regulated and monitored?
- What information must every DTC ad contain?
- How do the PhRMA DTC guidelines interplay with current FDA regulation?
- FDA's DTC Television User Fee Program
- Advertising and new media — how is Internet and e-mail advertising regulated?

3:30 **Afternoon Refreshment Break**

3:45 **Regulation and Dissemination of Off-Label Information**

*Carol A. Poindexter*
Partner
Fulbright & Jaworski LLP

*Joseph G. Poluka*
Partner
Blank & Rome LLP

- Overview of the FDA's regulation of off-label promotion
- How can information on off-label or unapproved uses of drugs and biologics be disseminated?
- What are the consequences of inappropriate off-label promotion?
- Survey of recent investigations, penalties, and settlements

5:00 **Master Class C Concludes**

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Basic training in core regulatory concepts for life sciences lawyers, business executives and policy analysts

September 18 – 19, 2014 | Omni Parker House | Boston, MA

**Wednesday, September 17, 2014**
1:00 p.m. – 5:00 p.m.
Pre-Conference Workshop
Workshop A:
Fundamentals of FDA Regulatory Law

**Friday, September 19, 2014**
1:00 p.m. – 5:00 p.m.
Interactive Post-Conference Master Classes:
In depth Hatch-Waxman, BPCIA, and Post-Approval Concerns

Master Class B: Hatch-Waxman and BPCIA: Overview of Biosimilars and Life Cycle Planning for Drugs and Biologics

Master Class C: Post-Approval Marketing Guidance and Preemption Protocols

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APPROVING MANAGER _____ POSITION _____

ORGANIZATION _____

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☐ I would like to receive CLE accreditation for the following states: _____. See CLE details inside.

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### Registration Fee

The fee includes the conference, all program materials, continental breakfasts, lunches and refreshments.

### Payment Policy

Payment must be received in full by the conference date. All discounts will be applied to the Conference Only fee (excluding add–ons), cannot be combined with any other offer, and must be paid in full at time of order. Group discounts available to individuals employed by the same organization.

### Cancellation and Refund Policy

You must notify us by email at least 48 hrs in advance if you wish to send a substitute participant. Delegates may not "share" a pass between multiple attendees without prior authorization. If you are unable to find a substitute, please notify **American Conference Institute (ACI)** in writing up to 10 days prior to the conference date and a credit voucher valid for 1 year will be issued to you for the full amount paid, redeemable against any other **ACI** conference. If you prefer, you may request a refund of fees paid less a 25% service charge. No credits or refunds will be given for cancellations received after 10 days prior to the conference date. **ACI** reserves the right to cancel any conference it deems necessary and will not be responsible for airfare, hotel or other costs incurred by registrants. No liability is assumed by **ACI** for changes in program date, content, speakers, or venue.

### Hotel Information

**American Conference Institute** is pleased to offer our delegates a limited number of hotel rooms at a preferential rate. Please contact the hotel directly and mention the "**ACI – FDA Boot Camp**" conference to receive this rate.

Venue: Omni Parker House
Address: 60 School Street, Boston, MA 02108
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