C5’s Forum on
US FDA Regulation for European Bio-Pharma Industry Players

A Comprehensive and Comparative EU/US Analysis of Key Rules, Systems and Strategies

7th & 8th December 2006 • Millennium Hotel Knightsbridge, London

Leading industry players and their advisors will share their specialist insight on the most important issues, including:

- Key tactics for constructively communicating with the FDA
- Strategic product position, launch and marketing in the EU and US
- Interaction and relationship of the FDA with European agencies
- Best practices for carrying out Clinical Trials in the EU and US
- Successfully complying with EU/US advertising and promotion requirements
- Drugs and biologics labelling in the EU and US
- Strategising the drug approval process and getting what you want
- Comparative analysis of risk management plans and requirements in the EU and US
- Effectively dealing with EU/US pharmacovigilance and post approval marketing
- Outline of key essentials on import/export to the US
- EU/US issues affecting your freedom to operate
- Litigation areas in the US concerning FDA regulations
- Comparative guide on developing and marketing medical devices
- Ensuring commercial compliance

CONFERENCE CHAIRMEN:

Kristine Ogozalek
Regulatory Affairs Manager, Compliance Officer, Lundbeck (USA)

William Vodra
Partner
Arnold & Porter LLP (Washington DC)

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Pharma, biotech and medical device companies are operating in an increasingly international environment. The US is the most important jurisdiction in the world and Europe-based companies must necessarily comply with the US FDA regulations and procedures if they wish to successfully obtain approval, import or market a product in the United States.

This eye-opening conference does not propose to get into the nitty-gritty of FDA rules and regulations but rather guide you through the FDA essentials, comparing the rules in place in the EU and the US, highlighting the systems’ similarities and differences and the way they impact you.

The focus will be on delivering a comprehensive guide on tactical ways to minimise legal and regulatory problems when carrying out business in the States as well as in the EU, saving you time and money. Your experienced speakers will also provide practical advice on how to maximise opportunities and profits.

The program includes incisive topic discussions aimed at outlining best business practices & strategies and learning about how to react when the FDA surprises you or disappoints you. There are sessions which focus on strengthening your knowledge of key comparative compliance and enforcement issues. The debate will also include identifying crucial regulatory issues to help you strategize your actions and optimize results. Also find out more about which areas currently constitute the hot litigation issues which centre on, or are heavily involved with, regulatory issues.

Last but not least, don’t miss out on excellent networking opportunities!

Hear from high-profile experts and authoritative industry players who will offer practical and comprehensive information and insights from their own experiences on:

- How the FDA is structured and organised
- Importance of communicating effectively with the FDA
- Practical considerations for organising a comparative clinical trial study
- Tips on speeding up the drug approval process
- Strategic product positioning in the EU and US
- Outcome and scope of the recent EU/FDA confidentiality arrangement review
- EU/US risk management requirements and developments
- Import/export procedures and set of responsibilities
- Drug safety and adverse events monitoring in the EU and US
- Follow-on biologics/biosimilars and supplementary protection certificates
- Parallels and differences between device and drug regulatory systems
- Differences in EU/US Paediatric legislation
- Litigation trends including federal pre-emption on product liability

Take this opportunity to hear from and network with industry leaders, top experts and colleagues. Be where your industry will be on 7th and 8th December. Register now to secure your place at this event by calling +44 20 7878 6888 or online at www.C5-Online.com/usfdaregulation

WHO SHOULD ATTEND?

- In Bio, Pharma, Medical Device Companies:
  - General Counsel
  - Head of Regulatory Affairs
  - Directors of Clinical Research
  - Compliance Officers
  - IP and Patent Lawyers
  - Marketing Managers

- Private Practice Lawyers Specialising in:
  - Healthcare
  - Life Sciences
  - Product Liability
  - Litigation
  - IP

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Practical Aspects on Successfully Managing and Handling an FDA cGMP Inspection

Stephen Payne
Partner
Sidley Austin Brown & Wood LLP (Washington DC)

FDA has broad authority to inspect any facility that manufactures, processes, packs or holds medical devices. FDA may inspect, without a warrant, any such facility at reasonable times, within reasonable limits, and in a reasonable manner. Moreover, some FDA inspections are unannounced, making advanced preparation necessary to ensure that the process goes smoothly.

It is essential that all establishments understand their rights and responsibilities with respect to FDA inspections, and have in place a detailed plan to prepare for and respond to such inspections. The leader of this masterclass will guide you through some of the major challenges that present themselves when facing an FDA cGMP inspection. This masterclass is designed to provide an in-depth understanding of how the FDA performs inspections, the type of information they are looking to see in place, and the variety of results that can occur from each inspection. You will be given the opportunity to examine the ways to prepare for an inspection, identify the typical trouble spots, pinpoint the crucial do’s and don’ts, and receive practical suggestions on how to deal with and respond to the FDA.

This intensive interactive session will deliver plenty of opportunities to raise questions and discuss the issues that concern you.

Topics covered will include:
- Identifying the issues of cGMP compliance
- Why the industry cares and what it has done in response
- Systems & risk
- Key regulations
  - validation
  - process control procedures
  - data integrity
  - failure investigations
  - lab controls
  - quality unit responsibilities
  - complaint handling
- FDA’s approach
  - US
  - international
- Preparing for an inspection
  - setting up your strategy and procedures
  - roles on the preparation team
  - practice
- Handling the inspection
  - responding to documentation requests
  - escorts and notes
  - other do’s and don’ts
- Responding to inspection observations
- Corrective Action/Preventive Action (CAPA)
- FDA enforcement
- Recalls
- Impact on other government enforcement and private litigation

Thursday 7 December 2006

8:00 Registration and Coffee
9:00 Chair’s Opening Remarks

Kristine Ogozalek
Regulatory Affairs Manager, Compliance Officer, Lundbeck (USA)
Overview of the EU/US clinical trials regime
- Ensuring manufacturing and clinical compliance
  - Good Laboratory Practice (GLP)
  - Good Manufacturing Practice (GMP)
  - Good Clinical Practice (GCP)
- Practical considerations for organising a comparative study in the EU and US
  - discrimination between the EU and US
- Issues relating to obtaining informed consent from clinical trial subjects
  - Recent developments and pipeline initiatives for clinical trials in the EU and US

1.00 Lunch

2:00 Strategic Product Positioning, Launch and Marketing in the EU and US

Nermeen Varawalla
Vice President Corporate Development
PRA International

- Obtaining marketing authorization in the US
  - FDA requirements - efficacy, safety, manufacturing, quality
  - differences from EU
- Understanding the competitor landscape
  - existing alternative products & therapies
  - competitor products in the pipeline
  - generic competition
- Product pricing
  - approaches to determine market pricing
  - third party payers and reimbursements
- Product positioning
  - labelling
  - advertising
  - inclusion on formularies
- Using clinical trials to facilitate product commercialisation
  - efficacy / safety claims
  - establishing superiority over existing treatments
  - KOL, Prescriber and Patient Advocacy Group relationships
  - post marketing surveillance

4:00 Relationship between Industry and the Medical Profession in the US: Identifying and Tackling the Issues

Kristine Ogozalek
Regulatory Affairs Manager/Compliance Officer, Lundbeck USA

- Antitrust laws
- Anti-kickback laws
  - drug samples
  - state laws
- OIG guidance
  - California compliance code
  - PhRMA code guidelines
- CME and grants
- Considerations for the industry
  - documentation
  - training
  - communication

4:45 Drugs and Biologics Labelling in the EU and the US

Gary C. Messplay
Partner, Head of Food and Drug Practice
Hunton & Williams LLP (Washington, DC)

Prof. Lucas Bergkamp
Partner, Business Practice Group
Hunton & Williams LLP (Brussels)

- Key regulatory requirements
  - investigational products
  - advanced therapy
  - paediatric drugs
- EU/US differences and similarities
- Final label and post-market activities
- Liability concerns
- Avoiding the pitfalls

5:45 Closing Remarks of the Chair and Conference adjourns

Friday 8 December 2006
10:15 Useful Tips on Risk Management in the EU and the US: A Comparative Analysis

John Poland
Senior Director, Regulatory Policy
Covance Late Stage Development Services
• Legal status of risk management requirements in the EU and US
• Overview of EU and US requirements for the risk management plan
• Examples of risk management activities
• Future developments
• Resource implications for sponsors

11:00 Morning Refreshments

11.15 Effectively Dealing with Pharmacovigilance: The Fundamentals of Post Approval Marketing

Maurits J.F. Lugard
Partner, Head of EU Regulatory Practice,
Sidley Austin Brown & Wood LLP (Brussels)
Stephen Payne
Partner
Sidley Austin Brown & Wood LLP (Washington DC)
• Overview of EU and US regulatory requirements
• Drug safety and adverse events monitoring
• Recent developments in EU and US drug safety
• Risk management options
• Pharma regulatory tools
  - the company core data sheet
  - mandating new clinical trials
• Post-marketing studies
• Government investigations and enforcement issues

12:15 Lunch

1:15 Outline of Key Essentials for Exporting to the US

Carolyn Kruse
President
Kruse Consulting Group Inc.
• Regulation of exports to the US
• Import procedures
• Standards required
• Manufacturer responsibilities
• Importer responsibilities
• Reasons for detention
• Tips for exporters
• Regulatory actions
  - administrative
  - judicial
• Exporting from the US to Europe
  - key issues and requirements

2:00 EU and US Issues Affecting Your Freedom to Operate?

Maria-Isabel Manley
Partner
Bristows
Maureen Bennett
Partner
Squire Sanders & Dempsey LLP (San Francisco)
• EU/US regulatory exclusivity periods
• Follow-on biologics / biosimilars: where do we stand?
  - what are the legal hurdles to overcome?
  - are the guidelines of any assistance?
• Bolar exemption: what does it cover?
• Supplementary protection certificates update
  - distinction between the EU/US
• Latest jurisprudence
• Paediatric legislation: the differences between the EU/US

3:00 Afternoon Refreshments

3:15 Comparative Guide on Developing and Marketing Medical Devices in the EU and US

William Vodra
Partner
Arnold & Porter LLP (Washington C)
Lincoln Tsang
Counsel
Arnold & Porter LLP (London)
• Overview of US and European Regulatory provisions
• The work of the Global Harmonisation Task Force
• Optimising the regulatory strategy:
  - product classification
  - product claims and substantiation
  - regulatory review requirement options
  - coverage and reimbursement considerations
• Conducting clinical research on experimental devices
• Obtaining government clearance or approval
• Parallels and differences between device and drug regulatory systems
  - good manufacturing practice requirements
  - adverse event monitoring and reporting
  - promotion and marketing restrictions
• Unique risk management issues for devices

4:15 What Are The “Hot Areas” in the United States Concerning FDA Regulations

Joseph Hetrick
Partner
Dechert LLP (US)
• Clinical trials
  - what use are claimants making of clinical trial data
  - how are clinical trial protocols and execution being called into question
  - the use of meta-analyses and sub-analyses in litigation
• Sales and marketing
  - when does marketing cross the line to “over-promotion”
  - what is happening with direct to consumer advertising
  - the fine line between true science and marketing
  - what is permitted concerning off-label uses
• Federal pre-emption of product liability claim
  - several very interesting recent decisions have come down in the United States indicating that traditional product liability claims in the pharmaceutical area may be pre-empted as a may be doomed to failure as a matter of law
  - what are the likely responses to these decisions and what is the true scope of the pre-emption?
• Non-traditional theories of recovery in pharmaceutical litigation
  - medical monitoring
  - securities litigation
  - third party payor suits
  - civil and criminal prosecutions by state and federal governments

5:15 Closing Remarks of the Chair and Conference Ends
US FDA Regulation for European Bio-Pharma Industry Players

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CONFERENCE

DATE: 7th & 8th December 2006
TIME: 9:00 a.m. - Registration and distribution of documentation from 8:30 a.m.
VENUE: Millennium Hotel Knightsbridge
ADDRESS: Knightsbridge, London, SW1X 9NU
TEL.: +44 (02) 20 7235 4377
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MASTERCLASS

DATE: 6 December 2006
TIME: 2:00 p.m. – 5:30 p.m.
CONFERENCE LANGUAGE: English

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CONTINUING EDUCATION

Conference Counts as 17 hours (Masterclass counts as 3 hours) towards Continuing Professional Development hours (Law Society Reference No.: BEJUFO)

DOCUMENTATION

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