PHARMACEUTICAL LAW ACADEMY 2014

A unique, residential programme providing a thorough grounding in pharmaceutical law - equipping you to tackle the sector’s latest legal issues and developments

16th-18th September 2014 • Gonville and Caius College, Cambridge University

Nowhere else will you gain fundamental practical explanations of some of the most complex pharmaceutical law areas alongside advanced commentary and guidance on the latest cases and important recent regulatory developments!

Attend this unique 3 day residential academy in beautiful Cambridge:

- Hear directly from many of those at the forefront of pharmaceutical law in Europe
- Draw on the vast experience of our exceptional speaker panel
- A separately bookable ‘Fundamentals Day’ complimenting the main conference as a crucial introduction or refresher to the overall pharmaceutical law landscape
- Themed interactive learning days focusing on the critical areas within Pharmaceutical law: Regulatory Round-up, Patent Protection & Competition Law
- Social events, including a quiz night, punting, and barbecue
- Valuable practical insights on the fundamental areas of pharmaceutical law including in depth consideration of competition law
- Cutting edge perspectives on recent case law including an SPC focus
- A NEW VENUE with beautifully appointed accommodation
- Unique case studies to consolidate all you’ve learned throughout the day

Don’t miss the opportunity to hear from this leading panel of experts, including:

CHAIRS
- Matthieu Guérineau, Director of the Contract Department, Les Laboratoires Servier
- Jerry Temko, General Counsel, Astellas Pharma

ALSO FROM INDUSTRY
- Marc Christian Bauer, Senior Legal Counsel, Amgen
- Susan Jones, Head Corporate Legal Antitrust, Novartis International AG
- Hilary Jones, Senior Corporate Counsel, European Regulatory Law, Pfizer

PLUS EXPERTS
- Carla Schoonderbeek, Partner, Hoyng Monegier
- Adrian Smith, Partner, Simmons & Simmons
- Peter Bogaert, Partner, Covington & Burling LLP
- Liz Cohen, Partner, Bristows LLP
- Bert Oosting, Partner, Hogan Lovells
- Sally Shorthose, Partner, Bird & Bird
- Marjan Noor, Partner, Simmons & Simmons
- Peter Rowland, Senior Associate, Herbert Smith Freehills
- Marie Manley, Partner & Head of Regulatory, Bristows LLP
- Marina Vickers, Associate in Regulatory Team, Bristows LLP
- Tim Worden, Partner, Taylor Wessing
- Kyriakos Fountoukakos, Partner, Herbert Smith Freehills
- James Killick, Partner, White & Case LLP
- Ruud van der Velden, Lawyer, Hogan Lovells International LLP

UP TO 20 HOURS CPD!
More Than Your Whole Annual Requirement!

Bookings hotline: +44 (0)20 7017 5503
email: professionalcustserv@informa.com
For the latest programme or to register:
www.ibclegal.com/pharma

This brochure has been produced using environmentally-friendly paper sourced from sustainable forests and is bleach-free
DAY 1 - Tuesday 16th September 2014 - Fundamentals Day

09.00 Chair’s Introduction to Pharmaceutical Law
Matthieu Guérineau, Director of the Contract Department, Les Laboratoires Servier

09.30 The Pharmaceutical Legal Framework
• The pharmaceutical legislation and process
• What is the role of the European Council, Commission and Parliament?
• European decision making system: comitology
• What are the different types of comitology procedures?
• What is the role of the Standing Committees?
• What does the comitology register contain?
• The EU Courts – preliminary rulings and dispute resolution
• The European Medicines Agency and its role in relation to national regulatory agencies
Carla Schoonderbeek, Partner, Hoyng Monegier

10.20 Understanding Clinical Trials
• What are they?
• When do they occur?
• What are the legal pitfalls
Liz Cohen, Partner, Bristows LLP

11.10 Morning Coffee

11.30 An Introduction to Marketing Authorisations
• Defining Marketing Authorisations and procedures under EU law
Marc Christian Bauer, Senior Legal Counsel, Amgen

12.15 Supplementary Protection Certificates Explained
• What are SPCs?
• Grounds and requirements
• When are they useful
Bert Oosting, Partner, Hogan Lovells International LLP
Ruud van der Velden, Lawyer, Hogan Lovells International LLP

13.00 Lunch

14.00 An Introduction to Advertising Medicinal Products for Human Use
• What are the features?
• What are the issues?

14.45 An Introduction to Pharmacovigilance
• What is Pharmacovigilance and why is it so important?
Sally Shorthose, Partner, Bird & Bird

15.30 Afternoon Tea

15.50 Introduction to Trademarks in the Pharmaceutical Field
• Relevance and importance of trademarks for pharmaceuticals
• Trademark choice, clearance, registration and the challenges for pharmaceutical marks
• Trademark conflicts and disputes
Adrian Smith, Partner, Simmons & Simmons

16.40 Introduction to Competition Law in the Pharmaceutical Sector
• Why is Competition law so important?
• When is it a problem
Kyriakos Fountoukakos, Partner, Herbert Smith Freehills
Susan Jones, Head Corporate Legal Antitrust, Novartis International AG

19.00 Dinner and Quiz

DAY 2 - Wednesday 17th September 2014 - Regulatory Round-up

09.00 Chair’s Introduction
Matthieu Guérineau, Director of the Contract Department, Les Laboratoires Servier

09.20 Clinical Trials - What to expect from the New Regulation?
• Why a new Regulation?
• What will it mean?
• Legal aspects of conducting clinical trials
• Trial subject confidentially and privacy
• The new data base and transparency of clinical trial data
• The wider context of transparency of trial data
Peter Bogaert, Partner, Covington & Burling LLP

10.10 The Pharmacovigilance & Risk Management
• Changes to legal responsibilities
Sally Shorthose, Partner, Bird & Bird

11.00 Morning Coffee

11.20 Regulatory Data Protection and Other Related Issues
• Principles of regulatory data protection
• New active substance and known active substance: scientific and regulatory assessment, designation and consequences
• The concept of the global marketing authorisation
• Regulatory Data Protection for known active substances and combination products
• Case law and pending cases:
  - The Lundbeck – escitalopram and Sepracor – Lunivia cases
  - The Teva combination case
  - The Novartis zoledronic acid cases
• Market exclusivity for orphan drugs – derogation and reduction
• Paediatric rewards
Carla Schoonderbeek, Partner, Hoyng Monegier

12.10 Biosimilars
• The role and nature of biologic products
• Legislative framework for biosimilar applications
• Track record of biosimilar applications
• Naming and substitution of biosimilars
• Biosimilars vs Biobetters: patent, data exclusivity and SPC issues
Marjan Noor, Partner, Simmons & Simmons

15.30 Afternoon Tea

16.40 Introduction to Trademarks in the Pharmaceutical Field
• Relevance and importance of trademarks for pharmaceuticals
• Trademark choice, clearance, registration and the challenges for pharmaceutical marks
• Trademark conflicts and disputes
Adrian Smith, Partner, Simmons & Simmons

19.00 Dinner and Quiz
13.00 Lunch

14.00 The EU Paediatric Regulation
- Reminder of scope of the EU Paediatric Regulation
- Five year review of the Regulation
- Rewards system: challenges and opportunities for the industry:
  - The PUMA concept
  - Balance between obligations and rewards
- Recent case law
- Financial Penalties for paediatric products

Hilary Jones, Senior Corporate Counsel, European Regulatory Law, Pfizer

14.50 Regulatory Case Study
The case study will thread together the IP regulatory rights issues discussed throughout the day in one highly practical example.

Marie Manley, Partner & Head of Regulatory, Bristows LLP
Marina Vickers, Associate in Regulatory Team, Bristows LLP

15.50 Afternoon tea

16.10 Debate on Case Study
Our expert panel will lead an interactive discussion on the issues raised in the case study and offer their experiences and practical suggestions for tackling them

Moderator: Marie Manley, Partner & Head of Regulatory, Bristows LLP
Sally Shorthose, Partner, Bird & Bird
Marc Christian Bauer, Senior Legal Counsel, Amgen
Hilary Jones, Senior Corporate Counsel, European Regulatory Law, Pfizer

18.00 Punting and BBQ (weather permitting)

DAY 3 - Thursday 18th September 2014 - Patent Protection and Competition Law

09.00 Chair’s Introduction
Jerry Temko, General Counsel, Astellas Pharma

09.20 Advertising of Prescription-Only Medicines and Interactions with Healthcare Professionals in the EU
- An overview of EU legislation and the industry self-regulatory framework
- EU caselaw highlights
- Distinguishing between promotional and non-promotional activities
- Interactions with healthcare professionals: summary of key legal and compliance aspects

Marc Christian Bauer, Senior Legal Counsel, Amgen

10.00 Advertising Law and Compliance - Questions for the Panel
Marc Christian Bauer, General Counsel, Astellas Pharma
Jerry Temko, General Counsel, Astellas Pharma

10.10 SPCs – European Case Law Update
An introduction to the SPC Regulation and the scope of the SPC Regulation:
- What do the CJEU’s rulings in Synthon and Generics mean in practice?
- Conditions for obtaining an SPC
- Does the Medeva line of cases leave anything unresolved for combination products?
- Article 3(d) and the Neurim case
- Duration of the SPC
- Scope of the SPC
- The Novartis case (Articles 4 and 5)
- Interaction with the Paediatric Regulation

Marie Manley, Partner & Head of Regulatory, Bristows

11.00 Patent Update
- Trends emerging in the English Patents Court
- Recent Pharma Patent Decisions
- Are our judgments becoming more harmonised with German, French and Dutch decisions?
- What does the litigation future hold?

Liz Cohen, Partner, Bristows LLP

11.45 Morning Coffee

12.05 Dealing Effectively With Parallel Trading Issues
- Parallel imports in Europe – latest legal update
- Exhaustion of rights
- Modifying original packaging: what are the rules?
- Repackaging and re-labelling issues
- Impact of the Syfrait v GSK (the GSK Greece case)

Tim Worden, Partner, Taylor Wessing

12.55 EU Vertical and Horizontal Block Exemption Regulations
Implications for the Pharmaceutical Industry
- Vertical Restraints: - Definition of an Agreement under EU Competition Law
- Resale Price Maintenance
- Horizontal Restraints: - Information Exchange
- R&D Agreements
- Specialisation Agreements
- Standard Setting

James Killick, Partner, White & Case LLP

13.20 Lunch

14.20 Pharma Sector Competition Law Developments
- Investigation and raids in the pharma sector
- The EC Pharma Sector Enquiry
- What has changed in the practice following the EC Sector Inquiry?
- The Commission’s latest stance on anti-competitive practices and patent settlement agreements
- The AstraZeneca case and the notion on dominance

James Killick, Partner, White & Case LLP
Peter Rowland, Senior Associate, Herbert Smith Freehills

15.10 Competition Law and IP Rights Case Study
The case study will thread together the issues already discussed throughout the day in one example with a principally competition law focus.

Bert Oosting, Partner, Hogan Lovells International LLP

16.00 Afternoon Tea

16.20 Debate on Case Study
Our expert panel will lead an interactive discussion on the issues raised in the case study and offer their experiences and practical suggestions for tackling them

Moderator: Bert Oosting, Partner, Hogan Lovells International LLP
James Killick, Partner, White & Case LLP
Marjan Noor, Partner, Simmons & Simmons
Jerry Temko, General Counsel, Astellas Pharma
Susan Jones, Head Corporate Legal Antitrust, Novartis International AG

17.20 Close of Conference
Special 20% discount available

Quote VIP Code FKW82478EMSPK:

WHEN AND WHERE

FKW82478

Tuesday 16th – Thursday 18th September 2014

Venue: Gonville and Caius College, Trinity St, Cambridge

CB2 1TA

The price per delegate includes full-board accommodation (Tuesday and Wednesday night), all meals (except drinks at the college bar) and evening networking activities. Additional nights accommodation is priced at £89.00 plus VAT and is on a first come, first served basis. To book please contact sarah.cole@ibclegal.com. Additional accommodation at the college is subject to availability.

PERSONAL DETAILS

1st Delegate Mr/Mrs/Ms

Job title Department Telephone Fax Email

Yes! I would like to receive information about upcoming events by email. By giving you my email address I am giving ONLY Informa companies the permission to contact me by email.

2nd Delegate Mr/Mrs/Ms

Job title Department Telephone Fax Email

Yes! I would like to receive information about upcoming events by email. By giving you my email address I am giving ONLY Informa companies the permission to contact me by email.

3rd Delegate Mr/Mrs/Ms

Job title Department Telephone Fax Email

Yes! I would like to receive information about upcoming events by email. By giving you my email address I am giving ONLY Informa companies the permission to contact me by email.

COMPANY DETAILS

Company Name

Postal Address

Telephone Fax

Nature of Business

Billing Address (if different from above address)

Billing Email Address:

UNABLE TO ATTEND - EVENT DOCUMENTATION

Nothing compares to being there - but you need not miss out! To order your online documentation simply tick the box, complete your details above and send the form along with payment.

Pharmaceutical Law Academy 2014 - £395 + VAT (20%)

Documentation orders can only be processed on receipt of credit card details. To ensure we provide the highest level of security for your credit card details we are unable to accept such payments via email or fax, which ensures that these details are never stored on our network. To make payment by credit card on-line, please enter your credit card details in our secure payments website that you will use when making your booking via the event website (the event web address is near the top of the booking form).

Alternatively call our customer service team on +44 (0) 20 7017 5503.

In the event of any changes to the event terms and conditions which can be found on our website. By completing and submitting this registration form, you confirm that you have read and understood the IBC Legal Delegate Terms and Conditions and you agree to be bound by them.

FKW82478

Please quote the above VIP code when registering.

T bounding box is subject to change without notice and may be amended at the absolute discretion of the organiser. The organiser reserves the right to vary or cancel the event or to change any details of the event at any time and for any reason, whether or not due to a force Majeure event, in such case without liability.

Data protection: The personal information which you provide to us will be held on a database. You agree that IBC Legal may share this information with other companies in the Informa Group or selected third parties who require it in connection with your attendance at the event. If you do not wish your details to be available to any companies outside the Informa Group, or selected third parties, please contact the Database Manager, Informa UK Limited, Maple House, 194 Euston Road, London, NW1 2BS UK. Tel: +44 (0) 20 7717 7777 or fax: +44 (0) 20 7717 7828 or email integrity@ibclegal.co.uk. Informa UK Limited is registered in England and Wales No: 1835199. Registered Office: 37-41 Mortimer Street, London W1T 3JH. VAT Registered No: (GB) 365 4626 36. IBC Legal Conferences is part of IIR Limited.