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BUSINESS SEMINARS

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MANAGEMENT forum

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A concise one-day seminar

Drafting and Negotiating Clinical Trial Agreements

16 May 2017 • 7 November 2017 London

Key topics covered in this seminar:

- Overview of the legal/policy landscape as it affects the terms of clinical trial agreements
- The typical clauses that make up a clinical trial agreement
- How to recognise and tackle key commercial and regulatory issues that arise
- Drafting and negotiating techniques to minimise disputes and maximise efficiency

'The training was useful and informative'

Shinichi Nishimura, Clinical Liaison Manager, Chugai Pharma Europe Ltd

'A good program and atmosphere for open discussion'

Marie Anne Punchard, Clinical Project Manager, TiGenix

'Very Informative, good coverage, content was comprehensive'

Drew Stafford, Contracts Associate, Quotient Clinical

Drafting and Negotiating Clinical Trial Agreements

16 May 2017 • 7 November 2017, London

Clinical trial agreements are some of the most important agreements for life sciences companies and the pharma industry. Clinical testing of new products cannot start until the sponsor and health care organisation have entered into an agreement, and the legislation and guidance set out details of what these agreements should include. If appropriate arrangements are not in place, a trial may not receive approval, or issues may arise with the integrity or validity of the data collected. Clinical trial agreements are therefore key to managing the relationships, risks and responsibilities of the parties involved, and ensuring that each party's interests are protected.

This intensive one-day programme, delivered by experts in the field, will provide you with an understanding of the key components of clinical trial agreements, where issues typically arise and how to resolve them. Through the use of a case study throughout the day, you will look at some of the typical clauses and issues that can arise, and consider these issues for your 'client'. There will also be an opportunity to practice negotiating specific clauses on behalf of your 'client'. By the end of the programme, you will be more confident in spotting and addressing the key issues that arise when negotiating and drafting clinical trial agreements.

Why should you attend?

This seminar will enable you to:

- **Recognise and address** the issues that arise when drafting and negotiating clinical trial agreements
- **Gain a better understanding** of the legal, contractual and practical issues that affect clinical trial agreements
- **Consider the issues** through the differing perspectives of sponsors and health care organisations
- **Complete practical exercises** on drafting and negotiating to consolidate your learning

Who should attend?

- Contract managers
- Clinical contract specialists
- Clinical trial managers
- R&D staff
- Regulatory specialists
- Lawyers and in-house legal teams
- Legal executives

Supporting documentation

Participants will receive supporting documentation that will be a valuable source of reference for the future. These course materials will include examples from pharmaceutical company clinical trial agreements, from the UK National Health Service model clinical trial agreements, and from other commonly used agreements.

'Well presented course with a good program and atmosphere for open discussion'

Marie Anne Punchard, TiGenix

Expert faculty

Jackie Mulryne is an Associate in the life sciences group at Arnold & Porter. She has a broad practice providing regulatory compliance and public policy advice, and has extensive experience advising commercial clients on clinical trial agreements, both within and outside the NHS, and variations across the EU.

Ewan Townsend is an Associate in the life sciences group at Arnold & Porter. He specialises in drafting, negotiating and advising on many of the common commercial contracts used by life sciences companies, as well as advising on regulatory matters, with a special interest in issues around manufacture, distribution and supply.

Adela Williams is Partner in the life sciences group at Arnold & Porter, and advises clients in relation to the regulation of medicinal products in the UK and at the EU level. She regularly advises on clinical trial issues and represents clients in product liability litigation arising from use of medicines in the research context.

ARNOLD & PORTER

Arnold & Porter LLP is an international law firm with over 800 attorneys in the USA, London and Brussels. The EU life sciences team has unrivalled experience in advising on every aspect of the regulation of medicines, devices, cosmetics, foods and borderline products. The team includes a number of lawyers with scientific qualifications, including two physicians. It is regularly ranked as the leading firm providing regulatory advice and specialist litigation services to the life sciences sector.

Dates and venue

16 May 2017
7 November 2017
The Rembrandt Hotel
11 Thurloe Place
London SW7 2RS
Tel: +44 (0)20 7589 8100
Web: www.sarova-rembrandthotel.com

The Rembrandt Hotel is directly across from London's Victoria and Albert Museum (V&A), within a 10 minute walk of the Natural History Museum, Science Museum, Hyde Park, Harrods and the Royal Albert Hall. The location is superb – surrounded by restaurants, bars, shops and cultural attractions. The venue's beautifully modernised Edwardian rooms were originally apartments for Harrods. You can stroll to South Kensington underground station in five minutes. From here, District, Circle and Piccadilly Tube lines take you straight to the City of London, Heathrow Airport and mainline train stations including Paddington and Victoria.

Accommodation

We have arranged a preferential rate for accommodation at this venue. To take advantage of this please contact: **reservations_rembrandt@sarova.com** and quote **FALCON**. There are limited rooms available at this rate so please book early.

For alternative accommodation solutions please visit our website: **falconbury.co.uk/accommodation**

Schedule

Registration will take place from 09.00-09.30. The course will start at 09.30 and finish at 17.00. One hour for lunch and two 15-minute refreshment breaks will be scheduled during the day.

The programme

9.00 Registration and refreshments

9.30 Introduction and outline of the programme

9.35 Overview of the legal/policy landscape as it affects the terms of CTAs

- What is a clinical trial?
- EU regulatory framework: What are the key regulatory considerations relevant to conducting a clinical trial?
- Introduction to the parties to the CTA and key roles and responsibilities
- Policy issues in public hospitals, e.g. UK NHS approval
- Other ethical/legal issues
- Standard contracts, e.g. NHS standard CTA
- Implications of Brexit

11.00 Refreshments

CASE STUDY

11.15 Negotiating and drafting CTAs

- Overview of issues that frequently come up in the negotiation/drafting of CTAs
- Introduction to case study
- Discussion of case study:
  - Definitions
  - Intellectual property and publication provisions
  - Use of data generated during the trial
  - Data protection, medical records, freedom of information, etc

12.45 Lunch

CASE STUDY

13.45 Negotiating and drafting CTAs

- Continued discussion of case study:
  - Manufacture of the investigational medicinal product
  - Warranties and indemnities
  - Liabilities and insurance requirements
  - Termination and its consequences

15.15 Refreshments

15.30 Additional considerations

- Introduction to differences between US, UK and Continental European legal systems and how they may affect contract drafting
- Unlicensed product vs off-label use
- First-in-man studies
- Investigator initiated studies
- Compliance and anti-corruption issues

16.00 Negotiation exercise

16.45 Closing remarks and questions

17.00 Close of seminar

'The training was useful and informative'

Shinichi Nishimura, Clinical Liaison Manager, Chugai Pharma Europe Ltd

'Interactive, energised and unconventional'

Raquel Rocha, Jurista, Sonae Center Servicos II

Falconbury In-house training

This exceptional training programme can be run for your whole in-house legal or contracts department at your offices or at any location of your choice. Running this event as an in-house programme is a cost-effective way of training four or more executives from your organisation. Our experts will come to you, saving your organisation time and money.

For your FREE consultation and to find out more about how we can work with you to solve your training needs please contact **Customer Services** on **+44 (0)20 7729 6677** or email **inhouse@falconbury.co.uk**

40% discount

We offer a 40% discount on the registration fee for members of universities, not-for-profit organisations and charities. Please claim the discount when you register.

THIS COURSE QUALIFIES FOR **6**CPD HOURS

A certificate of attendance for professional development will be available for each participant who completes the seminar.

Book before 14 March 2017 and SAVE £100/€140!

Drafting and Negotiating Clinical Trial Agreements

To book online go to: falconbury.co.uk/1948

Dates and venue

16 May 2017 **Ref: 9839**

7 November 2017 **Ref: 9954**

The Rembrandt Hotel
11 Thurloe Place
London
SW7 2RS
Tel: +44 (0)20 7589 8100
Web: www.sarova-rembrandthotel.com

Accommodation

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For alternative accommodation solutions please visit our website: **falconbury.co.uk/accommodation**

Three ways to book

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Fees and payment

EARLY BOOKING DISCOUNT — **Book BEFORE 14 March 2017**
£549.00 + VAT = £658.80 • **€769.00 + VAT = €922.80**

FULL PRICE — **Book AFTER 14 March 2017**
£649.00 + VAT = £778.80 • €909.00 + VAT = €1090.80

Multiple booking discount for 2nd or subsequent delegates – 15%
£551.65 + VAT = £661.98 • €772.65 + VAT = €927.18

Payment options

1. Invoice which can be paid by BACS (for bank account details please see the section in 'The Small Print' below) or by credit card to Falconbury Ltd.
2. Online through our secure website when registering.

Run this programme In-house for your whole legal team

A public training programme may not be the solution for your legal and commercial team. It may be more appropriate to involve only attendees from your organisation and tailor the programme to focus on the management challenges you face as a business.

If you have a legal and commercial team of five or more who can benefit from this training you might want to consider an in-house training solution. We bring our expert(s) to you, at a time and location of your choice, and can tailor this training to your specific needs through specially created scenario's and role-play's. The savings are significant when compared with multiple delegates on the public event.

To get a FREE consultation and to find out how we can work with you call **Customer Services** on **+44 (0)20 7729 6677** or email **inhouse@falconbury.co.uk**

To find out more please visit: **falconbury.co.uk**

Falconbury registered address: 10-12 Rivington Street, London EC2A 3DU. Company No. 3997398

The Small Print

FEE: The fee includes all meals and refreshments for the duration of the course and a complete set of course materials. If you have any particular requirements please advise customer services when booking.

HOW TO REGISTER AND PAY: A VAT invoice and booking confirmation will be sent within 7 days, please contact us if you have not heard anything after that time. Payment can be made by credit card or by bank transfer (for bank account details please see bank account details section). VAT no. 770008751. Any questions please contact Customer Services on +44 (0)20 7729 6677. ALL PAYMENTS MUST BE RECEIVED IN ADVANCE OF THE EVENT.

VAT RECLAIM INTERNATIONAL DELEGATES: If you are attending the course from outside the UK you can reclaim the VAT payable through HM Customs and Excise please visit their website at www.hmrc.gov.uk for a downloadable form or contact our customer services on info@falconbury.co.uk for more information.

MULTIPLE BOOKING DISCOUNTS: This discount may not be used in conjunction with any other offer.

CANCELLATIONS AND TRANSFER: Once we have received your booking the place(s) are confirmed.

Delegate	Up to 28 days before course	27 to 14 days before course	13 to 0 days before course
Cancellation	10% admin fee	100% admin fee	100% admin fee
Transfers	Free	10% admin fee	100% admin fee
Substitution	Free	Free	Free

A maximum of one transfer is allowed. After the transfer no cancellation can be accepted and the full invoiced fee will be charged. Transfers are subject to payment of the difference on higher value courses.
All cancellations must be received in written form.

PLEASE NOTE: Falconbury Ltd reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. If in the unlikely event that the course is cancelled Falconbury will refund the full amount and disclaim any further liability.

DATA PROTECTION: The personal information provided by you will be held on a database. Sometimes your details may be made available to external companies for marketing purposes. If you do not wish your details to be used for this purpose please email: **info@falconbury.co.uk**

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