DRAFTING AND NEGOTIATING CLINICAL TRIAL AGREEMENTS

16 July 2015, Conf No L7-5015

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MANAGEMENT FORUM

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Registration Information

Dates
16 July 2015 Start: 09.30 – Finish: 17.00

Registration & Coffee
16 July 2015 09.00

Venue and Accommodation
The Rembrandt Hotel, 11 Thurloe Place,
London SW7 2RS
Hotel Tel: +44(0)20 7589 8100
Hotel Fax:+44(0)20 7225 3476
Email: ***reservations_rembrandt@sarova.co.uk***
Subject to availability, a limited number of bedrooms have been reserved at the hotel at a special rate.

All bookings should be made directly with the hotel or online at *www.sarova.com/rembrandt* quoting promo code 'manforum'.

Directions
Opposite V&A Museum. Nearest underground station: South Kensington.
www.sarova-rembrandthotel.com/location-local-attractions

Fee
£598 + VAT if applicable. The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.

15% Early Bird Discount if booked before 1 June 2015

Conference No. L7-5015

For Cancellation Policy and T&Cs see website
NB: Cancellations must be received in writing by ***registrations@management-forum.co.uk***

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To Register

If you have NOT received confirmation seven days after registering please contact ***registrations@management-forum.co.uk***

Discounted Rates
Available on application for personnel from non-profit making organisations and registered charities.
Group discount available on request

If you do not want to receive future mailings from Management Forum please contact ***nick@management-forum.co.uk***
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MANAGEMENT FORUM

DRAFTING AND NEGOTIATING CLINICAL TRIAL AGREEMENTS

6 CPD HOURS

Covering topics such as:

- How the regulatory environment affects the content of clinical trial agreements
- Recognising and addressing issues that arise when negotiating and drafting clinical trial agreements
- The typical clauses in a clinical trial agreement
- Key differences in international clinical trial agreements (Europe and the US)
- Handling other clinical trial documents with a legal element

Seminar Leaders:

Mark Anderson Anderson Law LLP
Christine Bendall Pharview Ltd

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Register online at www.management-forum.co.uk or by phone on +44 (0)1483 730071, fax 730008

CPD CERTIFIED
The CPD Certification Service

16 July 2015
The Rembrandt Hotel, London

WHY SHOULD YOU ATTEND?

- Recognise and address the issues that arise when drafting and negotiating international clinical trial agreements (CTAs)
- Gain a better understanding of the legal, contractual and practice issues that affect CTAs concerning investigational medicinal products
- View the issues through the differing perspectives of sponsors, universities, hospitals and individual organisations
- Complete practical exercises on drafting to consolidate learning

* **Materials will include examples from pharmaceutical company CTAs, from the UK National Health Service standard CTA, and from other commonly used CTAs**

WHO SHOULD ATTEND?

- Contract Managers
- Clinical Contract Specialists
- Clinical Trial Managers
- R&D Staff
- Regulatory Specialists
- Lawyers
- Legal Executives

NB - 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.

SEMINAR LEADERS

Mark Anderson is an English solicitor (attorney) and former barrister who has over 25 years' experience of advising companies in technology-based industries, including pharmaceuticals, biotechnology and information technology.

Christine Bendall is a solicitor (non practising), and a regulatory consultant and Managing Director at Pharview Ltd. She has specialised in the law relating to the healthcare industry and the regulation of medicinal products since 1989.

ACCREDITATION

This seminar merits **6 hours** under the UK Solicitors Regulation Authority **self-accreditation scheme (ref. CJA/MAFO).**

DOCUMENTATION

Participants will receive a folder containing comprehensive documentation provided by the seminar leaders, which will be a valuable source of reference for the future.

A Certificate of Attendance for Professional Development will be given to each participant who completes the seminar

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Programme

09.30 ▶ **Introduction**
- Outline of today's programme
- Overview of issues that frequently come up in negotiation / drafting of CTAs

09.45 ▶ **Overview of the Legal/Policy Landscape as it affects the terms of CTAs**
- EU regulatory framework: What are the key regulatory considerations relevant to conducting a clinical trial?
- Policy issues in public hospitals, e.g. UK NHS approval (if NHS facilities, staff, patients, etc)
- Other ethical/legal issues (including regulation of consultancy terms)
- Standard contract terms, e.g. NHS standard CTA, ABPI indemnity
- Liability insurance requirements
- Employment law, intellectual property law and contract terms for investigators
- Data protection, medical records, freedom of information, etc

11.00 ▶ **Coffee**

11.15 ▶ **Clause-by-Clause Review**
- Who are the parties to the CTA?
- Roles of the hospital, investigator, university, CRO, drug manufacturer, sponsor, et al.
- Work obligations and payments
- Terms dealing with regulatory issues, e.g. pharmacovigilance
- Intellectual property provisions
- Termination and its consequences
- Other terms

12.00 ▶ **Drafting Exercise *followed by Lunch***

13.45 ▶ **Clause-by-Clause Review continued, including "Legal" Clauses**
- Overview of some differences between US, UK and Continental European legal systems and how they affect contract drafting
- Choice of law and jurisdiction in the CTA
- Liability terms: Warranties, representations, covenants, indemnities, etc
- Liability, indemnities and insurance in CTAs

15.15 ▶ **Tea**

15.30 ▶ **Other Documents with a Legal Element**
- Patient and donor consent forms
- Subcontracting and consultancy agreements
- Drug supply agreements
- CRO agreements
- Data archiving agreements
- Protocol, technical agreement, etc
- Insurance policies

16.15 ▶ **Review of a University's CTA – Group Discussion**
- What is the role of each party?
- Terms that would not be acceptable or desirable for the sponsor
- Terms that are essential or desirable for the university
- How should these terms be negotiated?

17.00 ▶ **Close of Seminar**