Book before 21 September 2018 and SAVE £100 / €140

Intellectual Property for Pharma Regulatory Affairs

To book online go to: **management-forum.co.uk/2364** W

Dates and venue

5 November 2018 **Ref: 10296**
8 May 2019 **Ref: 10434**

The Rembrandt Hotel
11 Thurloe Place
London SW7 2RS
Tel: +44 (0)20 7589 8100

Programme schedule

Registration and refreshments:	09.00
Start of course:	09.30
Close of course:	17.00

Accommodation

We have arranged a preferential rate for accommodation at the venue. To take advantage of this please state you are a Management Forum delegate. There are limited rooms available at this rate so please book early to avoid disappointment.

Email: reservations_rembrandt@sarova.co.uk
Web: www.sarova-rembrandthotel.com

For information on alternative accommodation please visit our website:
management-forum.co.uk/accommodation

Three ways to book

management-forum.co.uk | **info@management-forum.co.uk** | **+44 (0)20 7749 4730**

Fees and payment

EARLY BOOKING DISCOUNT **Book BEFORE 21 September 2018**
£599.00 + VAT = £718.80 • €839.00 + VAT = €1006.80

FULL PRICE **Book AFTER 21 September 2018**
£699.00 + VAT = £838.60 • €979.00 + VAT = €1174.80

Multiple booking discount for 2nd or subsequent delegates - 15%
£594.15 + VAT = £712.98 • €832.15 + VAT = €998.58

Payment options

1. Invoice which can be paid by bank transfer or credit / debit card
2. Online through our secure website when registering

In-house TRAINING

Management Forum In-house training

Coming to Management Forum for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

To get a **FREE** consultation and to find out how we can work with you call **Aleksandra**, our in-house training expert, on **+44 (0) 20 7749 4730** or email ***inhouse@management-forum.co.uk***

To find out more please visit: ***management-forum.co.uk***

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.

PLEASE NOTE: Management Forum 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. In the unlikely event that the course is cancelled Management Forum will refund the registration fee and disclaim any further liability.

For event cancellation policy and T&Cs see our website

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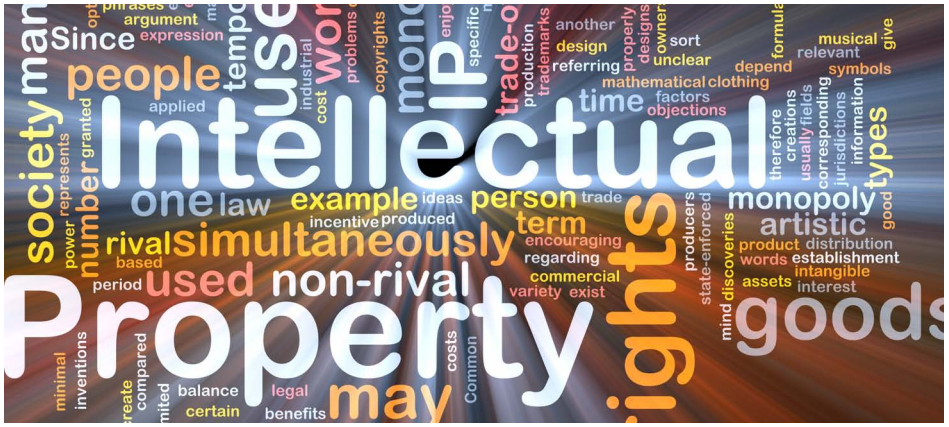
MANAGEMENT forum

Intellectual Property for Pharma Regulatory Affairs

Understand the impact of IP on regulatory strategy

5 November 2018 • 8 May 2019 London



Benefits in attending:

- **Gain** an overview of IP and how it contributes to a company's overall regulatory strategy
- **Understand** key IP issues including patents, copyright and freedom to operate and how they impact on regulatory affairs
- **Discuss** data and market exclusivity for global pharmaceutical products
- **Discuss** EU & FDA regulatory processes, their differences and the link to patents

Expert trainer:
Andrew Willis, Independent Consultant in Advanced Regulatory Affairs and Pharmaceutical Development

Includes: Interactive discussion session

CPD CERTIFIED The CPD Certification Service

Intellectual Property for Pharma Regulatory Affairs

5 November 2018 • 8 May 2019, London

Why should you attend?

This practical one day course will provide an overview of Intellectual Property (IP) for those working in regulatory affairs. IP is a fundamental contributing factor to the overall regulatory strategic approach that a company may take and recognition of the different aspects of IP and influences is essential in modern regulatory affairs. Attendance will enable you to understand IP aspects and their impact and influence on regulatory strategy. Key issues covered will include patents, trademarks and copyright as well as data and market exclusivity for global pharmaceutical products. The course will also discuss the EU and FDA regulatory process, highlighting one of the fundamental differences between EU and US systems and the link to patents.

Who should attend

This seminar will be of interest to development and regulatory managers working in the pharmaceutical industry. It will also be relevant to anyone requiring an overview of the key IP issues relating to regulatory affairs.

Expert trainer

Andrew Willis, currently works as an independent consultant providing expert advice and training on global regulatory solutions and pharmaceutical development. Previously, Andrew worked for Catalent Pharma Solutions as VP Regulatory Affairs and Consulting Services. Catalent is the world's leading contract manufacturer and distributor of pharmaceuticals, and Andrew was head of a team of internal and external regulatory affairs consultants.

Andrew qualified as a Chemist from the University of Glamorgan, after which he furthered his understanding of pharmaceutical development, working as a research chemist with Parke Davis. He has ten years manufacturing and analytical experience prior to entering regulatory affairs as a Senior Executive Officer with responsibility for submission of European MAAs and project management of development programs.

Andrew currently has a total of twenty eight years pharmaceutical experience with extensive knowledge in the development and manufacture of sterile, solid oral, inhalation, topical and biotech pharmaceutical products. These experiences have allowed knowledge of many biotech products requirements with experiences of growth hormones and multiple cancer treatments, including development and clinical registration of the first genetically modified live bacterium for such treatment.

A certificate of attendance for professional development will be available to each participant who completes the course

Programme

- **Introduction and welcome**
- **What is Intellectual Property (IP)**
  - An overview of:
    - Patents
    - Exclusivity
    - Copyright
    - Trade secrets
- **What is a patent**
  - Defining the patent
  - Uses of a patent
  - Patents and generic developments
  - Generic legislation for the EU
  - Understanding freedom to operate
- **Global exclusivity**
  - Data exclusivity in the US
  - Data and market exclusivity in the EU
  - Global overview of exclusivity
- **Influence of IP on regulatory strategy**
  - US paragraph
  - Patent declaration
  - Overlap of patents and exclusivity
- **Product naming and trademarks**
- **Copyright**
  - The influence and impact on regulatory affairs
- **Practical exercise on FDA regulatory process and link to patents**
- **Special cases**
  - Paediatric legislation
  - Orphan drugs
- **Use of patents in development strategy**
- **Close of meeting**

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