IPI Academy

falconbury



*Presented by*
**Falconbury**

# Drafting Commercial Contracts for the Pharmaceutical Industry

**19-20 May 27**
+ 10-11 November 27

A two-day practical and interactive training course focusing on current contract drafting, negotiating, best practice and related issues within the pharmaceutical, biotech and life sciences sectors.

**Format:**
Classroom, Live online

**CPD:**
12 hours for your records

Certificate of completion

# Course overview

**In such a highly regulated industry and in these turbulent and uncertain times, understanding the key challenges of negotiating and drafting an effective and watertight contract on an international level are complex topics.** They can be difficult for even the most well-equipped in-house lawyer and most often it is not the lawyer in the driving seat.

Commercial managers from all areas of the pharmaceutical industry are leading negotiations and drafting and managing key contracts on a daily basis. It is vital that both legal counsel and commercial executives not only have the key skills and tactics to create a win:win scenario but also the knowledge to ensure any agreement is within current laws and regulations. The alternative is the exposure of the organisation to unnecessary risk and costly disputes.

This training programme will:

- **Deliver** an in-depth examination of intellectual property issues that affect pharmaceutical industry agreements
- **Focus** on competition regulations pertinent to pharmaceutical industry agreements
- **Analyse** the commercial and legal issues affecting pharmaceutical industry agreements
- **Examine** collaboration and licensing agreements

This unique and highly interactive two-day training course looks at all stages of the contracting process and aims to deliver applied training through a balanced blend of practical learning. The presenters will use a mixture of practical exercises and cases from the pharmaceutical industry to ensure you leave the course with the knowledge and skills to perfect all stages of the contracting process.

## Benefits of attending

By attending this training course, you will:

- **Update** your practical skills when drafting effective licensing and collaboration agreements
- **Explore** the current issues relating to IP including the Unitary Patent and Unified Patent Court
- **Understand** the key intellectual property issues affecting pharmaceutical industry agreements
- **Explore** the implications of SPCs for pharmaceutical industry agreements
- **Learn** how to draft contracts to avoid anti-trust infringement
- **Familiarise** yourself with the key commercial and legal issues that affect pharmaceutical industry agreements
- **Gain** knowledge of the key issues in clinical trial agreements, contract manufacturing agreements and co-promotion, co-marketing and distribution agreements, and material transfer agreements
- **Get to grips** with competition law relevant to doing deals in the pharmaceutical industry and best practice tactics to use

## Who should attend?

Personnel from R&D, clinical, regulatory, commercial, sales and marketing, manufacturing, distribution and purchasing functions, including:

- In-house counsel
- Commercial and contract managers
- Business development managers
- Purchasing and procurement personnel
- Heads of legal departments
- Legal advisers
- Patent, IP, trade marks or licensing counsel

# Programme

## Day 1

**Understanding licensing and collaboration agreements**

- Precontractual documents and the role of the term sheet
- Scope of the licence
- The interplay of key commercial terms, including:
  - governance and dispute resolution
  - performance obligations and termination rights
  - financial terms
- Boilerplate clauses, including law and jurisdiction

**Workshop: Understanding licensing and collaboration agreements**

**The Unitary Patent and the UPC**

- Latest developments
- Implications for the pharmaceutical industry

**Third-party IP rights – freedom-to-operate searches and implications for pharmaceutical industry agreements**

- Evaluating your freedom to operate
- Different approaches to infringement in Europe
- Assessment of injunction risk
- Mitigating risk and pre-launch patent strategies more generally
- Strategies for obtaining freedom to operate including via licensing
- Freedom-to-operate warranties and indemnities
- Payments and royalty stacking
- Enforcement against infringers
- No-challenge clauses
- Benefits of recording your licence

**Supplementary protection certificates (SPCs) – securing the full commercial potential of your product**

- What are SPCs?
- What are the implications for pharmaceutical industry agreements?
- The duration of the SPC
- What does the SPC cover?
- Combination products
- Basic patents and basic follow-on SPCs
- Leveraging the full commercial value of your property

**Understanding and drafting R&D agreements**

- The scope and purpose of R&D agreements
- Key terms and conditions
- Limitations of experimental use defence to patent infringement
- The 'Euro Bolar' defence: Article 10(6) Directive 2001/83/EC explained
- The varying scope of the 'Euro Bolar' defence across the EU and how it has been implemented in UK law

## Day 2

**Medicines regulations using regulatory processes to define contractual obligations**

- An introduction to regulatory law
- Brief contrast of differing regulatory regimes: medicines/ devices
- Milestones in approving medicines
- Using regulatory processes and milestones in defining contractual obligations
- Common pitfalls and hot spots

**Key issues in clinical trials and related agreements**

- Introduction to clinical trials
- Outline of principal EU and UK legislation
- Horizon scanning: preparing for regulatory change
- Structuring clinical trial agreements
- Engaging CROs
- Key agreement terms and obligations
- Liability, indemnities and insurance

**Key issues in contract manufacturing agreements**

- The importance of the GMP audit
- Issues with technology transfer
- Apportionment of risk and reward
- Secondary sources of supply
- Building a supply chain
- Other key issues

**Key issues in co-promotion, co-marketing and distribution agreements**

- Introduction to the agreements
- Scoping the deal
- Preparing for contingencies and termination
- Key characteristics of the distribution relationship
- Key terms – scope of rights and responsibilities, restrictions, minimum purchase requirements, territory

**Key issues in material transfer agreements**

- The purpose of the agreement
- The scope of the agreement
- Key terms and conditions
- Key issues to be aware of

**Introduction to relevant EU competition law rules**

- Article 101 TFEU and 102 TFEU: restrictive agreements and practices and abuse of dominance in pharmaceutical markets
- The December 2010 Horizontal Cooperation Guidelines
- The Jan 2011 R&D Block Exemption – strategy for early joint research
- The Technology Transfer Block Exemption – dos and don'ts for licensing in and out
- The Vertical Agreements Block Exemption and Vertical Restraints Guidelines – designing distribution models in the EU
- Specialisation Agreements Block Exemption
- Implications of Brexit

**Practical workshop: Current competition law issues**

- Reduced and exclusive distribution agreements
- Licensing in and out
  - The new technology transfer exemption
- Quota schemes and other devices for protecting domestic needs
- Discount schemes for dominant companies

# Presenters



**Mario Subramaniam**

Mario is a partner at Bird & Bird and an IP and transactions specialist with extensive experience in the Life Sciences. He advises global Life Science clients on strategic IP licensing, collaboration and partnering transactions. He also supports those clients with M&A, joint ventures, asset acquisitions and disposals, strategic manufacturing, supply and outsourcing arrangements. Prior to qualifying as a solicitor, Mario worked as a research scientist in the fields of tumour immunology and molecular biology. Having spent a significant period of his career in-house advising Life Science clients, Mario brings a wealth of experience and a unique perspective to clients contemplating strategic transactions and partnerships. His experience and approach also brings great synergy to Bird & Bird's outstanding Life Sciences offerings, allowing an unrivalled opportunity to support clients with their most pressing challenges.



**James Agnew**

**James Agnew** is a supervising associate at Simmons & Simmons. He has worked on a range of contentious and non-contentious intellectual property matters including commercial licensing, collaboration agreements, software protection, settlement proceedings and the intellectual property aspects of corporate transactions, financings and commercial arrangements. James also advises on life sciences regulatory issues including the promotion of medicines and devices and interactions with healthcare professionals. He has experience in a wide range of industries, including life sciences, TMT, finance, Fintech, energy and defence, with a focus on transactions involving intellectual property.



**Fred Nicolle**

**Fred Nicolle** is a UK and European qualified patent attorney (CPA, EPA) at Simmons & Simmons. He has over 15 years experience specialising in patent prosecution and contentious matters for the life sciences sector. He has particular expertise in pharmaceuticals, medical devices, consumer health products, cosmetics, foods and health supplements. He graduated from the University of Cambridge with a Master of Natural Sciences degree with a final year research project in synthetic organic chemistry.

Fred has extensive experience of contentious patent proceedings in opposition at the European Patent Office and in national litigation, having defended patents for numerous commercially important products. Notable examples include the defence of patents for Noctiva™ (desmopressin acetate nasal spray), Bendeka® (bendamustine HCl injection), Revlimid® (lenalidomide), Xeplion®/Invega Sustenna® (paliperidone palmitate), wound dressings, and contact lenses.

Fred is featured in The Legal 500 and IAM Patent 1000 as a recommended patent attorney.



**Stephen Reese**

Stephen Reese is a partner at Clifford Chance and advises clients on both contentious and non-contentious intellectual property matters including patents, trade marks, trade secrets and copyright. Stephen represents and advises a broad range of clients in relation to the protection, exploitation and enforcement of their intellectual property rights. With significant experience representing clients within the life sciences and technology fields, Stephen has acted on some of the most significant licensing transactions in the life sciences industry. Since 2010, Stephen has been listed as one of IAM's Top 250 Patent Licensing specialists.



**Ewan Townsend**

Ewan Townsend is a Partner at Arnold & Porter's London office and assists clients in the life sciences sector on regulatory and commercial matters. He has experience with a broad range of regulatory issues that arise throughout the medicinal product and medical device life cycle, including research and development, clinical trials, marketing authorisations, manufacturing, distribution, advertising, pricing and reimbursement. Ewan's work also includes drafting and negotiating commercial agreements for his life sciences clients, such as licence agreements, manufacturing, distribution and supply agreements, clinical trial agreements and service agreements, and advising on the intellectual property and regulatory issues that arise in the context of those transactions.

# Presenters



**Niels Ersbøll**

Niels Ersbøll, Partner, Arnold & Porter LLP, advises clients on EU competition law in relation to cartels and restrictive practices, merger control, abuse of dominance and State aid. He is currently involved in several pending EU cartel investigations. He advises on merger control investigations by the European Commission and competition authorities worldwide for clients such as General Electric, Boston Scientific, Pfizer, and Sanyo. Where investigations (mergers or cartels) are run by several authorities in parallel, he assists with overall strategy and coordination. Niels also has significant experience helping clients with designing and implementing compliance measures and conducting internal investigations and audits.



**Sharmela Kalmer**

Sharmela Kalmer is a Partner at Gowling WLG (UK) LLP. Sharmela is a trusted advisor to a number of emerging and established innovative technology and life sciences companies operating in a range of sectors, including biotech and medtech. With a wealth of industry experience, Sharmela's sector knowledge gives her a solid understanding of the opportunities and issues faced by clients and how to navigate these issues to access new market opportunities.



**Niels Ersbøll**

**Niels Christian Ersbøll** is a partner in the EU Antitrust practice, chair of the European Competition practice, and head of the Brussels office. He mainly advises clients on EU competition law in relation to merger control, cartels and restrictive practices, and abuse of dominance, where he has more two decades' experience. Niels also has significant expertise in advising clients on EU sanctions and export control matters.

He has assisted clients in obtaining merger control clearance on a number of significant transactions before the European Commission and coordinating submissions to competition authorities worldwide for clients such as Pfizer, Boston Scientific and AT&T. He has significant experience assessing filing requirements, devising strategy, dealing with review and designing and negotiating remedies.

In relation to cartels, Niels has successfully acted for companies seeking leniency (immunity as well as fine reductions) before the European Commission, he has appeared before the EU General Court on appeal of European Commission decisions, and is advising on follow-on damage claims. Recently, Niels also has represented individual directors in cartel proceedings, and acted for a whistle blower. He also has significant experience helping clients with designing and implementing compliance measures and conducting internal investigations and audits.

Outside investigations related work, Niels regularly advises clients in relation to, for example, distribution and pricing arrangements, parallel trade, and various forms of cooperation agreements and strategic alliances between competitors. He acts for clients in many industries, and has particular experience within the life sciences, media and the transport & logistics sectors.

As a reflection of his deep understanding of the industry, since the declaration of the Covid-19 pandemic, Niels has also been working extensively with the vaccine industry to advise on a multitude of aspects of vaccine and antiviral procurement by governments and international organisations including the EU, the African Union, COVAX and CARICOM.

Moreover, Niels also regularly advises clients on EU sanctions questions, notably in rapidly changing regulatory environments, especially regarding EU sanctions on Russia. He helps companies establish EU sanctions compliance plans and commercial strategies as well as obtaining authorisations from competent Member States authorities.



**Sam Fisher**

Sam is an Associate Solicitor in CMS' Intellectual Property team in London. He advises clients principally in the biotechnology, technology and media sectors, on a range of hard and soft IP and connected commercial issues. He has experience litigating in the High Court, Court of Appeal and at the Intellectual Property Office.

Prior to his legal career, Sam spent eight years managing trade mark licensing campaigns as well as at a biotechnology start-up.

# Course dates

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|---|---|---|
| **19-20 May 27** | **Classroom**<br>Venue TBC<br>*Course code 17198* | GBP **1,399** ~~1,599~~<br>EUR **1,959** ~~2,239~~<br>USD **2,247** ~~2,559~~<br>**Until 24 Mar** |
| **10-11 November 27** | **Live online**<br>09:00-17:00 **UK (London)** (UTC+00)<br>*Course code 17475* | GBP **1,199** ~~1,399~~<br>EUR **1,679** ~~1,959~~<br>USD **1,927** ~~2,239~~<br>**Until 15 Sep** |

## How to book

**Online:**
ipi.academy/234

Alternatively contact us to book, or if you have any queries:

**Email:**
info@ipiacademy.com

**Phone:**
+44 (0)20 7749 4749

## Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

## Further information

**Fee**
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

**Please note**
IPI Academy (and our training partners) 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, we will refund the registration fee and disclaim any further liability.

**Terms and conditions**
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

# Reviews

★★★★★

**I was hoping to have a detailed analysis of all the aspects a legal who works in a pharmaceutical company may encounter and how to deal with it. I must say the webinar was very beyond my expectations and I definitely accomplished my goal (and more!). I am in the pharmaceutical industry just from 2022, and this two days helped me a lot.**

**Margherita Aina**
Legal Specialist
NTC S.r.l.
Nov 12 2025

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★★★★★

**My vote is definitely a 10/10: the webinar dealt with all the topics (and more..) I wanted to explore, as I work with it every day. I liked a lot also all the PPT presentations. All speakers were excellent, and the way of explaining very clear and prepared. I found the topics very engaging.**

**Margherita Aina**
Legal Specialist
NTC S.r.l.
Nov 12 2025

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★★★★★

**I hoped to improve my knowledge in the field of in-licensing and out-licensing agreements. I am completely satisfied. I got answers to my questions, structured my knowledge, received new, previously unknown to me information Everything was great.**

**Karīna Kudore**
Lawyer
Olpha
May 21 2025

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★★★★★

**Very concentrated and structured content. All speakers had high level expertise on the topics presented. Useful for in-house practitioners (lawyers, BD) in the pharmaceutical industry as a guide to the main topics in contract drafting. I have expanded my knowledge [on] license agreement issues, IP issues, Co-development agreements.**

**Lana Zida**
Lawyer
Olpha
May 21 2025

## Run this programme in-house for your whole team

Coming to IPI Academy 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.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:



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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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