IPI Academy

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Presented by
Falconbury

Drafting Commercial Contracts for the Pharmaceutical Industry

20-21 May 2026
+ 11-12 November 2026

A two-day practical and interactive seminar 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 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 programme 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 seminar with the knowledge and skills to perfect all stages of the contracting process.

Benefits of attending

By attending this seminar, 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 One Year On

- 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.

Tom Carver

Tom Carver is a partner at White & Black Legal. He has broad experience in patent litigation (infringement and validity) in pharmaceuticals, medical and mechanical devices and electronics, including advice concerning threats provisions. Tom co-ordinates and manages litigation in multiple jurisdictions, and has particular expertise in biotech patent litigation. Tom has a degree in genetics and worked on the first patent case in the UK relating to genetically modified organisms, Monsanto v Cargill, and the first patent case in the UK on DNA sequences, Eli Lilly v Human Genome Sciences. He has been involved in some of the most significant patent cases in the UK in recent years. Tom lived in China for three years, where he managed intellectual property enforcement for Western clients, including Dyson. His experience includes patent (design, utility and invention), trade secret, trade mark and copyright litigation against companies in provinces across China in sectors including capital and consumer goods, cosmetics and medical devices. He also has experience of non-judicial IPR enforcement in China at trade fairs, online and by Customs seizures.

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.

Presenters

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.

Peter Rudd-Clarke

Peter Rudd-Clarke specialises in helping businesses navigate regulatory challenges and liability risks, particularly in the life sciences, healthcare and consumer products sectors.

Peter advises a range of businesses including medical device companies, software producers, pharmaceutical manufacturers, service providers and producers of lifestyle products.

His regulatory experience includes advising on the regulation of medical devices and consumer products, as well as CE/UKCA marking, clinical trials, regulatory investigations, the application of industry codes and ongoing compliance matters.

The litigation and risk management side to Peter's practice involves defending manufacturers of complex products against liability claims, often across multiple jurisdictions; as well as advising clients on product recalls and corrective actions.

Peter is ranked in the Legal 500.

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.

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.

Presenters

Sharmela Kalmer

Niels Ersbøll

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.

Course dates

20-21 May 2026	**Classroom** London *Course code 15708*	GBP **1,399** ~~1,599~~ EUR **1,959** ~~2,239~~ USD **2,247** ~~2,559~~ **Until 15 Apr**
11-12 November 2026	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 16523*	GBP **1,199** ~~1,399~~ EUR **1,679** ~~1,959~~ USD **1,927** ~~2,239~~ **Until 07 Oct**

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

★★★★★

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

★★★★★

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

★★★★★

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:

ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com

YESIM NURKO
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com

Harry ALTAMONT
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com

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.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipiacademy.com