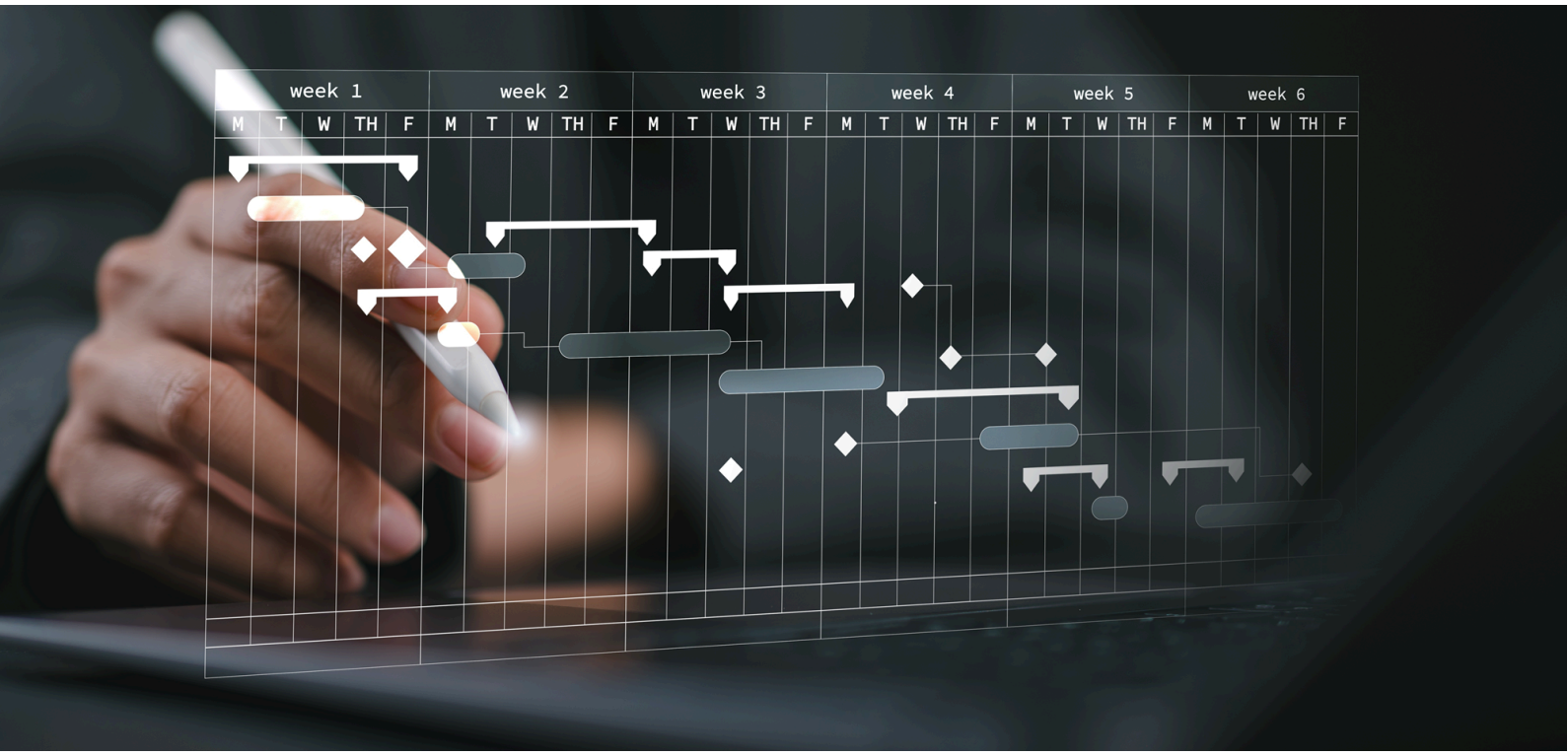
IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Project Management for Regulatory Affairs Professionals

20-21 April 2026
+ 8-9 October 2026

Drive regulatory success with this two-day course for RA and Regulatory Operations professionals. Master practical project management tools, stakeholder strategies, and risk planning through a focused, real-world regulatory case study.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overveiw

Regulatory Affairs (RA) plays a pivotal role in ensuring that medicines reach patients efficiently and compliantly. With increasing global complexity - multiple markets, evolving health authority requirements, accelerated pathways, and cross-functional dependencies - effective project management has become essential for RA professionals at every level.

This two-day interactive course is designed specifically for Regulatory Affairs and Regulatory Operations professionals who plan, co-ordinate, and deliver successful submissions and lifecycle projects. Through a blend of technical project management tools and interpersonal leadership skills, participants will learn how to manage timelines, stakeholders, and regulatory deliverables with confidence and precision.

Participants will also gain practical insights into risk management, resource allocation, and communication strategies tailored to the regulatory environment. The programme includes interactive sessions applying techniques to a regulatory case study, with the option to use your own project for real-world relevance. There is no need to disclose any confidential information.

Benefits of attending

By the end of the course, participants will be able to:

- **Apply** project management methodologies to regulatory submission and lifecycle projects
- **Develop** and manage regulatory plans, risk registers, communication plans, and tracking systems
- **Integrate** Regulatory Operations effectively with cross-functional partners
- **Strengthen** interpersonal and leadership skills to manage diverse teams and stakeholder expectations
- **Recognise** how project management enhances regulatory compliance, efficiency, and strategic decision-making

Who should attend

This course is designed for professionals working in Regulatory Affairs and Regulatory Operations across pharmaceuticals, biotechnology, and medical devices, including:

- Regulatory Affairs Associates/Specialists/Office
- Regulatory Project Managers/Coordinators
- Regulatory Affairs Managers/Senior Managers
- Regulatory Operations Specialists/Managers
- Regulatory Submissions Leads
- Regulatory Business Support professionals
- Anyone delivering regulatory or submission-related projects

It is ideal for both newer professionals seeking structure in managing regulatory projects and experienced managers aiming to enhance cross-functional efficiency and leadership impact.

Programme

Day 1

Understanding project management in the regulatory context

- What defines a "project" in Regulatory Affairs? (submissions, renewals, MA variations, etc.)
- The Five P's framework for managing submissions and lifecycle projects
- Overview of project management methodologies, including waterfall and agile
- Lessons learned from previous Regulatory Affairs projects

Regulatory project objectives and strategies

- Defining clear project goals, scope, and deliverables
- Balancing the Time-Cost-Quality-Regulatory Triangle
- Aligning project objectives with business and regulatory strategies
- Considering regulatory options and pathways

Project planning and scheduling for regulatory projects

- Developing a Regulatory Project Plan (RPP)
- Integrating the Target Timeline Plan (TTP) into project planning
- Conducting effective project kick-off meetings
- Using Work Breakdown Structures (WBS)
- Creating responsibility matrices (RACI) to clarify roles across RA and Operations teams
- Constructing Gantt charts to define deliverables, dependencies, and milestones
- Budget and resource considerations in regulatory projects
- Developing a communication plan
- Building a regulatory-specific risk register and developing contingency plans
- Using project management software and tracking systems

Work breakdown structures, RACI and Gantt Charts

Risk registers, contingency planning and communication planning

Project management tools and tracking systems

Day 2

Cross-Functional and cross-cultural stakeholder management

- Effective communication and gaining project buy-in
- Managing stakeholder expectations (internal management, regulatory bodies, partners)
- Communicating effectively with project stakeholders across cultures
- Managing cross-functional communication between Regulatory, CMC, QA, Clinical, and regulatory agencies

Project execution and control

- Monitoring submission readiness and progress (tracking systems, dashboards, KPIs)
- Regulatory Operations as the hub of project coordination
- Key performance indicators (KPIs) for RA project performance
- Effective meetings, reporting, and escalation management

Leadership

- The evolving role of the Regulatory Project Manager / Lead
- Core regulatory leadership competencies
- Leadership styles and adaptability
- Leading without direct authority - motivating diverse teams to achieve common goals
- Motivation and performance in achieving regulatory milestones
- Stages of team development toward cross-functional performance
- Conflict-resolution styles and approaches

Time management, project review and closure

- Time-management processes for regulatory affairs projects
- Conducting a regulatory post-project review
- Documenting lessons learned and best practices
- Embedding continuous improvement into future projects

Future of RA project management: using artificial intelligence

Presenter

Laura Brown

Dr Laura Brown is an independent pharmaceutical project management and training consultant and Senior Lecturer for the MSc in Clinical Research at the School of Pharmacy, University of Cardiff. Laura has more than 25 years' experience of managing projects in the pharmaceutical industry and has worked for several companies including Wellcome, Hoechst Marion Roussel, Good Clinical Research Practices and Phoenix International. Laura has completed an MBA, with specialisation in project management. She is also the external project management expert for a pharmaceutical e-learning MSc module in project management and the author of two books on the subject including the leading title, Project Management for the Pharmaceutical Industry.

Course dates

20-21 April 2026	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 16836*	GBP **999** ~~1,199~~ EUR **1,399** ~~1,679~~ USD **1,607** ~~1,919~~ **Until 16 Mar**
8-9 October 2026	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 16838*	GBP **999** ~~1,199~~ EUR **1,399** ~~1,679~~ USD **1,607** ~~1,919~~ **Until 03 Sep**

How to book

Online:
ipi.academy/3374

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

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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