Advance
Regulatory Consulting

Entry to Regulatory
Expert Regulatory Services

Introduction to Regulatory Affairs

Course Brochure

June-2025 Update

www.entrytoregulatory.com
contact@entrytoregulatory.com

As seen in:

C+D · Royal Society of Chemistry · TOPRA · JPAG Joint Pharmaceutical Analysis Group

Start Your Regulatory career

Invest in yourself, access the free sample course or sign up to the full course on:

https://www.entrytoregulatory.com/how-to-get-a-job-in-regulatory-affairs

Main website:
www.entrytoregulatory.com

If you have any questions, you can send them to
contact@entrytoregulatory.com
Or ask your question using the website live chat (please provide your email as well so you can get a response)

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What is Regulatory Affairs?

A profession responsible for the licensing and compliance of medicines to government regulatory standards through submissions to agencies that demonstrate the quality, safety and efficacy of a medicine.

Regulatory affairs professionals are responsible for keeping up to date with legislation and guidelines, ensuring medicines comply with regulatory requirements, authoring and preparing regulatory submissions throughout the lifecycle of a medicine, creating regulatory strategies and managing projects.

Why Regulatory Affairs?

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- **Make a Difference -** Make a difference to the lives of millions of patients across the world who rely on lifesaving medicines.
- **Gain Job Stability -** Medicines regulations around the world are increasing. Increasing regulations means a higher demand for regulatory affairs professionals. There are many jobs available for experienced professionals
- **Work Flexibly -** Most jobs allow working from home for 2-3 days a week (hybrid working). Some roles are homebased. Hours are flexible as long as core hours (10am-3pm) are adhered to. Part time work is available.
- **Gain Great Career Prospects -** The usual starting salary is £50,000k. This rises to £80,000 for managers and then increases to £150,000+ as you gain more experience. Obtain other benefits such as an annual bonus, shares, car allowance, health and dental insurance, pension, retail discounts, competitive pension and international travel
- **Enjoy working in the cutting edge of science -** Professionals gain knowledge of regulations, pharmaceutical science and commercial strategy. With constantly evolving technology and regulations, there is always something new to learn. You can specialise in a specific area

Regulatory Affairs Salaries and Benefits

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- Work from home multiple times a week
- High salary
- Great career progression
- Generous benefits
- High demand
- Specialist role
- Will keep you interested
- Benefits patients worldwide
- Flexible hours and part time work
- Potential for international travel
- Bonus and shares

United Kingdom

Associate - £50,000
Manager - £80,000
Director - £110,000
Executive - £150,000+

United States

Associate - $100,000
Manager - $140,000
Director - $250,000
Executive - $350,000

Europe

Associate - €60,000
Manager - €80,000
Director - €110,000
Executive - €200,000+

Switzerland

Associate - 100,000 CHF
Manager - 140,000 CHF
Director - 200,000 CHF
Executive - 250,000 CHF

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Is Regulatory Experience Needed?

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Getting into Regulatory Affairs is **Hard**

We conducted a study to find out why

For an entry level regulatory affairs role, there were **400** applicants

- 40 had regulatory affairs experience
- 23 had a regulatory qualification / course
- 116 had pharmaceutical industry experience
- 221 didn't have regulatory or industry experience

Which applicants would you interview?

Regulatory affairs work experience increases your chances of getting an entry level role

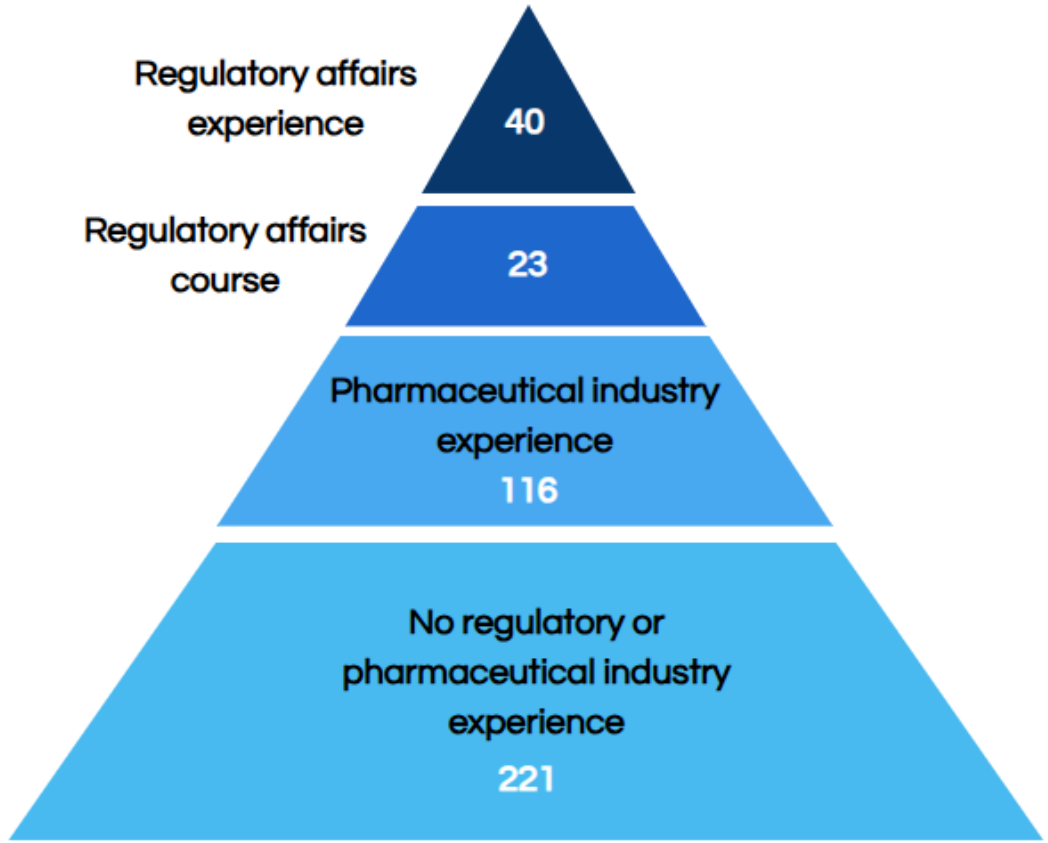
No regulatory affairs work experience

400 job applications (0.25% success rate)

Regulatory affairs work experience

10 job applications (10% success rate)

Entry level Regulatory Affairs Role Applicants



Recruiters will only consider those with regulatory experience

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Benefits of the Regulatory Introductory Course

Getting your first role in regulatory affairs is hard!

- **Most jobs require work experience, regulatory knowledge and specific skills.**
- **Entry level jobs are highly competitive, CVs need to show high attention to detail and interview performance needs to be exceptional compared to other candidates**

Here is how we can help

Regulatory Knowledge

We provide training on the core regulatory topics that all new regulatory professionals should know

Work Experience

We provide you with work experience through real life assignments and providing feedback. Something to put on your CV

Specific Skills

We help you develop skills through the work experience we provide and by optimising your CV

CV Review

Our regulatory experts review your CV and provide written and oral feedback

Interview Practice

Our regulatory experts carry out a mock interview with you and provide feedback

Additional Training Available

Once you land your first regulatory role, we provide further specialised training to help you excel in your career

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What is this Course About?

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Are you interested in getting an entry level role in regulatory affairs but have no experience or are you working in regulatory affairs but would like to have a more comprehensive knowledge of it. If so, then this course is for you.

This is the most comprehensive regulatory affairs course available, providing you with a strong foundation in regulatory affairs by increasing your baseline knowledge, offering you the hard-to-get real world work experience to enhance your skills. Additionally, we provide job search support and mentoring to secure your career in regulatory affairs.

The comprehensive lecture series covers the detailed regulatory requirements for pharmaceutical products in the EU, US and UK and an introduction to clinical regulatory affairs and medical device regulatory affairs. You will obtain a certificate and professional reference upon completion of the course.

In addition, you will obtain real life work experience in regulatory affairs, through case studies and work experience assignments that can enhance your CV and improve your relevant skills.

Following completion of the course you will benefit from job search support (CV review, mock interview, job search support videos and resources and job search mentoring until you get a relevant job) to ensure you secure your career in regulatory affairs.

By joining you will also be part of an exclusive regulatory professional community that benefits from ongoing advice and mentoring.

This course is run by our experts who have over 10 years of regulatory affairs experience in pharmaceutical companies and regulatory health authorities. It is remote and part-time over a month to fit around your work and studies.

Invest in your future and start your professional journey today.

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Who is this Course For?

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Who is it for?

- If you are interested in becoming a regulatory affairs professional but have limited or no experience – Full course
- If you are working as a regulatory affairs professional but would like to gain a broader knowledge of regulatory affairs – Core course
- If you would like to expand your regulatory experience to additional areas (e.g. clinical trials, marketing authorisations, US, EU, UK) – Core Course

Course Objective

- To equip those with little or no regulatory affairs experience with the knowledge, experience, skills and support to get a career in regulatory affairs.
- To provide a broad knowledge of EU, UK and US regulatory affairs and experience in clinical trial, marketing authorisation and variation regulatory submissions

Entry Requirements

- Holder of a science, engineering or law degree (or equivalent)
- Studying for a degree in science or engineering (or equivalent)

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Course Benefits

40+ CPD hours of lectures and learning

Expert tutor with over 10 years of experience

1 Month of Work Experience (part-time)

European, UK and United States Regulations covered

On-Demand Lecture Recordings & Live Tutor Support

Job search mentoring Until you get a job

Careers Hub Job search training videos and resources

Real World Case Studies after every lecture

Remote and part-time to fit around your work or studies

Expert CV review (rated 9 out of 10 by past students)

Exclusive Community for each cohort

Lifetime access Course book provided

Mock interview & interview preparation package

Industry recognised certificate

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New Careers Hub

AI READY

Exclusive job search training videos and resources covering:

- Where to apply for jobs
- How to stand out from the crowd
- How to find hidden jobs
- How to use AI for job applications
- How to apply for many jobs quickly
- How to get recruiters to come to you

Keeping you ahead of other applicants

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Course Leader

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Follow me on

Rabiea

Director

Qualifications and Experience

I am a UK registered pharmacist with over ten years of regulatory affairs experience gained from working in the UK Regulatory Health Authority (MHRA) as an Assessor and several global pharmaceutical companies, such as, GSK, MSD and Bayer.

My experience covers the entire product lifecycle, from clinical trial applications through to new drug applications and post-approval changes. I have worked on various medicinal products, including gene therapy, biologicals, vaccines, medical device combinations, consumer products (OTC), small molecule and generic medicinal products.

I have successfully delivered multimillion-dollar regulatory approvals and cost savings repeatedly for pharmaceutical companies throughout the EU, US, UK, and rest of world markets.

I am passionate about regulatory affairs and providing exceptional regulatory support for pharmaceutical companies to accelerate innovation and deliver for patients. Furthermore, I am passionate about training other regulatory professionals and growing the profession.

MSD MHRA GSK EUROPEAN MEDICINES AGENCY Biogen BAYER

How did I get into Regulatory Affairs?

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Rabiea

Director

Follow me on

- I qualified as a UK registered Pharmacist and then began work as a community locum pharmacist
- Although I enjoyed working in the frontline of healthcare, after I while, I felt things were becoming repetitive and I wasn't being challenged enough
- I reflected on what I enjoyed learning about in University and realised that I enjoyed the drug development, pharmaceutical analysis and formulation topics.
- What job incorporates these areas, I thought.
- After some research, I realised it was regulatory affairs. There were some other benefits of working in regulatory affairs that I liked too.
- So, I started applying and applying. I had no regulatory experience or significant pharmaceutical experience so it was a challenge
- After 80 applications, I got an interview with the MHRA for a Pharmaceutical Assessor role.
- I can still remember that interview and must say it was the hardest interview of my career!
- **But when I reflect on my journey, I think there should have been an easier way and that is why I developed this course, to provide you with the regulatory knowledge and experience to make it easier for you to find your first regulatory role.**

MSD MHRA GSK EUROPEAN MEDICINES AGENCY Biogen BAYER

Why Choose Us?

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	Entry to Regulatory	Others
Comprehensive Lecture Series	✓	✓
Expert Teacher (former MHRA)	✓	✓
Case Studies	✓	✓
Certificate and Professional Reference	✓	✗
Work Experience	✓	✗
Job Search Mentoring and Resources	✓	✗
40+ CPD hours of learning	✓	✗
Expert CV Review	✓	✗
Mock Interview	✓	✗
European, UK and United States Regulations	✓	✗
Exclusive Professional Community	✓	✗
Online Recorded Course with Live Support	✓	✗

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Course Feedback

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'I am very happy of course to finally transition from academia to...medtech... and so I really really recommend this course'

Liviana Mummolo [Career Change]

Past role: Postdoc Researcher
Role obtained: Regulatory Affairs Trainee (Medical Devices)

(Scientific Postdoc Researcher)

'I can't recommend this enough. It is more than just a service; it is life changing. I had many interviews and got my first regulatory affairs job with a medical devices company. Thank you'

Ms. T.A. [Career Change]

Past role: Pharmacy Dispenser
Role obtained: Regulatory Affairs Officer (Medical Devices), Regulatory Affairs Manager

(Biomedical Sciences Degree)

'This is truly exceptional when it came to obtaining a specific job I was pursuing. By the end, I was able to receive multiple job offers. I secured a job with GlaxoSmithKline!'

Mr. H Malik [Graduate]

Past role: Laboratory Scientist
Role obtained: Project Coordinator (GSK), Quality Assurance Executive

(Pharmaceutical Science Degree)

'I've gained a strong foundation in regulatory affairs, such as CTD structure, MAA change controls, variations and CMC, as well as undertaking work experience. I gained critical skills such as teamwork and effective communication'

Ms. S.A. [Undergraduate]

Past role: Student
Role obtained: Regulatory Affairs placement offer from GSK

(Biochemistry Degree)

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Success Stories from Past Students

From postdoc researcher to regulatory affairs trainee

Liviana Mummolo was a postdoc researcher looking to break into the pharmaceutical industry. But she had no pharma or regulatory affairs experience and didn't know where to start. She embarked on this course , where she gained significant regulatory knowledge. Her CV was reviewed and she gained multiple interviews. After her mock interview, she received two job offers. She then received further advice on how to choose between offers. She is now working as a regulatory affairs trainee for a medical devices company.

From pharmacy dispenser to regulatory affairs manager

Ms. T.A. wanted a career change. She was a pharmacy dispenser with a Biomedical Science degree but was unfulfilled in her role. With a keen interest in pursuing a career in regulatory affairs, she embarked on the course. After her CV was reviewed, she gained multiple interviews and with the support of a mock interview, was offered a Regulatory Affairs Officer position for a Medical Devices company. More recently, she has progressed to a Regulatory Affairs Manager position within the same company

From pharmaceutical science graduate to landing a job at GSK

Mr. H Malik was a recent pharmaceutical science graduate with only several months of laboratory experience. He had no previous pharmaceutical or regulatory affairs experience but wanted to break into the pharmaceutical industry. After his CV was reviewed, he received an entry level job offer from GSK as a Project Coordinator, which he accepted. Following this position, he moved into quality assurance, holding several positions, including as an QA executive.

From biochemistry student to receiving a GSK regulatory affairs placement offer

Ms. S.A. was a Biochemistry undergraduate and aspiring regulatory affairs professional. With limited work experience, she wanted to gain a regulatory affairs placement in a pharmaceutical company to improve her career options. However, regulatory affairs placements for undergraduates are highly competitive. To stand out from the crowd she undertook this regulatory training and her CV was reviewed. This enabled her to obtain a Regulatory Affairs placement offer from GSK.

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Student Feedback

4.60
Average Rating

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2025 Course Feedback Report

Overall Course Feedback

8/10 means 8 points out of 10, where 10 out of 10 (10/10) is highly satisfactory and 0 out of 10 (0/10) is unsatisfactory.

- **Overall Course Rating 4.6 stars out of 5 stars**
- Regulatory affairs knowledge increased from 3/10 to 8/10 after the course
- Likelihood of recommending the course was 8/10
- Quality and content of course book rated 8/10
- Knowledge of course tutor rated 9/10
- Confidence of applying for entry level regulatory role increased from 4/10 to 8/10 after the course
- Quality of lecture content rated 9/10
- Quality of case studies rated 9/10
- Quality of work assignments rated 9/10
- Satisfaction with quality of CV review 9/10

Rabiea was really supportive and knowledgeable throughout the course. I liked having the course book to annotate and keep, it is a great resource. The work experience assignments were a great way to consolidate knowledge gained from the lectures and see how the content would be applied in a professional setting. I enjoyed using the case studies to quickly test what I had learnt at the end of each lecture.
This course is a very well-structured introduction to regulatory affairs, and it covers different aspects of the field. I enjoyed the work assignments and the quiz at the end of every lesson. It also gives all the knowledge to start in a RA role. I also found the mock interview and the CV preparation very useful.
excellent course
All were well prepared and professionally presented, informative and easy to digest. Wish to have more regular live session with instructor for learning discussion and assignment answers
The course was very useful. I learnt alot from the overall course.
''The course was well-structured, with engaging lectures, and insightful work experience assignments that effectively reinforced the learning. Overall, it provided a comprehensive and valuable experience."
The lectures were well-structured and contained valuable content. Both the case studies and the work experience assignments were particularly useful, closely reflecting real-world tasks in regulatory roles. While they were challenging-especially for someone new to the field - they provided an excellent learning opportunity.

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Half Course

- **11+** CPD Hours of Learning
- EU, UK and US Regulations
- Expert ex MHRA Tutor
- Industry Recognised Certificate
- Real World Case Studies

Core Course

- **40+** CPD hours of learning
- EU, UK, US Regulations
- Expert ex MHRA Tutor
- Industry Recognised Certificate
- Real World Case Studies
- **Work Experience** (1 month, part time)
- **Lifetime access** (Course Book)

Full Course

- **40+** CPD hours of Learning
- EU, UK and US Regulations
- Expert ex MHRA Tutor
- Industry Recognised Certificate
- Real World Case Studies
- **Work Experience** (1 month, part time)
- **Lifetime access** (Course Book)
- **Additional Work Experience** Project for Course Graduates **
- **Job Search Mentoring** (until you get a job)*
- **Careers Hub Training Resources**
- **Expert CV Review**
- **Mock Interview**
- **Exclusive Professional Community**

Introduction to Regulatory Affairs

Course Comparison

The course description above is the most accurate representation of what will be included in the course. However, it is subject to change.
**In the country where you have long term right to work (where you have a valid sponsorship/visa already)*
*** Subject to availability. When work is available you will be notified but this is not guaranteed. due to dependency on the regulatory work available.. Past project: regulatory intelligence*

Introduction to Regulatory Affairs Course – Lectures

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Half Course Lectures
11+ hours

- Welcome and Course Overview
- Drug Development and What is Regulatory Affairs?
- What is the Role of the Regulatory Affairs Professional?
- Background of Medicines Legislation - US, EU, UK
- EU and UK Regulatory Procedures Part 1
- EU and UK Regulatory Procedures Part 2
- US Regulatory Procedures
- Regulatory Control of Clinical Trials - EU, US, UK
- EU and UK Marketing Authorisation Applications
- US New Drug Applications
- Variations and Lifecycle Management - EU, US, UK

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Full Course Lectures
40+ hours
Half Course plus;

- Clinical Regulatory Affairs and Regulatory Writing
- Introduction to Medical Device Regulations - EU, US
- Introduction to Pharmacovigilance and Risk Management
- eCTD Content - Introduction and Module 1, Regional Administrative Information
- eCTD Content - Module 2, Summaries
- eCTD Content - Modules 3, Quality, CMC
- eCTD Content - Modules 4 and 5, Non-clinical, Clinical
- Labelling of Medicines in the EU and US Part 1
- Labelling of Medicines in the EU and US Part 2
- Regulatory Strategy
- Response to Agency Questions
- Agency Meetings and Scientific Advice – US, EU, UK

Work Assignments: Clinical trials, Marketing Authorisation Applications, Variations and Regulatory Strategy

Core Course Lecture Series
40+ hours
Same as Full Course

- Same lectures as the full course.

Work Assignments:
- Clinical Trials
- Marketing Authorisation Applications
- Variations
- Regulatory Strategy

The programmes above are the most accurate representation of what will be covered in the course. However, they are subject to change.

IMPD IND MAA NDA BLA ANDA Generics Biosimilar Scientific Advice

Complementary Alternative Medicine SmPC PL Labels Prescribing Information

Package Insert User Testing Module 1 Module 2 Module 3 Agency Meetings

Module 4 Module 5 Clinical Trials Marketing Authorisation Applications Variations

Type IA Type IAIN

What will you Learn?

Type IB Type II PAS

Annual Reportable CBE30 CBE0 ICH MHRA FDA EMA Regulatory Strategy CFR

Regulation Directive Guideline Recommendations FD&C Act Pharmacovigilance

Medical Writing Medical Devices Class I device Class IIa Class IIb Class III

Medical Device Combination Biological Chemical Phase I Phase II Phase III Phase IV Response to Agency Questions

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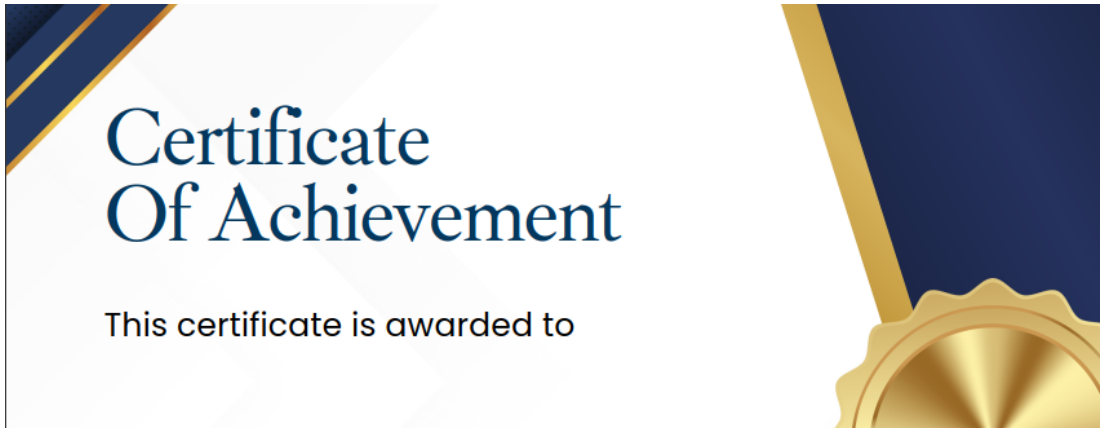
What Job Support Will You Get?
CV Review and Certificate

Certificate

A pharmaceutical industry recognised certificate will be provided on completion of the course. This will have an addendum that includes all modules covered in the course.
The content of this course meets industry standards regarding it relevancy, currentness and alignment to industry practices.
You will get a professional work reference based on the work assignments you have completed.

CV Review

At the end of the course, you will update your CV to include this course (certifications and training section) and the work experience, and skills gained (work experience section). Your CV will be reviewed by an expert and detailed feedback to enhance your CV, stand out from the crowd and increase your chances of getting an interview will be provided. Once your CV is optimised you can start applying for regulatory roles.



What Job Support Will You Get?

Mock Interview, Job Search Support and Exclusive Professional Community

Mock Interview

Once you are successful in your job application and gain an interview, you can participate in a mock interview with our experienced hiring manager to ensure your interview technique will enable you to get the job. Our experienced hiring managers have extensive experience in recruiting candidates for large pharmaceutical companies.

Exclusive Regulatory Professional Community

Upon signing up to the course you will gain admission into our exclusive regulatory professional community. Here you can socialise, ask questions and receive advice from each other and the course tutor.

Ongoing Job Search Support (until you get a relevant role)

- Job recommendations
- Advice on specific job search questions
- Where to apply for jobs
- How to stand out from the crowd
- How to find hidden jobs
- How to use AI for job applications
- How to apply for many jobs quickly
- How to get recruiters to come to you

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What Experience and Skills Will You Gain?

Work Experience Assignments

Work Experience Assignments

Course work assignments that will give you real life regulatory work experience. The assignment consists of a real-life scenario and takes you through several tasks to work through the regulatory solution for that scenario. You will receive a new assignment each week, which will be reviewed. You will receive one assignment for each stage of the product lifecycle (full course) or choose two assignments (EU or US course). This will enable you to gain entry level regulatory affairs experience.

Work experience assignments covering the following topics will be provided:

- Clinical Trials
- Marketing Authorisation Applications
- Variations
- Regulatory Strategy

Marketing Authorisation Application Work Experience Assignment (abbreviated)

Your company are filing a MAA in the EU. You are responsible for preparing the Module 1 documents

What reference will you use to identify what Module 1 documents are required for an EU MAA?

Where and how will you obtain these documents in your company?

How will you check that the QP declaration prepared conforms with regulatory requirements?

The QP has drafted the following QP declaration. Review and provide your comments of it from a regulatory perspective...

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What Experience and Skills Will You Gain?
Case Studies

Case Studies
Each presentation in the lecture series includes case study scenarios which are discussed in the presentation. These are working examples of each topic and how they apply to real life practice. It will give you the opportunity to apply your knowledge to real world examples during the presentation.

Based on your learnings from the presentation you will apply your knowledge to real life situations.
You will attempt the case study and then the answer will be discussed step by step.
You will have the opportunity to ask questions to clarify your understanding.

EU Variations Presentation Case Study

For commercial reasons, supply chain wishes to change the active substance supplier (substance is not biological)

Q. What variation classification(s) do you propose and what other questions would you ask the supply chain manager to help you in your assessment? Refer to the EU Classification Guide

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What Experience and Skills Will You Gain?

Work Experience Project(s)

Work Experience Project(s)

After completing the full course, you may have the opportunity to work on additional regulatory project(s). When this work is available, course graduates will be informed and can opt into these projects.

The nature of these projects will depend on the regulatory work available. This work experience is a remote, part-time voluntary internship. It is subject to availability and attendee participation is at the discretion of the course tutor.

Past project example: Regulatory intelligence project

Should you perform well during the voluntary work experience there may be an opportunity for paid work. However, this is not guaranteed.

When and How will the Course Be Taught?

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Full & Core Course

See the website and contact, contact@entrytoregulatory.com for the next course date

The course is remote and part-time to fit around your work and studies

WEEK 1	WEEK 2	WEEK 3	WEEK 4

Each week:
5 hours of Lectures + 1 hour of Case Studies + 4 to 8 hours of Work Assignment

WEEK 5+

(For Full Course only)

- Industry recognised certificate
- Careers hub
- Expert CV review
- Job search support & mentoring until you get a job
- Mock interview
- Interview preparation package

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How to Plan your Learning?

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
1 to 2 hours of lectures and case studies each weekday					4 to 8 hours work assignment	Rest

The course dates and description above are accurate at the time of writing but are subject to change.

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When and How will the Course Be Taught?

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Full Course

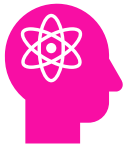
See website or contact contact@entrytoregulatory.com for course dates

The course is held part time over a month:

1. The lecture recordings will be released each weekend, giving you one week to view them on-demand before the next set are released. You will have access to these recordings on-demand to study at your own pace. If you have any questions while learning, you can ask in the course group chat.
2. You will work on the case studies from the lectures each week and then view the answer with an opportunity to ask questions in the course group chat.
3. Work experience assignments will be set for you on the weekend and will be due the following weekend. Work experience assignments will cover the broad concepts of the course e.g. clinical trials, marketing authorisation applications, variations and regulatory strategy
4. You will have lifetime access to course material through the course book
5. Towards the end of the course, you will submit your CV for review and then update it and apply for entry level roles.
6. By being part of the exclusive professional community, you will receive job support, including notifications of entry level roles, advice and signposting to other useful resources and information.
7. You will gain access to the careers hub, containing job search training videos and resources
8. Once you have an interview our experts will run a mock interview to help you secure the role.

On-demand recorded lectures

Job search support



CV and interview review

Work experience assignments

Real world case studies

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The course dates and description above are accurate at the time of writing but are subject to change.

When and How will the Course Be Taught?

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Core Course

See website or contact contact@entrytoregulatory.com for course dates

The course is held part time over a month:

1. The lecture recordings will be released each weekend, giving you one week to view them on-demand before the next set are released. You will have access to these recordings on-demand to study at your own pace. If you have any questions while learning, you can ask in the course group chat.
2. You will work on the case studies from the lectures each week and then view the answer with an opportunity to ask questions in the course group chat.
3. Work experience assignments will be set for you on the weekend and will be due the following weekend. Work experience assignments will cover the broad concepts of the course e.g. clinical trials, marketing authorisation applications, variations and regulatory strategy
4. You will have lifetime access to course material through the course book

On-demand recorded lectures

Work experience assignments

Real world case studies

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The course dates and description above are accurate at the time of writing but are subject to change.

What Will You Learn? – Full & Core Course Lectures

Advance Regulatory Consulting

The lectures in this page are also covered in the Half Course

Welcome and Course Overview
- What is regulatory affairs?
- What is this course about?
- Course benefits, feedback, tutor experience
- What will you learn (detailed)
- What experience and skills will you gain?
- What Job Support will you get?
- Learning portal

Drug Development and What is Regulatory Affairs?
- Medicine types, regulation and history
- Drug development process
- The role of regulatory affairs
- The regulatory framework
- Regulatory authority responsibilities and procedures

What is the Role of the Regulatory Affairs Professional?
- The regulatory environment
- The role of the regulatory affairs professional
- Career progression, salary and benefits
- The skills and responsibilities needed
- Regulatory work that you will be involved in
- Real regulatory submission examples

Background of Medicines Legislation - US, EU, UK
- The global regulatory environment
- The role and structure of the FDA, EMA and MHRA
- The standards, legislation and guidance for the US, EU and UK
- The laws underpinning US, EU and UK medicines regulation
- Regulatory hot topics

EU and UK Regulatory Procedures Part 1
- The EU and UK regulatory environment
- The phases of a clinical trial
- EU & UK clinical trial procedure and timelines
- EU Marketing Authorisation Application procedure and timelines
- EMA scientific committees

EU and UK Regulatory Procedures Part 2
- The centralised procedure
- The decentralised procedure
- The mutual recognition procedure
- The UK marketing authorisation application procedures
- EU and UK variation procedures

US Regulatory Procedures
- The United States regulatory environment
- US clinical trial procedure and timelines
- New drug application procedure and timelines
- New drug application assessment
- Accelerated procedures
- US Post-approval procedures

Regulatory Control of Clinical Trials - EU, US
- The history of clinical trials
- The phases of a clinical trial
- The laws underpinning clinical trials in the EU, UK and US
- What are the EU and US clinical trial submissions and timelines
- What is in the US clinical trial application?
- What is in the EU and UK clinical trial application?
- How are EU, UK and US clinical trial applications maintained?
- Ethics committee's role and process

EU and UK Marketing Authorisation Applications
- What is a marketing authorisation application?
- The legislation underpinning marketing authorisation applications
- Structure and content of the CTD
- New Marketing Authorisation Application
- Generics
- Biosimilars
- Other application types
- Accelerated procedures

US New Drug Applications
- What is a new drug application?
- The legislation underpinning new drug applications
- New drug applications
- Abbreviated new drug application
- Biological license applications
- Biosimilars
- Complementary and alternative medicine

Variations and Lifecycle Management - EU, US
- What are post-approval submissions?
- Where do they arise from?
- What is the legislation underpinning post-approval submissions in the EU, US and UK?
- EU, UK and US minor post-approval changes
- EU, UK and US moderate post-approval changes
- EU, UK and US major post-approval changes
- Other variation types

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The programmes above are the most accurate representation of what will be covered in the course. However, they are subject to change.

What Will You Learn? – Full & Core Course Lectures

The lectures in this page are NOT covered in the Half Course

Advance Regulatory Consulting

Clinical Regulatory Affairs and Regulatory Writing Part 1
- What are the clinical trial phases (detailed)?
- The benefit, risk balance
- What is in the EU and US clinical trial applications?
- What is in the IB?
- What is in the Clinical Protocol?
- What is in the IMPD?
- Paediatric Investigation Plans (PIPs)
- The role of clinical regulatory affairs professionals
- The role of medical writers

Introduction to Medical Device Regulations - EU, US
- Types and classifications of medical devices in the EU and US
- EU and US medical device regulations
- EU and US medical device regulatory authorities
- EU and US medical device registration procedures
- Drug device combinations

Introduction to Pharmacovigilance and Risk Management
- What is an adverse drug reaction?
- Pharmacovigilance and risk management
- Pharmacovigilance regulations and regulatory authorities
- Signal detection
- Post-marketing surveillance

eCTD Content - Introduction and Module 1, Regional Administrative Information
- Overview of the CTD structure
- Detailed look at Module 1 subsections

eCTD Content - Module 2, Summaries
- Detailed look at Module 2 subsections

eCTD Content - Modules 3, Quality, CMC
- Detailed look at Module 3 subsections
- (drug substance and drug product)

eCTD Content - Modules 4 and 5, Non-clinical, Clinical
- Detailed look at Module 4 subsections
- Detailed look at Module 5 subsections

Labelling of Medicines in the EU and US Part 1
- SmPC content
- Prescribing Information content

Labelling of Medicines in the EU and US Part 2
- Patient Information Leaflet content
- Package insert content
- EU and US label requirements
- User testing

Regulatory Strategy
- Regulatory strategy examples
- How to create a regulatory strategy?
- Types of regulatory strategy
- Clinical trial regulatory strategy
- MAA regulatory strategy
- Variations regulatory strategy

Responding to Agency Questions
- How to respond to agency questions?
- How are responses prepared?
- Types of agency questions
- Common agency questions
- How to avoid agency questions
- Learning from agency questions

Agency Meetings and Scientific Advice – US, EU, UK
- FDA meeting types, timelines and preparation
- EMA meeting types, timelines and preparation
- MHRA meeting types and preparation

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When and How will the Course Be Taught?

Entry to Regulatory
Expert Regulatory Services

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Half Course

Instant access once purchased

1. The half course recordings will be available for viewing on-demand. You will have access to these recordings on-demand to study at your own pace.
2. You will work on the case studies from the lectures and then view the answer

On-demand recorded lectures

Real world case studies

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The course dates and description above are accurate at the time of writing but are subject to change.

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Frequently Asked Questions

Is this course relevant to countries other than UK, EU or US?

Yes, there are modules which are directly applicable to other countries such as eCTD content. There are topics that are indirectly applicable. These topics are still relevant as other countries align their regulations to the EU or US and filings are made to the EU or US first and then updated slightly for other countries.

Have any questions?

Email them to:
Contact@entrytoregulatory.com

Or book a call here

Course Fees & Discounts

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- Pay in 5 monthly instalments

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