Advance
Regulatory Consulting

Entry to Regulatory
Expert Regulatory Services

Introduction to Regulatory Affairs

Course Brochure

Jan-2025 Update

www.entrytoregulatory.com
contact@entrytoregulatory.com

Start Your Regulatory career

Invest in yourself, access free sample material or sign up to the 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.

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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. 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 £30,000-40,000k. This rises to £50,000-70,000 for managers and then increases to £120,000+ 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

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, as well as offering you the hard-to-get real world work experience to enhance your skills. Additionally, we provide job search support 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 and job search support 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 support.

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 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
- If you are working as a regulatory affairs professional but would like to gain a more comprehensive knowledge of regulatory affairs
- If you would like to expand your regulatory knowledge and skills to additional areas (e.g. regulatory submissions, US, EU, UK)

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 comprehensive knowledge of EU, UK and US regulatory affairs and experience in 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 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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Follow me on

Rabiea

Director

- 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

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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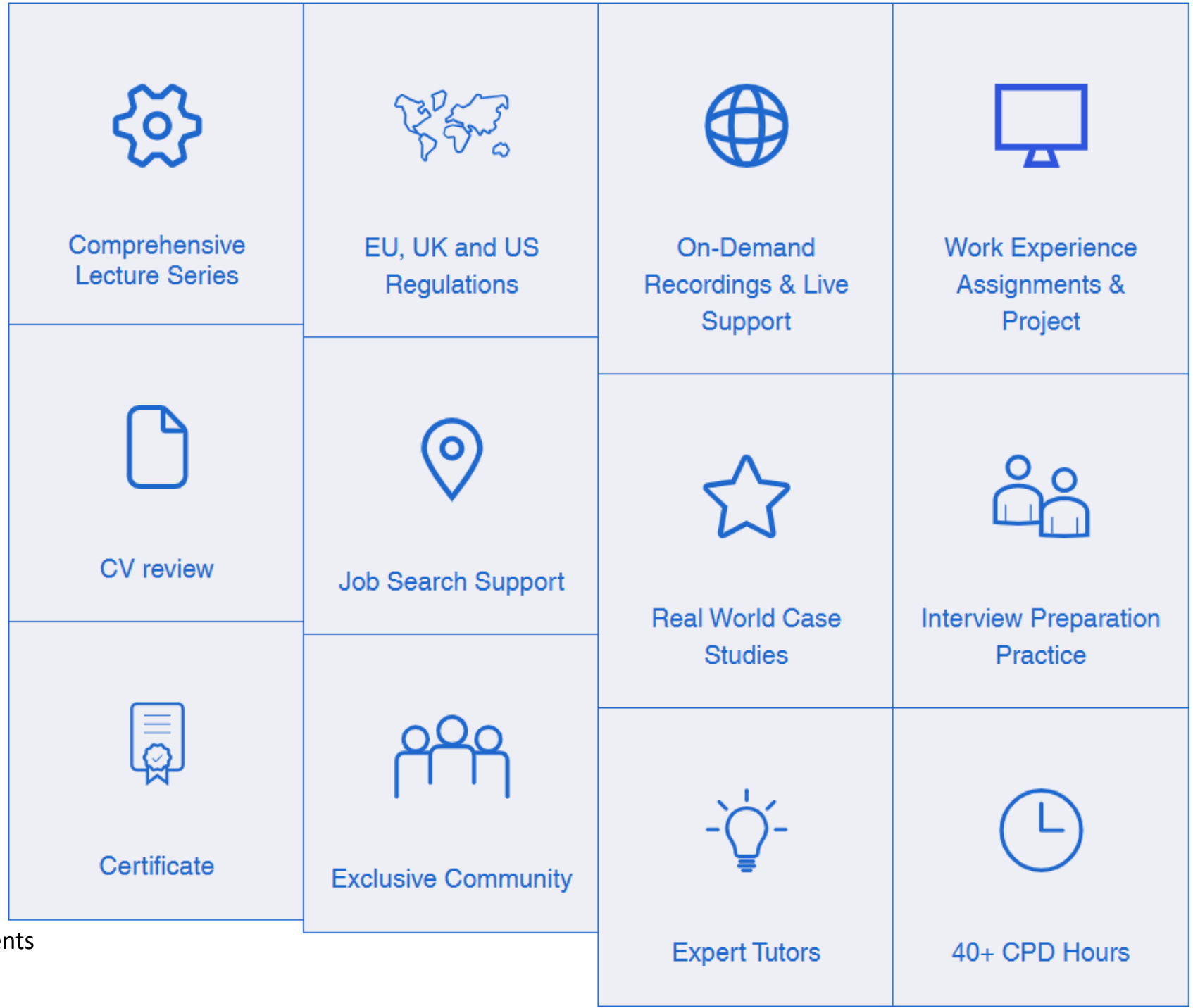

The full course is part-time over a month to fit around your work and studies

Each week, aim to spend

- 5 hours watching lectures
- 1 hour attempting case studies
- 4+ hours on work assignment

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Why Choose Us?

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Entry to Regulatory
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	Entry to Regulatory	Others
Comprehensive Lecture Series	✓	✓
Expert Teacher (former MHRA)	✓	✓
Case Studies	✓	✓
Certificate and Professional Reference	✓	✗
Work Experience Assignments	✓	✗
Job Search Support	✓	✗
40+ CPD hours of learning	✓	✗
CV Review	✓	✗
Interview Preparation	✓	✗
EU and US Covered	✓	✗
Exclusive Professional Community	✓	✗
Online Recorded Course with Live Support	✓	✗

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Course Feedback

'I can't recommend this service 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]
Role obtained: Regulatory Affairs Officer (Medical Devices), Regulatory Affairs Manager
(Biomedical Sciences Degree)

'This service 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]
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]
Regulatory Affairs placement offer from GSK
(Biochemistry Degree)

Industry Feedback

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'Having attended a similar course from another training provider, I can definitely say that this course is of a better quality, as it provides delegates with real regulatory experience and individualized feedback. You can gain experience in real regulatory tasks. The course book is well thought out and one topic flows to the next'

Mrs. A.H
Former MHRA Scientific Assessor

'The CVs of candidates who have completed this course stand out a lot more with the additional experience and course information. The course looks great. I will recommend it.'

Senior Recruiter

'I like the case study as it gets you to think and put it into practice. Not just hearing. I though that was really productive'

'I really enjoyed the presentation'

'Thank you for the interesting reminder and refresher. It was great. Thanks so much'

'I didn't have much knowledge in this area, but it was very easy to follow through. Especially the keywords. They were easy to understand'

Regulatory and non-regulatory professionals attending the Regulatory Strategy Webinar

Introduction to Regulatory Affairs

Course Comparison

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Half Course

- 11+ CPD Hours of Lectures
- EU, UK and US Regulations
- Certificate on Completion
- Real World Case Studies

EU or US Course

- 30+ CPD hours of lectures
- EU, UK **OR** US Regulations
- Certificate on Completion
- Real World Case Studies
- **Work Experience (2 weeks)**
- **CV Review**
- **Course Book**

Full Course

- 40+ CPD hours of Learning
- EU, UK and US Regulations
- Certificate on Completion
- Real World Case Studies
- **Work Experience (4 weeks)**
- **Further Work Experience Project for Course Graduates** **(subject to availability)**
- **CV Review**
- **Mock Interview**
- **Job Search Support** **(until you get a relevant job)**
- **Exclusive Professional Community**
- **Course Book**

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The course description above is the most accurate representation of what will be included in the course. However, it is subject to change.

Introduction to Regulatory Affairs Course – Lectures

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Half Course Lectures
11+ hours

- Welcome and Course Overview Part 1
- Welcome and Course Overview Part 2
- 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
- EU and UK Marketing Authorisation Applications
- US New Drug Applications
- Variations and Lifecycle Management - EU, US

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Full Course Lectures
40+ hours

Half Course plus;

- Clinical Regulatory Affairs and Regulatory Writing Part 1
- Clinical Regulatory Affairs and Regulatory Writing Part 2
- 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

EU or US Lecture Series
30+ hours

Full Course, but;

- Will either cover EU and UK topics or US topics.
- The general lectures will be the same, However,
- Lectures on Regulatory Strategy and Response to Agency Questions will not be included

Work Assignments: Choose two from:

- 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

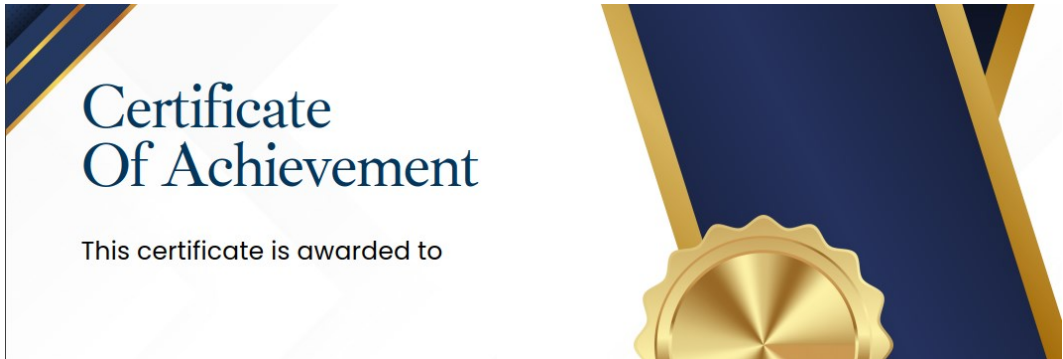
Certificate

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

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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)

- Signposting on where to apply for jobs
- Frequent job recommendations
- Advice on specific job search questions
- Job search guidance and tips
- Careers hub

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?

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.

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 Will You Learn? – Full Course Lectures

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Lectures in Bold will also be covered in the Half Course

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Welcome and Course Overview Part 1
- **What is regulatory affairs?**
- **What is this course about?**
- **Your regulatory journey**
- **Course benefits, feedback, tutor experience**
- **Half course vs. full course**
- **What will you learn (detailed)**

Welcome and Course Overview Part 2
- **What experience and skills will you gain?**
- **What Job Support will you get?**
- **Learning portal**
- **Work assignments information**

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 clinical trial procedure and timelines**
- **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 national procedure**
- **The UK international recognition procedure**
- **EU and UK variation procedures**

US Regulatory Procedures
- **The American 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 laws underpinning EU and US clinical trials**
- **What are the EU and US clinical trial submissions and timelines**
- **What is in the US clinical trial application?**
- **What is in the EU clinical trial application?**
- **How are EU and US clinical trial applications maintained?**
- **Ethics committees role and procedures**

EU and UK Marketing Authorisation Applications
- **Structure and content of the CTD**
- **New Marketing Authorisation Application**
- **Generic application**
- **Biosimilar**
- **Herbal applications**
- **Accelerated procedures**

US New Drug Applications
- **Reference product**
- **Market exclusivity**
- **New drug application**
- **Abbreviated new drug application**
- **Biological and biosimilars**
- **Complementary and alternative medicine**

Variations and Lifecycle Management - EU, US
- **EU and US minor variations**
- **EU and US moderate variations**
- **EU and US major variations**
- **Other variation types**

Clinical Regulatory Affairs and Regulatory Writing Part 1
- What are the clinical trial phases (detailed)?
- What is in the EU and US clinical trial applications?
- What is in the IB?
- What is in the Clinical Protocol?

Clinical Regulatory Affairs and Regulatory Writing Part 2
- What is in the IMPD?
- PIPs
- The role of clinical regulatory affairs professionals
- The role of medical writers

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What Will You Learn? – Full Course Lectures

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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
- Pharmacovigilance regulations and regulatory authorities
- Adverse reactions, adverse events
- Signal detection
- Risk management
- Post-marketing surveillance

eCTD Content - Introduction and Module 1, Regional Administrati
- Overview of the CTD contents
- 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
- Package leaflet content
- Package insert content
- EU and US label requirements
- User testing

Regulatory Strategy
- Regulatory strategy examples
- How to create a regulatory strategy?
- Regulatory strategy in development
- Regulatory strategy for MAA submissions
- Regulatory strategy for variations

Response 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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What Will You Learn? – EU/UK Lectures

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- Half course vs. full course
- What will you learn (detailed)

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- What experience and skills will you gain?
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- The role of regulatory affairs
- The regulatory framework
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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 - EU, UK
- The global regulatory environment
- The role and structure of the EMA and MHRA
- The standards, legislation and guidance for the EU and UK
- The laws underpinning 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 clinical trial procedure and timelines
- 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 national procedure
- The UK international recognition procedure
- EU and UK variation procedures

Regulatory Control of Clinical Trials - EU
- The laws underpinning EU clinical trials
- What are the EU clinical trial submissions and timelines
- What is in the EU clinical trial application?
- How are EU clinical trial applications maintained?
- Ethics committees role and procedures

EU and UK Marketing Authorisation Applications
- Structure and content of the CTD
- New Marketing Authorisation Application
- Generic application
- Biosimilar
- Herbal applications
- Accelerated procedures

Variations and Lifecycle Management - EU
- EU minor variations
- EU moderate variations
- EU major variations
- Other variation types

Clinical Regulatory Affairs and Regulatory Writing Part 1
- What are the clinical trial phases (detailed)?
- What is in EU clinical trial applications?
- What is in the IB?
- What is in the Clinical Protocol?

Clinical Regulatory Affairs and Regulatory Writing Part 2
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- EU medical device regulations
- EU medical device regulatory authorities
- EU medical device registration procedures
- Drug device combinations

Introduction to Pharmacovigilance and Risk Management
- Pharmacovigilance regulations and regulatory authorities
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- Signal detection
- Risk management
- Post-marketing surveillance

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- 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 Part 1
- SmPC content

Labelling of Medicines in the EU Part 2
- Package leaflet content
- EU label requirements
- User testing

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

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? – US Lectures

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- Work assignments information

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- Drug development process
- The role of regulatory affairs
- The regulatory framework
- Regulatory authority responsibilities and procedures

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- The role of the regulatory affairs professional
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- The skills and responsibilities needed
- Regulatory work that you will be involved in
- Real regulatory submission examples

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

US Regulatory Procedures
- The American 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 - US
- The laws underpinning US clinical trials
- What are the US clinical trial submissions and timelines
- What is in the US clinical trial application?
- How are US clinical trial applications maintained?
- Ethics committees role and procedures

US New Drug Applications
- Reference product
- Market exclusivity
- New drug application
- Abbreviated new drug application
- Biological and biosimilars
- Complementary and alternative medicine

Variations and Lifecycle Management - US
- US minor variations
- US moderate variations
- US major variations
- Other variation types

Clinical Regulatory Affairs and Regulatory Writing Part 1
- What are the clinical trial phases (detailed)?
- What is in the US clinical trial applications?
- What is in the IB?
- What is in the Clinical Protocol?

Clinical Regulatory Affairs and Regulatory Writing Part 2
- What is in the IND?
- PIPs
- The role of clinical regulatory affairs professionals
- The role of medical writers

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

Introduction to Pharmacovigilance and Risk Management
- Pharmacovigilance regulations and regulatory authorities
- Adverse reactions, adverse events
- Signal detection
- Risk management
- Post-marketing surveillance

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? – US Lectures

Entry to Regulatory
Expert Regulatory Services

Advance
Regulatory Consulting

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eCTD Content - Introduction and Module 1, Regional Administrati
- Overview of the CTD contents
- 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 US Part 1
- Prescribing Information content

Labelling of Medicines in the US Part 2
- Package insert content
- US label requirements
- User testing

Agency Meetings and Scientific Advice – US
- FDA meeting types, timelines and preparation

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

When and How will the Course Be Taught?

Entry to Regulatory
Expert Regulatory Services

Full Course

Each week, aim to spend

- 5 hours watching lectures
- 1 hour attempting case studies
- 4+ hours on work assignment

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

WEEK 1

Week 1 Lectures
Week 1 Case Studies
Week 1 Work Assignment

WEEK 2

Week 2 Lectures
Week 2 Case Studies
Week 2 Work Assignment

WEEK 3

Week 3 Lectures
Week 3 Case Studies
Week 3 Work Assignment

WEEK 4

Week 4 Lectures
Week 4 Case Studies
Week 4 Work Assignment
CV Review
Job Search Support

WEEK 5+

Certificate
Job Search Support
Mock Interview

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?

Entry to Regulatory
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Full Course

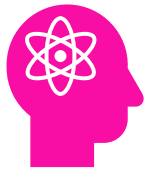
Jan 2025, March 2025, May 2025

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 a specialist topic (e.g. clinical regulatory affairs, medical devices or labelling).
4. Course lectures will be available for you to view for a period of time. You can also order the printed lecture handouts.
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. Once you have secured 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

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?

Entry to Regulatory
Expert Regulatory Services

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EU or US Course

WEEK 1

Week 1 Lectures
Week 1 Case Studies
Week 1 Work Assignment

WEEK 2

Week 2 Lectures
Week 2 Case Studies
Week 2 Work Assignment
CV Review
Certificate

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?

Entry to Regulatory
Expert Regulatory Services

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EU or US Course

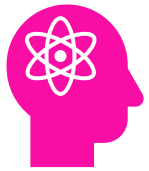
Jan 2025, March 2025, May 2025

The course is held part time over two weeks:

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 forum
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 forum.
3. Work experience assignments will be set for you on the weekend and will be due the following weekend. You can select two work experience assignments from the following topics: clinical trials, marketing authorisation applications, variations and/or a specialist topic (e.g. clinical regulatory affairs, medical devices or labelling).
4. Course lectures will be available for you to view for a period of time. You can also order the printed lecture handouts.
5. Towards the end of the course, you will submit your CV for review and then update it and apply for entry level roles.

On-demand recorded lectures

EU, UK or US Regulations



CV review

Work experience assignments

Real world case studies

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?

Entry to Regulatory
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Half Course

From September 2024 onwards

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

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 instalments

- Pay in 3 monthly instalments (Klarna)
- Pay in 5 monthly instalments

One off fee

- Pay on registration
- Pay in 30 days (Klarna)

Discounts for those

- Unemployed for a prolonged period of time
- In full time education
- Working for charities full time
- From low-income countries
- Working in academia or government agencies
- Multiple bookings

contact contact@entrytoregulatory.com to enquire about discount

Learn more about Course Fees Here

Start Your Regulatory career

Invest in yourself, access free sample material or sign up to the 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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contact@entrytoregulatory.com