Advance
Regulatory Consulting

Entry to Regulatory
Expert Regulatory Services

Comprehensive Regulatory Affairs Course

Course Brochure

July -2026

July 2026

www.entrytoregulatory.com

As seen in:

ROYAL SOCIETY OF CHEMISTRY · UCL · TOPRA · C+D · JPAG JOINT PHARMACEUTICAL ANALYSIS GROUP

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

Start Your Regulatory Career

Invest in yourself, speak to us, access the free regulatory course or sign up to the full course on:
https://www.entrytoregulatory.com/how-to-get-a-job-in-regulatory-affairs

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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)

Entry to Regulatory
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Contents

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Your Background and the Journey

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Undergraduate

Science Graduate

Graduate role

Entry level regulatory role

Regulatory manager

Experienced regulatory professional

Shape your career

What is your education and employment background?

No Career Pathway

Undervalued

Bored

Confused

Unfulfilled

Ignored

Underpaid

Demotivated

Exhausted

Overworked

Frustrated

No work-life balance

Not reaching my full potential

Hopeful

Curious

Inspired

Where are you now and where would you like to go?

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

How Will This Impact Your Life?

Regulatory Affairs Salaries 2026

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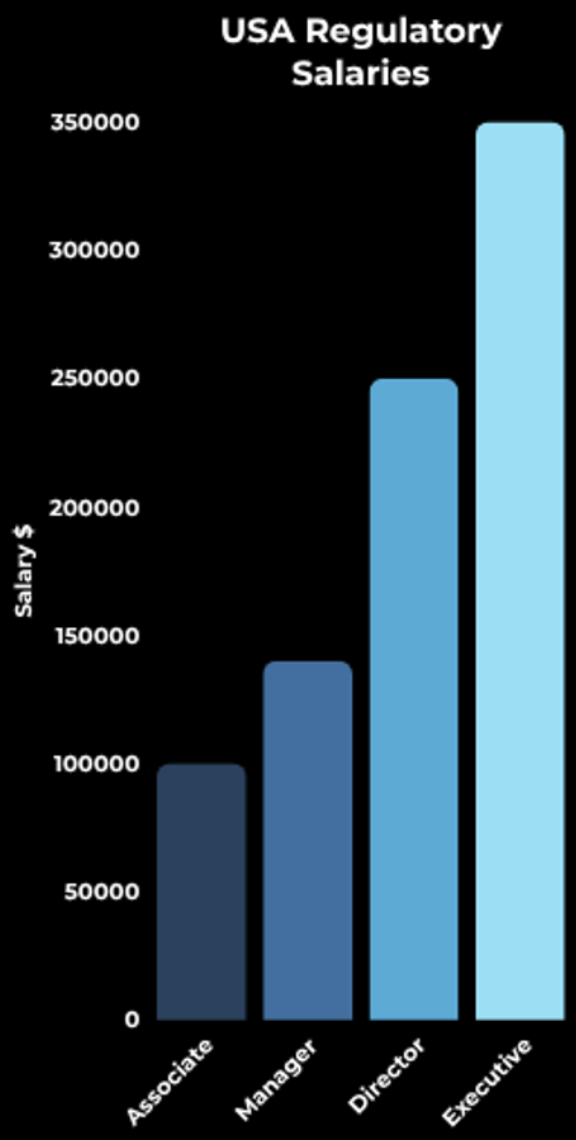

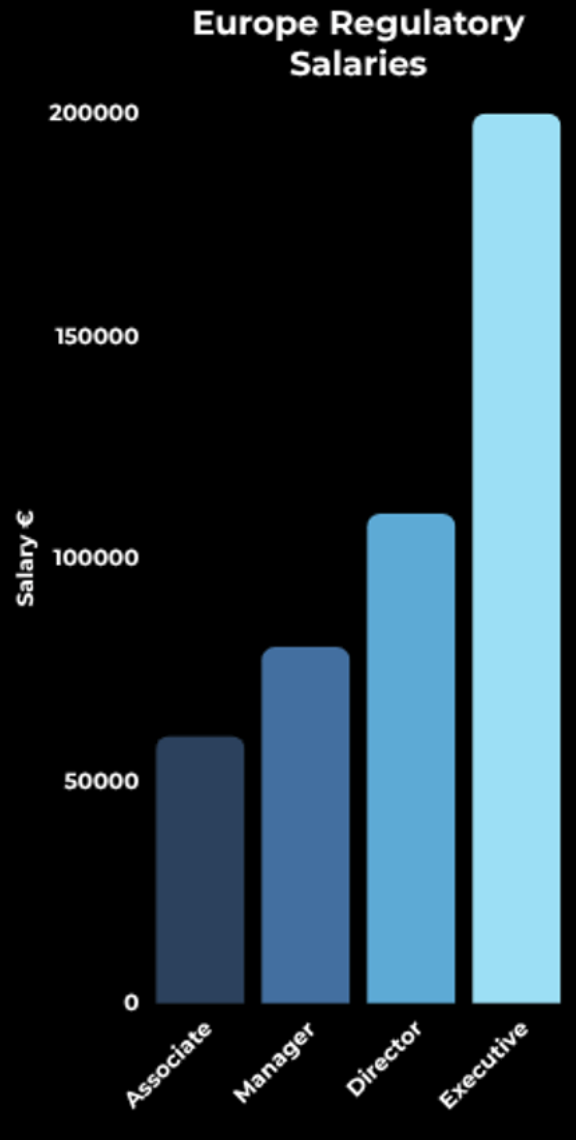

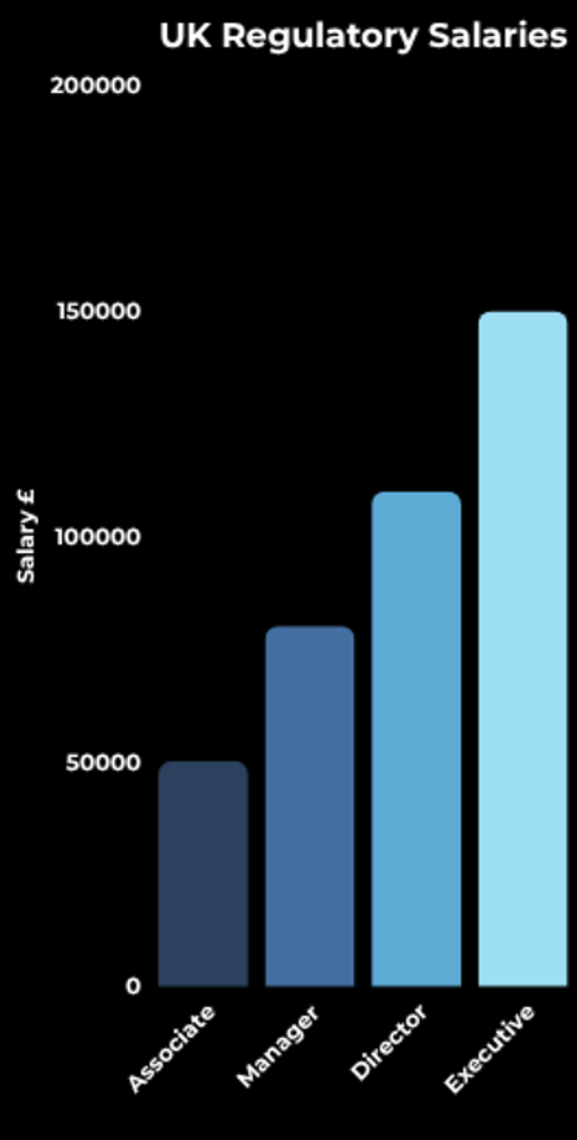

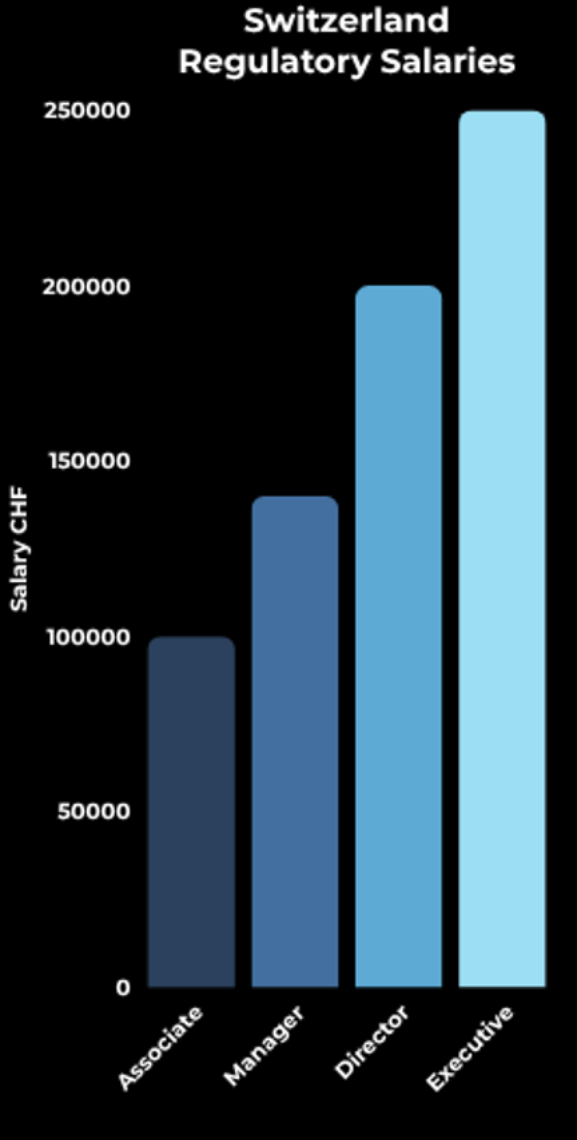

How to Get Regulatory Affairs Knowledge, Work Experience and Careers Mentoring to Land Your Dream Job

(at any stage of your career)
(even without previous experience)
You just need a life science or healthcare degree

Past students have done this within 2 weeks to 9 months of starting our training*

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Who am I?

GSK

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EUROPEAN MEDICINES AGENCY

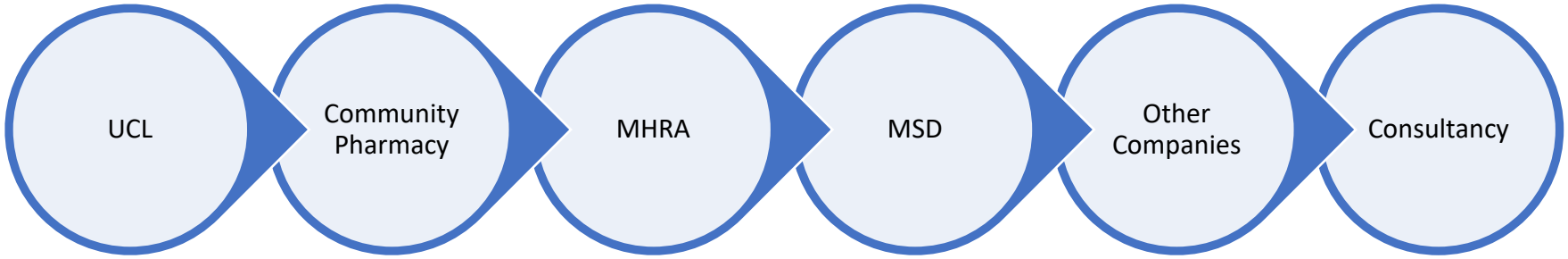
BAYER

UCL

MHRA

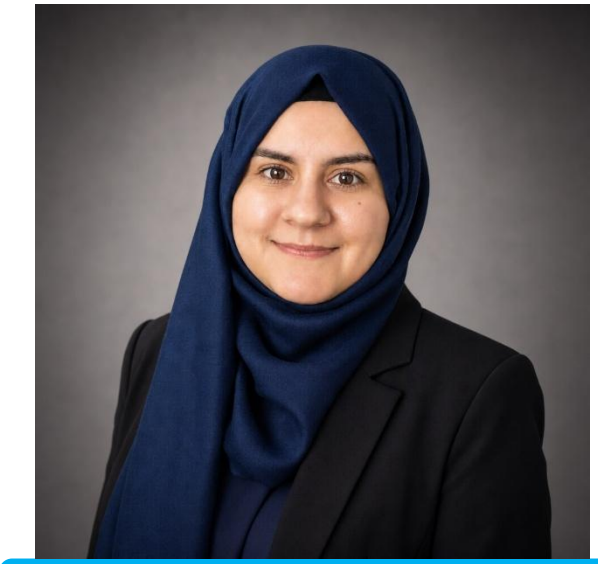
Biogen

Advance Regulatory Consulting



LloydsPharmacy

MSD



Rabiea

CEO Advance Regulatory Consulting
Entry to Regulatory

Honorary Associate Professor, UCL

Former MHRA Agency Reviewer

I am an Honorary Associate Professor at UCL, a former MHRA Agency Reviewer and CEO of Advance Regulatory Consulting (regulatory affairs consultancy) and Entry to Regulatory (regulatory affairs training company). I have over a decade of regulatory affairs experience gained from working for the UK Regulatory Health Authority (MHRA) as an Agency Reviewer and several large 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 cell and gene therapeutics, 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 numerous 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 and biotechnology companies to accelerate innovation and deliver for patients. Furthermore, I am passionate about training other regulatory affairs professionals and growing the profession.

Follow me on LinkedIn Rabiea Regulatory

How did I get into Regulatory Affairs?

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Rabiea

CEO Advance Regulatory Consulting
Entry to Regulatory

Honorary Associate Professor, UCL

Former MHRA Agency Reviewer

I started my career working as a locum community pharmacist, but I felt unfulfilled and stagnant in my career. I started looking at other options and stumbled across regulatory affairs. Regulatory affairs stood out to me as it involved merging the science with regulatory requirements - something I enjoy to this day.

But it wasn't easy moving into regulatory affairs with no pharma experience. Most jobs required regulatory experience. But how could I get it before getting my first chance. I kept applying. After 80 application, I eventually moved into the MHRA as a CMC Regulatory Assessor.

This was the start of my regulatory career, and I was able to find out exactly how to assess Module 3 of the CTD and what mistakes companies were making. I then built a successful career working for the largest global companies, such as GSK, MSD and Bayer. Now I have my own regulatory affairs consultancy, and I serve clients across the globe.

Follow me on

Rabiea Regulatory

But looking back I realised that the hardest part of my career wasn't the work, it was getting into regulatory affairs. So, I built the training that I wish I had when I was starting out. Training that gives in depth real regulatory work experience, regulatory knowledge and careers mentoring so you don't have to struggle to make the move into regulatory affairs, the way I did.

MSD MHRA GSK EUROPEAN MEDICINES AGENCY Biogen BAYER

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.***

[Rabiea, Entry to Regulatory]

**Medicines, cosmetics, foods, animal products, etc.*

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What do Regulatory Professionals do?

- Preparation of a novel, complex Phase I/II fermentation product submission for the EU (IMPD) and US (IND), within a few months
- Regulatory strategy, preparation and submission of several biological product IMPD Substantial Amendments which were approved without Agency question
- Simultaneous preparation and submission of 5 rest of world MAAs for a biological product, which were approved within several months of submission
- Strategising and preparing several EU and rest of world responses to agency questions simultaneously to gain a 100% approval rate. More than 50 grouped variations were approved across 107 licenses, saving the company several million euros.
- Maintenance of company reputation by co-leading the intense compliance review of a manufacturing site within a week and simultaneously preparing and submitting the corresponding grouped variation with 54 different changes and a regulatory authority commitment. This was approved without agency question
- Preventing the supply issue of a critical medicine on the market by coordinating and executing the EU agency communication strategy for the non-compliant batches, preparing the grouped variation and managing key stakeholders. The grouped variation, with 29 changes was approved within 10 days with no validation issues or agency questions and more than two million dollars was saved from EU sales alone.
- Conducting the regulatory authority assessment for more than 10 MAAs and 50 variations. This covered a vast range of products and regulatory procedures

Influencing Agencies **Making a difference for patients/public health** **Professionalism**

Continuity of Supply of commercial and clinical trial medicines **Economic savings and gain**

Enabling patient access to life saving medicines **Global medicines availability** **Maintaining high quality standards**

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Why Are You Not Getting Hired?
What Skills, Knowledge and Experience Do You Need?

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Large Pharma Job Description Example

Education/ Experience Required:

- Bachelor's degree in Pharmacy, Biology, Pharmacology or related Life Sciences is required.
- Master of Science degree or Doctorate in Biochemistry, Biology, Microbiology, Chemistry, Toxicology, Pharmacology or in Management, such as a Master of Business Administration degree, is considered an **asset**.
- Minimum of one to three years of **experience** in the pharmaceutical industry.
- Working **knowledge** in the preparation, filing, and approval of various submission types with Health Authority, and basic negotiation and networking skills.
- Experience with Biologics, small molecules, medical devices, quality-related changes, and clinical trial applications are considered an **asset**.
- Basic **knowledge** and understanding of the Regulatory Legislation and Regulations, its policies and related guidelines.
- Computer proficient.
- **Experience** with electronic regulatory submissions is considered an **asset**.

Essential **Skills** and Abilities:

- Able to effectively and efficiently work either on his/her own or in a **team** environment.
- Able to take key actions and demonstrate behavioural anchors that support all Company core **competencies**.

Note: Job descriptions may change slightly based on company requirements, but the key requirements of Skills, Knowledge and Experience are the same.

We provide you with the regulatory affairs experience, knowledge and skills highlighted… and more..

I will show you exactly how to get the experience, knowledge and skills needed in the next pages

But First, 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

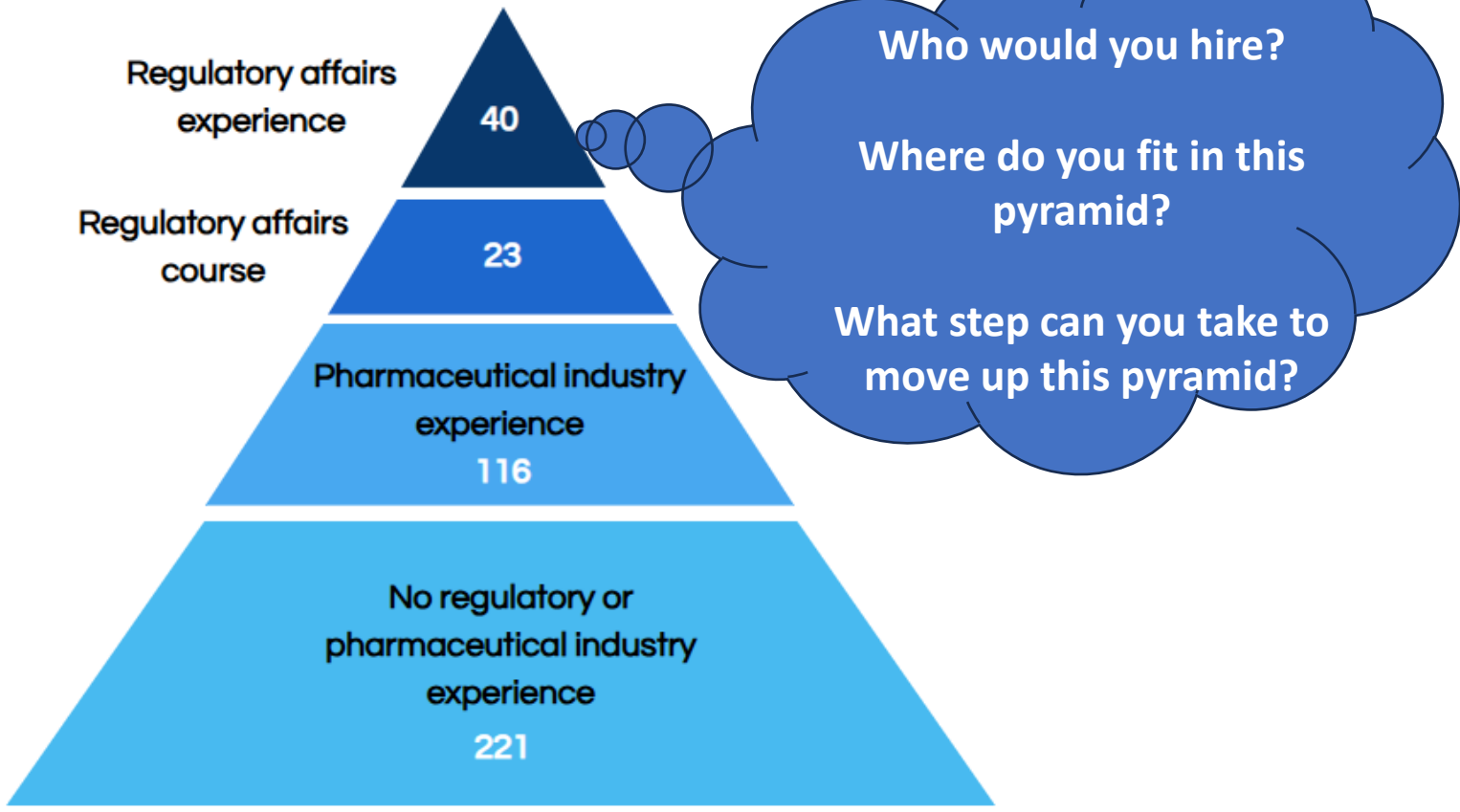
No regulatory affairs work experience

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

We Can Give You 3 Months of Regulatory Work Experience

United States, European and UK regulatory submissions OR Global regulatory submissions (Global Course)

Full Lifecycle Covered

- **Clinical Trials** – IND or IMPD authoring, CMC, Module 3
- **MAA or NDA**, Variations or post-approval changes – Module 1
- **Variations or post-approval changes** – quality, safety and clinical changes. Module 1, Module 2, Module 3. Variations (Type IA, IAIN, IB) or post-approval changes (Annual Reportable, CBE-0, CBE-30)
- **Regulatory strategy**

Regulatory Experience Recognised By

- Health authorities
- Large pharma
- Biotechs,
- Medical device companies, etc.
- Generic companies
- Consultancies
- NHS

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Does It Help?

Yes, Our Course Graduates Have Started Careers With: AMGEN Lonza MHRA WOCKHARDT

Within 2 weeks to 9 months of starting our course*

4.60
Average Rating

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GSK Takeda NHS National Institute for Health Research

kenvue my life DLRC werfen

Accellerate ALLIANCE And others...

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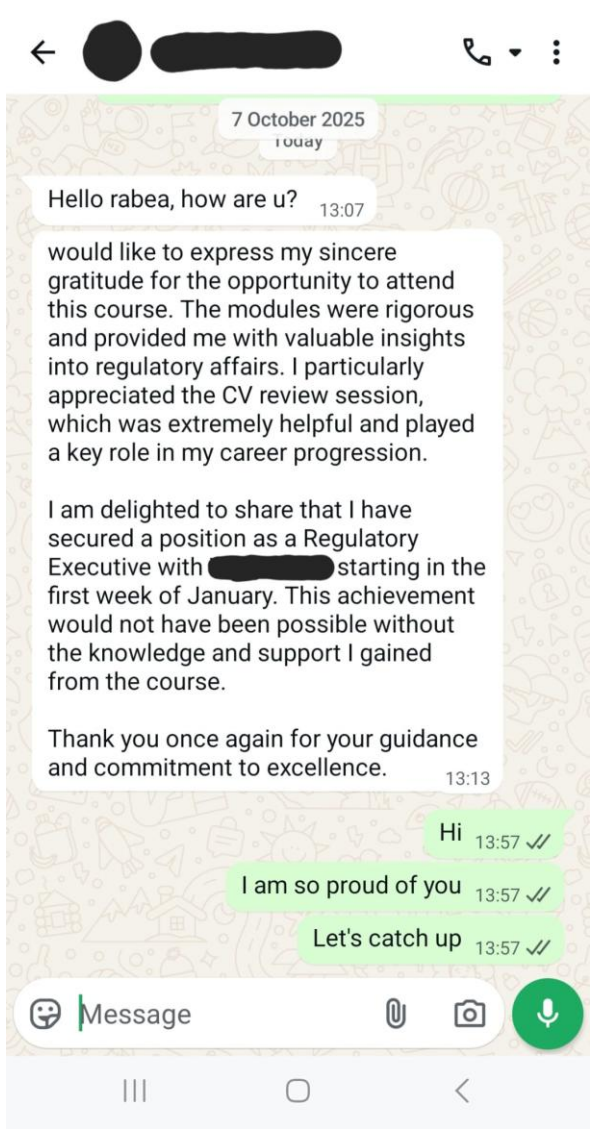
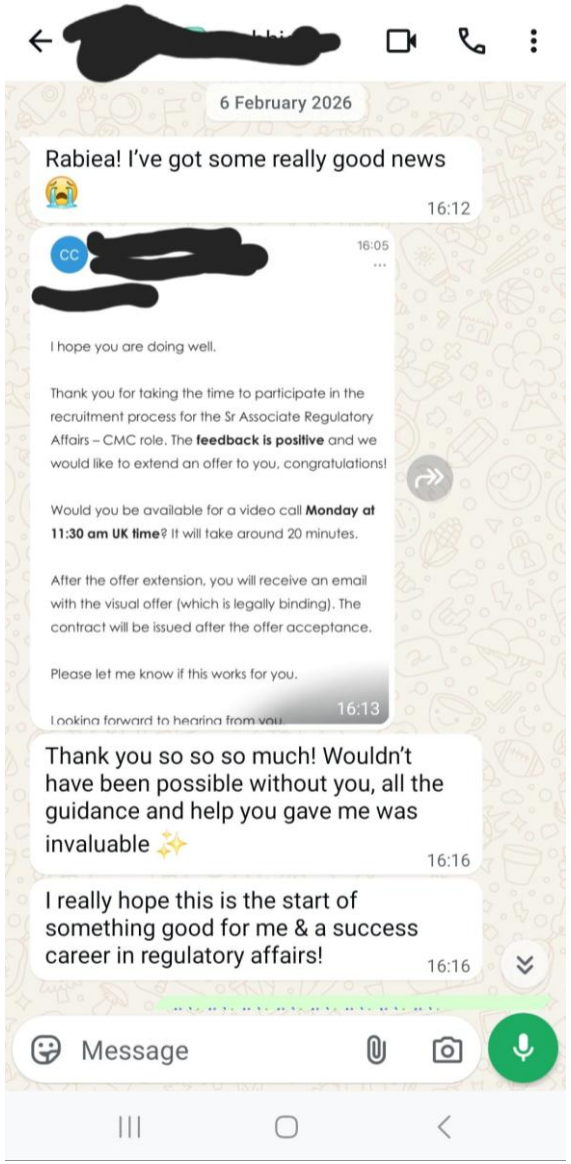
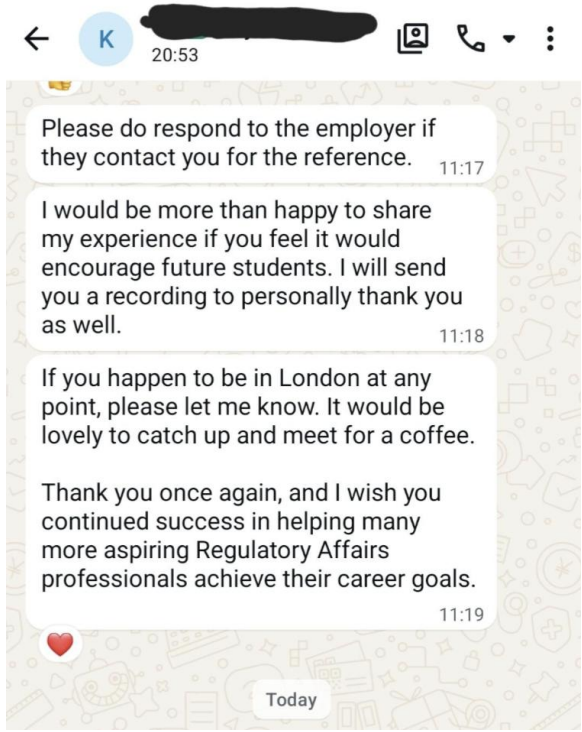
Ready to Join Them?

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

Student Success Stories







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* Based on past students. However, this is dependent on the effort you put into the course, work experience and job search process, as well as other factors. We will support you as much as possible. Success of past students is not a guarantee of your success. Your results will vary depending on region, education, effort, application, experience, and background. We cannot guarantee that you will be successful if you employ the advice specifically or generally. Consequently, your results may significantly vary from theirs. However, we will support you as much as possible. Specific experiences are mentioned for informational purposes only.

Does Our Training Work? Course Success Stories

*Time taken to get an offer for a Regulatory role from start date of Regulatory cohort joined

Name	Previous role	Qualification	Regulatory Experience	Time Taken To Get Regulatory Offer*	New role	Company type	Course Rating	Feedback
Forhad	Senior research scientist	Biochemistry BSc	No previous regulatory knowledge or experience	4 months	MHRA regulatory role	Health Authority	⭐⭐⭐⭐⭐	It covered all of my questions in terms of understanding regulatory in the pharmaceutical industry. After finishing the course, I had a lot of knowledge that I didn't have before. The course enabled me to create a suitable CV and I got called for 3 interviews and was offered 2 jobs. I chose the role with the MHRA. If you want to gain knowledge in regulatory affairs, you will learn a lot, get practical experience, have the support throughout and there is nothing quite like it.
Tan	Pharmacy Dispenser	Biomedical Sciences BSc		1 month	Regulatory affairs officer (progressed to manager)	Medical devices company	⭐⭐⭐⭐⭐	'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'
Liviana	Post-Doc Researcher	PhD, Biologics		7 months	Regulatory affairs Specialist	Medical devices company	⭐⭐⭐⭐⭐	I am very happy of course to finally transition from academia to medtech and so I really really recommend this course because it really helped me in understanding the basics of regulatory affairs and how a regulatory affairs professional can work in a pharma company and how they can interact with other departments and are involved in the development of a new drug or medical device.
Noor	Senior principal scientist	PhD neurobiology and neurosciences		1 month	Regulatory CMC lead	Large Pharma	⭐⭐⭐⭐⭐	Thank you very much for your support and guidance throughout this process. I am about to start a new CMC lead position which includes regulatory responsibilities. I wanted to let you know that the job search resources you provided have been extremely helpful.
Jasvir	Hospital Pharmacist	Pharmacy MPharm		4 months	MHRA Regulatory role	Health Authority	⭐⭐⭐⭐⭐	I really felt like the course was very comprehensive and has given me a good idea of what a role in regulatory affairs involves. There was a lot that I've learnt that would have been difficult to do by myself. Compared to other offerings on the market I feel like this course has good value for money.
Prahbjot	QC Senior Scientist	Pharmacology MSc		4 months	Senior Regulatory Affairs Associate	Biotech	⭐⭐⭐⭐⭐	'I did the course and realised that I don't know anything about regulatory affairs before this. I thought I did. But actually I did not know anything. So this course gave me so much knowledge, so much insight, so much experience. It has really opened up my mind and made me employable. I actually ended up getting 4 or 5 regulatory interviews and recently I accepted a job at Amgen for senior regulatory affairs specialist. Without the course, I would not have been able to get this. To anyone that is hesitant or in two minds or in a position where they are applying and not hearing back, then this course is the next step for you to speed things up. I am very grateful for this course. I am very excited for what the future holds. I would definitely advise you to do the course. It is worth every penny. It's worth the investment. It is an investment in your career.'

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Does Our Training Work? Course Success Stories

*Time taken to get an offer for a Regulatory role from start date of Regulatory cohort joined

Name	Previous role	Qualification	Regulatory Experience	Time Taken To Get Regulatory Offer*	New role	Company type	Course Rating	Feedback
Tejaswi	Unemployed	Pharmacology MSc	No or some previous regulatory knowledge or experience	6 months	Regulatory Affairs Associate	Generics CMO	⭐⭐⭐⭐⭐	I honestly cannot thank you enough for all your support, guidance and mentorship throughout my journey. Actually, your course has been a turning point in my career and you know what, this knowledge, the practical insights you have given me and the Regulatory material you provided gave me the confidence and skills I needed to secure this role and especially your mentorship helped me to understand the industry, prepare effectively and stay motivated throughout the process. You have given me so much motivation and you supported me with whatever questions I asked and you guided me like my guru. Achieving this position would not have been possible without your course and your continuous encouragement and the experience I gained through completing the course. This has made a significant difference during my interviews, and it has helped me to stand out as a candidate. I'm genuinely grateful for everything you have done for me. Thank you so much.
Adebukola	Senior Project Manager	Pharmacy Msc		4 months	Regulatory Executive	Generics	⭐⭐⭐⭐	I would recommend the course to people in my situation because it will give you a deep dive understanding of how the regulations with the UK and EU markets work and that will give you the self-confidence during your interviews. The course provided valuable insights into regulatory affairs, particularly around CTA, NDA, and post-approval variations and helped build a strong foundational understanding of these processes. The case studies were excellent. They offered practical, real-world scenarios that made the concepts more tangible and easier to apply. This was one of the strongest aspects of the course. I felt the work assignments were really good. The CV support was really good and that really helped.
Federica	Deputy manager	Post-Doc Molecular and Cell Biology		2 weeks	Commercial Associate	Regulatory Consultancy	⭐⭐⭐⭐⭐	I truly recommend this course because it provides both direct insight into regulatory affairs and practical work experience. Thank you for organising it, it has been a life-changing experience. I liked the structure of the course. It was clear and well organised. I liked the cohort support in discussing the assignment. Overall, I am happy and suggesting the course to friends. Thank you so much! During the interview, I mentioned that I had started the course, which would allow me to gain more direct exposure to the regulatory affairs role. I explained what the course was covering, in particular, clinical trial documentation (such as the Investigator's Brochure and Clinical Protocol) and the Marketing Authorisation Application. I also mentioned that the course provides valuable work experience, including exposure to EU and US variations. I believe these details helped demonstrate my genuine interest in the field and strong motivation. Even though I was only in the first two weeks of the course, I think this made a real difference.

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What is this Course About?

Are you interested in moving into regulatory affairs but have no experience
Or are you working in regulatory affairs but would like to fill in the gaps in your knowledge and experience to enhance your career?
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 regulatory affairs experience to add to your CV and job search mentoring and resources to secure your career in regulatory affairs.

You will gain real regulatory work experience, covering regulatory submissions throughout the medicine lifecycle (IMPD, IND, NDA, MAA, variations and/or post-approval changes), as well as case studies to enhance your learning. This experience can be added to your CV and a work reference will be provided.

Moreover, the comprehensive lecture series covers detailed regulatory requirements for pharmaceutical products in Europe, United States and the UK (Global course covers other countries), as well as an introduction to clinical regulatory affairs, medical devices and pharmacovigilance. This will increase your knowledge and support your career. You will obtain an industry-recognised certificate upon completion of the course.

Following completion of the course you will benefit from job search support (expert CV preparation, mock interview, job search support videos and resources and job search mentoring) until you get a 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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Get Regulatory Affairs Experience, Knowledge and Job Search Mentoring

Getting your first role in regulatory affairs is hard!

- **Most jobs require regulatory 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 you with comprehensive training on key global regulatory requirements and submissions

Work Experience

We provide you with work experience through real life work assignments. You can add this experience to your CV and get a work reference.

Specific Skills

We help you develop skills through work experience, and we bridge your previous skills by optimising your CV

CV Review

We provide you with in-depth CV support to make sure you stand out from the crowd based on our experience reviewing 100s of regulatory CVs

Job Search Mentoring

Interview Practice

We provide you with job search mentoring, which includes training and resources and tailored advice

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

Additional Work Experience Available

After the course we can provide you with additional work experience and training to further develop your regulatory skills and enable you to specialise and excel in your career. Additional charge applies.

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Entry to Regulatory Expert Regulatory Services

Full Regulatory Affairs Course Details

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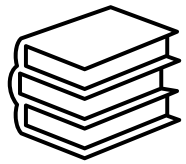
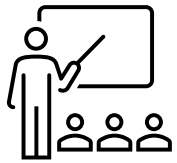
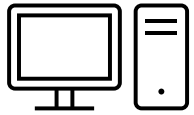
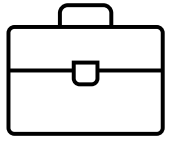
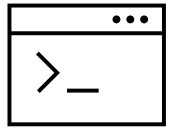
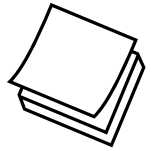
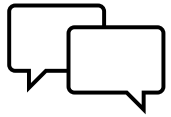
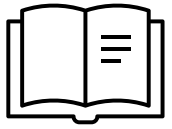
							
50+ CPD hours of lectures and learning	**Expert professor tutor, former health authority reviewer** with over 10 years of experience	**3 months of regulatory work experience** (part-time)	**European, UK and United States** regulations covered	**Remote and part-time** to fit around your work or studies	Expert **Regulatory CV Preparation x1**	Industry recognised **certificate**	Get **up to 12 months additional work experience.** Additional charges apply
							
On-demand **lecture recordings** and **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	**Mock interview x1** and interview resources	**Lifetime access** (course book. Additional charge) 3-months access to online resources	Exclusive cohort **professional community**	**Live calls** Regular Q and A sessions and Job search drop in calls

Fixed Start Dates – Cohort Groups Minimum entry requirement: life science, healthcare or chemistry degree or undergraduate Get more work experience for an additional charge

Last Updated Apr 2026

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

Further Work Experience & Mentoring

Regular Live Q and A webinars

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Regular Live Job Search Mentoring drop in sessions
Bi-weekly meetings where you can get direct support with your job applications

Additional work experience (additional charge)
Gain between 2 to 12 months of additional regulatory affairs work experience – available once you graduate from the course

Work experience projects (when available)
Once you graduate from the course, you will join our exclusive regulatory alumni community. If additional work experience projects are available e.g. regulatory intelligence, then we will give you the exclusive opportunity to apply. These roles are not advertised anywhere else. However, It is subject to availability, not guaranteed and depends on projects available and your performance and background. This work experience is a remote, part-time voluntary internship. Past projects in Regulatory intelligence.

Part 2 of the Introduction to Regulatory Affairs Course
Is the Global Regulatory Affairs course – get experience with global regulatory submissions across the full lifecycle (additional charge)
Includes Canada, UAE, Saudi Arabia, Switzerland, Australia, New Zealand and more.

Entry to Regulatory
Expert Regulatory Services

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

Why Choose Us?

Entry to Regulatory
Expert Regulatory Services

	Entry to Regulatory	Others
Comprehensive Lecture Series	✓	✓
Expert Teacher (Assoc. Prof. CEO, former MHRA)	✓	✓
Case Studies	✓	✓
Certificate and Professional Reference	✓	✗
3 Months of Work Experience	✓	✗
Job Search Mentoring and Resources	✓	✗
50+ CPD hours of learning	✓	✗
Expert CV Review	✓	✗
Mock Interview	✓	✗
European, UK and United States (or Global) Regulations	✓	✗
Exclusive Professional Community	✓	✗
Online Recorded Course with Live Support and ad-hoc Q and A sessions	✓	✗

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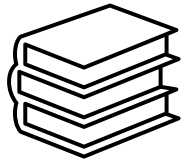
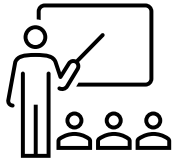
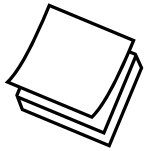
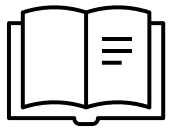
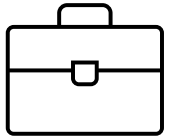
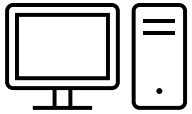
Global Regulatory Affairs Course Details

						
50+ CPD hours of lectures and learning	**Expert professor tutor, former health authority reviewer** with over 10 years of experience	**3 months of regulatory work experience** (part-time)	Real world **case studies** after every lecture	**Remote and part-time** to fit around your work or studies	**Lifetime access** (course book. Additional charge) 3-months access to online resources	Industry recognised **certificate**
	 					
Choose 2 or 4 global regions for lectures and work experience: Canada, Middle East GCC (UAE, Saudi Arabia, etc.), Australia, New Zealand, United States, Europe, UK, South Africa, Switzerland, Asia (China, Singapore, Japan), Russia, Turkiye, Brazil, Mexico					On-demand **lecture recordings** and **live tutor support**	Get **up to 12 months additional work experience.** Additional charges apply

Start Anytime Minimum entry requirement: life science, healthcare or chemistry degree or undergraduate Get careers support for an additional charge

www.entrytoregulatory.com

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Who Is This Course For? What Will You Get?

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Where You Are Now

Scientists	**Academics**	**Healthcare Professionals**	**Pharma Professionals**
Regulatory Professionals	**Other Scientific Roles**	**Recent Graduates**	**Undergraduates**

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Worst Case

We will give you

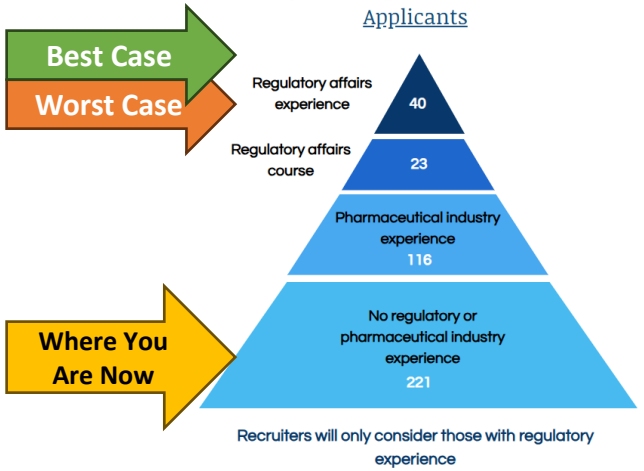
- 3 months of regulatory work experience including clinical trials, MAA/NDA and variations/post-approval changes
- 50+ hours of EU, US and UK full lifecycle regulatory knowledge
- Job search mentoring and careers support until you get a job
- Industry-recognised certificate, work experience and work reference for your CV

Based on your experience and our training, we will help you move into

Best Case

Entry-level Regulatory Role	**Mid-level Regulatory Role**	**Senior-level Regulatory Role**	**Pharma Role**
Medical Devices Role	**Health Authority Role**	**Graduate Regulatory Role**	**Regulatory Student Placement**

Entry level Regulatory Affairs Role Applicants



✅ Past students have gained a regulatory affairs job on average, 2 weeks to 9 months from starting the course*

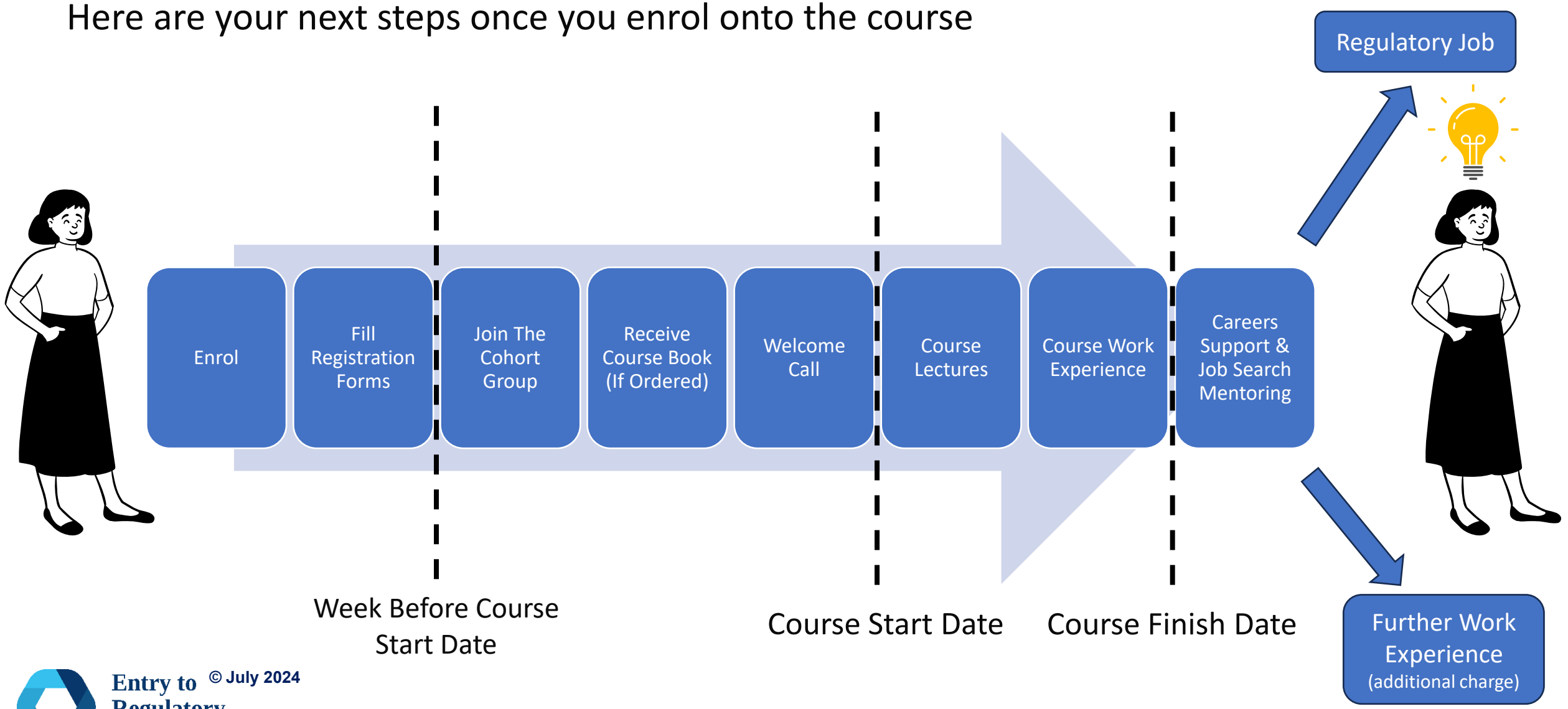
Not sure if this is for you? Ask us at contact@entrytoregulatory.com

Next Steps After Enrolment

www.entrytoregulatory.com

Advance Regulatory Consulting

Here are your next steps once you enrol onto the course



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When and How will the Full Course Be Taught?

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

Course Timeline	
Month 1	Week 1 **Introductory Lectures** and case studies Week 2 **Europe Lectures** and case studies Week 3 **US Lectures** and case studies Week 4 **Advanced Lectures** and case studies
Month 2	**CV Review**, [Apply for Jobs] Work Assignment 1 – **Variations/Post-approval** Work Assignment 2 – **Regulatory Strategy**
Month 3	Work Assignment 3 – **MAA/NDA** Work Assignment 4 – **Clinical – IMPD/IND** **Apply for Jobs**
Month 4+ Until you get a job	**Careers Hub, Apply for Jobs Job Search Mentoring, Mock Interview**
Additional Work Experience	Get an **additional 2 to 12 months** of regulatory **work experience** covering more regulatory submissions (additional charge applies)

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Spend 6 Hours per Week

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Example

Month 1

- 6 hours per week watching lectures and attempting case studies

Month 2 and 3

- 4+ hours per week on work assignments
- 2 hours per week on CV updates and applying for jobs

Remember: The day and time that you do these tasks is up to you. Just make sure you complete 6 hours each week

E.g. 1 hour per day Mon to Sat OR
1.5 hours on Mon, Tue, Wed, Thu OR
2 hours on Fri, Sat, Sun OR
3 Hours on Sat and Sun

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

www.entrytoregulatory.com

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

Course Fees & Discounts

Payment Options

- Pay in one go (or in 30 days)
- Pay in 3 monthly instalments (Klarna, PayPal)
- Pay in 5 monthly instalments

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Discounts For Those

- From low-income countries
- Unemployed
- In full-time education
- NHS workers
- Working in academia, government agencies or charities full time
- Multiple bookings

Contact, contact@entrytoregulatory.com to enquire about discount *See the Course Fees here*

www.entrytoregulatory.com

Is It Worth It?

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Return On Investment Case Studies*

Tejaswi, was **unemployed** when she joined the course

- After the course she moved into regulatory affairs with a starting salary of **£30,000**
- In 5 years time, this should increase to up to £80,000
- **Tejaswi return on investment is 1500% or 15x**
- Then after 5 years it should be 4000% or 40x

Liviana, was working in **academia** when she joined the course

- After the course she moved into regulatory affairs with a starting salary of **90,000 CHF**
- In 5 years time, this should increase to up to 140,000 CHF
- **Liviana's return on investment is 1000% or 10x**
- Then after 5 years it should be 3500% or 35x

Prahbjot, was working in **quality** when she joined the course

- After the course she got into regulatory affairs with a starting salary of **£50,000**
- In 5 years time, this should increase to up to £80,000
- **Prahbjot's return on investment is 500% or 5x**
- Then after 5 years it should be 2000% or 20x

* Based on past students. However, this is dependent on the effort you put into the course, work experience and job search process, as well as other factors. We will support you as much as possible. Success of past students is not a guarantee of your success. Your results will vary depending on region, education, effort, application, experience, and background. We cannot guarantee that you will be successful if you employ the advice specifically or generally. Consequently, your results may significantly vary from theirs. However, we will support you as much as possible. Specific experiences are mentioned for informational purposes only.

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Try It Out - Free Regulatory Affairs Course

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3-hour self-paced recorded course that you can do in your own time. There is even a work experience assignment and case study for you to try out. It is based on the content of the full Introduction to Regulatory Affairs course which provides 50+ CPD hours of learning, 3 months of regulatory work experience / internship and job search support until you get a job.
So, by doing this course, you get a sneak peak of the full regulatory course. If you are interested in investing in yourself and starting your professional journey in regulatory affairs, join today.

What you will learn:

- ✓ How to develop a regulatory strategy for a MAA
- ✓ What is in a Marketing Authorisation Application?
- ✓ What is in the CTD (overview)?
- ✓ How to classify an EU variation?
- ✓ How to author Module 1 of the CTD
- ✓ The structure of the FDA and EMA
- ✓ What is the drug development process?
- ✓ What is regulatory affairs?
- ✓ Why have a career in regulatory affairs?
- ✓ Regulatory affairs salary, benefits, career progression
- ✓ What do regulatory affairs professionals do?
- ✓ How to get a job in regulatory affairs?
- ✓ Full Introduction to Regulatory Affairs Course info
- ✓ How to get regulatory affairs experience and job mentoring

https://www.entrytoregulatory.com/regulatory-affairs-courses

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Email your questions to:
contact@entrytoregulatory.com

IMPD IND MAA NDA BLA ANDA Generics Biosimilar Scientific Advice

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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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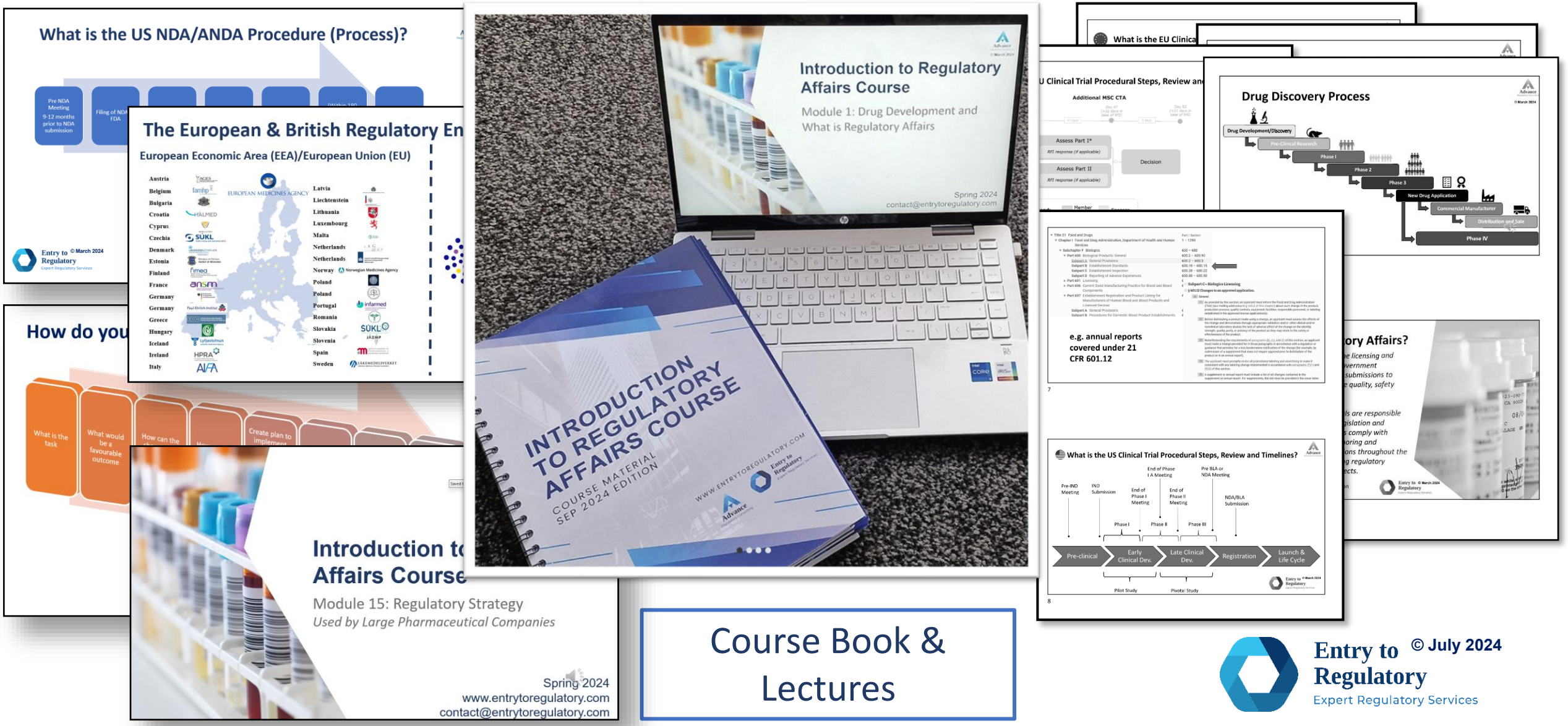
Lectures & Course Book – What You Will Get



Course Book & Lectures

Entry to Regulatory
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What Will You Learn? – Full & Core Course Lectures

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Welcome and Course Overview
- What is regulatory affairs?
- How is the course structured
- Full course details
- How to excel in the course and move into regulatory
- Learning portal
- Course timeline and deadlines

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

Pharmaceutical Industry Departments and Organisation
- Types of pharma and biopharma companies
- Company structure types
- Key departments and job levels
- Regulatory interface with other departments (detailed)

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 committee's 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

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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

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Clinical Regulatory Affairs and Regulatory Writing
- 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?
- What is in the IMPD?
- 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
- Pharmacovigilance regulations and regulatory authorities
- Adverse reactions, adverse events
- Signal detection
- Risk management
- Post-marketing surveillance

eCTD Content - Introduction and Module 1, Regional Administrative Information
- 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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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? – Global Course Lectures

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Choose 2 or 4 global regions for lectures and work experience:

Canada, Middle East GCC (UAE, Saudi Arabia, etc.), Australia, New Zealand, United States, Europe, UK, South Africa, Switzerland, Russia, Turkiye, Brazil, Mexico, Asia (China, Singapore, Japan, South Korea, Hong Kong), and more

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- Full course details
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- Learning portal
- Course timeline and deadlines

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- 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

eCTD Content – Detailed evaluation of all CTD Modules
- Module 1 – Regional Information, Admin
- Module 2 - Summaries
- Module 3 – Quality, CMC, Drug Substance, Drug Product
- Module 4 – Non-clinical
- Module 5 - Clinical

These Modules Will Be Covered For Each Region You Choose & You Will Get 1 to 2 Work Assignments For Each Region You Choose

Region 1 - Background of Medicines Legislation
- The regional regulatory environment
- The role and structure of the Health Authority
- The standards, legislation and guidance
- The laws underpinning medicines regulation
- Regulatory hot topics

Region 1 - Regulatory Procedures
- The regulatory environment
- Clinical trial procedure and timelines
- New Drug Application procedure and timelines
- New Drug Application assessment
- Post-approval procedures

Region 1 - Regulatory Control of Clinical Trials
- The laws underpinning clinical trials
- What are the clinical trial submissions and timelines
- What is in the clinical trial application?
- How are clinical trials applications maintained?
- Ethics committees role and procedures

Region 1 – New Drug Applications
- Contents of a New Drug Application – Regional Specific + M1
- Types of New Drug Applications
- Reference Product and Market Exclusivity
- Generic / Abbreviated applications
- Biological and Biosimilar applications
- Accelerated Procedures

Region 1 – Post-approval Changes and Lifecycle Management
- Minor post-approval changes
- Moderate post-approval changes
- Major post-approval changes
- Other post-approval change types

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

What Experience and Skills Will You Gain?

Work Experience Assignments

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Work Experience Assignments

Course work assignments that will give you real life regulatory submissions work experience. The assignment consists of a real-life scenario and takes you through several tasks to work through the regulatory submission for that scenario. You will work on **four** work assignments, covering the full product lifecycle. This can be added to your CV as regulatory work experience and you will get a work reference.

For the Global Course, you will get regulatory work experience for the global regions that you have chosen.

Full Course work experience will cover United States, European and UK regulatory submissions. Which are the regulatory standard

Full Course – Full Lifecycle Covered

- **Clinical Trials** – IND or IMPD authoring, CMC, Module 3
- **Commercialisation** - MAA or NDA, Variations or post-approval changes – Module 1
- **Post-approval** - Variations or post-approval changes – quality, safety and clinical changes. Module 1, Module 2, Module 3. Variations (Type IA, IAIN, IB) or post-approval changes (Annual Reportable, CBE-0, CBE-30)
- **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

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

Try out the sample work assignment in the free course
https://www.entrytoregulatory.com/regulatory-affairs-courses

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What Job Support Will You Get?
CV Review and Certificate

Certificate

A pharmaceutical (and medtech) 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.

Expert CV Preparation

During the course, our expert will help you prepare a regulatory CV that has already helped many people move into regulatory affairs. Your new CV will include this course (certifications and training section) and the work experience, and skills gained (work experience section). Our expert will help you make a CV that stands out from the crowd and increase your chances of getting an interview. 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.

Expert Regulatory Job Search Support (until you get a job)

- 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

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

Try out the sample case study in the free course
https://www.entrytoregulatory.com/regulatory-affairs-courses

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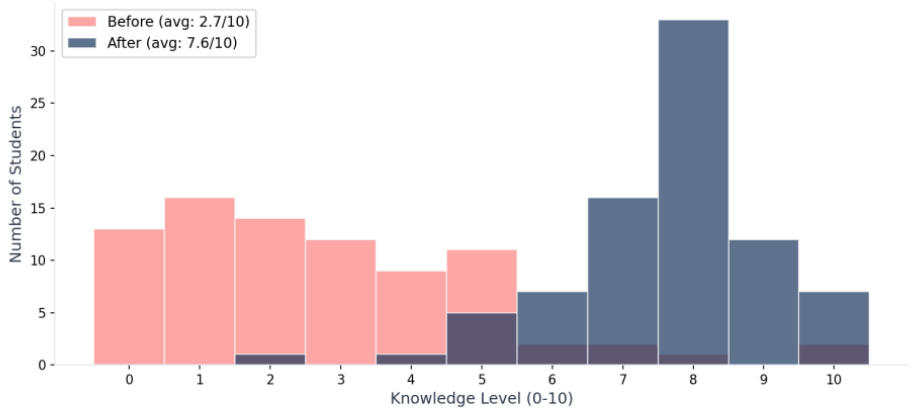
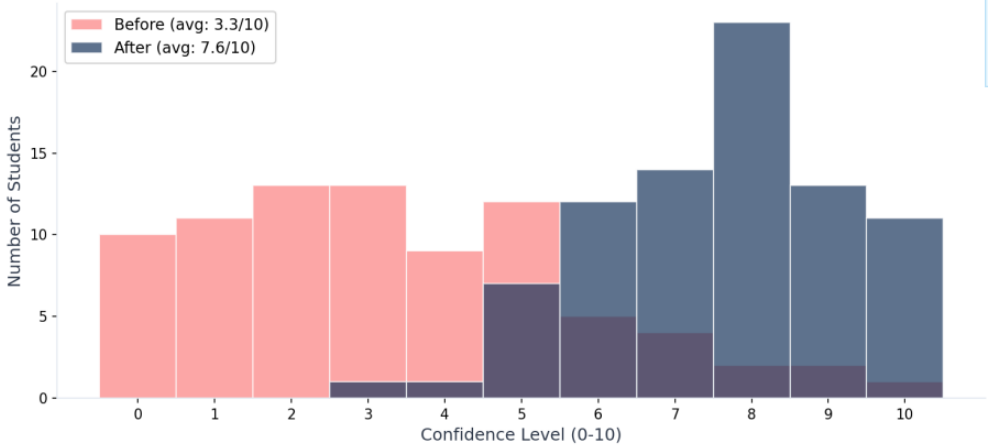
Course Rating

Knowledge in Regulatory Affairs: Before vs After Course



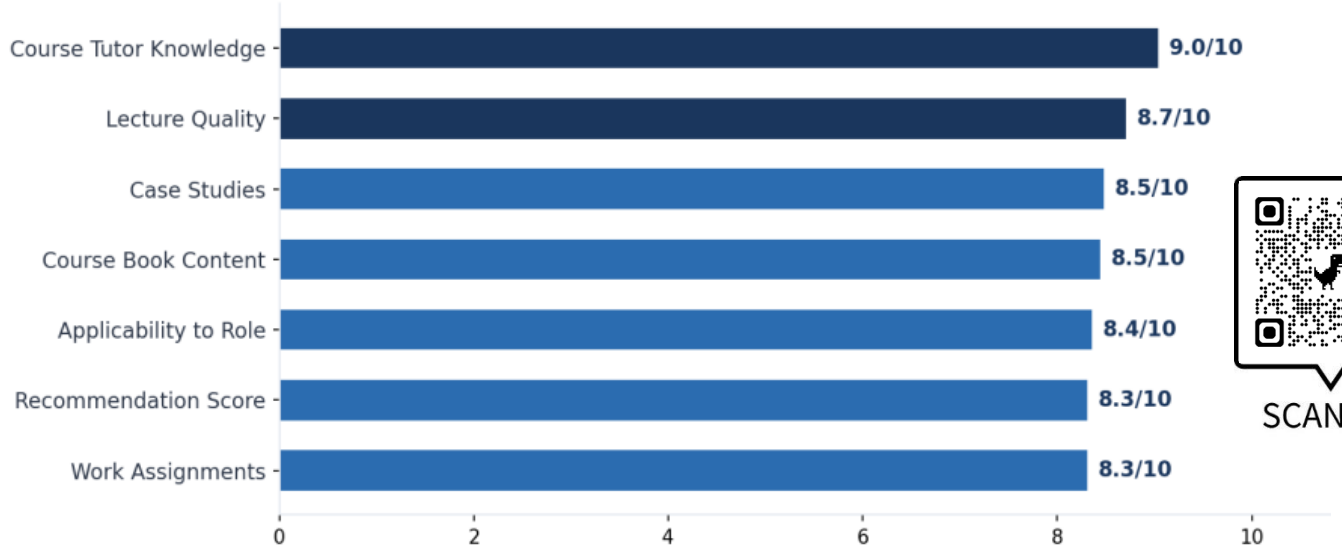
Insight: Students reported an average knowledge increase of **4.9 points** (from 2.7 to 7.6 out of 10), representing a **179% improvement** in regulatory affairs knowledge. Before the course, most students rated themselves between 1-4; afterwards, the majority rated their knowledge between 7-10, demonstrating the course's effectiveness in building comprehensive regulatory understanding.

Confidence in Applying for Regulatory Roles: Before vs After



Insight: Student confidence in applying for entry-level regulatory affairs positions increased by an average of **4.3 points** (from 3.3 to 7.6 out of 10), a **127% boost**. This significant shift demonstrates that the course not only builds knowledge but also empowers students with the practical confidence needed to pursue regulatory careers.

Key Performance Metrics Summary



SCAN ME

Insight: Every course component scored above 8.0 out of 10, reflecting consistently high quality across all aspects of the programme. The course tutor's knowledge led with 9.0/10, followed by lecture quality at 8.7/10. The practical elements — case studies (8.5/10) and work assignments (8.3/10) — were highly valued, highlighting the course's strong emphasis on real-world application.

Rating	Stars	Percentage
5 Stars	★★★★★	41.5%
4 Stars	★★★★	42.7%
3 Stars	★★★	14.6%
2 Stars	★★	1.2%
1 Star	★	0.0%

OVERALL RATING

4.2/5

84% rated 4-5 stars

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Student Feedback

OVERALL RATING

4.2/5

84% rated 4-5 stars

Farah

★★★★★

25 March 2026

Really great course, very informative, diverse with the range of lectures and the assignments were an excellent way to get experience! The work assignments were an excellent look into the type of work that would be carried out The course book is helpful for the note taking and to follow whilst watching the lectures. Really great lecture videos and the flow of the lectures were great too. Everything was explained clearly, and you can tell the tutor is highly experienced and knowledgeable. Really helpful to be able to test what you've learnt after watching each video. Great intro intro the course to actually understand and grasp what regulatory affairs is all about and the expectations of a regulatory affairs professional. A great range of content regarding regulatory affairs and its involvement in clinical trials in the US, EU and the UK. A dive into INDs MAAs and understanding variations was in depth and very very interesting to. the detailed ECTD content was in depth and very informative. I think the CV review is a great addition overall, and to be able to have the course and experience sections clearly written out is super super helpful.

Olga

★★★★★

25 March 2026

An absolutely excellent, informative# well structured and detailed course. The Module videos, including the assignment answer videos were excellent. Content was extremely well explained and very informative. In particular, the assignments served to consolidate the module learning. Would like to have several more blank pages to make notes. Extremely detailed# well explained and informative. Very useful. Hugely useful- helped to consolidate module learning. Order of lectures and content was well paced and well organised. Variations proved the most complex for me. Still well organised. Excellent Excellent

Ammara

★★★★★

06 April 2026

The course was well-structured and provided a good balance between theory and practical learning. the lectures and case studies. the course book is well structured and organized. lectures are amazing and very inofrmative. case studies were good and informative give us time for brainstorming what was taught. The work experience assignments were very useful and practical. They helped me understand how theoretical knowledge is applied in real industry settings. they were all good. very informative comprehensive knowledge for all modules. informative and amazing. it was good

SCAN ME

Federica

★★★★★

25 March 2026

I liked the structure of the course. It was clear and well organised. I liked the cohort support in discussing the assignment. Overall I am happy and suggesting the course to friends. Work assignments and lectures The landed a job in a regulatory consulting company which makes the book super helpful in my daily routine. Lectures in module 1 were a bit repetitive. Module 2-4 were perfect, they went straight to the point. Clear and concise lectures. They were really helpful to understand documents and their structure. I pike this one and the job assignment. Well structured, clean and concise. This was my favourite. I liked the lecture and the connection with the assignment.

Hema

★★★★★

24 January 2026

Lectures were good, understandable. case studies & Assignments- (Work Experience) gave a practical real time work experience confidence. we learnt a lot especially while doing assignments with peer discussions, Q& A sessions. Overall course was designed well, even for the new comers, Non science background people to cope up well, Appreciate your Guidance! work assignments & case studies Was good & Understandable! Good Information Good & Practical Exposure, to gain confidence , Well made Good Very Informative, Also include USA guidelines &Work; assignment related to USA guidelines, for the ones who stay in USA Very Informative

Additional Work Experience

Get 2 to 12 months of regulatory affairs work experience to increase your career opportunities
Enhance your regulatory career through more regulatory experience, knowledge and skills.

2 months work experience options

- European regulatory submissions
- US regulatory submissions
- UK regulatory submissions
- Europe and US regulatory submissions

4 months work experience options

Europe and US regulatory submissions
Europe and UK regulatory submissions
US regulatory submissions*
Europe regulatory submissions*

Eligibility Criteria

To get additional work experience, you must have completed one of the following

- Entry to Regulatory Full Comprehensive Regulatory Affairs Course, Core Course or Global Course – provide certificate
- Regulatory affairs degree or masters – provide certificate
- 1 to 2 years regulatory experience – provide CV and LinkedIn

www.entrytoregulatory.com
contact@entrytoregulatory.com

Get 2, 3, 6 or 12 months of additional regulatory work experience covering more regulatory submissions (additional charge applies). Contact Rabiea

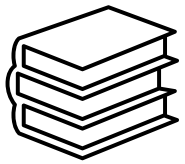
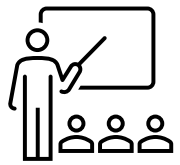
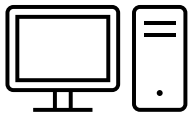
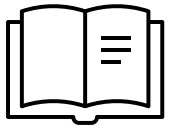
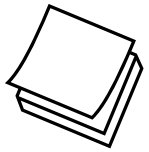
European	United States	Canada	Middle East
Australia/ NZ	UK	Switzerland	Other Countries
Medical Devices	CMC	Clinical Trials	Biologics

And more….

Work experience countries
Canada, Middle East GCC (UAE, Saudi Arabia, etc.), Australia, New Zealand, South Africa, Switzerland, EU, USA, UK, Asia (China, Singapore, Japan), Russia, Turkiye, Brazil, Mexico and more…

Work experience regulatory submissions
Clinical trials, NDA / full submissions, post-approval changes / variations and more…

Core Regulatory Affairs Course Details

				
50+ CPD hours of lectures and learning	**Expert professor tutor** with over 10 years of experience	**3 months of regulatory work experience** (part-time)	**European, UK and United States** regulations covered	**Remote and part-time** to fit around your work or studies
				
On-demand **lecture recordings** and **live tutor support**	Industry recognised **certificate**	**Lifetime access** (course book. Additional charge) 3-months access to online resources	Real world **case studies** after every lecture	Get **up to 12 months additional work experience.** Additional charges apply

Start Anytime

Minimum entry requirement: life science, healthcare or chemistry degree or undergraduate

Get more work experience or careers support for an additional charge

Entry to Regulatory
Expert Regulatory Services

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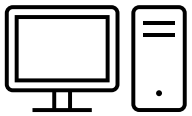
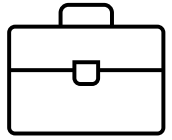
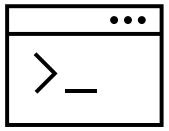
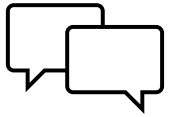
Careers Support Details

							
One to One **mentoring** through messages or calls	**Job search mentoring until you get a job**	Careers Hub **Job search training** videos and resources	**Expert careers advisor** with over 10 years of experience	**Mock interview** and interview resources	**Lifetime access** to **online** careers hub	Comprehensive **CV review**	**Live calls** Job search drop in calls (discretionary)

Start Anytime
Minimum entry requirement: degree or undergraduate
Get regulatory lectures and work experience for an additional charge

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Course Fees & Discounts

Payment Options

- Pay in one go (or in 30 days)
- Pay in 3 monthly instalments (Klarna, PayPal)
- Pay in 5 monthly instalments

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Discounts For Those

- From low-income countries
- Unemployed
- In full-time education
- NHS workers
- Working in academia, government agencies or charities full time
- Multiple bookings

Contact, contact@entrytoregulatory.com to enquire about discount *See the Course Fees here*

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Is It Worth It?

Advance Regulatory Consulting

Return On Investment Case Studies*

Tejaswi, was **unemployed** when she joined the course

- After the course she moved into regulatory affairs with a starting salary of **£30,000**
- In 5 years time, this should increase to up to £80,000
- **Tejaswi return on investment is 1500% or 15x**
- Then after 5 years it should be 4000% or 40x

Liviana, was working in **academia** when she joined the course

- After the course she moved into regulatory affairs with a starting salary of **90,000 CHF**
- In 5 years time, this should increase to up to 140,000 CHF
- **Liviana's return on investment is 1000% or 10x**
- Then after 5 years it will be 3500% or 35x

Prahbjot, was working in **quality** when she joined the course

- After the course she got into regulatory affairs with a starting salary of **£50,000**
- In 5 years time, this should increase to up to £80,000
- **Prahbjot's return on investment is 500% or 5x**
- Then after 5 years it will be 2000% or 20x

* Based on past students. However, this is dependent on the effort you put into the course, work experience and job search process, as well as other factors. We will support you as much as possible. Success of past students is not a guarantee of your success. Your results will vary depending on region, education, effort, application, experience, and background. We cannot guarantee that you will be successful if you employ the advice specifically or generally. Consequently, your results may significantly vary from theirs. However, we will support you as much as possible. Specific experiences are mentioned for informational purposes only.

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Start Your Regulatory career

Invest in yourself, speak to us, access the free regulatory course or sign up to the full course on:
https://www.entrytoregulatory.com/how-to-get-a-job-in-regulatory-affairs

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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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Entry to Regulatory - Training

Entry to Regulatory
Expert Regulatory Services

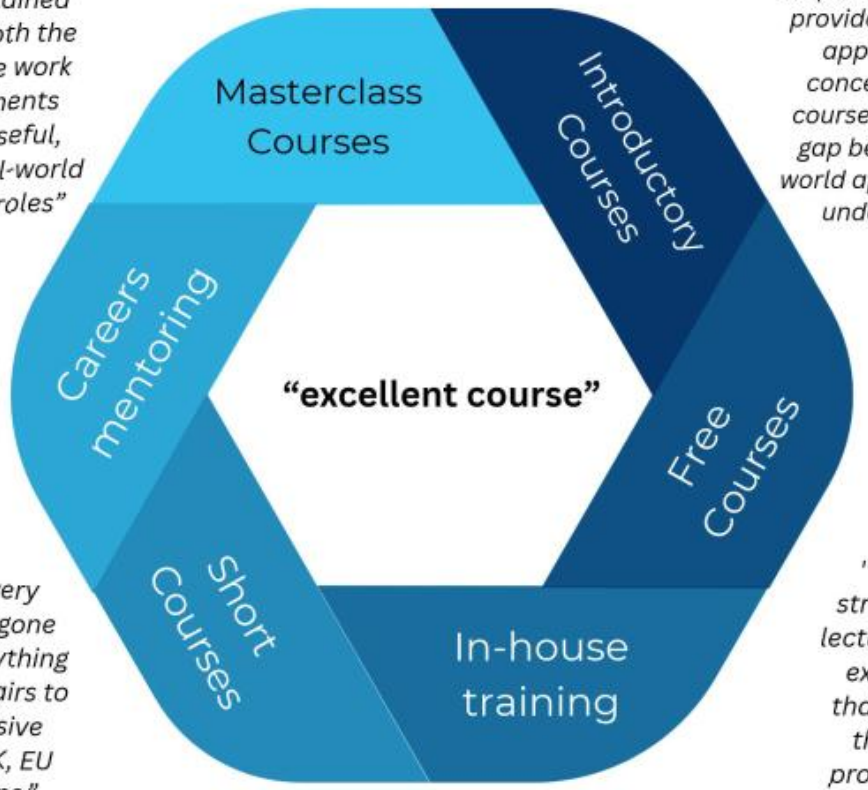
We Are A Leading Industry Training Provider

Our Courses Include:

- ✓ Real work experience & case studies
- ✓ Industry recognised certification
- ✓ MHRA expert course leader
- ✓ Flexible online learning
- ✓ Live tutor support
- ✓ Career mentoring
- ✓ Course books

"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"

"I found the work assignments to be particularly valuable as they provided a practical, hands-on approach to applying the concepts learned during the course. They helped bridge the gap between theory and real-world application, enhancing my understanding and skills."



"The lectures are very detailed and I have gone from not knowing anything about regulatory affairs to having comprehensive knowledge of the UK, EU and USA regulations."

"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."

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We Can Help You With:

- Clinical trials regulatory support
- CMC support
- Regulatory Submission Preparation
- Expert Regulatory Advice
- Regulatory Strategy
- Health Authority Meetings
- Risk Identification and Mitigation
- Manufacturing site transfers
- Regulatory Procedural Support
- Project Management
- Gap Analysis
- Regulatory Authoring
- Response to Agency Questions
- Regulatory Compliance
- Change Management
- Process and System Improvements
- Regulatory Training
- Global Regulatory Intelligence

Case Studies

- Led regulatory strategy and IMPD preparation for 5 biological/gene therapy medicines in Phases 1 and 2 of development, gaining a 100% approval rate with no agency questions.
- Prepared and submitted BLAs for a monoclonal antibody, registering it in 5 markets.
- Prevented the supply issue of a medicine by leading the EU health authority communication strategy and grouped variation. Approval was obtained in 10 days, without any agency questions and a $2million+ cost saving.
- Strategised and prepared EU and rest of world responses to agency questions simultaneously, resulting in a 100% approval rate for 50 grouped variations across 107 licenses, saving several millions of euros.

Client Feedback

Head of Department, Biotech

'They have completed one of our more challenging submissions, providing some expert input and writing for the submitted IMPD. They have provided some insight and direction into a more structured authoring, review and approval process for regulatory submissions.'

Director, Biogen

'Their leadership, CMC regulatory expertise, and operational awareness have been invaluable in helping the team remain on track to completing the IND submission. They are well organized, have excellent communicational skills, both oral and written...they are knowledgeable, self-motivated, work with a sense of urgency, and are great team players.'

Director, Biotech

'They are extremely knowledgeable and experienced (in regulatory strategy and scientific advice meetings). They were very organised and diligent, with a good communication style.'

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July 2026

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