

A Career in Big Pharma

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Media Disclaimer



*To confirm that the opinions you hear from me are **totally my own** and do not reflect the views and opinions of GSK in any way.*

Academic background



Sir William Perkins's School and The University of Aberdeen

A Levels:

Human Biology, Chemistry and German

AS Levels:

Music and Critical Thinking

Never thought I'd pursue a career in science!

So why did I study Immunology at the University of Aberdeen?

Industrial Placement, GSK Stevenage



My first experience of 'Big Pharma'

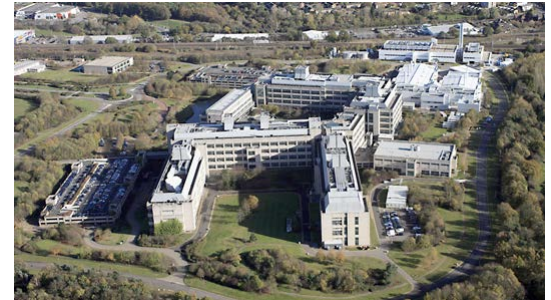
First-hand experience of science in industry

Development of both professional and personal skills

Experience real 'working life'

Opportunity to put learnings from
university into practice

Build on existing knowledge



What I learned



How to stay in science without actually doing science...

Still had a passion for science

Didn't want a career in a laboratory

Enjoyed working in an office and in a large pharmaceutical organisation

Wanted to work with lots of different people

Arranged work experience in Global Patents Department = eye-opener!

Graduation

What next?



PhD?

Scientific publishing?

Clinic/hospital work?



Further qualifications?

Teaching?

Patent Law?

Regulatory Affairs (R&D) Future Leaders Programme



Using passion for science to help make safe, life-changing medicines more available to patients worldwide

Life-science graduates

2 year scheme, 4x 6 month rotations

Insight into the breadth, depth and influence of pharmaceutical industry

Structured training programme

Differentiated development

Volunteer opportunities

The Application Process

Be honest and take your time!



What is Regulatory Affairs?



Relatively new profession

Government desire to protect public health by controlling **safety, quality and efficacy** of medicinal products, devices, cosmetics, agrochemicals, pesticides and veterinary medicines

Pharmaceutical regulatory affairs ensures that medicinal products and devices meet rigorous standards set by regulatory agencies across the world

Regulatory Affairs Professionals



What do we do and how do we do it?

Collect, collate and evaluate scientific data to confirm SQE of drugs

Maintain scientific and technical knowledge of healthcare products

Create and present submission and registration documents to authorities
e.g. CTAs, MAAs

Ensure products meet regulators' expectations

Keep current with ever-changing global agency requirements/guidelines

Areas within Regulatory Affairs



4x 6 month rotations

Labelling

- Ensuring information for prescribers (doctors and pharmacists) and patients is accurately and clearly expressed and maintained.
- Support global management of prescribing information throughout product lifecycle – CSI/GDS.

CMC (Chemistry, Manufacturing and Controls)

- Supporting data for drug substance, formulation development and manufacture which underpins the quality of our medicines

UK LOC (Regional Teams)

- Regionally focused teams supporting UK and Ireland – working with variety of products across a number of therapy areas (respiratory, cardiovascular, immuno-inflammation, infectious diseases, neurosciences and dermatology).

Therapeutic

- Defining and implementing the global regulatory strategy, interacting with project teams and regulatory agencies.
- Focused on the data that supports the clinical efficacy and safety of our products.

Areas within Regulatory Affairs

Additional rotations



Quality and Risk Management and Professional Development

- Providing regulatory governance and training

Regulatory Operations

- Publishing regulatory dossiers and supporting the management of submissions/records.

Big Pharma and Regulatory Affairs



Personal rewards and challenges

Fulfils both my interest in science and my real want to improve the health of patients	Stressful and demanding
Holistic view of drug development	Sometimes easy to feel small
Crucial role in the development of novel products that may positively impact patient's lives	
Unparalleled resources	
Working with innovative products alongside individuals with lots of expertise	
Personal and professional development opportunities	
Exciting - always something new to learn	
'Lynch pin'	
Healthy work-life balance	

Furthering my career in Big Pharma

Professional and personal development



Opportunities to progress both up and across the business

Global company → global opportunities

Secondments

Volunteering opportunities

MSc in Regulatory Affairs

(TOPRA and The University of Hertfordshire, requires 2 years' experience in Regulatory Affairs)

Work more closely with regulatory agencies e.g. MHRA, EMA, FDA

What I've learnt so far...

Experience is key!



Forge new relationships
and network whenever
possible

Actively seek out
new and
interesting
opportunities

Be willing to adapt,
flex and stretch

Be bold and
proactive

Make your ambitions
and goals known

Take the time to re-focus



Any Questions?