A Career in Big Pharma

Beatrice Tilt, GSK
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?

Clinichospital work?

Scientific publishing?

Teaching?

Further qualifications?

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!

1. Application Form and CV
2. Online Test
3. First round video interview
4. Assessment Centre
5. Offer!
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
<table>
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<tr>
<th>Areas within Regulatory Affairs</th>
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<td><strong>4x 6 month rotations</strong></td>
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### 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*

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

What I’ve learnt so far...

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?