Regulatory Affairs in Life Science

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What is healthcare regulatory affairs?

- Regulatory affairs developed due to government concern to protect public health and product safety and efficacy in areas such as pharmaceuticals, veterinary medicines & medical devices

- Regulatory professionals are key to the delivery of safe and effective treatments to patients
Why it matters!
Without proper regulation...
From Compound to Drug

In practice many larger companies maintain compound libraries of many millions.
The Drug Development Process

IDEA

12-15 years

Disease Selection
Gene to Target
Target to Lead
Lead to Candidate Selection
Candidate Selection to FTIH
FTIH to PoC
PoC to Commit to Phase II
Phase II
File & Launch
Life Cycle Mgt

Commit to Product Type
Commit to Target
Drug Discovery Lead series identified
Commit to Candidate
Commit to first testing in humans
Commit to Product Devt
Commit to Phase III
Commit to File & Launch
Approval & Launch

Create and Make it
Test it
Register and Expand it

Uncertainty

Confidence in drug and disease

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THREE KEY ITEMS WHICH MUST ALWAYS BE PROVEN:

- QUALITY
- SAFETY
- EFFICACY

- Increasingly the pharmaco-economics of new products is being considered.
What regulatory affairs involves

- Licensing, marketing and legal compliance of pharmaceutical and medical products
- A combination of science, legal and business – ensuring well designed and validated data with appropriate statistics and discussions
- Ensuring adherence and compliance with health authority guidelines and regulations
- Liaising internally between research, production and business development and externally with health authority personnel, inspectors and European regulators
- Information and intelligence gathering to try to anticipate change – keeping up to date with draft guidelines, European Directives and national laws and regulations.
Where regulatory interfaces with other departments

- Other regulatory affairs groups
- Clinical research
- Marketing artwork labelling
- Legal and intellectual property
- Drug safety/Pharmacovigilance
- Manufacturing and quality
- Regulatory authorities
- Business strategy & marketing
What you might do!

Put together regulatory submissions
Write regulatory dossiers
Analyse data to ensure suitability for regulatory submission
Develop regulatory and development strategies for new products
Sit on a global project development team
Project manage a development or submission programme
Manage products post licensing
Manage a region or territory
Why choose regulatory affairs?

- It is a dynamic, fast-paced environment
- It has a positive impact on society
- It interfaces with many different functions/teams
- It is a hybrid of science, business & communication
- It is a responsible job & with a practical application of science
- It recruits from diverse academic/industrial science backgrounds
- There are opportunities to work in many different business areas, eg medical devices, active ingredients, biopharmaceuticals

PLUS:

- Good opportunities to progress & develop
- Potential for international travel & flexible working conditions (hours/locations, etc)
- Opportunities to specialise (pharmaceutics, compliance, operations, publishing, consultancy)
What do I need to become a regulatory professional?

A scientific background (usually pharmacy, chemistry or biological sciences)

- Skills include:
  - Interest in a wide range of scientific disciplines
  - Excellent written and verbal communication skills
  - Team working and negotiation skills
  - Problem solving – creative thinking
  - Project management
  - Attention to detail
  - Flexibility and ability to work in a dynamic and constantly changing environment

A knowledge of legal frameworks, processes and procedures can be learned!
Getting started...

- Look for work experience opportunities – in a healthcare related setting if possible
- Build a good, relevant and accurate CV
- Look out for graduate training schemes and apprenticeship opportunities
- Join TOPRA as a student member!
To find out more go to www.topra.org/careers

This careers guide is available on Amazon, but is free for student members.
Career long approach to professional development
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