Research Governance

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Overview

- Research background
- Career pathway
- Review of some career opportunities outside of academia and R&D
- Company set-up
- Research Governance
- Barriers to career progression and their resolution
- Summary

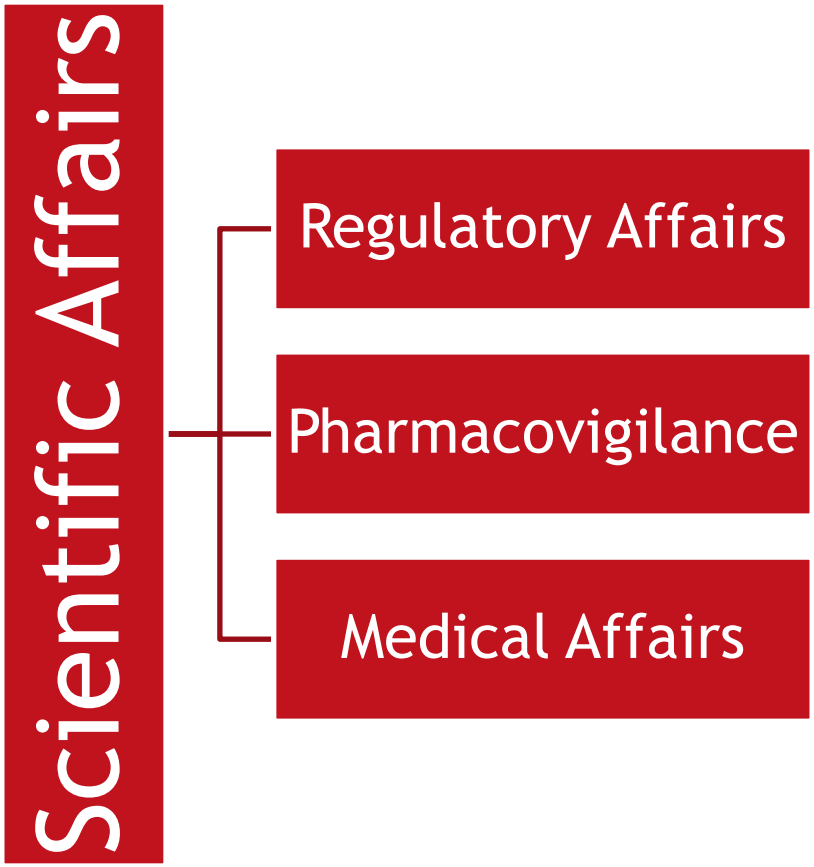
Research Background

- Qualified as a Pharmacist (2003)
- Started PhD with Professor Karl Malcolm and Professor David Woolfson (2003)
- Thesis title ‘Novel drug release modification strategies from silicone intravaginal rings’
- Attracted to this project for two main reasons
    1. Supervisors
    2. Topic would provide me with a good understanding of formulation development
- Awarded PhD in 2006

Senior Regulatory Affairs Scientist (Galen)

- Writing Marketing Applications for new products
- Providing advice in-house and to external customers
- Licence maintenance
- Due diligence for product acquisitions
- Central role within a pharmaceutical company
- Almost every meeting or project involved regulatory personnel
- Multidisciplinary role
- Translation of R&D into patient treatments
- Usually a unit within Scientific Affairs

Scientific Affairs



Key Relationships

- Good communication across teams
- Marketing focus
    1. Review of marketing material for compliance with ABPI
    2. Provision of information for promotion purposes
    3. Answering queries from public/HCP
    4. Defending the company when a complaint is made
- Quality and Clinical Teams

  Ensuring that studies/products are managed efficiently

Translational Research / Medicine

- This term originated in 1990s and was initially meant to encourage academia to show ‘real’ benefits and expedite research findings into new medicines, treatments, etc.
- Now there is a much narrower interpretation of what this term actually means that follows industry expectations
- Britannica define this as ‘a process that is aimed at expediting the development and commercialization of known therapies’
- Funders now strongly link awards with translational potential

Compliance Manager Clinical Studies (Almac)

- Review of Clinical Trial Applications
- GMP manufacture of Investigational Medical Product
- Regulatory guidance
- Investigation of incidents
- Host audits and regulatory inspections
- GxP guidance
- Implement systems and new services for Clients eg Early Access Programmes

GxP

- **Good Laboratory Practice (GLP)** – refers to the quality standard expected in laboratories conducting regulated non-clinical studies. The principles are defined in 2004/10/EC and are not restricted to the pharmaceutical sector

- **Good Clinical Practice (GCP)** – the definition from the EU Directive 2001/20/EC states "Good clinical practice is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects."

Good Manufacturing Practice (GMP)

- A common term used to describe manufacturing requirements of medicinal products. Often referred to as current Good Manufacturing Practice (cGMP) to indicate the ever changing nature. Unlike Good Clinical Practice, demonstrating cGMP equivalency throughout the world is complex

Radiopharmacist

- Responsible for ensuring PET pharmaceuticals were manufactured to GMP
- Providing professional advice
- Initially shocked, but gained great experience working in a resource deprived facility
- Made a real difference to the facility and resolved major issues

Review of Some Career Opportunities Outside of Academia and R&D

- Regulatory, Pharmacovigilance, Quality, Clinical, Marketing, Business Development, Legal
- PhD is a distinct advantage
- Flexible career
- In the US the fixed boundaries of these roles have disappeared and hybrid roles for Industry/Academia are now common
- Global jobs

Regulatory Consultancy

- Formed a limited company last year leading on from self-employed work
- Only a micro-business at present
- Enjoy being involved in any project that can benefit patients
- Mainly interested in providing specialist advice
- Comply with the University's Conflict of Interest Policy

Research Governance

- Part of a team located in the Research and Enterprise Directorate
- Provide governance function for the whole of the University
- Review ethics applications
- Sponsor oversight
- Attend the School of Medicine, Dentistry and Biomedical Sciences Research Ethics Committee
- Ensure compliance with HTA
- Support research integrity

Queen's Research Governance Policies

- Code of Good Conduct and Integrity in Research (under review)
- Policy on the Ethical Approval of Research.
- Regulations relating to research involving human participants
- Regulations Governing the Allegation and Investigation of Misconduct in Research

Barriers to Career Progression and their Resolution

Industry

- Locally there is a limited pharmaceutical industry
- Can be hard to get ‘global’ experience in your chosen field
- Some roles are subject to long working hours and extended travel abroad

University

- Perception of ‘central’ University staff

Summary

- A wide range of very rewarding careers are available outside of traditional R&D posts
- Movement between Departments is encouraged
- Global job
- Opportunity to offer consultancy services if you have the right experience
- Academia is a rapidly changing environment with hybrid roles becoming more common