And you may ask yourself—Well...How did I get here?

Talking Heads, 1984
What is Regulatory Affairs?

Why is Regulatory Affairs Needed? – The Remit

The Regulatory Environment

Regulatory Affairs and Product Lifecycle

What makes a good Regulatory Professional?

A Career in Regulatory Affairs
What is Regulatory Affairs?
What is Regulatory Affairs?

- **Regulatory Affairs:**
  - Is a unique mix of science and management to achieve a commercially important goal within a drug-development organisation.
  - Touches everything relating to drugs from the earliest non-clinical studies, through development, into routine manufacture and marketing.
  - Can add significant impact for patients and drug companies.
What is Regulatory Affairs?

- Why a discipline within its own right?

Diagram:
- Science
- Management
- Legislation
- Commercialisation
Why is Regulatory Affairs Needed?

- Drug development and commercialisation is highly regulated
- The path to drug registration (Marketing Approval) is paved with good intention but can be complicated
- Things change....constantly!
Why is Regulatory Affairs Needed?
Why is Regulatory Affairs Needed?

- **Design =**
  - Development Plan

- **Co-ordination =**
  - Writing/reviewing, supervising

- **Construction =**
  - Assembling & Submission Management

- **Testing =**
  - Where are the weaknesses?
Why is Regulatory Affairs Needed?
The Regulatory Environment

- Drug regulations
  - National Laws
    (e.g. UK - Medicines Act, US- CFR)
  - Regional Laws (EC directives)
  - National and Regional Guidelines
  - International Guidelines (ICH)

- Procedures
The Regulatory Environment

- **Says who?**
  - National and/or Regional (Federal) Government
  - Industry
  - Professional bodies
Other Factors
- Politics
- Media

Grey areas
- Always a interesting challenge
The Development Plan

- A “road map”
- Includes all the disciplines relating to drug development and commercialisation
  - Science (Pharmaceutical, Non-clinical, Clinical)
  - Commercial (Marketing, Manufacture, Supply)
  - Resources (Funding, Manpower)
- Defines the most efficient route to success
- Living document
Regulatory Dialogue

- Every product is different
- Pharmaceutical, Non-clinical and Clinical issues emerge in all stages of development
- Regulatory guidelines don’t always address problems encountered
- Discussion with the Regulatory Agencies is usually required at some point
- Dialogue must be open and honest but mindful of the consequences
The Regulatory Submission

- Building the CTD Pyramid
  - Data
  - Summaries
  - Product information
    - Summary of Product Characteristics
  - Administrative information
Regulatory Procedures

- National
  - UK, US

- EU Community
  - Mutual Recognition
  - Decentralised

- EU Centralised
  - EMEA – European Medicines Agency
A Typical Procedure

- Duration 9-12 months
- A mix of agency review time and company response time
- May be subject to “clock stops” or a continuous process
- Early approval to market is more important than early submission of a dossier
- Can be bureaucratic
Submission Management

- Anticipating the questions –
  - Gap analyses/Question spotting
  - Timings
  - Need for additional data

- Communicating -
  - Internally – your team, management
  - Externally – the assessors, experts

- Controlling resource -
  - What else is going on?

- Getting things done in the right time-frame
The Product Lifecycle

- Clinical Trial Applications and INDs
- Orphan Drugs
- Company initiated changes
  - Variations
  - Mergers/takeovers
  - OTC status
- Environmental changes
  - Emerging safety issues
  - New standards
A Good RA Professional?

- Team player
- Communicative
- Ability to work with and respect other disciplines (scientific and non-scientific)
- Decisive
- Diligent
- Authoritative

- Commercially aware
- Always willing to learn
- Flexible
- Open to non-scientific challenges
- Creative
- Good IT skills
A Typical Career

- 1-3 years executive level
- 3+ years senior level
- Associate director
- Director
- Vice President
- President
Training & Support

- On the job
- TOPRA
  - Regulatory Affairs Introductory Course
  - CRED Courses
  - MSc in Regulatory Affairs (University of Wales)
  - MSc in MTRA (Cranfield)
- Symposia/Conferences TOPRA/DIA/RAPS
- Internal Company training
- External organisations
Opportunities

- **International Opportunities**
  - Projects, secondments, relocation

- **Shaping the future within companies**

- **Outside industry**
  - Trade bodies
  - Become a regulator!

- **Sub-specialties**
  - Regulatory Operations
  - Regulatory Intelligence

- **Other industry disciplines**
But I’m a Specialist...

- You can specialise but this may lead to pigeon-holing
- You can choose to work for organisations specialising in a therapeutic area
- REMEMBER - Good science is applied more or less every day