

NIH FelCom Career Development Workshop

Regulatory Affairs

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Typical career path in Reg Affairs

- Nothing typical
- Origins in Clinical, CMC, Project Management, Research, PharmD
- More people now obtaining BS or MS in Reg Affairs
- On-the-job training and experience still irreplaceable
- Lifelong learning
- Experience often narrow: drugs, biologics, devices, phase I – III studies; NDA/BLA/PMA; post-marketing
- Big pharma, small biotechs, government
- CRO offers accelerated learning: drugs, biologics, devices; global clients; all phases of development

My path

- BS Biology
- 7 years laboratory technician (biotech companies)
- Project Management
- On-the-job training and entry level position in Regulatory Affairs (Biotech company)
- CRO
- Small to mid size Biotech companies
- On-the job training continues

General Landscape of Reg Affairs

- Enormous breadth of information --- cannot know everything
- Evolving global standards
- Different local regulations for countries/regions
- Differences between: National Regulatory Authorities; FDA therapeutic divisions; FDA reviewers
- More important to know how/where to find answer
- Cross-functional coordination necessary for development of regulatory strategies

Skills important for success

- Enjoys working with variety of stakeholders, internally and externally
- Excellent communicator (written, oral)
- Active listener: make sure stakeholder knows they have been heard
- Understands concerns/needs of non-regulatory stakeholders (e.g., Business Development, Clinical Affairs, Research)
- Functions in environment of constantly changing priorities
- Enjoys fielding a variety of questions
- Open minded
- Able to rely on common sense for problem-solving
- Adapts easily to change and acts as a change agent
- Willing to use consultants, as necessary

Advice

- Join Regulatory Affairs Professionals Society (RAPS): training courses, resources, annual meeting
- Take exam to obtain RAPS Regulatory Affairs Certification (RAC): US, EU, CAN, or General Scope
- Access FDA Webcasts and slides from previous presentations on internet
- Join Linked-In Regulatory forums
- Develop network of Regulatory Affairs colleagues
- Target desired company or institution and request information interview with Regulatory Affairs professional
 - Path to current job?
 - Typical day?
 - Positives / negatives?

Thank you!