Product Development: From Academics to Regulatory Affairs

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My Educational Background

- Undergraduate – BS in Biology at Kentucky Wesleyan College

- Graduate School – Ph.D. Anatomy and Neurobiology at University of Kentucky
  - Development of neurotrophic peptides as therapeutics for Parkinson’s disease
  - T32 Training Grant on Translational Neuroscience
Education Continued

- **Post-docs**
  - Wake Forest University
    - Development of neural prosthesis in non-human primates
  - University of Louisville
    - Development of a protein-based HIV prophylactic

- **Certificate Programs**
  - Intro to Regulatory Affairs – UC San Diego
  - Project Management – UofL
  - Regulatory Affairs: Medical Devices and Pharmaceuticals – RAPS
  - RAC – Certified in US Regulatory Affairs
- Assistant Professor
  - UofL – Pharmacology and Toxicology Dept.
  - Program Manager – PREVENT
  - Regulatory Core Leader – PREVENT
  - Regulatory Consultant

- Director of Biomanufacturing and Regulatory Affairs
  - GROW Biomedicine, LLC
Structure of the PREVENT U19 Program

Internal Oversight
Steering Committee

Core D
Regulatory oversight

Core A
Administrative oversight

External Oversight
NIH Program Management
Scientific Advisory Board

Project 1
Critical Path Activities

Project 2
Preclinical Safety and Efficacy Studies

Project 3
Clinical Studies

Core B
Product Development

Core C
Pharmacokinetics and Pharmacodynamics

Regulatory Consulting
Invention to Commercialization

- There is a wide difference between contemplating an invention and putting the manufactured article on the market.
  -- Thomas Edison

- 1879 Filed Patent on incandescent light bulbs
- 1882 First Public building to use Edison bulbs
Commercialization of Healthcare Products

- The world’s most regulated industry, matched only by nuclear power.
Academics to Regulatory Affairs

- Academics – Invention/Discovery
- Regulatory Affairs – Facilitates and guides product development with a focus on regulatory compliance.
- Regulatory knowledge can help guide drug or device research in an Academic setting to add value to a discovery.
- Some of you may be considering transitioning from Academics to a career in Regulatory Affairs.
US Regulatory Affairs

- Compliance With What?
- In the US
- Code of Federal Regulations
  - 21 CFR for FDA
    - 21 CFR 1 – 99 General
    - 21 CFR 100 – 199 Food
    - 21 CFR 200 – 299 Drugs General
    - 21 CFR 300 – 499 Drugs Humans
    - 21 CFR 500 – 599 Drugs and Feed Animals
    - 21 CFR 600 – 699 Biologics
    - 21 CFR 800 – 899 Medical Devices

https://www.ecfr.gov/cgi-bin/text-idx?SID=4cec9b75b5dcbb03791e3997e56dd810&mc=true&tpl=/ecfrbrowse/Title21/21chapter1.tpl
International Regulatory Affairs

- Most countries have their own regulatory bodies that carry the rule of law.

- Started by US, EU, Japan, Canada, and Switzerland regulatory agencies in partnership with industry representatives (WHO, USP, PhRMA).
- Additional Member Countries; China, Korea, Brazil, Chinese Taipei, and Singapore
- Other organizations and countries have roles as observers; Russia, India, Mexico, etc..
Drug Development Pathway


* The average R&D cost required to bring a new, FDA-approved medicine to patients is estimated to be $2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.


Device Development Pathway

NEW MEDICAL DEVICE

CLASS I
low risk

CLASS II
moderate/controlled risk

CLASS III
high risk

exceeds limits of exemption

510(k)
substantially equivalent to predicate?

no

yes

< 4000 patients per year in U.S.

de novo 510(k)
no predicate

HDE
probable benefit outweighs risk

PMA
reasonable assurance of safety and efficacy

exempt

CLEARANCE TO MARKET DEVICE

APPROVAL TO MARKET DEVICE

https://www.fda.gov/media/90419/download
Functions of a Regulatory Professional

- Interpreting regulations and advising on impact and management strategies
- Preparing submission documents
- Serving as a liaison between developers and the FDA
Organizations & Regulatory Jobs

- **Organizations**
  - Clinical Research Organizations
  - Government Agencies
  - Hospitals
  - Healthcare Organizations
  - Academic Institutions
  - Drug and Device Developers

- **Jobs**
  - Regulatory Specialists
  - Regulatory Writer
  - Regulatory Strategist
  - Compliance Officer
  - Quality Assurance
  - Clinical Research Associate
IND Submissions

How Many IND submissions from 2012 – 2016? Academic vs Industry?

https://www.fda.gov/media/106231/download
IND Submissions

15233

https://www.fda.gov/media/106231/download
Product Development Teams

- Academics (Regulatory or Clinical Support Core and Principle Investigator’s Team)
  - Clinical Research Coordinator
  - Regulatory Specialist

- Industry
  - Project Manager
  - Regulatory Affairs
  - Clinical Affairs
  - CMC
  - Preclinical
  - Medical Affairs
Drug and Device Regulatory Jobs Outlook

- US Bureau of Labor and Statistics estimates an 8% increase until 2028 in drug and device regulatory jobs.
- New and expanding areas of regulation:
  » Vaping
  » Medical Cannabis Products
  » Recreational Cannabis Products
  » Gene Therapy Products
  » Human Device Interface Products
  » Global Approval Strategies
Regulatory Jobs

- The biggest concentration of jobs are in San Diego, San Francisco, Boston, Philadelphia, and Durham.
- However there are many positions regionally; Chicago, Nashville, Atlanta, Indianapolis, Cincinnati, and even Louisville.
- **Amgen, Genentech, UPS** all have drug/device distribution centers located here that require regulatory and QA Specialists.
- US World Meds, HEMA Biologics, Catalent, Bexion, Medpace, CTI
- [https://regulatorycareers.raps.org/jobseekers/](https://regulatorycareers.raps.org/jobseekers/)
- [https://www.biospace.com/](https://www.biospace.com/)
Regulatory Affairs Certifications

- Regulatory Affairs Professional Society
  - Regulatory Affairs Certification (RAC)
  - [https://www.raps.org/](https://www.raps.org/)

- American Society for Quality
  - Certified Quality Engineer (CQE)
  - [https://asq.org/](https://asq.org/)

- Society of Clinical Research Associates
  - Certified Clinical Research professional (CCRP)
  - [https://www.socra.org/](https://www.socra.org/)

- All are certifications you may find people in regulatory positions attaining. However, there are differences in focus, and you need to find the one that fits your career path.
Regulatory Resources

- **ICH**
  - [https://www.ich.org/](https://www.ich.org/)

- **eCFR**
  - [https://www.ecfr.gov/cgi-bin/ECFR?page=browse](https://www.ecfr.gov/cgi-bin/ECFR?page=browse)

- **Regardd**
  - [http://regardd.org/](http://regardd.org/)

- **FDA Guidance Docs**
  - [https://www.fda.gov/regulatory-information/search-fda-guidance-documents](https://www.fda.gov/regulatory-information/search-fda-guidance-documents)
Books of Interest

Reference

Non-Fiction

DRUGS From Discovery to Approval

FDA Regulatory Affairs

THE BILLION-DOLLAR MOLECULE

Genentech The Beginnings of Biotech
Regulatory Educational Opportunities

- **Northeastern University – Master’s Program**
  - [https://cps.northeastern.edu/academics/program/master-science-regulatory-affairs-drugs-biologics-and-medical-devices-online](https://cps.northeastern.edu/academics/program/master-science-regulatory-affairs-drugs-biologics-and-medical-devices-online)

- **Temple University – Master’s Program**
  - [https://pharmacy.temple.edu/admissions/admissions-requirements/qara-non-thesis-ms](https://pharmacy.temple.edu/admissions/admissions-requirements/qara-non-thesis-ms)

- **Purdue University – Master’s Program**
  - [https://engineering.purdue.edu/ABE/academics/Professional%20Programs/BIRS/index_html](https://engineering.purdue.edu/ABE/academics/Professional%20Programs/BIRS/index_html)

- **San Diego State – Master’s Program**
  - [https://regsci.sdsu.edu/admission-process/](https://regsci.sdsu.edu/admission-process/)

- **University of Georgia – Master’s Program**
  - [http://rs.rx.uga.edu/](http://rs.rx.uga.edu/)
Introduction to Medical Product Regulatory Affairs

- Spring 2020
- PHTX 634
- 1 hr course, Monday mornings 9am

- Introduction to ICH guidelines, Code of Federal Regulations, and FDA guidance on drugs, biologics, and devices

- If you would like a UofL Certificate program in Regulatory Affairs, send me an email to discuss. j.fuqua@louisville.edu
Acknowledgements