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

My Current Roles

- 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

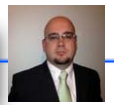
Steering Committee

Core A
Administrative oversight

External Oversight

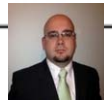
NIH Program Management

Scientific Advisory Board



Core D
Regulatory oversight

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
    - 21CFR 800 – 899 Medical Devices

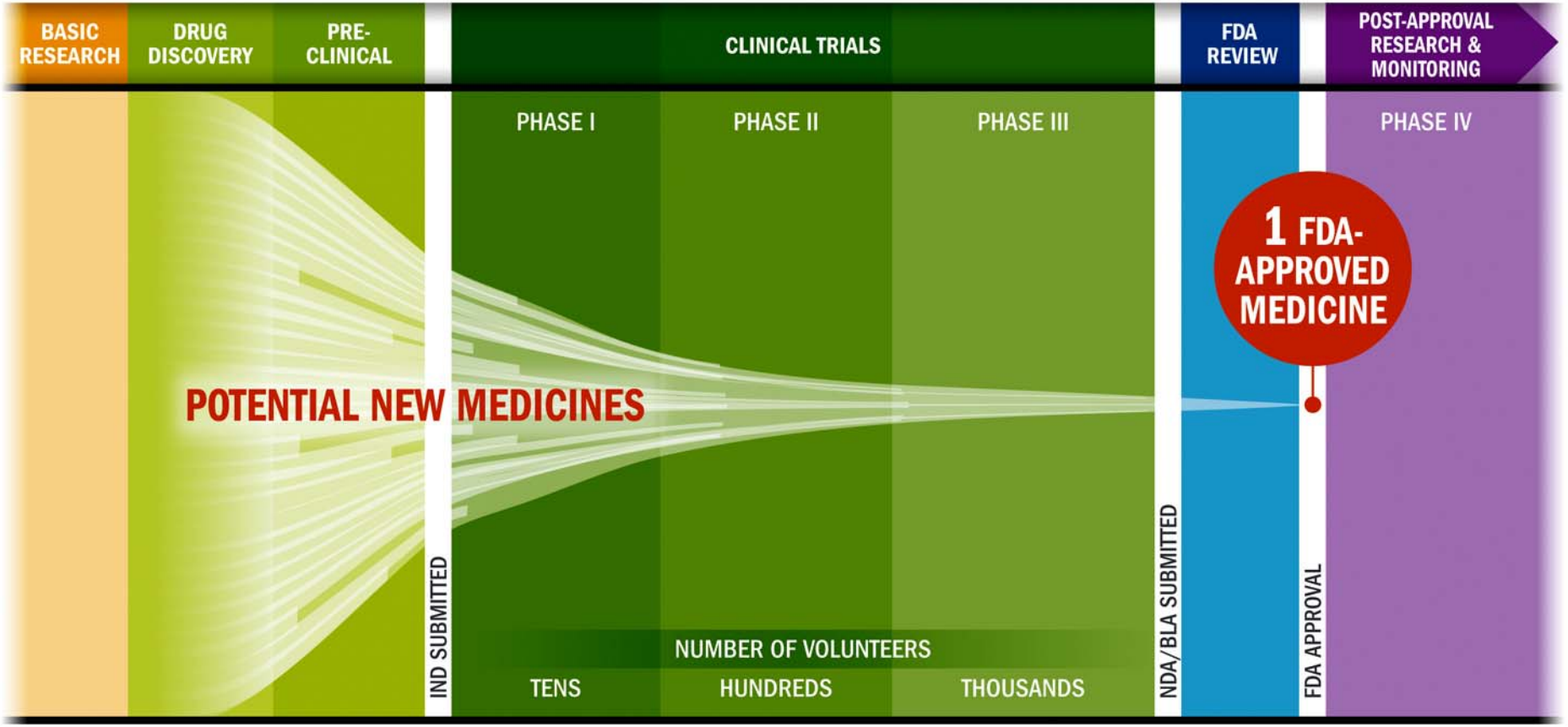
https://www.ecfr.gov/cgi-bin/text-idx?SID=4cec9b75b5dcbd03791e3997e56dd810&mc=true&tpl=/ecfrbrowse/Title21/21chapterI.tpl

International Regulatory Affairs

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

- ICH Guidances https://www.ich.org/page/ich-guidelines
  - 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



Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

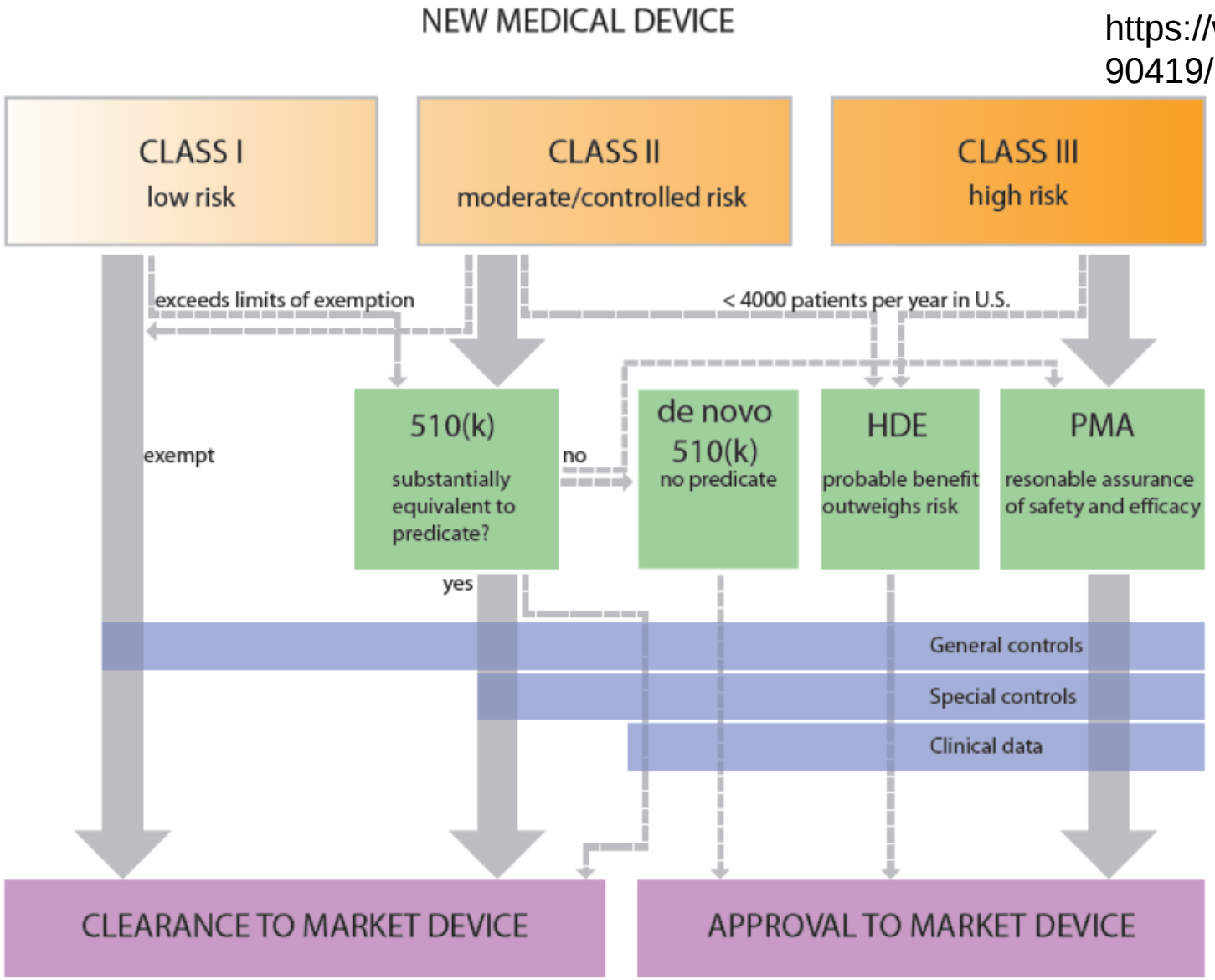
* The average R&D cost required to bring a new, FDA-approved medicine to patients is estimated to be $2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.

Source: PhRMA adaptation based on Tufts Center for the Study of Drug Development (CSDD) Briefing: "Cost of Developing a New Drug," Nov. 2014. Tufts CSDD & School of Medicine., and US FDA Infographic, "Drug Approval Process," http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/UCM284393.pdf (accessed Jan. 20, 2015).

From PhRMA adaptation: https://catalyst.phrma.org/the-drug-development-and-approval-process-is-about-much-more-than-the-final-okay

Device Development Pathway

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

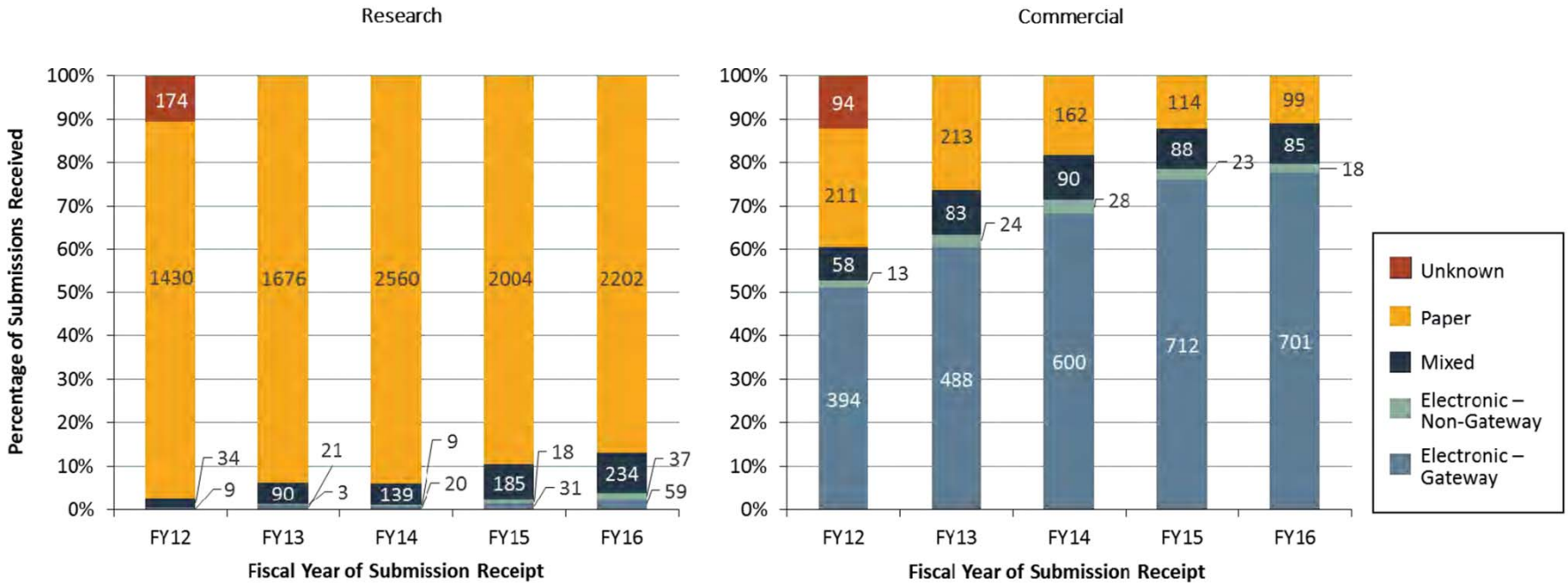
Organizations & Regulatory Jobs

- 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

NIH National Institute of Allergy and Infectious Diseases

Medtronic

IND Submissions



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

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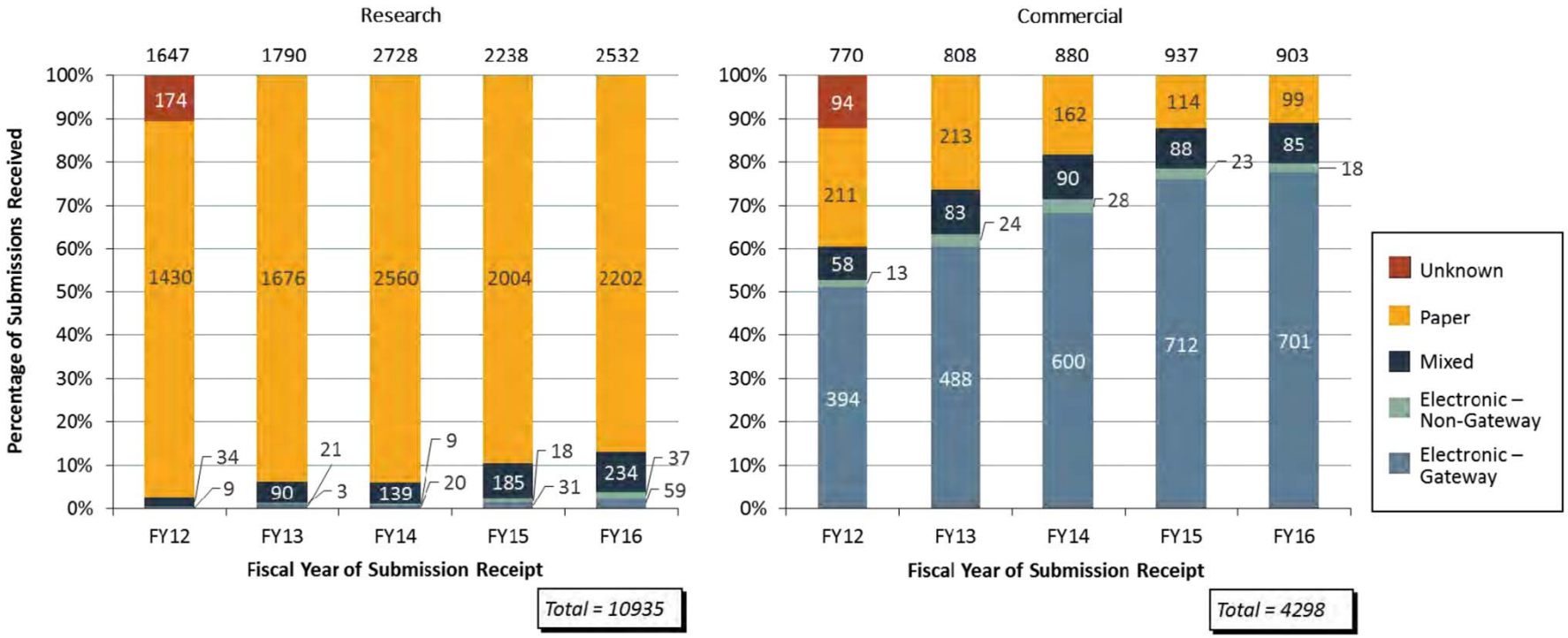
IND Submissions



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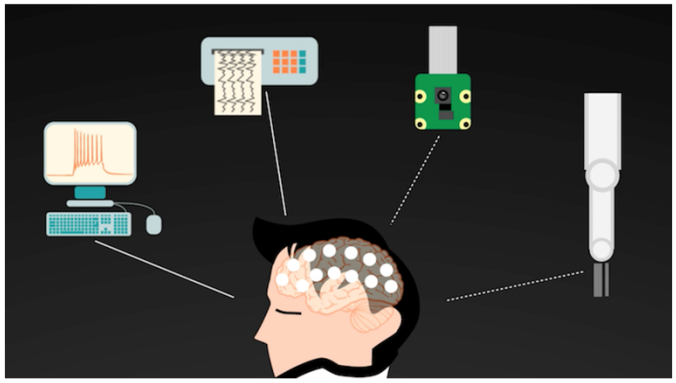
Product Development Teams

- 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://www.biospace.com/

Regulatory Affairs Certifications

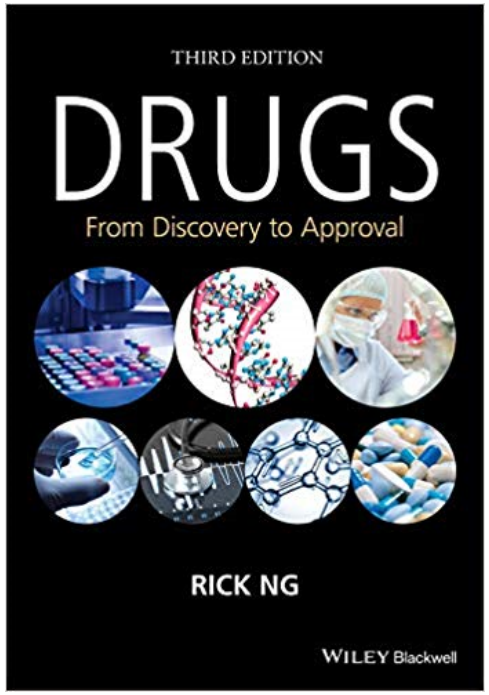
- Regulatory Affairs Professional Society
  - Regulatory Affairs Certification (RAC)
  - https://www.raps.org/
- American Society for Quality
  - Certified Quality Engineer (CQE)
  - https://asq.org/
- Society of Clinical Research Associates
  - Certified Clinical Research professional (CCRP)
  - https://www.socra.org/
- 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

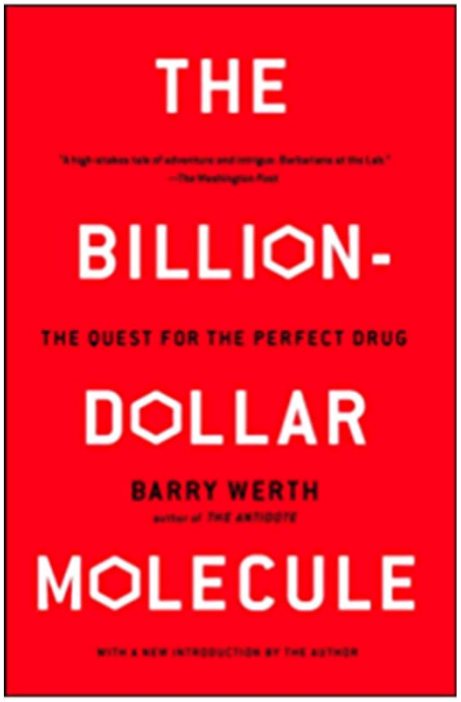
- ICH
  - https://www.ich.org/
- eCFR
  - https://www.ecfr.gov/cgi-bin/ECFR?page=browse
- Regardd
  - http://regardd.org/
- FDA Guidance Docs
  - https://www.fda.gov/regulatory-information/search-fda-guidance-documents

Books of Interest

Reference



Non-Fiction



Regulatory Educational Opportunities

- Northeastern University – Master's Program
  - 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
- Purdue University – Master's Program
  - https://engineering.purdue.edu/ABE/academics/Professional%20Programs/BIRS/index_html
- San Diego State – Master's Program
  - https://regsci.sdsu.edu/admission-process/
- University of Georgia – Master's Program
  - 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

Q-GRFT PREVENT
Griffithsin-based Rectal Microbicides for the PREvention of Viral ENTry

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