UCI Division of Continuing Education

Career Pathways: Breaking into the Business of Regulatory Affairs & Biotechnology

Agenda

- 5:30 – 6:00 Networking & Appetizers
- 6:00 – 6:10 Outlook & Educational Options, Dave Dimas
- 6:10 – 6:30 Biotech in the OC, Del Stagg
- 6:30 – 6:50 Why Regulatory Affairs?, Terri Richmond
- 6:50 – 7:10 Other Career Paths and Roles , Karen Jimenea
- 7:10 – 8:00 Question & Answer

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Introductions

Dave Dimas, Ph.D.

Director, Engineering, Science, & Technology Programs

UCI Division of Continuing Education

Faculty, Department of Mechanical and Aerospace Engineering, UCI

Del Stagg, Ph.D.

Vice President of Regulatory, Alphaeon, Irvine, CA

Principal, Stagg Regulatory Consultants, Irvine, CA

Terri Richmond, Ph.D.

Director, Global Regulatory Affairs, Allergan

Karen Jimenea, MBA

Director, Chief Medical Office Global Operations, Allergan

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Employment/Career Outlook

*According to the Bureau of Labor Statistics, the number of technical positions related to the clinical trails industry (Medical and Clinical Laboratory Technologists and Technicians) will grow 18% and (*Medical and Health Services Managers) will grow 17% *between 2014 and 2024 due to increasing health care industry demands and an increase in the aging population that is expected to lead to a greater need to diagnose/treat medical conditions, such as cancer or type 2 diabetes.*

http://www.bls.gov/ooh/healthcare/medical-and-clinical-laboratory-technologists-and-technicians.htm

Average Regulatory Affairs Specialist salaries for job postings in **California** are 8% higher than average Regulatory Affairs Specialist salaries for job postings nationwide.

http://www.careersinpublichealth.net/careers/regulatory-affairs-specialist#context/api/listings/prefilter

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OC Corporations Hiring:

Advice for New Regulatory Professionals

Be Proactive

Expand you Network

Relate to Human Level

Ask Questions

Seek Out Mentors

Stretch Yourself

Develop a Plan

40 YEARS RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY Driving Regulatory Excellence™

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http://www.raps.org/Regulatory-Focus/RAPS-Latest/2016/05/12/24937/8-Pieces-of-Advice-for-New-Regulatory-Professionals/

Educational Opportunities

UCI DCE Certificate Programs	Northeastern University	University of Wisconsin-Platteville	University of Nebraska-Lincoln
• Regulatory Affairs and Compliance • Medical Product Development • Clinical Trials	• Master of Science in Regulatory Affairs for Drugs, Biologics, Medical Devices	• Online Master of Science in Engineering	• Online Master in Engineering Management (MEM)

Graduates from **UCI Division of Continuing Education's** are eligible to transfer credits to the above three Colleges.

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Regulatory Affairs & Compliance

Required Courses - Pharma Track (10 units)	Units
Introduction to Regulatory Affairs and Compliance for Drugs, Biologics, and Medical Devices	2
Regulatory Requirements for Pharmaceutical Products	3
Fundamentals of Clinical Trials	3
Post-Approval Compliance Requirements for Pharmaceutical Products	2
Required Courses - Device Track (10 units)	**Units**
Introduction to Regulatory Affairs and Compliance for Drugs, Biologics, and Medical Devices	2
Regulatory Requirements for Medical Devices	3
Regulatory Affairs for Post-Market Approval	2
Regulatory Affairs Planning and Management: Concept Review and Evaluation	3
Elective Courses (5 credit units)	**Units**
Drug Safety and Pharmacovigilance	2
Medical Product Quality Systems	3
Medical Product Marketing	3
Medical Product Crisis Management	1.5
Overview of Global Regulatory Affairs	3
Biomedical Business and Legal Management Essentials	3
Medical Product Life-Cycle Management	3
Application of ICH Guidelines - Regulatory Strategy Development and Dossier Preparation	2

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Medical Product Development

REQUIRED COURSES (9 credit units)	Units
Medical Product Life-Cycle Management	3
Regulatory Requirements for Medical Devices	3
Regulatory Requirements for Pharmaceutical Products	3
Medical Product Quality Systems	3
ELECTIVE COURSES (6 credit units)	
Regulatory Affairs	
Medical Product Marketing	3
Application of Good Clinical Practices	3
Biomedical Business and Legal Management Essentials	3
Quality and Compliance	
Medical Product Manufacturing	3
Process Validation for Medical Product Development	3
Medical Device Risk Management	3
Fundamentals of Clinical Trials	3
Good Laboratory Practices	1.5
Engineering and Science	
Applied Anatomy and Physiology for Clinical Studies	4
Medical Device Design and Evaluation	3

Clinical Trials

REQUIRED COURSES (10.5 credit units)	Units
Regulatory Requirements for Medical Devices	3
Regulatory Requirements for Pharmaceutical Products	3
Fundamentals of Clinical Trials	3
Application of Good Clinical Practices	3
Human Subjects Safety in Clinical Trials	1.5
ELECTIVE COURSES (5.5 credit units)	
Applied Anatomy and Physiology for Clinical Studies	4
Good Laboratory Practices	1.5
Clinical Data Management	1.5
Clinical Trials Internship	3
Clinical Trials Project Management	3

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Del Stagg, PhD

Vice President of Regulatory
Alphaeon, Irvine, CA

Principal
Stagg Regulatory Consultants, Irvine, CA

Instructor, Pharmaceutical Regulations
UCI DCE

Objectives:

1. Describe why Regulatory Affairs is one of the best positions to have in a medical products company
2. Describe my career path in medical products industry: Devices, Clinical Research Organizations (CRO), Pharmaceutical, Bio-tech and consulting
3. Offer suggestions on connecting with the industry to find a job that fits the interests and skills of the individual
4. Discuss observations of high job performers that enhance the probability for promotion and other job opportunities

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Del Stagg:
Regulatory Affairs Professional

1	• What is Regulatory Affairs?
2	• Why is it a good position?
3	• How do you get into Regulatory Affairs?
4	• What are the rewards?

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Del Stagg:
What is Regulatory Affairs?

- Regulatory Affairs is responsible for understanding the regulations that govern how products are developed, tested, manufactured and marketed

- Regulatory Affairs need people with backgrounds in biology, chemistry, engineering, information technology, pharmacology, quality, toxicology, clinical sciences, writing and management

- Regulatory Affairs professionals can be found in both industry and regulatory agencies

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Del Stagg:
Why is Regulatory Affairs a good position?

- Regulatory Affairs is involved in product development as members of project teams that set the strategy for development, manufacturing, non-clinical and clinical studies and communications with FDA and other regulatory agencies

- Regulatory Affairs is involved in the development and building of the manufacturing plants where products are made

- Regulatory Affairs is involved with Marketing and marketing products

Del Stagg:
How do you get into RA?

- Develop skills and experience in one of the sciences that contribute to product development (chemistry, engineering, non-clinical and clinical evaluations), manufacturing and marketing (most difficult part)
- Learn the regulations that apply to the type of products in which you are interested (biologics, drugs or devices)
- Take courses that provide instruction in applying the regulations to industry – in California, UCI DCE courses, USC, SDSU
- Join Regulatory Organizations such as OCRA, RAPS

RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY

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Del Stagg:
What are the rewards?

- Satisfaction of knowing that you were an integral part in obtaining approval to market beneficial products
- Satisfaction of knowing that your efforts made it possible for the product to improve a patient's medical condition and quality of life
- Job security – there are not enough Regulatory Affairs professionals to cover all the companies that intend to develop medical products.

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Del Stagg: My career story

Graduate school at DUKE

- Medical School and Medical Research University
  - Research Supported by Grants (e.g. NIH/NSF)
  - Laboratories tied to clinical departments
- Career Choice - Either stay in academic research of go into industry

Opportunity

- North Carolina had established RTP (Research Triangle Park) to foster cooperation between the Universities and Industry.
- Only research could be conducted in RTP.

Del Stagg: My career story

- Through network connections, I learned about a research position at Becton Dickinson (B-D) a medical device company
  - Positions as scientist conducting biological tests on new products
  - Tested products about 1-3 years before they went to market
  - Research required reports that were sent to corporate headquarters

- Participated in team meetings to review progress on a product development
  – members of the team read my reports and asked about my research

- After asking about how the reports were used, I learned they were reviewed by RA professionals and sent to the FDA – What was the FDA?

- My questions lead to an **opportunity** to conduct technical reviews of regulatory submissions - leading to a new career

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Del Stagg: My career story

- Worked for B-D 13 years before accepting a new **opportunity** with a CRO. Another Career Choice

- Joined a small CRO with personnel from BW and Glaxo to develop a combination product of a drug and special delivery device
  - CRO had experience with drug regulations, no experience with device development or regulations (my area of expertise)
  - Good opportunity to learn and train to be a clinical monitor
  - Learned important lessons on clinical study design, case report forms, clinical monitoring (volunteered to learn new skill and help company)
  - Learned about drug regulations from senior regulatory professionals that were willing to share knowledge and experiences (great mentor)

- Restructuring occurred and many of the regulatory professionals were not happy and began looking for another job opportunities

Del Stagg: My career story

- Joined Allergan as Director of Regulatory Affairs
  - Worked at Allergan for 5 years
  - Responsible for new ophthalmic products
  - Great boss who required us to learn the entire regulatory position (Development to Marketing)
- Resigned for an **opportunity** to join a start-up company for a senior position (opportunity for increased responsibility)
  - Company was bought by a larger pharm company and the job was transferred to the company on the East Coast
  - Asked my old boss for a recommendation (don't burn bridges) and;
- Allergan asked me to return!
  - Responsible for global regulatory affairs for BOTOX
  - Retired from Allergan in 2005
  - Value of Product Marketed ~ $ 4 B

Del Stagg: My career story

- Joined a small BioTech company in San Diego
  - Completed PMA and obtained approval a Class 3 device
  - On Management Team that fired the CSO and President, but saved the Company – a year later I resigned
- On the train ride home was I was offered a position in San Diego
  - Small Contract Manufacturing Organization (CMO)
  - 2 year project to help develop GMP procedures
- After completing tasks I “retired” but was asked by a former employee to help with an IDE for a new device in Orange County
  - 6 week project before holidays - 2 ½ years - 510(k) for Class 2 device
- Teaching UCIDCE course and consulting
- Fall of 2013 - offered a RA position in a new company with 8 persons that was acquired 3 months later by Alphaeon
- Completed development for a new biologic ~ 3 ½ years
- Mentored successor for her RA career

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BioTech Market in OC and San Diego

Medical Devices	Pharmaceuticals	Biologics	FDA's LA District Office	Websites to search jobs in CA
• 20 % of all device companies are located in Southern California • Orange Country, 582 companies listed with contact information • San Diego, 419 companies listed with contact information	• Fewer Pharmaceutical companies in Southern California	• Strongest area for new growth – small companies need experienced personnel to wear multiple hats	• Investigators, Scientists, Laboratory TechniciansInvestigators, Scientists, Laboratory Technicians	• www.thelabrat.com • www.socalbio.org

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Finding a Job and Developing a Career

Find first job consistent with your education:

Biology – biological testing – R&D / QA Laboratory

Clinical Research – CRO / Clinical Department

Microbiology – microbiological testing – QA Laboratory

Chemistry – analytical testing, formulator – QA / Contract Laboratory

Engineering – design, testing, quality – Medical Device Co

Computer Science – circuit design, programming, documentation

Nursing – hospital / clinic – Clinical Research in BioTech

English – writing – medical writing in Clinical Research

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Finding a Job and Developing a Career

- First job may be in a medical product support company
  - Consider a CRO (Clinical Research Organization)
  - Consider a CMO (Contract Manufacturing Organization)
  - Consider A Temporary Employment Organization
    - Great way to open a door at a company
    - Do a good job and you will get noticed for a position
    - Determine if the contract has a Temp to Hire clause

- Take courses at UCI DCE or Northeastern University

- Take advance degree courses at USC, SDSU

- Look for internship positions (some legal and salary concerns)
  - If you have any experience (even very limited) always help
  - Look for opportunities to cross train within the company

Finding a Job and Developing a Career

- Join Organizations supporting the industry
  - OCRA – Orange County Regulatory Affairs
  - SDRAN – San Diego Regulatory Affairs Network
  - ACRP – Association of Clinical Research Professionals
    - Los Angeles Chapter
    - San Diego Chapter
- Keep in touch with classmates who have similar interests as they may find a position and learn of other positions

Developing a Career

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Terri Richmond, PhD

Director, Global Regulatory Affairs
Allergan, Irvine, CA

My Career

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Why Did I Choose Regulatory Affairs?

- Application of scientific background to support approval of new therapeutics
- Cross-functional interaction with multiple teams (with diverse backgrounds)
- Challenging opportunities with new therapeutics and constantly changing regulatory environments

Key Learnings in My Career

- Work & think hard, challenge yourself, and always be open to new opportunities
- Network - Expose yourself to people in your desired field (eg. RAPS, OCRA).
- Ask questions. Be willing to listen & learn.
- It's a small world. Treat everyone with respect and kindness.

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Karen Jimenea, MBA

Director, CMO Global Operations
Chief Medical Office · Allergan, Irvine, CA

Objectives:

- Describe typical roles and career paths for Medical Affairs and Operations in the Pharmaceutical Industry
- Share insight on my personal experience with entering the Life Sciences industry and changing career paths
- Provide overview of Allergan – a multi-specialty healthcare company in Irvine, CA

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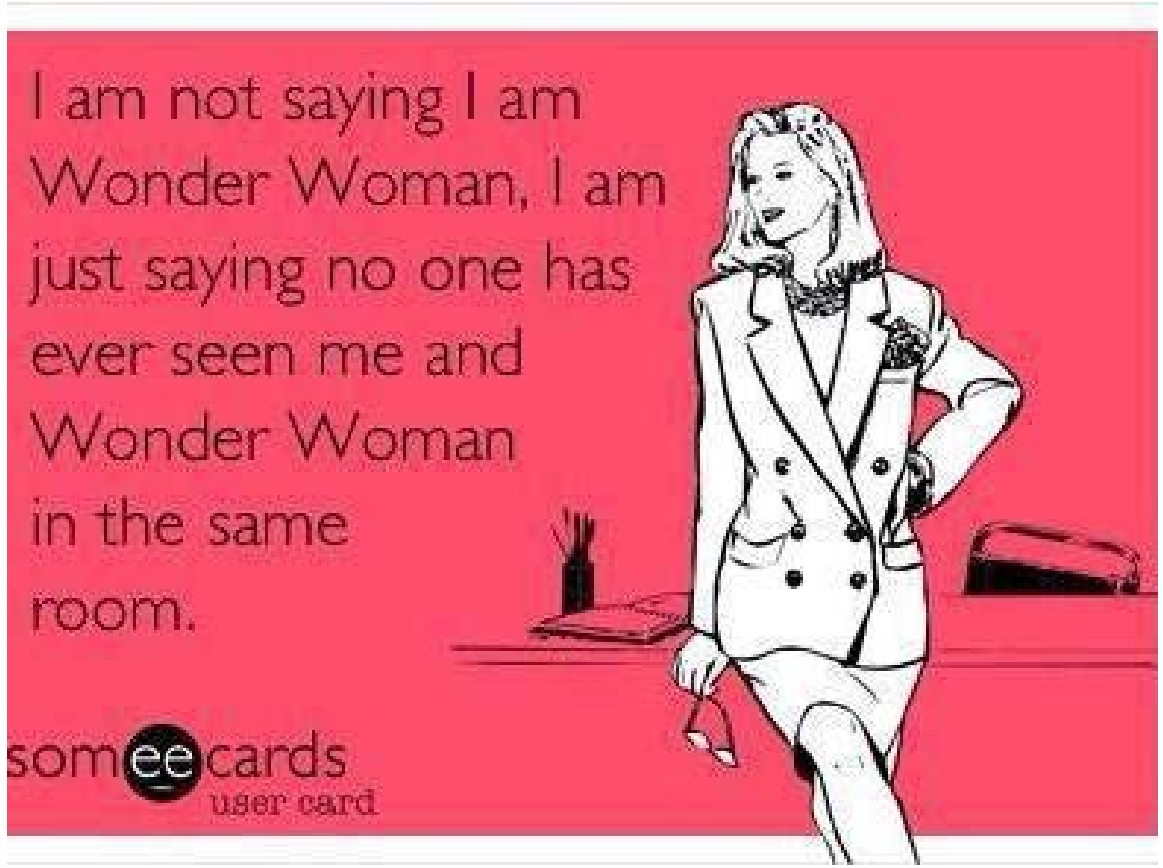
Karen Jimenea:
“Leaning in” whenever possible!



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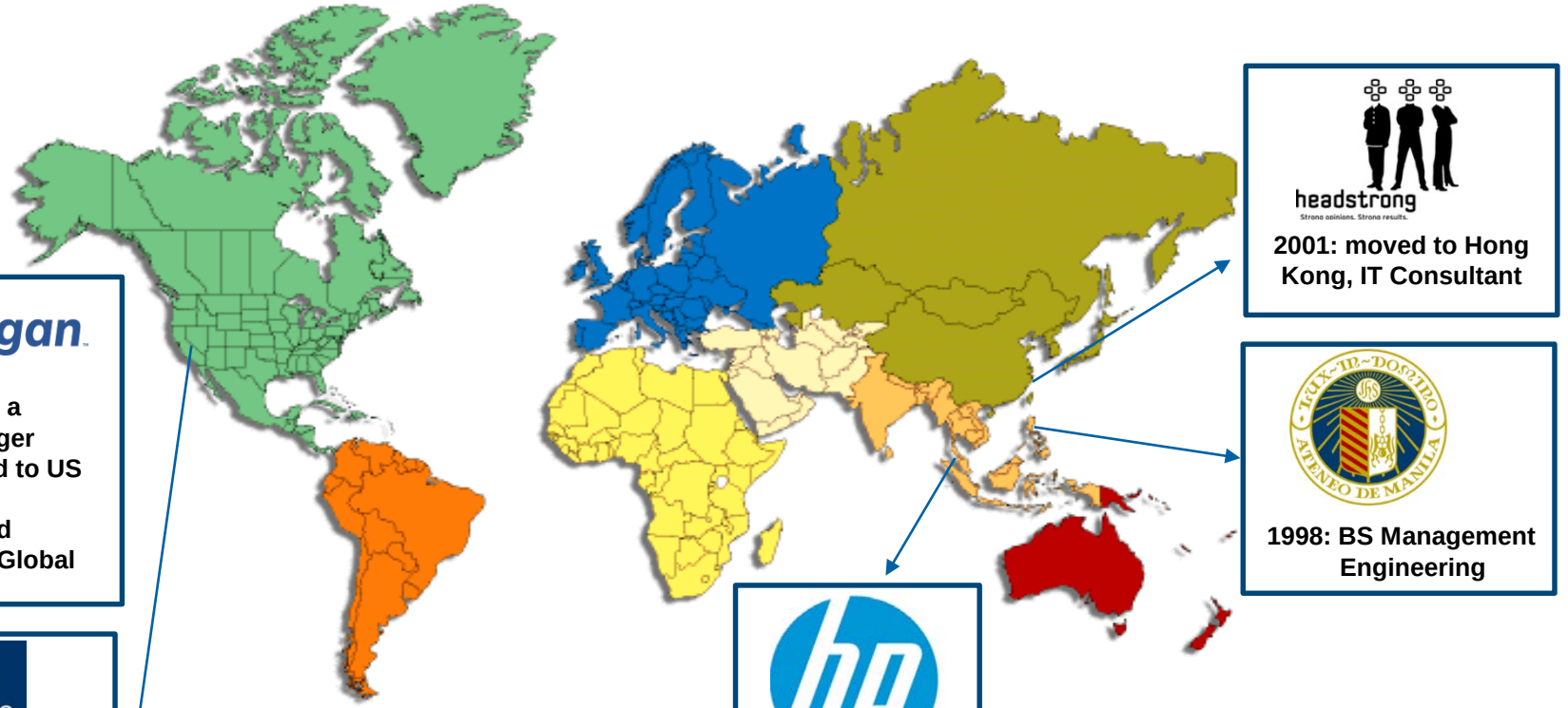
Karen Jimenea: Background



2001: moved to Hong Kong, IT Consultant

1998: BS Management Engineering

2003: moved to Singapore, CRM Consultant for HP

2011: joined as a Systems Manager
2014: expanded to US Operations
2015: appointed Director, CMO Global Operations

2011: UCI FEMBA

2004: moved to California, CRM Consultant and then IT Lead from 2006 - 2011

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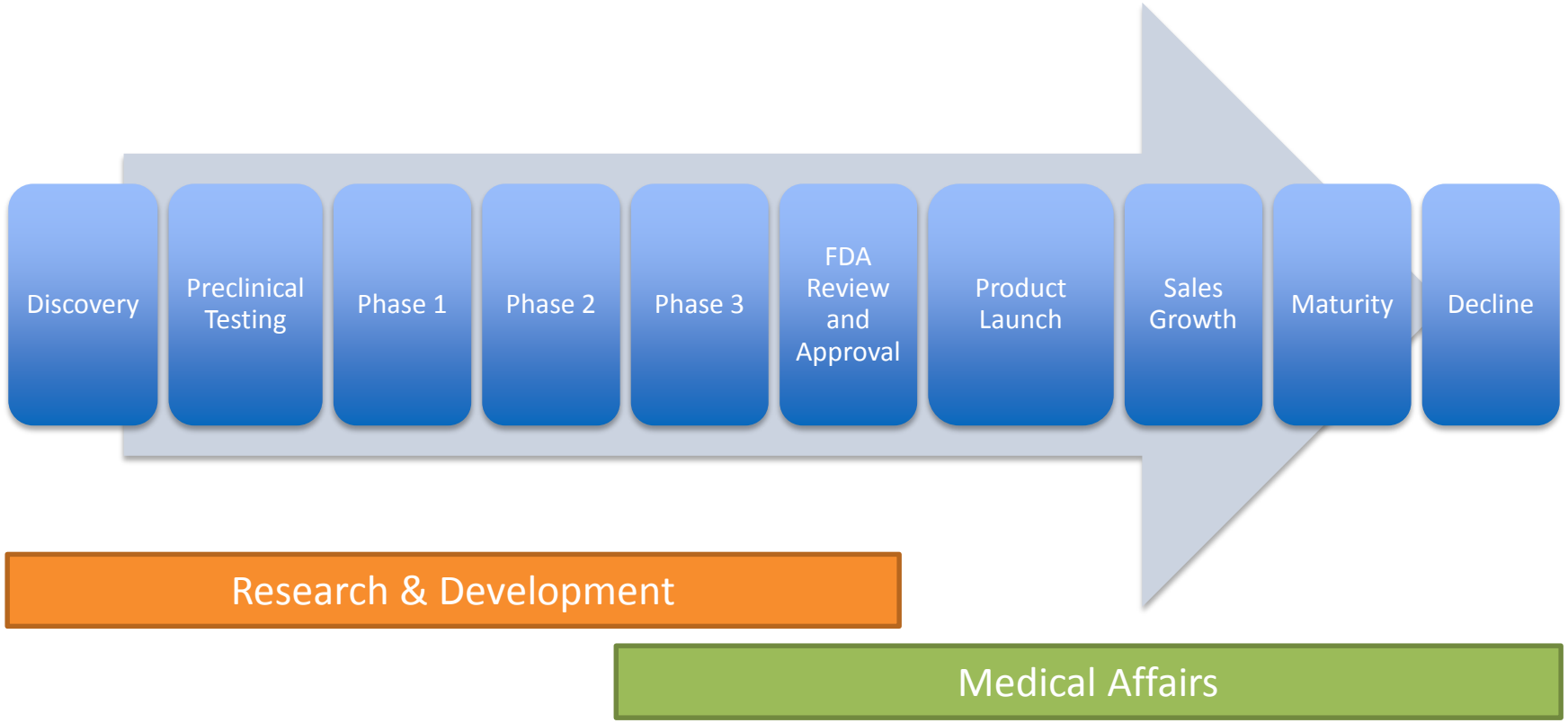
Pharmaceutical Product Lifecycle



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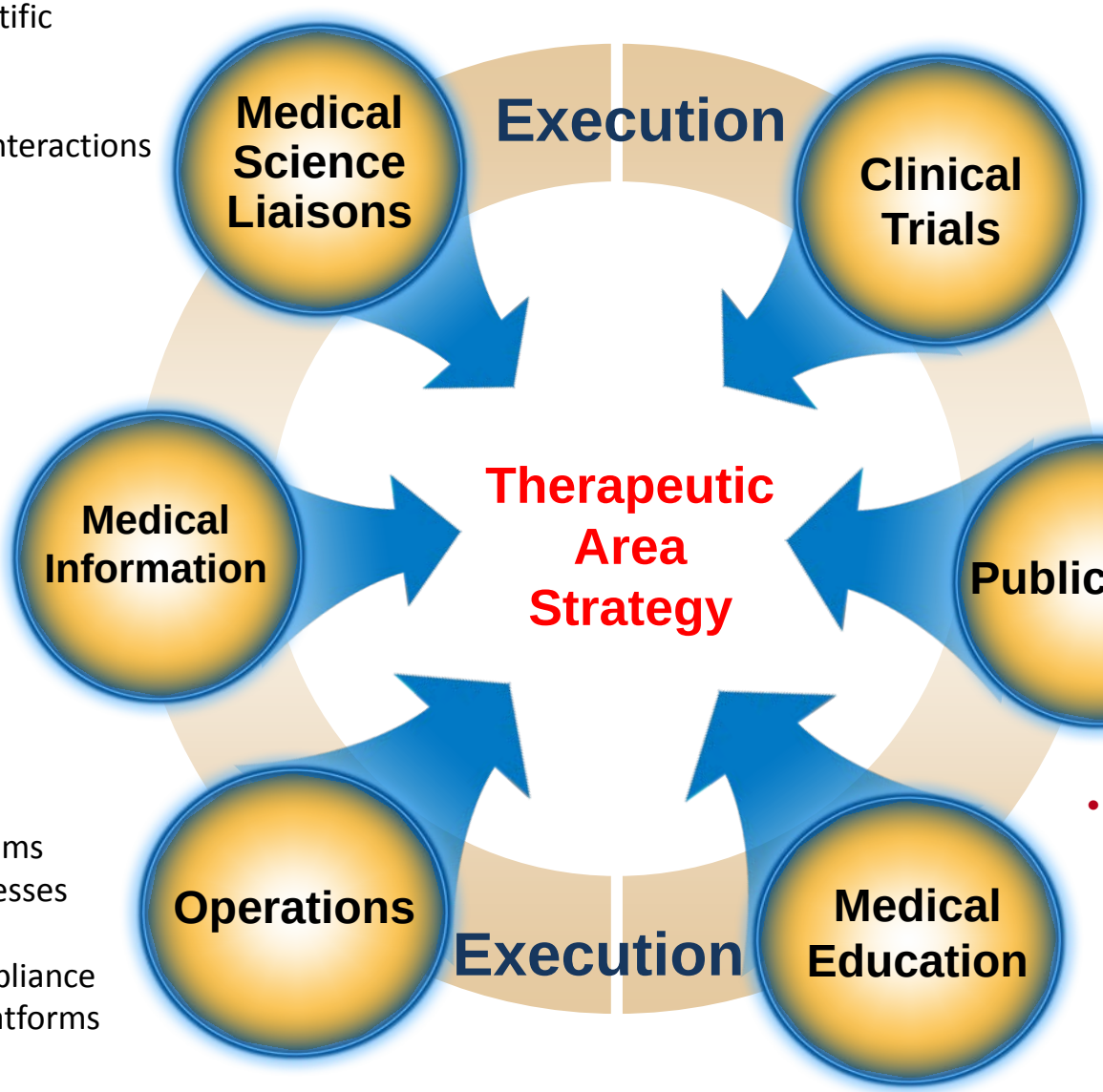
Medical Affairs Functions



- Field based, scientific backgrounds
- TA aligned
- Thought Leader interactions

- Post-marketing trial execution
- Globally aligned
- Phase 4 trials
- Investigator Initiated Trials
- Collaborative research

- Call center for patients and HCPs
- Dissemination of unbiased clinical information (SRLs)
- Current literature review
- Ad/Prom support

- Data driven
- Congress, Posters, Podium, Papers, Abstracts

- Systems
- Processes
- SOPs
- Compliance
- IT platforms

- Provides medical education to the clinical community e.g. injector training

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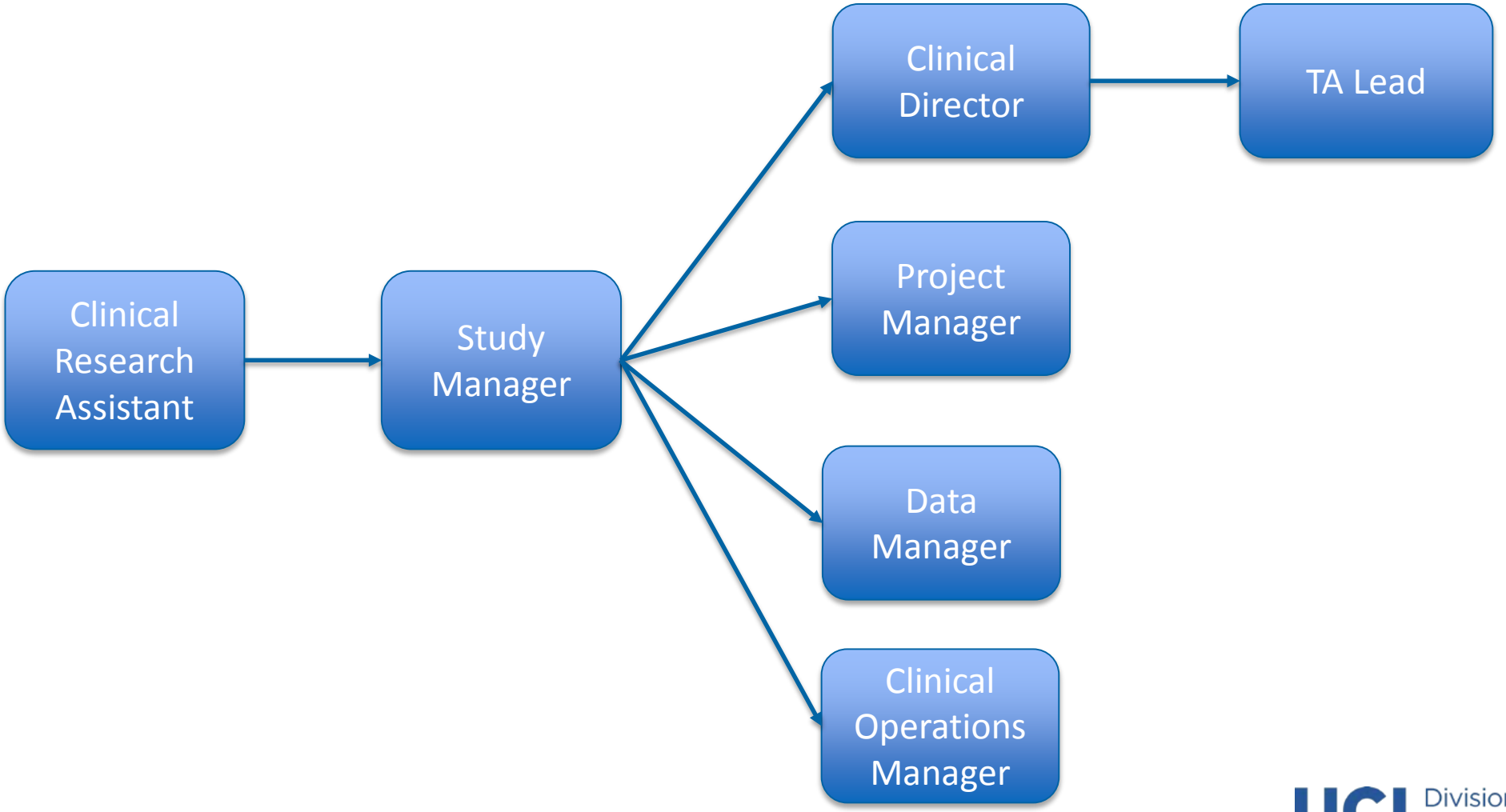
Karen Jimenea: Clinical Trials



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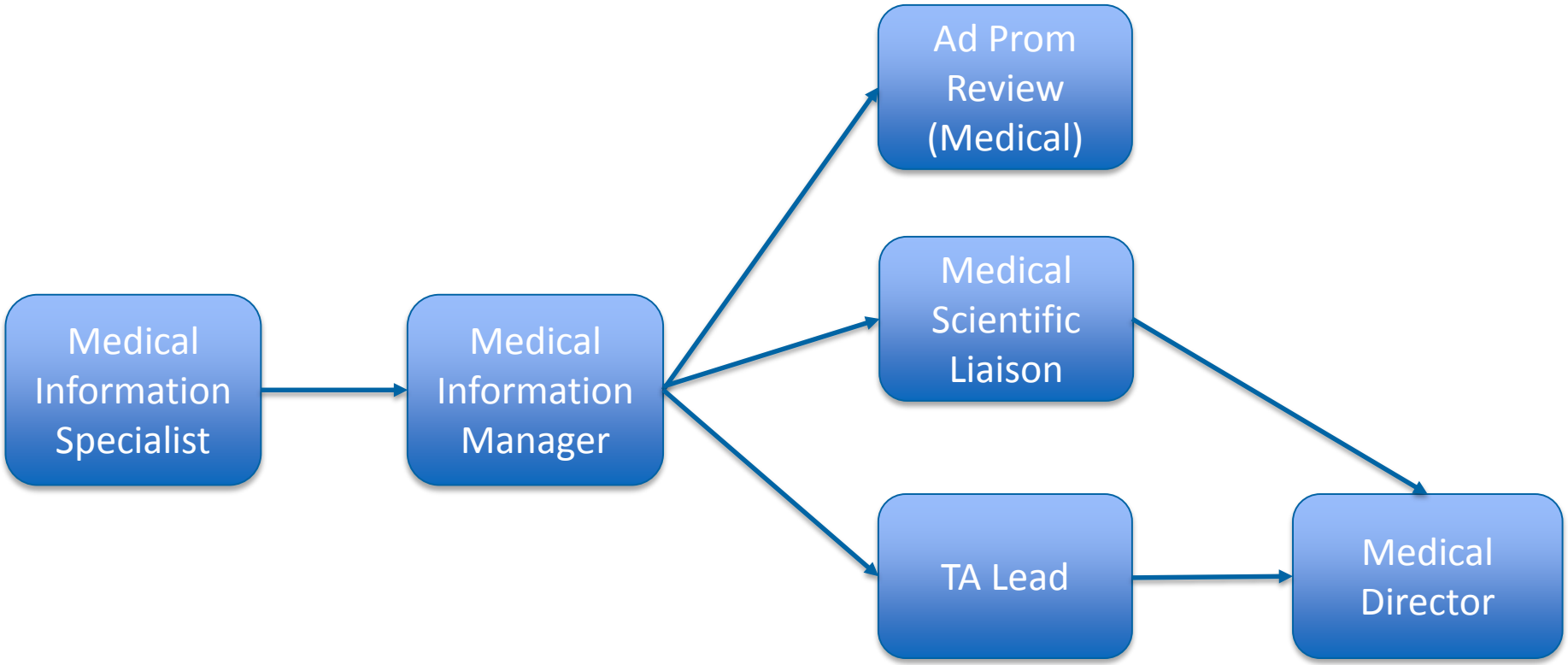
Karen Jimenea: Medical Information



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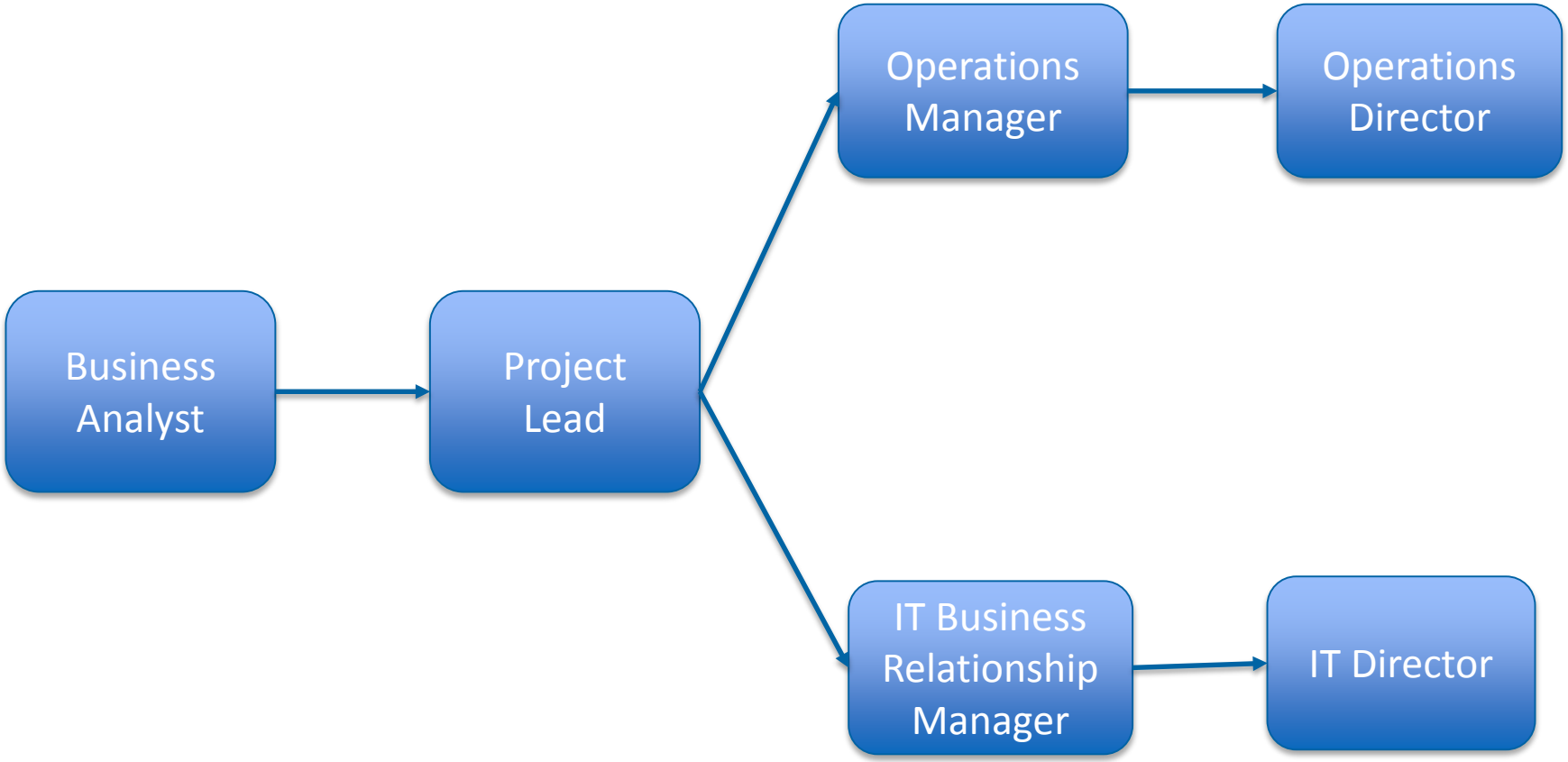
Karen Jimenea: IT/Operations



Karen Jimenea:
Ways to Connect with Industry

- Professional Societies
  - DIA
  - OCRA
  - RAPS
- LinkedIn
- Scientific meetings/Conferences
- Alumni Associations/Mixers
- Explore internship opportunities

DIA
Drug Information Association

40 YEARS
RAPS
Regulatory Affairs Professionals Society
Driving Regulatory Excellence™

OCRA
Orange County Regulatory Affairs Discussion Group

LinkedIn

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ALLERGAN IS A BRANDED GROWTH PHARMA LEADER

FULLY INTEGRATED GLOBAL HEALTHCARE COMPANY

2016 Branded Revenue

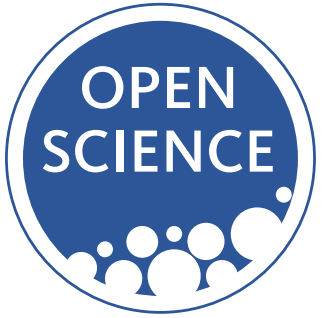
2016 Branded R&D Investment

Sustained Branded Revenue Growth

Committed Employees

Therapeutic Areas

Operating in over 100 Countries



Employs Open Science R&D Model

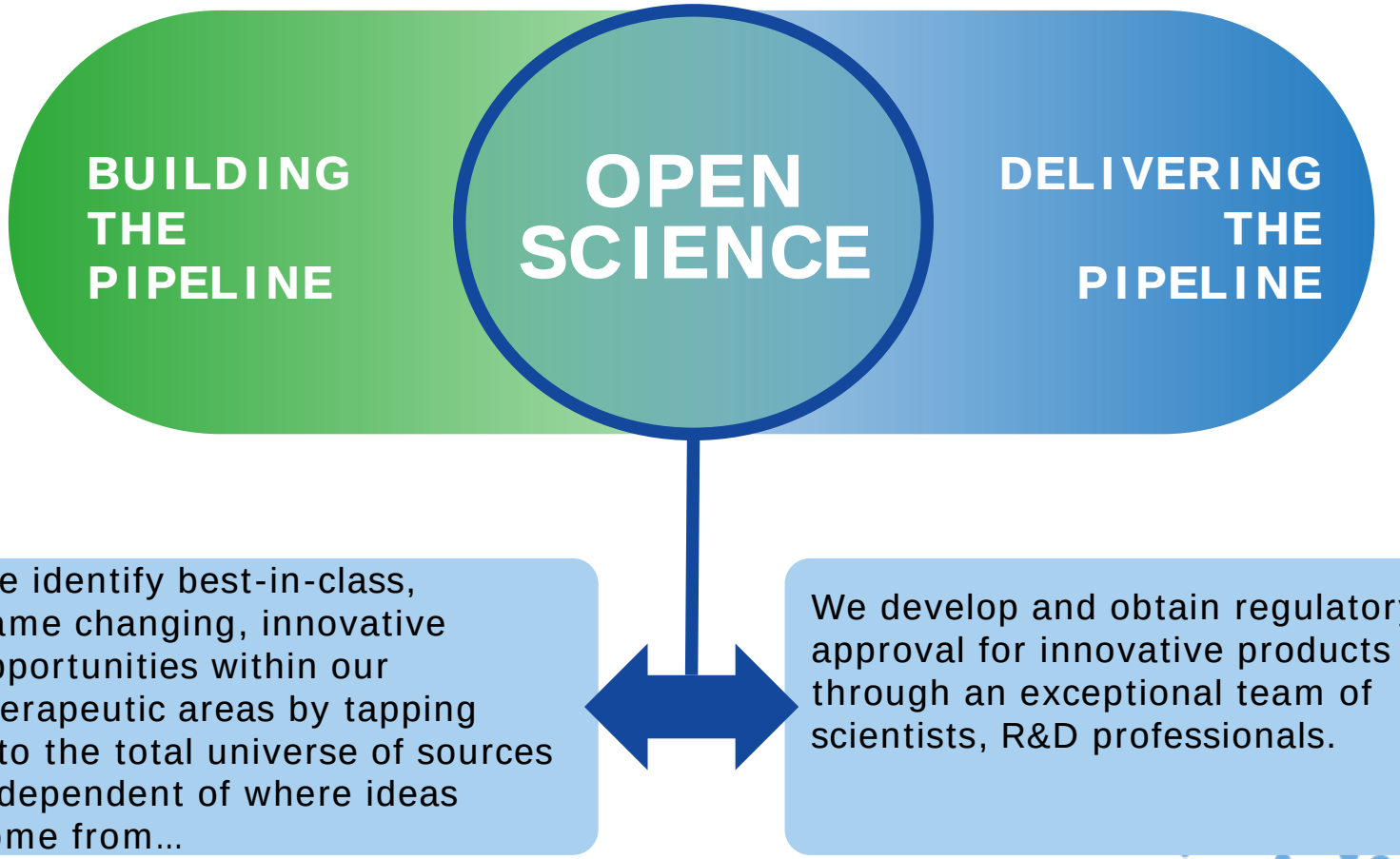
Allergan

OUR GLOBAL FRANCHISES SPAN 7 THERAPEUTIC AREAS

OPEN SCIENCE IS BUILDING AND DELIVERING OUR PIPELINE

"Over the past 15 years, the pharmaceutical innovation ecosystem has shifted…the driving source of innovation is coming from smaller biotechnology and specialty pharma companies, as well as academia. Open Science defines our position in this new ecosystem – as a magnet for game-changing ideas and innovation."

– Brent Saunders,
CEO, President and Chairman



Allergan

OUR SOCIAL CONTRACT WITH PATIENTS

Principle 1: Invest & Innovate

Principle 2: Access & Pricing

Principle 3: Quality & Safety

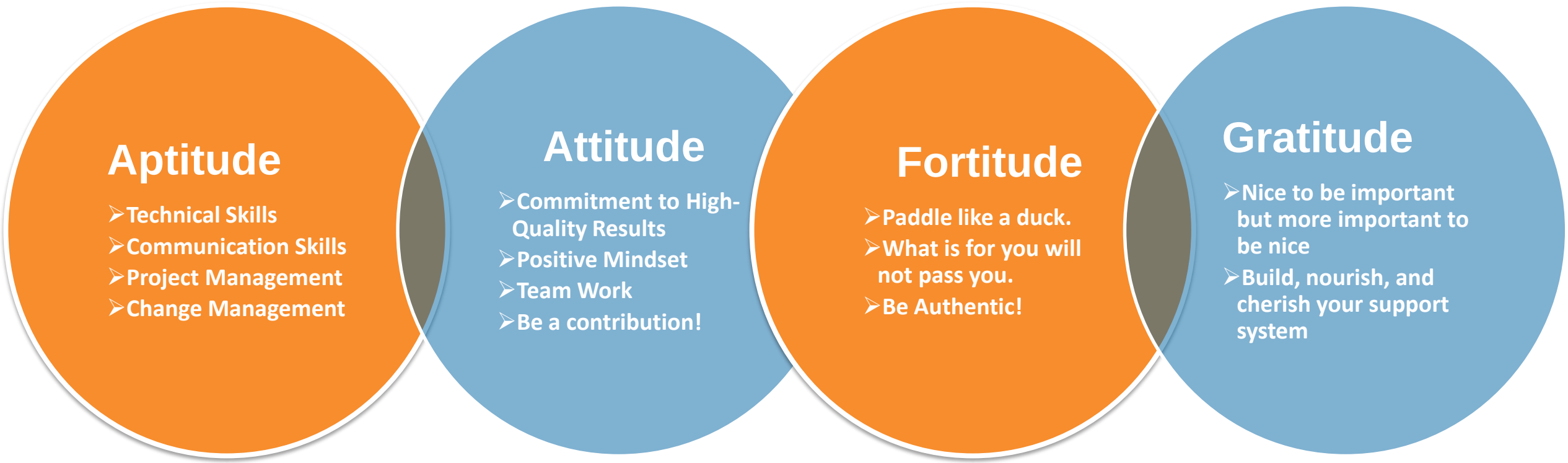
Principle 4: Education

RESPONSIBLE PRICING IDEALS

- *We will price our products in a way that is commensurate with, or lower than, the value they create.*
- *We will enhance access to patients.*
- *We will work with policy makers and payers to facilitate better access to our medicines.*
- *We will not engage in price gouging actions or predatory pricing.*
- *We will limit price increases.*
- *We will not engage in the practice of taking major price increases without corresponding cost increases as our products near patent expiration.*
- *We commit to providing an aggregate view of the net impact of price on our business.*

Allergan

Food for Thought



Thank you!

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Contact **Us**

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- **Fax:** 949-824-1220 | **Website:** https://ce.uci.edu/

Northeastern University College of Professional Studies

- **Ashley Battle, Enrollment Coach** - cpsadmissions@neu.edu or 1.877.668.7727
- **Address:** 360 Huntington Avenue, 50 Nightingale Hall, Boston, MA 02115
- **Website:** www.northeastern.edu/cps

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Resource Information

FDA websites for obtaining free updates on changes in regulations:

- http://www.fda.gov/AboutFDA/ContactFDA/ucm2005606.htm
- http://www.fda.gov/AboutFDA/ContactFDA/UCM2005607.htm

BIOCOM website for obtaining information on CRO and CMOs in Southern California:

- https://biocom.org/initiatives/cro_initiative/
- http://biocomcro.org
- http://biocom.contractresearchmap.com/biocom/directory

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Professional Organizations

http://www.medicaldevices.org/

www.raps.org

www.socra.org

http://www.socalbio.org/

These organizations have resources for certification, jobs, seminars, and recruiter info. If you are looking to network with like minded people these are great places to start.

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Question & Answer

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