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

Wednesday, April 20, 2016
Agenda

- 6:00 – 6:15 Welcome – Dave Dimas
- 6:15 – 6:40 Overview of Biotech Careers - Miles McLennan
- 6:40 – 7:00 Why Regulatory Affairs? - Terri Richmond
- 7:00 – 7:20 Educational Options – Dave Dimas
- 7:00 – 8:00 Question & Answer
Introductions

Dave Dimas, Ph.D.
*Director, Engineering, Science, & Technology Programs*
*UC Irvine Extension*

Miles McLennan, MBA
*Sr. Director, Global Phase 4 / IIT Trial Management*
*Allergan*

Terri Richmond, Ph.D.
*Senior Manager, Global Regulatory Affairs*
*Allergan*
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.
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 Extension courses, USC, SDSU

- Join Regulatory Organizations such as OCRA, RAPS
Developing a Career

- Learn your job function well and try to be the best
- Volunteer for / accept assignments when presented
- Establish good relationships with your co-workers
- Earn the respect of your immediate boss
- Learn as much as you can and train someone else for your job
- Switching career paths within a company after establishing yourself
Sr. Director, Global Phase 4/IIT Trial Management
CMO (Medical Affairs) · Allergan, Irvine, CA

Instructor, Medical Device, Product Lifecycle Management
UCI Extension (2013)

Objectives:

1. Describe typical roles, careers, and career paths for pharmaceutical, bio-tech, and medical device manufacturers
2. Offer advice on how to approach connecting with the industry to find a job that fits their interest and background
3. Provide overview of Allergan – a multi-specialty healthcare company in Irvine, CA
Miles McLennan: Strategic, Tenacious, Flexible

“We’re looking for someone who can stretch with the demands of this job. Are you flexible?”
Miles McLennan: Background

- BS – Business Administration California State University, Sacramento
- MBA - Northeastern University, Boston
- Bayer, New Haven, CT
  - Sales / Sales Training
    - Sales Management
    - Product Management
- Allergan, Irvine, CA
  - Product Management
  - Marketing Team Leadership
  - Medical Affairs Global Operations
  - CMO Operations /Trial Execution
Miles McLennan: “Getting in” to Industry

8 months + job search!
Miles McLennan: Ways to Connect with Industry

- Make it a priority
- Professional Societies
  - DIA
  - OCRA
  - RAPS
- LinkedIn
- Scientific meetings
- Explore internship opportunities (or try to create one)
Pharmaceutical Product Lifecycle

- Discover
- Preclinical Testing
- Phase 1
- Phase 2
- Phase 3
- FDA Review and Approval
- Product Launch
- Sales Growth
- Maturity
- Decline

Research & Development

Medical Affairs
Miles McLennan: R&D

- Professional
- Scientist
- R&D Leadership
- CMC
- Medical Writing
- Medical Affairs
- Regulatory Affairs
- Project Management
Medical Affairs Functions

- Medical Science Liaisons
  - Field based, scientific backgrounds
  - TA aligned
  - Thought Leader interactions

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

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

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

- Operations
  - Systems
  - Processes
  - SOPs
  - Compliance
  - IT platforms

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

Therapeutic Area Strategy

UCI Extension
Allergan is a $23 billion diversified global pharmaceutical company and a leader in a new industry model - Growth Pharma. The company is anchored by strong and sustainable brand franchises, a leading global generics business, a premier pipeline, highly efficient operations and an experienced management team creating an unrivaled foundation for long-term growth.
OUR WORLD-RENOWNED BRANDS

Our company is committed to partnering with healthcare providers to deliver innovative treatments addressing medical needs across a broad spectrum of therapeutic categories.

<table>
<thead>
<tr>
<th>Dermatology &amp; Aesthetics</th>
<th>Botox, Juvederm, Natrelle, Voluma, Aczone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Nervous System</td>
<td>Saphris (lamotrigine), Fetzima (levomepromazine), Namenda (memantine)</td>
</tr>
<tr>
<td>Eye Care</td>
<td>Restasis, Alphagan, Lumigan, Ozurdex, Refresh Optive</td>
</tr>
<tr>
<td>Women’s Health &amp; Urology</td>
<td>Levostrim P, Estrace, Rapaflo, Liletta</td>
</tr>
<tr>
<td>Gastroenterology &amp; Cystic Fibrosis</td>
<td>Linzess (linaclotide), Asacol HD, Delzicol (mesalamine)</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Bystolic (nabivadol), Avycaz (ceftazidime-avibactam)</td>
</tr>
<tr>
<td>Anti-Infectives</td>
<td>Teflaro (tobramycin), Dalvance (dalfopristin)</td>
</tr>
</tbody>
</table>
Research & Development

Fueling R&D with ~$1.7 Billion Investment

Allergan’s strategically focused R&D engine is built on novel compounds in specialty and primary care markets where there is significant unmet medical need, and fueled by an investment of approximately $1.7 billion in 2015. With an innovative product development portfolio exceeding 20 near-term projects and a world-class generics pipeline, which continues to hold an industry-leading position in First-to-File opportunities in the U.S. and more than 1,000 marketing authorizations globally, we are uniquely positioned within our industry to ensure our development activities support sustainable long-term organic growth.
THE WORLD WILL KNOW US AS “GROWTH PHARMA”

1. Diversified revenue stream and exceptional global commercial footprint
2. Sustainable commercial franchises – commitment to partnering with physicians, specialists, pharmacists and patients
3. Productive Investment in R&D; Development-focused portfolio expansion
4. Powerful global supply chain recognized as a leader in customer service
5. Highly-efficient SG&A spending
6. Experienced management and passionate global employee team committed to success

“GROWTH PHARMA”
Miles McLennan: Summary & Recommendations

- Network

- Do your homework / Haunt job postings

- Align education/background as appropriate for company needs
  - Certification programs
  - Transferrable skills (Payer experience)
  - Internship
  - Professional Societies
    - DIA
    - OCRA
    - RAPS

- Get in somewhere
Sr. Manager, Global Regulatory Affairs
Allergan, Irvine, CA

My Career

Ms (USC)  PhD (University of Toronto, Canada)  Allergan – Consultant, Regulatory CMC  Allergan – Regulatory Affairs  Allergan – Australia  Amgen - Biosimilars  Allergan – Regulatory Affairs
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 (e.g., RAPS, OCRA).
- Ask questions. Be willing to listen & learn.
- It’s a small world. Treat everyone with respect and kindness.
Educational Opportunities

UC Irvine Extension Certificates:

- Medical Product Development Certificate
- Clinical Trials Certificate
- Regulatory Affairs and Compliance Certificate Program

Northeastern University:

- Master of Science in Regulatory Affairs for Drugs, Biologics, Medical Devices
- Biopharmaceutical Domestic Reg. Affairs Certificates
- Biopharmaceutical International Reg. Affairs Certificate
- Medical Devices Regulatory Affairs Certificate
## Medical Product Development

<table>
<thead>
<tr>
<th>Course #</th>
<th>REQUIRED COURSES (9 credit units)</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>BME X408</td>
<td>Medical Product Life-Cycle Management</td>
<td>3</td>
</tr>
<tr>
<td>EECS X445.2 OR EECS X445.26</td>
<td>Regulatory Requirements for Medical Devices OR Regulatory Requirements for Pharmaceutical Products</td>
<td>3</td>
</tr>
<tr>
<td>MGMT X442.6</td>
<td>Medical Product Quality Systems</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Course #</th>
<th>ELECTIVE COURSES (6 credit units)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MGMT X445</td>
<td>Medical Product Marketing</td>
</tr>
<tr>
<td>MED X413.4</td>
<td>Application of Good Clinical Practices</td>
</tr>
<tr>
<td>BME X414</td>
<td>Biomedical Business and Legal Management Essentials</td>
</tr>
</tbody>
</table>

### Regulatory Affairs

- MGMT X445: Medical Product Marketing - 3 units
- MED X413.4: Application of Good Clinical Practices - 3 units
- BME X414: Biomedical Business and Legal Management Essentials - 3 units

### Quality and Compliance

- EECS X445.22: Medical Product Manufacturing - 3 units
- BME X407: Process Validation for Medical Product Development - 3 units
- BME X406: Medical Device Risk Management - 3 units
- BIO SCI X450: Fundamentals of Clinical Trials - 3 units
- MED X413.41: Good Laboratory Practices - 1.5 units

### Engineering and Science

- BME X405: Applied Anatomy and Physiology for Clinical Studies - 4 units
- EECS X445.23: Medical Device Design and Evaluation - 3 units

For the most current schedule of classes, please go online to the UCI Extension catalog at [www.unex.uci.edu](http://www.unex.uci.edu).

Note: Schedules are subject to change.
### Clinical Trials

<table>
<thead>
<tr>
<th>Course #</th>
<th>REQUIRED COURSES (10.5 credit units)</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>EECS X445.2</td>
<td>Regulatory Requirements for Medical Devices</td>
<td>3</td>
</tr>
<tr>
<td>OR</td>
<td>Regulatory Requirements for Pharmaceutical Products</td>
<td>3</td>
</tr>
<tr>
<td>EECS X445.26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BIO SCI X450</td>
<td>Fundamentals of Clinical Trials</td>
<td>3</td>
</tr>
<tr>
<td>MED X413.4</td>
<td>Application of Good Clinical Practices</td>
<td>3</td>
</tr>
<tr>
<td>BME X403</td>
<td>Human Subjects Safety in Clinical Trials</td>
<td>1.5</td>
</tr>
</tbody>
</table>

### ELECTIVE COURSES (5.5 credit units)

<table>
<thead>
<tr>
<th>Course #</th>
<th>Course Title</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>BME X405</td>
<td>Applied Anatomy and Physiology for Clinical Studies</td>
<td>4</td>
</tr>
<tr>
<td>MED X413.41</td>
<td>Good Laboratory Practices</td>
<td>1.5</td>
</tr>
<tr>
<td>MED X413.43</td>
<td>Clinical Data Management</td>
<td>1.5</td>
</tr>
<tr>
<td>MED X413.44</td>
<td>Clinical Trials Internship</td>
<td>3</td>
</tr>
<tr>
<td>MED X413.45</td>
<td>Clinical Trials Project Management</td>
<td>3</td>
</tr>
</tbody>
</table>

For the most current schedule of classes, please go online to the UCI Extension catalog at [www.unex.uci.edu](http://www.unex.uci.edu).

*Note: Schedules are subject to change*
## Regulatory Affairs & Compliance

<table>
<thead>
<tr>
<th>Course #</th>
<th>Required Courses - Pharma Track (10 units)</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHRMSCI X480</td>
<td>Introduction to Regulatory Affairs and Compliance for Drugs, Biologics, and Medical Devices</td>
<td>2</td>
</tr>
<tr>
<td>EECS_X445.26</td>
<td>Regulatory Requirements for Pharmaceutical Products</td>
<td>3</td>
</tr>
<tr>
<td>BIO SCI X450</td>
<td>Fundamentals of Clinical Trials (3 units)</td>
<td>3</td>
</tr>
<tr>
<td>PHRMSCI X481</td>
<td>Post-Approval Compliance Requirements for Pharmaceutical Products</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Course #</th>
<th>Required Courses - Device Track (10 units)</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHRMSCI X480</td>
<td>Introduction to Regulatory Affairs and Compliance for Drugs, Biologics, and Medical Devices</td>
<td>2</td>
</tr>
<tr>
<td>EECS X445</td>
<td>Regulatory Requirements for Medical Devices</td>
<td>3</td>
</tr>
<tr>
<td>BME X413.2</td>
<td>Regulatory Affairs for Post-Market Approval</td>
<td>2</td>
</tr>
<tr>
<td>BME X412</td>
<td>Regulatory Affairs Planning and Management: Concept Review and Evaluation</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Course #</th>
<th>REQUIRED COURSES (5 credit units)</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHRMSCI X493</td>
<td>Drug Safety and Pharmacovigilance</td>
<td>2</td>
</tr>
<tr>
<td>MGMT X442.6</td>
<td>Medical Product Quality Systems</td>
<td>3</td>
</tr>
<tr>
<td>MGMT X445</td>
<td>Medical Product Marketing</td>
<td>3</td>
</tr>
<tr>
<td>BME X409</td>
<td>Medical Product Crisis Management</td>
<td>1.5</td>
</tr>
<tr>
<td>PHRMSCI X490</td>
<td>Overview of Global Regulatory Affairs</td>
<td>3</td>
</tr>
<tr>
<td>BME X414</td>
<td>Biomedical Business and Legal Management Essentials</td>
<td>3</td>
</tr>
<tr>
<td>BME X408</td>
<td>Medical Product Life-Cycle Management</td>
<td>3</td>
</tr>
<tr>
<td>PHRMSCI X495</td>
<td>Application of ICH Guidelines - Regulatory Strategy Development and Dossier Preparation</td>
<td>1.5</td>
</tr>
</tbody>
</table>

For the most current schedule of classes, please go online to the UCI Extension catalog at [www.unex.uci.edu](http://www.unex.uci.edu).

*Note: Schedules are subject to change*
Transfer Agreement

Northeastern University’s College of Professional Studies and University of California Irvine, Extension have identified an opportunity to developed a course credit transfer agreement to provide UC Irvine Extension Certificate students with pathways to pursue their educational goals.
University of California Irvine Extension

- **David Dimas, Director** - ddimas@uci.edu or 1.949.824.9722
- **Jennifer Mortensen, Program Manager** – j.mortensen@uci.edu or 1.949.824.5380

- **Address:** P.O. Box 6050, Irvine, CA 92616-6050
- **Fax:** 949-824-1220 | **Website:** [www.extension.uci.edu](http://www.extension.uci.edu)

Northeastern University College of Professional Studies

- **Irina Kulinets, Director** – i.kulinets@neu.edu
- **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](http://www.northeastern.edu/cps)
FDA websites for obtaining free updates on changes in regulations:

- [http://www.fda.gov/AboutFDA/ContactFDA/ucm2005606.htm](http://www.fda.gov/AboutFDA/ContactFDA/ucm2005606.htm)
- [http://www.fda.gov/AboutFDA/ContactFDA/UCM2005607.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/](https://biocom.org/initiatives/cro_initiative/)
- [http://biocomcro.org](http://biocomcro.org)
- [http://biocom.contractresearchmap.com/biocom/directory](http://biocom.contractresearchmap.com/biocom/directory)
Any Questions