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

Tuesday, March 12, 2013
University Club, Room C
5:30-7:30pm
Agenda

5:30 - 6:00  Networking and Appetizers
6:00 - 6:10  Welcome – Dave /Eric
6:10 - 6:30  Biotech in the OC (Del Stagg)
6:30 - 6:50  Overview of Biotech Careers (Miles McLennan)
6:50 - 7:00  Educational options at UCI (Dave Dimas)
7:00 - 7:10  Degree options from Northeastern (Eric Kupferberg)
7:10 - 7:30  Q&A
35 + years experience in product development, pre-clinical testing, clinical evaluation, registration and manufacturing of pharmaceutical, biologic and medical devices. During his career he has been responsible for US and Internationals registration of products.

Dr. Stagg has served as a US technical expert working with scientists from the Regulatory Agencies of the US, EU and Japan to develop standards for evaluating the safety of medical products.

He has always looked for ways to enhance communications among regulatory professionals and the regulatory agencies and was founder of both the Orange County Regulatory Affairs (OCRA) Discussion Group and the North Carolina Regulatory Affairs Forum (NCRAF).

Dr. Stagg and Elaine Messa, Director (Ret, LA District Office worked together to create the first of the annual FDA-OCRA Regulatory Educational Conferences that are important for communication between industry and FDA.
Miles McLennan is Sr. Director of Operations for Global Medical Affairs at Allergan responsible for GMA processes, systems, and planning.

He has more than two decades of management experience in pharmaceutical product commercialization including the assessment of product development candidates, collaboration with development and project management teams, clinical trial support, and extensive experience with pre/post launch marketing.

He received an MBA from Northeastern University, a BS in Business Administration (Marketing) from CSU Sacramento and is a Certified Medical Education Professional (CCMEP).
Regional Demand - High Tech Jobs

**Patent Density**

- LA: 21.7
- OC: 59.5
- San Diego: 52.2

**Tech Employ Density**

- Orange County: 3,000
- San Diego: 2,500
- Los Angeles: 1,750
Educational Options at UC Irvine

Individual Courses and Certificate Programs in:

- Medical Product Development
- Clinical Trials
- Regulatory Affairs
Educational Options at UC Irvine

### Medical Product Development

#### Clinical Than

#### Regulatory Aff

**Please Note:** Candidates who wish to take both EECS X445.2 and EECS X445.26 may count one as an elective.

<table>
<thead>
<tr>
<th>Prerequisite Courses</th>
<th>Required Courses (9 units)</th>
<th>Elective Courses (6 units)</th>
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<tbody>
<tr>
<td><strong>Course #</strong></td>
<td><strong>Title</strong></td>
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<tr>
<td>EECS X445.2</td>
<td>Regulatory Requirements for Medical Devices (3 units)</td>
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<tr>
<td>EECS X445.26 OR EECS X445.26</td>
<td>Regulatory Requirements for Pharmaceutical Products (3 units)</td>
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<tr>
<td>EECS X445.26</td>
<td>Regulatory R Quality Systems (5 units)</td>
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<tr>
<td>MGMT X442.6</td>
<td>Biomedical Business and Legal Management Essentials (3 units)</td>
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<tr>
<td>BME X413</td>
<td>Regulatory A Affairs</td>
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<td>BME X412</td>
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<tr>
<td>EECS X445.22</td>
<td>Medical Product Manufacturing (3 units)</td>
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<td>MGMT X413.4</td>
<td>Application of Good Clinical Practices (3 units)</td>
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<tr>
<td>MGMT X446</td>
<td>Medical Product Marketing (3 units)</td>
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<tr>
<td>BME X414</td>
<td>Biomedical Business and Legal Management Essentials (3 units)</td>
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<tr>
<td>BME X409</td>
<td>Biomedical B</td>
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<tr>
<td>BME X414</td>
<td>Biomedical B</td>
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<tr>
<td>EECS X429.6</td>
<td>Design of Experiments for Superior Product and Process Performance (3 units)</td>
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<tr>
<td>BME X406</td>
<td>Medical Device Risk Management (3 units)</td>
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<tr>
<td>BIO SCI X459</td>
<td>Fundamentals of Clinical Trials (3 units)</td>
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<tr>
<td>MED X413.41</td>
<td>Good Laboratory Practices (1.5 units)</td>
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<tr>
<td>Engineering and Science</td>
<td>Applied Anatomy and Physiology for Clinical Studies (4 units)</td>
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<tr>
<td>EECS X445.23</td>
<td>Medical Device Design and Evaluation (3 units)</td>
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**Note:** The table above outlines the required and elective courses for the Medical Product Development program at UC Irvine. Candidates are advised to consult the program guidelines for any additional requirements or prerequisites.
OC Corporations hiring:

- Allergan
- Beckman Coulter
- Alcon
- Edwards Lifesciences
- Medtronic
- Toshiba
- AMO Advanced Medical Optics
- BBraun Sharing Expertise
- Sybron Dental Specialties
- Applied Medical
The Good News

- 4,964 Technology Companies in the OC*
- Total Payroll of $8.2B
- 95,047 jobs
- OC 14\textsuperscript{th} in the Nation (NYC, DC, San Jose, Boston, Dallas – top 5)
  - Consumer Electronics
  - Bio Tech
  - Electronic Components
  - Space/Defense
  - Photonics (Optics)
- Recovery is in skilled labor jobs

*Source TechAmerica
Transfer Agreement between UCI and Northeastern

Completion of the UC Irvine Extension Certificate equates to transfer credits for 3-5 courses in the Northeastern University Master of Regulatory Affairs for Drugs, Biologics, and Medical Devices Program
Del Stagg, PhD
Principal, Stagg Regulatory Consultants
Irvine, CA

Instructor, Pharmaceutical Regulations (2013)
UCI Extension, Irvine, CA
Objectives

Describe why Regulatory Affairs is one of the best positions to have in a medical products company

Describe my career path in medical products industry:

Devices, Clinical Research Organizations (CRO), Pharmaceutical, Bio-tech and consulting

Offer suggestions on connecting with the industry to find a job that fits the interests and skills of the individual

Discuss observations of high job performers that enhance the probability for promotion and other job opportunities
What is Regulatory Affairs
Why is it a good position
How do you get into Regulatory Affairs
What are the rewards
What is Regulatory Affairs?

RA is responsible for understanding the regulations the govern how products are developed, manufactured and marketed.

RA needs persons with backgrounds in biology, chemistry, engineering, pharmacology, quality, toxicology, writing, clinical sciences and management.

RA professionals are found in industry and regulatory agencies.
Regulatory Affairs Professional

Why is it a good position?

RA is involved in product development project teams that set the strategy for development, manufacturing, clinical studies and communications with FDA and other regulatory agencies.

RA is involved in the development and building of the manufacturing plants where products are made.

RA is involved with Marketing and marketing products.
How do you get into Regulatory Affairs?

Develop skills and experience in one of the sciences that contribute to product development, manufacturing and marketing (most difficult part)

Learn the regulations that apply to the company’s products

Take courses that provide instruction in applying the regulations in industry – in California, UCI extension courses, USC, SDSU

Join Regulatory Affairs Organizations
What are the rewards?

Satisfaction of knowing that you were an integral part in obtaining approval to market the product

Satisfaction of knowing that your efforts made it possible for the company to market the product to help patients improve their condition

Job security – there are not enough Regulatory Affairs professionals to cover all the companies that intend to develop medical products.
My career story

Graduate school at DUKE Medical School and Medical Research University
Either stay in academic research or go into industry

North Carolina had established Research Triangle Park (RTP) to foster cooperation between the Universities and Industry. Only research could be conducted in the Park.
Friend in Graduate School knew of a research position at Becton Dickinson (B-D) a medical device company.

I applied and got the job as a scientist conducting biological tests and developing pre-clinical models to evaluate new products. Research required reports that were sent to corporate headquarters.
My career story

I was asked to participate in a team meeting to review progress on a product development. I met new persons who had read my reports and asked about my research.

I asked what the company did with the reports and was told they were sent to the FDA.

The person was in Regulatory Affairs.

My question lead to an opportunity to conduct technical reviews of regulatory submissions - leading to a new career.
My career story

Worked for B-D 13 years and made a decision to not relocate to New Jersey for a higher position.

That decision was career limiting with that company.

Left the Company to join a small CRO with personnel from BW and Glaxo to develop a combination product of a drug and special delivery device.

The CRO had experience with drug regulations,

No experience with device development or regulations

Had time to learn and train to be a clinical monitor

Learned important lessons on clinical study design, case report forms, clinical monitoring
My career story

There were two senior regulatory professionals who were interested in learning about device regulations and I wanted to learn about drug regulations.

We held weekly meetings and exchanged information on the regulations (drugs for devices).

Volunteered to review the CMC section of a regulatory submission and caught error that saved company $$$. 
My career story

The President named his “girl friend” to be head of Regulatory and fired the senior regulatory professionals.

Started looking for another opportunities.

A Management Consultant Firm with an office in California found lots of jobs in California and arranged for interviews at several companies in OC and SD.
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 field

Resigned to join a start-up company for a senior position

Company was bought and job was transferred East

Asked my old boss for a recommendation and

Allergan asked me to return –

Responsible for global regulatory affairs for BOTOX

Retired from Allergan in 2005
Your own career story

Joined a small BioTech company in San Diego
Rode the train to San Diego every day
Completed PMA and obtained approval for product
On Management Team that fired the CSO and President
On the train ride home was I was offered a position
Small Contract Manufacturing Organization (CMO)
~ 2 year project to help develop GMP procedures
Retired but was asked by a former employee to help
with an IDE for a new device in Orange County
~ 6 wks project - 2 ½ years - 510(k) for Class 2 device
Teaching UCI extension course and consulting
BioTech market in OC/LA and San Diego

Medical products companies in Southern California

Medical Devices
> (~ 20 % of all device companies are located in Southern California)

Pharmaceuticals
> Fewer Pharmaceutical companies in Southern California

Biologics
> Strongest area for new growth – Small companies need experienced personnel to wear multiple hats

FDA’s LA District Office

Investigators, Scientists, Laboratory Technicians
Medical Device Companies in Orange County

Medical Devices in Orange County, California

http://www.madeinoc.com/index.cfm?fuseaction=advanced_search_results&id_cluster=72&simple_search=1&website_keywords=Medical%20Devices

582 companies listed with contact information
Medical Device Companies in San Diego County

Medical Devices in San Diego County
http://www.manta.com/mb_53_D1_24D/medical_equipment_device/san_diego_ca

419 companies listed with contact information

BIOcom
http://www.biocom.org
BioTech & Biopharma Companies in Orange County
www.socalbio.org/resources/old-directories/orange_bitech.htm

Alacrity Biosciences
Aeolus Pharmaceuticals
Allergan
Allvivo Vascular
AMDL
American Avid Bioservices
Avanir Pharmaceuticals
Biodot
Biomerica, Inc.
Cenomed Biosciences
Clairient
eGene
Genofi
Hycore Biomedical, Inc. (Hybridoma Sciences)
IDM Pharma
ImmPORT Therapeutics Inc
Immunotopics
Ista Pharmaceuticals
Kadmus Pharmaceuticals, Inc
Miragene
Mitos Pharmaceuticals
Molecular Biologicals International
Numira
Peregrine Pharmaceuticals Inc (Techniclone)
PrimeCell Therapeutics
Pyxis Labs
Regenesis
Spectrum Pharmaceuticals (NeoTherapeutics)
Syagen Technology
Teva Parenteral Medicines, Inc.
Thuris Corporation
Valeant Pharmaceuticals
Vetrio Retinal Technologies

34 Companies listed
BioTech & Biopharma Companies in San Diego County

www.thelabrat.com

Acadia Pharmaceuticals
Accelovance
Accumetrics
ACON Laboratories
ADVENTRX Pharmaceuticals
Agilent Technologies
Alere
Allermed Laboratories
Alliance Pharmaceutical
Allylix
Althea Technologies
Ambit Biosciences
Amira Pharmaceuticals
Amylin Pharmaceuticals
Anadys Pharmaceuticals
AnaptysBio
Apricus Biosciences
Aptiv Solutions
AquaBounty Technologies

Ardea Biosciences
Arena Pharmaceuticals
AVIVA Biosciences
Becton Dickinson
BioAtla
Biocept
BioMedica
Biogen Idec
Biosite Diagnostics
BioSurplus
BrainCells
Cadence Pharmaceuticals
Calmune
Carolus Therapeutics
Cato Research
Celgene
Ceregene
Charles River Laboratories
ChemDiv
BioTech & Biopharma Companies in San Diego County

Clinimetrics
Conatus Pharmaceuticals
Cypress Bioscience
Cytori Therapeutics
eBioscience
EMD Chemicals
Exelixis
Fate Therapeutics
Gen-Probe
Genomatica
Genzyme
Halozyme Therapeutics
Harbor BioSciences
Helicon Therapeutics
Histogen
Hospira
HUYA Bioscience International
IASO Pharma
Ichor Medical Systems
Illumina
INC Research
InflammaGen Therapeutics
Inovio Biomedical Corporation
iTherX
Ligand Pharmaceuticals
Lpath
MabVax Therapeutics
Marshall Edwards
MediciNova
MicroConstants
Mixture Sciences
MultiGEN Diagnostics
Neurocrine Biosciences
NuVasive
Ocera Therapeutics
OncoSec Medical
Optimer Pharmaceuticals
Organovo
BioTech & Biopharma Companies in San Diego County

Orphagen Pharmaceuticals  Santarus
Pacira Pharmaceuticals  Senomyx
PAREXEL International  Sequel Pharmaceuticals
Perceptive Informatics  Sequenom
Pfenex  Sialix
PharmaNet Development Group  SRI
Pharmatek Laboratories  Strategic Enzyme Applications
Polynoma  Synbiotics
PolyPeptide Laboratories  Tioga Pharmaceuticals
PPD  Tracon Pharmaceuticals
PRA International  Tragara Pharmaceuticals
Prometheus Laboratories  Trius Therapeutics
Promosome  VentiRx Pharmaceuticals
Quidel  Verenium
Quintiles  Vertex Pharmaceuticals
Receptos  Vical
ResMed  Volcano Corporation
RetroVirox  Zacharon Pharmaceuticals
REVA Medical  Zogenix

114 companies listed
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 – QA / Contract Laboratory
- Engineering – design and testing – Medical Device Co
- Computer Science – circuit design & programming
- Nursing – hospital / clinic – Clinical Research in BioTech
- English – writing – medical writing in Clinical Research
Finding a job and developing a Career

First job may be in a medical product supporting company
Consider a CRO (Clinical Research 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 like the UCI Extension courses
Look for internship positions (some legal and salary concerns)
If you have experience (even very limited) always help
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

Be punctual (on time)
Don’t watch the clock – get the assignment done rapidly
Learn your job function well and try to be the best
Volunteer for / Accept assignments when presented

Assignments are offered when managers have confidence that you can do the job – it may be a stretch to meet, but the rewards are worth the effort

Establish good relationships with your co-workers

That will make the work environment more enjoyable
If they transfer and like you, they may recommend you at their new company
Developing a Career

Earn the respect of your immediate boss
  Be really good at your job
  A good boss will assign more responsibilities because he/she wants to be promoted (see next bullet)
  You will always need recommendations

Learn as much as you can and train someone else for your job
  You can’t be promoted until someone else can do your job

Develop the skills to function at the next level
Developing a Career

Switching Career Paths within a Company

After establishing yourself as a dependable and likable employee look for opportunities to advance.

Ask what your colleagues are doing and why they like their jobs (the grass is not always greener on the other side).

Evaluate whether your current skill sets will work in the new position or will you have to learn more.

Consider a lateral move to get “in-line” for a career in the new area.
Developing a Career

Career in Regulatory Affairs

Most interesting position within the Company
Work on project teams developing new products
Interact with the FDA to submit and obtain approval for new products

Need persons with experience in:
> Manufacturing and analytical testing,
> pre-clinical research,
> clinical research,
> medical writing

It is harder to learn the science than the regulations
Miles McLennan
Sr. Director, Global Operations
Global Medical Affairs • Allergan, Irvine, CA

Instructor, Medical Device
Product Lifecycle Management (Winter 2013)
UCI Extension, Irvine, CA
Objectives

> Describe typical roles, careers, and career paths for pharmaceutical, bio-tech, and medical device manufacturers

> Offer advice on how to approach connecting with the industry to find a job that fits their interest and background

  ● Benefits of being strategic, tenacious, and flexible

> Provide overview of Allergan – a multi-specialty healthcare company • Irvine, CA
We’re looking for someone who can stretch with the demands of this job. Are you flexible?
My Background

> BS – Business Administration
  California State University, Sacramento

> MBA - Northeastern University, Boston

> Bayer, New Haven, CT
  ● Sales, Training, Sales Management
  ● Product Management

> Allergan, Irvine, CA
  ● Product Management / Marketing Teams
  ● Medical Affairs / Global Operations
How did Miles “get in” to Industry?

8-month+ job search!

Dupell Brokerage Co.
Hayward, CA

Graduation!

On Campus Interviews

Pharma Interview

Pharma Interview

Pharma Interview

Pharma Interview

Employment!
Hang in there
The Struggle is Part of the Process!
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)
Career Path – Sales & Marketing

- Sales Territory
- Sales Management
- Sales Training
- Sr. Sales Management
- Product Management
- Sales/Marketing Operations
- Sales/Marketing Leadership
- Global Strategic Marketing
Career Path – R&D

- Professional
- Scientist

- R&D Leadership
- CMC
- Medical Writing
- Medical Affairs
- Regulatory Affairs
- Project Management
Career Path – R&D

- Clinical Project Assistant
- Site Management Associate
- Study Manager
- Clinical Director
- Data Management
- Project Management
- Regulatory Affairs
- TA Lead
Allergan, Inc.
Allergan is a multi-specialty health care company established more than 60 years ago with a commitment to uncover the best of science and develop and deliver innovative and meaningful treatments to help people reach their life’s potential.
Headquartered in Irvine, California

- We have approximately 10,800 highly dedicated and talented employees
- With a presence in more than 100 countries.
- In 2012, our total product net sales reached $5.7 Billion
Focus on Medical Specialties

- **BOTOX® Therapeutic** 16%
- **BOTOX® Cosmetic** 15%
- Ophthalmics 47%
- Facial Aesthetics 7%
- Breast Aesthetics 7%
- LATISSE® 2%
- Obesity Intervention* 3%
- Skin Care 3%

A broad portfolio of pharmaceutical, biologics and medical devices to help improve patients’ lives

Follow R&D technologies into specialties

Build presence within specialties organically and through acquisitions

*Discontinued Business
Eye Care

ACULAR LS® (ketorolac tromethamine ophthalmic solution) 0.4%
ACUVAIL® (ketorolac tromethamine ophthalmic solution) 0.45%
ALOCRIL® (nedocromil sodium ophthalmic solution) 2.0%
ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.1% and 0.15%
ALPHAGAN® (brimonidine tartrate ophthalmic solution) 0.2%
COMBIGAN® (brimonidine tartrate/timolol maleate ophthalmic solution) 0.2%/0.5%
ELESTAT® (epinastine HCL ophthalmic solution) 0.05%
LUMIGAN® 0.03% (bimatoprost ophthalmic solution)
LUMIGAN® 0.01% (bimatoprost ophthalmic solution)
OZURDEX® (dexamethasone intravitreal implant) 0.7mg
PRED FORTE® (prednisolone acetate ophthalmic suspension, USP) 1%
REFRESH® Brand of Artificial Tears
REFRESH® OPTIVE™
RESTASIS® (cyclosporine ophthalmic emulsion) 0.05%
ZYMAXID™ (gatifloxacin ophthalmic solution) 0.5%

Above products are approved and available in the United States
Products to Help Improve Patients’ Lives

Medical Aesthetics

Facial Aesthetics

*BOTOX® Cosmetic (onabotulinumtoxinA)*
*LATISSE® (bimatoprost ophthalmic solution) 0.03%*
*JUVÉDERM®*
*JUVÉDERM® XC*

Breast Aesthetics

*NATRELLE® Collection of Breast Implants and Tissue Expanders*

Physician Dispensed Creams

*SkinMedica®*
*VIVITÉ®*
*MD FORTE®*
*PREVAGE® MD*

Above products are approved and available in the United States
Products to Help Improve Patients’ Lives

**Neurosciences**
- BOTOX® (onabotulinumtoxinA)

**Urologics**
- BOTOX® (onabotulinumtoxinA)

**Medical Dermatology**
- ACZONE® (dapsone) Gel 5%
- AVAGE® (tazarotene) Cream 0.1%
- AZELEX® (azelaic acid cream) 20%
- FLUOROPLEX® (fluorouracil) 1.0% Topical Cream
- TAZORAC® (tazarotene) Cream and Gel 0.1%

Above products are approved and available in the United States.
Key Elements to Our Success

• Lean, efficient and entrepreneurial teams of talented, dedicated people; unique blend of management skills
• Innovative products
• Leadership in specialties
• Global infrastructure
• Fully integrated R&D with broad technology pipeline
• Track record of investing to create markets with favorable global mega-trends
• Large enough to command sufficient resources to drive markets, small enough for nimble execution
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
Questions?
Regulatory Affairs: A Broad Perspective

Eric D. Kupferberg, PhD
Senior Fellow
12 March 2013
Regulatory Stages for New Drugs

- Pre-Clinical Research
- Clinical Studies
  - Phase 1
  - Phase 2
  - Phase 3
- NDA Review
  - Accelerated Development/Review
  - Treatment IND
  - Parallel Track
- Institutional Review Boards

Industry Time
FDA Time
IND Submitted
NDA Submitted
Review Decision

- Sponsor/FDA Meetings Encouraged
- Early Access: Subpart E
- Sponsor Answers Any Questions from Review
- Advisory Committees
Six critical sub-strategies of the Japan approval process
Problem with Learning “On the Job”

• Knowledge is limited to what the company currently “does” not what it might “want to do” or what it will “have to do”

• Reproduce isolation of regulatory affairs

• Under-prepared for mergers and acquisitions

• Limited ability to advance the profession through research & publications
What is the Intermediate RA Work?

• Guide product through entire life-cycle, including clinical trials, approval, labeling, marketing, and post-market surveillance

• Manage products “across” business units, including legal department, QA/QC, marketing, finance

• Agility in working with teams and communicate
The Life Cycle of Biomedical Products

Strategic Planning

Pre-Market

R&D

Clinical

Submission/Registration

Manufacturing

Post-Market

Advertising/Promotion

Labeling

Diligence

Regulatory Operations

Regulatory Strategy

Ethics

Professional Development

Trade Issues

Risk Management

Negotiation/Compensation

Post-market surveillance
What is Advanced RA Work?

- Proficiency in several technical areas, including science, medicine, policy analysis, economics
- Ability to accommodate development of new product areas (e.g., nanotechnology, combination products, tissue engineering, genetic therapy)
- Strong leadership skills, even without formal authority
What is Advanced RA Work?

- Interpretation of international regulations and understanding of trade issues
- Lobby governments for changes in regulations, laws, and health policies
- Work with investors and executives
- Ability to create sustainable competitive advantages for host organization
Crucial Role of “Regulatory Strategy”