WORKING IN REGULATORY AFFAIRS AT GENENTECH

Sarah Lockwood, Program Manager Regulatory Affairs
Amy Schroeder, Associate Program Manager Regulatory Affairs
Overview

- How did we end up in Regulatory Affairs?
- Genentech Introduction
- Overview of Regulatory Affairs
- Genentech Product Development Regulatory
- Regulatory Affairs Internship
How did we get here?

Sarah
- Hometown Latham, NY
- University of Rochester Undergraduate
- UCD BMB Graduate Student and Postdoctoral Scholar
  - Segal Lab/DEB
- Genentech
  - Regulatory Affairs Internship
  - Full Time Regulatory at Genentech

Amy
- Hometown St. Louis, MO
- Undergraduate Truman State
- RA in Plant Biology
- UCD BMB Graduate Student
  - Privalsky Lab/DEB
- Genentech
  - Research Internship
  - Regulatory Affairs Internship
  - Full Time Regulatory at Genentech
Genentech Fast Facts

• Founded in 1976
• Became a member of the Roche Group in March 2009
• Headquartered in South San Francisco, California
• Approximately 14,000 employees
• Headquarters for all Roche pharmaceutical operations in the U.S.
  - 35+ medicines approved for people with various serious or life-threatening diseases
  - US Pharmaceutical 2015 sales: $18.4 billion*
  - Genentech’s Research and Early Development group (gRED) has more than 30 potential new medicines in development

*17,616 CHF m; average exchange rate 0.96.
R&D Structure Fosters a Diversity of Approaches

Independent centers for Research and Early Development

- Genentech
- Roche
- Chugai

External Innovation

Roche Partnering - Managing over 150 partnerships

Global Product Development
Manufacturing
Commercialization

Roche Pharma
Genentech makes 35+ medicines for people with serious diseases.

<table>
<thead>
<tr>
<th>Year</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>1986</td>
<td>Activase</td>
</tr>
<tr>
<td>1987</td>
<td>Roche</td>
</tr>
<tr>
<td>1993</td>
<td>Nutropin AV™</td>
</tr>
<tr>
<td>1996</td>
<td>Pulmozyme®</td>
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<tr>
<td>1997</td>
<td>Rituxan</td>
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<tr>
<td>1998</td>
<td>Herceptin®</td>
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<tr>
<td>1999</td>
<td>Tarceva®</td>
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<tr>
<td>2000</td>
<td>Lucentis®</td>
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<tr>
<td>2001</td>
<td>Envedge®</td>
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<tr>
<td>2002</td>
<td>Ramucirumab</td>
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<tr>
<td>2003</td>
<td>ALKIN®</td>
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<tr>
<td>2004</td>
<td>Gazyva®</td>
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<tr>
<td>2006</td>
<td>Venclexta®</td>
</tr>
<tr>
<td>2010</td>
<td>Pegasys®</td>
</tr>
<tr>
<td>2011</td>
<td>CellCept®</td>
</tr>
<tr>
<td>2012</td>
<td>Valcyte®</td>
</tr>
<tr>
<td>2013</td>
<td>Xeloda®</td>
</tr>
<tr>
<td>2014</td>
<td>Tamiflu®</td>
</tr>
<tr>
<td>2015</td>
<td>Cotellic® tablets</td>
</tr>
<tr>
<td>2016</td>
<td>Alecensa®</td>
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</tbody>
</table>

2015: Cotellic® (cobimetinib) tablets
2016: Venclexta® venetoclax tablets
REGULATORY AFFAIRS
Regulatory Affairs: The bridge between the pharmaceutical company and the government agency
Role of Regulatory Affairs

- Keep track of the ever-changing legislation and guidelines
  - Provide advice on interaction with health authorities
  - Carry out negotiations with regulatory agencies necessary to obtain marketing authorization for products
- Submission of registration documents to regulatory agencies
  - Monitor progress of submissions
  - Arrange meetings between company and regulatory agencies
  - Respond to queries as they arise
  - Ensure registration/approvals are granted without delay
- Ensure compliance of the product development plan with current regulations
- Handle inspections from health authorities
- Manage post-marketing activities required by health authorities
Importance of Regulatory Affairs

Company success depends on reduction of time taken for a drug to reach market
- Study design
- Label negotiations

Inadequate reporting of data may prevent a timely positive evaluation of a marketing application
Regulatory Deliverables & Tasks

- Decision Points
  - Target Identification
  - Research
- Development Phase
  - Target Assessment
  - Lead Identification
  - Optimation
  - Phase 0
  - Phase I
  - Phase II
  - Phase III
  - Phase IV
- Entry Into Human Decision
- Filing Decision
- IND/CTA
- Pre-Ph3 Deliverables
- NDA/BLA/MAA
- Briefing Packages, Regulatory Assessments, Responses, Etc.
Genentech Regulatory Affairs – Departments

- Labeling
- Program Management
- Documentation
- Advertising & Promotions
- Compliance
- Regulatory Intelligence
- Technical Regulatory
- Operations
Product Development Regulatory Program Management

<table>
<thead>
<tr>
<th>Job Role</th>
<th>Primary Objective of the Job</th>
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<tbody>
<tr>
<td>Regulatory Support</td>
<td>Support of PDR Program Managers in regulatory responsibilities.</td>
</tr>
<tr>
<td>Regional Partner</td>
<td>Responsible for regional (EU, US, ROW) regulatory strategic and operational management of a project, or part of a complex project, or a portfolio of projects</td>
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<tr>
<td>Principal Partner</td>
<td>Responsible for regional (EU, US, BRICKMT) regulatory strategic and operational management of a complex project or portfolio of complex projects; provides regional line management to partners working on the same project(s)</td>
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<tr>
<td>GRL</td>
<td>Accountable for regulatory management of a project(s) and leading a matrix team of regulatory professionals</td>
</tr>
<tr>
<td>Senior GRL</td>
<td>Accountable for global regulatory management of a complex project(s), leading a matrix team of regulatory professionals, and line managing regulatory program managers on the same project.</td>
</tr>
<tr>
<td>Team Leader</td>
<td>Provides regional line management and regulatory leadership to a group of PDR personnel within a specific Franchise; serves as deputy to line management as necessary</td>
</tr>
</tbody>
</table>
| Franchise Head      | • Provides leadership and strategic regulatory oversight for their designated franchise across the projects portfolio  
                      • Provides line management, people development, and performance management for their designated franchise  
                      • Global PDR representative on TA Franchise for designated disease area and provides regulatory leadership to decisions specific to the designated franchise  
                      • Member of relevant PDR TA leadership team  
                      • Provides leadership to peer review and other TA committees  
                      • Serves as a deputy to Global TA Head, as required |
Global Development Team Composition

Global Development Team
(Led by the GDTL)

- Project Management
- Clinical Operations
- Safety Science
- Regulatory
- Biometrics
- Medical Affairs
- Clinical Science
- ClinPharm/Tox/PKPD
- Biomarkers/Translational Medicine
INTERNSHIP OPPORTUNITIES
Internship Opportunities in Regulatory Affairs

- 6mo+ paid Internship in Regulatory Affairs
  - Program Management, Documentation, Labeling, Compliance, Regulatory Intelligence
- Hands on experience within regulatory affairs
- Encouraged to explore other departments at Genentech
- Must be within 2 years of graduating

To Apply: send your resume and a cover letter outlining your interest to schroeder.amy@gene.com or lockwood.sarah@gene.com
FDA’s Structure and Organization

- **Office of Medical Products and Tobacco**
- **Other Offices (Food, Veterinary Products, Operations, etc.)**
- **Center for Drug Evaluation and Research (CDER)**: Regulates prescription and over-the-counter drugs, and therapeutic biologics
- **Center for Biologics Evaluation and Research (CBER)**: Regulates blood, vaccines, allergens, tissues, cellular, and gene therapies
- **Center for Device and Radiological Health (CDRH)**: Regulates medical devices (incl. CDx) and radiation-emitting devices (lasers, x-rays etc.)
- **Other Centers**

More information can be found at [http://www.fda.gov/AboutFDA/CentersOffices/default.htm](http://www.fda.gov/AboutFDA/CentersOffices/default.htm)
FDA’s Structure and Organization: CDER

*Office of Drug Evaluation IV not pictured*
A History of Firsts

1st Biotech company and IPO
1st To produce a human protein (somatostatin)
1st To clone human insulin using recombinant DNA technology
1st Biotech medicine on the market (recombinant human insulin – licensed to eli lilly)
1st Recombinant biotech medicine manufactured and marketed by a biotech company (nutropin)
1st Therapeutic antibody approved for cancer in the united states (rituxan)
1st Personalized medicine (herceptin)
1st Anti-angiogenesis treatment for people with cancer (avastin)
1st Biologic for asthma (xolair)
1st Biologic for cystic fibrosis (pulmozyme)
1st Treatment to improve vision in up to 40% of patients with wet AMD (lucentis)
1st FDA-approved medicine for people with advanced forms of the most common skin cancer (erivedge)
1st Antibody-drug conjugate approved for people with advanced HER2+ breast cancer (kadycla)
1st Medicine approved with the FDA’s breakthrough therapy designation (gazyva)
1st Treatment approved under FDA pathway for neoadjuvant use in breast cancer (perjeta)