

Amy C. Schroeder, Ph.D.

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Recent Work Experience:

Product Development Regulatory- Associate Program Manager May 2015- present
Genentech, South San Francisco, CA

- Managing timelines and regulatory strategy across PhI and PhIII trials
- Leading pre-meeting packages for FDA meetings
- Management and alignment of cross-functional team preparation for FDA meetings
- Responsible for the preparation, coordination, and content of FDA submissions
- Reviewer and owner of critical regulatory documents
- Regulatory representative on multiple global PhI and PhIII clinical study teams
- Responsible for developing regulatory strategy and environment presentations

Product Development Regulatory- Project Management Oncology Intern 2014-May 2015
Genentech, South San Francisco, CA

- Regulatory support across multiple global PhII and PhIII clinical study teams
- Reviewer of regulatory documents (label updates, protocols, FDA pre-meeting packages)
- Support in preparation of pre-meeting package material for FDA
- Experience with supporting marketed product and early development regulatory activities
- Regulatory intelligence research and presentations to cross-functional teams
- Responsible for the preparation, coordination, and content of FDA submissions

Discovery Research and Early Development (gRED) Molecular Biology Metabolism Intern Fall 2013
Genentech, South San Francisco, CA

- Characterization of a potential target therapy for diabetes and obesity
- Responsible for overall project design and execution and cross functional project collaboration
- Resulted in peer reviewed publication (March 2016)

Graduate Research Assistant 2009-2014
Microbiology Department, University of California Davis, Davis, CA

- Investigating the ability of thyroid hormone receptors to sense T₄ (3,5,3',5'-tetraiodo-L-thyronine) as a direct-acting agonist
- Resulted in four peer reviewed publications, multiple professional conference posters and presentations
- Laboratory and personnel management including safety regulations

Relevant Skills and Experience:

Leadership/Management:

Collaborative team player
Ability to adapt to new challenges
Strong organizational skills
Prioritizing Multitasker
Proactive problem solver

Communication:

Developed oral presentation skills
Strong editing and writing abilities
Efficient with new subjects/concepts
Adaptive presentation capabilities
Analytical critical thinking

Scientific Experience:

9 peer-reviewed publications
Endocrinology (nuclear receptors)
Oncology (breast cancer)
Biochemical/Cell Techniques
Next generation sequencing

Education:

- **Ph.D. in Biochemistry and Molecular Biology with a Designated Emphasis in Biotechnology**
University of California, Davis Davis, CA 2009-2014
- **B.S. in Biology with Chemistry Minor (with honors)**
Truman State University Kirksville, MO 2004-2008

Awards and Fellowships:

- NSF Graduate Research Fellowship (2010-2014)
 - Phi Sigma Honors Society (2011-2014)
 - Presidential Poster Endocrinology Society (2013)
 - UC Davis Graduate Travel Award Winner (2013)
 - ASPB Travel Grant 2009
 - Truman State Teaching Assistant Award 2008
 - ASPB Biologists Summer SURF award 2007
 - REF-REU Fellowship 2006
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