HEIDI M. PETERSEN
Co-Founder of REGBIOPARTNERS

May 2025-Present | **Independent Consultant** | **Mountain View, CA**

Senior Regulatory Consultant/Advisor

- Provide regulatory strategy to companies seeking highly experienced/hands on regulatory leader

June 2023-May 2025 | **Spruce Biosciences** | **South San Francisco, CA**

Senior Vice President, Regulatory Affairs and Quality Assurance

- Managed regulatory and quality functions efficiently, achieving results while reducing budget
  - Very hands-on approach required for a Regulatory/Quality department where I was the sole full-time employee
    - Identified a highly skilled group of consultants to assist on an as-needed basis
  - Provided global regulatory strategy on development of rare disease programs
  - Revamped quality management system since date of hire
- Led management of Japanese corporate partnership on Congenital Adrenal Hyperplasia (CAH) development program
- Worked with business development on multiple in-licensing opportunities
- Member of Executive Management Team

November 2021-June 2023 | **Mereo BioPharma** | **London, UK/ Redwood City, CA**

Senior Vice President, Regulatory Affairs

- Provided global regulatory strategy on development of oncology and rare disease programs
- Worked with therapeutic leads to develop novel regulatory approaches for clinical programs
  - Wrote Core Regulatory Documents in a very short timeframe that successfully led to new INDs and early/late-stage milestone regulatory meetings
- Worked with business development on out-licensing and in-licensing opportunities
- Member of Executive Management Team

December 2019-June 2020 | **Kartos Therapeutics** | **Redwood Shores, CA**

Vice President, Regulatory Affairs

- Provided global regulatory strategy on development of company's oncology products
- Managed multiple programs that moved rapidly and dynamically and achieved every regulatory milestone

June 2017-July 2019 | **Immune Design (IMDZ) acquired by Merck in March 2019** | **South SF, CA**

Vice President, Regulatory Affairs

- Provided global regulatory strategy on development of company's immuno-oncology products at the Phase 1, 2 and 3 stage of clinical development
- Led regulatory team to develop documents for global regulatory submissions and meetings
- Led interactions with global regulatory agencies
- Led successful regulatory interactions and due diligence with Merck regulatory
  - Member of senior leadership team that oversaw successful acquisition of IMDZ by Merck
- Member of Executive Management team responsible for company progress and strategic direction

October 2013-June 2017 | Independent Consultant | Mountain View, CA

Senior Regulatory Consultant/Advisor

- Provided global regulatory strategy on the development of drug, biologic, and drug/device products
- Managed and prepared documentation for regulatory filings from pre-IND to NDA/BLA; CTA to MAA
- Prepared companies and developed briefing packages for meetings with regulatory agencies (FDA, EMA, and ex-US country-specific regulatory agencies)
- Led and facilitated discussions with regulatory agencies
- Developed Target Product Profiles for companies at all stages of product development

November 2008–August 2013 | BN-Immunotherapeutics | Mountain View, CA

Vice President, Regulatory Affairs and Quality Assurance (2011-2013); Sr. Director, Regulatory Affairs and Quality Assurance (2010-2011); Director, Regulatory Affairs (2008-2010)

- Led regulatory meetings/discussions with FDA (End of Phase 2), RAC (first RAC public meeting of a Phase 3 protocol on a gene therapy product), and ex-US regulatory agencies
- Prepared and managed briefing documents for US and ex-US regulatory meetings
- Prepared and managed submissions for FDA and ex-US regulatory agency review (successfully cleared to Phase 3 in over 14 ex-US countries)
- Managed Regulatory and Quality Groups
- Led regulatory activities related to partnering/due diligence
- Member of Executive Management Team

2004-November 2008 | Independent Consultant | Mountain View, CA

Regulatory Affairs Consulting

- Provided regulatory strategy on investigational drug, drug/device, and biologic products (primarily in the indication areas of oncology and infectious disease)
- Prepared and managed regulatory submissions:
    - IND, CTA/IMPD, DMF/MF, NDA
- Prepared companies for meetings with regulatory agencies and led regulatory meetings
- Participated in partnering/due diligence activities

2002-2004 | Independent Consultant | Mountain View, CA

New Business Development Consulting

- Identified and evaluated new technologies and products that had the potential to complement and expand upon in-house technology and expertise
- Developed road-show materials: business plans, presentations, term-sheets and preliminary market forecasts
- Analyzed and summarized incidence and prevalence data to support market forecasting efforts

1997-2002	Pharmacyclics	Sunnyvale, CA

Director, Business Development (2000-2002); Assoc. Director, Business Development (1999-2000)

- Corporate Development
  - Developed and conducted in-depth presentations of Pharmacyclics' technology and products in support of partnering activities with pharmaceutical and biotechnology companies
  - Participated in deal term-sheet preparation and licensing negotiations
  - Directed alliance management: oversaw joint research, development and commercial committees composed of Pharmacyclics and partner company personnel
- Technology Evaluation/In-Licensing
  - Identified complementary technologies and products to expand corporate portfolio
  - Prepared scientific and technical evaluations of potential product and technology in-licensing candidates
  - Drafted term sheets and participated in, or led negotiations to acquire new technologies

Manager, Regulatory Affairs (1997-1999)

- Managed regulatory affairs of one of Pharmacyclics' two core technologies developed for cardiovascular, oncology and ophthalmology indications
  - Led regulatory strategy and managed document submissions for drug/device combination products
- Managed alliances with companies that licensed technology for ex-US markets, or for indications not within Pharmacyclics' clinical expertise (ophthalmology)

1995-1997	Chiron Corporation	Emeryville, CA

Senior Regulatory Associate III

1992-1995	ALZA Corporation	Palo Alto, CA

Senior Regulatory Associate II

ADDITIONAL WORK EXPERIENCE:

Senior Medical Writer/Editor, Kaiser Permanente, Oakland, CA (1991-1992)

Project Manager, HIV Transmission Study, UCSF, San Francisco, CA (1988-1990)

Program Associate, NY Academy of Medicine, New York City, NY (1985-1988)

EDUCATION

Master of Public Health, Columbia University (nutrition/epidemiology concentration)
Bachelor of Science in Biology, Tulane University: Award: Tulane University Scholar Student

LANGUAGES

Conversational German