ELIZABETH M. ALESSI, MTOPRA

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EXPERIENCE

Inozyme Pharma, Inc.

Executive Director, Regulatory Affairs, Medical Writing and Pharmacovigilance March 2023 – Present
Senior Director, Regulatory Affairs, Medical Writing and Pharmacovigilance September 2021 – February 2023
Director, Regulatory Affairs and Medical Writing March 2021 – August 2021
Associate Director, Regulatory Affairs March 2020 – February 2021

As Head of Regulatory Affairs, Medical Writing and Pharmacovigilance, responsible for development and implementation of innovative global regulatory strategies to support product development and commercialization; represent the company with domestic and international regulatory authorities; provide oversight of as well as develop and grow the Regulatory Affairs, Medical Writing, and Pharmacovigilance functions.

Biogen

Global Regulatory Lead October 2019 – March 2020
Associate Director, Global Regulatory Product Leadership, Global Safety and Regulatory Sciences

Responsible for developing and delivering innovative, breakthrough global regulatory strategies for product development and approval, in alignment with the global business strategy; responsible for leading a comprehensive and strategic approach to developing and executing integrated global regulatory strategies that account for the complex interplay between major Health Authorities (including US, EU, JP, and China); represent the company with domestic and international regulatory authorities, contractors and corporate partners; and provide regulatory support for various departments, projects, and teams/committees.

Biogen

Senior Manager, Global Regulatory Project Leadership, Global Safety and Regulatory Sciences February 2018 – October 2019

Working with the Global Regulatory Lead / as acting Global Regulatory Lead: develop and implement global regulatory strategies for products in all phases of development; prepare and coordinate effective regulatory correspondence and submissions; identify and assess opportunities for innovative regulatory approaches to support product development; provide strong regulatory representation on project teams; actively participate in and contribute to regulatory policy development; and participate in department and company initiatives/workstreams, providing the Global Regulatory perspective and expertise.

Proteostasis Therapeutics, Inc.

Manager, Regulatory Affairs December 2016 – February 2018

Originally working with the Director of Regulatory Affairs and then leading the Regulatory Affairs function, developed and implemented regulatory strategy for innovative development programs in cystic fibrosis; prepared and coordinated regulatory correspondence and submissions (e.g., INDs and CTAs, meeting requests and briefing documents, Fast Track and Orphan Designation requests, responses to agency information requests, IND and CTA amendments); served as primary sponsor contact with Agencies; served as regulatory lead on project and program teams; provided guidance to cross-functional teams on regulatory strategy and activities; performed regulatory research and intelligence; managed vendor/consultant activities.

Cerulean Pharma Inc.
Manager, Regulatory Affairs August 2015 – December 2016
Worked closely with the Vice President of Regulatory Affairs to build a high-value Regulatory Affairs team and function; created and implemented efficient regulatory processes and solutions; evaluated, managed and completed regulatory projects consistent with company goals and strategy; prepared and coordinated regulatory correspondence and submissions (e.g., meeting requests and briefing documents, Fast Track and Orphan Designation requests, responses to agency information requests, IND amendments); served as primary contact with FDA; participated in planning and execution of activities to support oncology development programs; served as regulatory lead on project and program teams; provided guidance to cross-functional teams on regulatory strategy and activities; performed regulatory research and intelligence; created and managed regulatory archive; contributing member of SOP development team; managed CRO and consultant activities.

Shire
Senior Regulatory Affairs Associate, Global Regulatory Affairs February 2015 – July 2015
Regulatory Strategist (US, Canada) for programs in early development through post-marketing; led preparation and submission of agency meeting requests and briefing documents; supported preparation of and participated in a successful Pre-NDS meeting with Health Canada; led preparation of an NDS; provided regulatory guidance to key internal stakeholders; worked with Global Regulatory Lead and others as appropriate to develop and implement regulatory strategy; served as primary contact with FDA and Health Canada; supported preparation and submission of Clinical Trial Applications; responded to agency information requests; liaised with and supported International Regulatory colleagues as needed; oversaw lifecycle maintenance activities; served as Regulatory representative on internal cross-functional teams; managed CRO activities.

Shire
Regulatory Affairs Associate II, Global Regulatory Affairs August 2012 – January 2015
Regulatory Strategist (US, Canada) for programs in early development through post-marketing; led successful submission of two supplemental BLAs and responses to agency questions, supported multiple agency teleconferences and negotiations, leading to approval; led successful submission of an SNDS and supported responses to requests for information, leading to approval; served as primary contact with FDA; supported preparation and submission of agency meeting requests and briefing documents; supported preparation and submission of an original IND; supported development of protocols to address postmarketing requirements and led successful submission; oversaw lifecycle maintenance activities; acted as liaison with International Regulatory colleagues and provided ad hoc support; provided regulatory guidance to key internal stakeholders; served as Regulatory representative on various cross-functional teams; contributing member of Global Regulatory Affairs SOP and WI development teams; managed CRO activities.

Shire Human Genetic Therapies (Shire)
Intern, Global Regulatory Affairs May 2011 – August 2012
Under appropriate supervision, served as the Regulatory Affairs lead/managed regulatory activities for designated projects; assisted in preparing, compiling,

reviewing and processing regulatory submissions and correspondence; ensured consistency, completeness and adherence to standards/guidelines for regulatory submissions; coordinated and consulted with other departments on the content, review and assembly of regulatory documentation; led/participated in inter-departmental project/regulatory submission working teams and provided clear and consistent regulatory guidance; performed regulatory research and intelligence.

Revere Aquatics
Founder/Head Coach, *Revere SandSharks Swim Club* 2007 – 2016
Established and managed the operation of a competitive youth swim team competing at the local, regional and national level.

Dana-Farber Cancer Institute
Clinical Research Coordinator, *David B. Perini, Jr. Quality of Life Clinic* 2006 – 2007
Managed a research study designed to assess the effect of an educational intervention on breast cancer screening attitudes and behaviors of female Hodgkin's disease survivors.

Intern, *David B. Perini, Jr. Quality of Life Clinic* 2005 – 2006
Supported the preparation and Institutional Review Board (IRB) submission of the above described research protocol, which successfully obtained IRB approval.

EDUCATION

Simmons College, Boston, MA
B.S. in Biochemistry (Psychology Minor) 2008

ADDITIONAL COURSEWORK

Regis College, Weston, MA
Regulatory and Clinical Research Management Graduate Program Summer 2010 – Fall 2013

Harvard University Extension School, Cambridge, MA
Graduate-level Coursework 2008
Biostatistics, Graduate Research Methods and Scholarly Writing (Biological Sciences)

CERTIFICATIONS

Licensed Product Owner (ScrumInc.)
Licensed Scrum Master (ScrumInc.)

MEMBERSHIPS

Regulatory Affairs Professionals Society (RAPS)
The Organisation for Professional in Regulatory Affairs (TOPRA)
Beta Beta Beta National Biological Honor Society
Psi Chi National Honor Society in Psychology

PUBLICATIONS AND PRESENTATIONS

"Re-engaging the Disconnected: Educational Intervention with Long-term Female Hodgkin's Survivors"
Third author of poster presented on behalf of Dana-Farber Cancer Institute, *Boston, MA* 2007