Samantha Greene

Head of Regulatory Affairs

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Summary

Head of regulatory affairs with 15 years in drug and biologic development, leading regulatory strategy for a clinical-stage oncology biotech. Has filed 9 INDs, secured Breakthrough Therapy designation and led FDA meetings from pre-IND to end-of-phase 2, with a 7-person team covering CMC, clinical and regulatory operations.

Experience

Head of Regulatory Affairs

Kendall Square Oncology — Cambridge, MA — 06/2022 - Present

Clinical-stage biotech with 3 antibody-drug conjugates in phase 1 to 3 trials.

- Lead a team of **7** across regulatory strategy, CMC regulatory and regulatory operations.
- File and maintain 4 active INDs, including annual reports, protocol amendments and IND safety reports.
- Direct 6 Type B and C FDA meetings and an end-of-phase 2 meeting that agreed the pivotal design.
- Advise the CEO and board on regulatory risk and EU and Japan plans ahead of a 2027 BLA.

Director, Regulatory Affairs

Fenway Biotherapeutics — Boston, MA — 03/2017 - 05/2022

Immunology biotech with 3 clinical programs.

- Directed regulatory strategy for 3 immunology programs, filing 5 INDs and 2 EU clinical trial applications.
- Secured Orphan Drug designation for 2 programs and Fast Track for 1.
- Built an in-house eCTD publishing group, saving $400K a year in vendor fees.

Regulatory Affairs Manager

Route 128 Pharmaceuticals — Waltham, MA — 06/2011 - 02/2017

Small-molecule drug developer.

- Managed IND amendments and annual reports for 4 programs.
- Wrote briefing documents for 8 FDA meetings across phase 1 and 2.
- Coordinated Module 1 and 2 content for 1 NDA approved on its first cycle.

Education

Doctor of Philosophy

Boston University

Pharmacology

Boston, MA

05/2011

Skills

INDs	—	FDA	—	Regulatory Strategy	—	Breakthrough Therapy Designation
Orphan Drug Designation	—	CMC Regulatory	—	eCTD	—	BLA
NDA	—	ICH Guidelines				

Certificates

Regulatory Affairs Certification (RAC-Drugs)

Regulatory Affairs Professionals Society (RAPS)

11/2014