

## Elizabeth Caruso

### Associate

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New York

Life Sciences and Healthcare Regulatory

Life Sciences

Digital Health

Medtech

CooleyREG

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Elizabeth is an associate in Cooley's global life sciences and healthcare regulatory practice, where she counsels pharmaceutical, biologic, medical device, digital health, food, dietary supplement and cosmetic companies on US Food and Drug Administration (FDA) regulatory compliance issues, such as research, development and commercialization issues, clinical trial conduct, and responding to FDA inspection observations. She advises on a wide range of contracts in the life sciences space, such as clinical trial agreements, contract research organization (CRO) agreements, pharmacovigilance agreements and quality agreements. She also routinely provides regulatory support for various corporate and licensing transactions. Elizabeth joined Cooley in 2024 from another international law firm, where she also worked on M&A transactions, licensing and collaboration deals, and royalty monetizations involving life sciences companies.

As an associate in the global life sciences and healthcare regulatory practice group at Cooley, Elizabeth helps companies in the food, drug, biologic, cosmetic, dietary supplement and medical device spaces navigate regulatory and compliance issues they may encounter during research, development and through commercialization of their products.

Elizabeth is particularly interested in the conduct of clinical trials and provides counsel on a variety of trial-related issues and contracts, such as CRO agreements, clinical trial agreements, informed consents, pharmacovigilance agreements and quality agreements. She also provides counsel on regulatory compliance issues, such as developing standard operating procedures and responding to FDA Form 483 observations.

Elizabeth routinely provides regulatory support on transactions, such as mergers and acquisitions, financings, initial public offerings (IPOs), follow-on offerings, and licensing and collaboration deals involving life sciences companies. As part of these transactions, she conducts comprehensive regulatory due diligence and assists in drafting favorable regulatory terms for clients.

Prior to joining Cooley, Elizabeth worked on M&A transactions, licensing and collaboration deals, and royalty financings for life sciences companies at another international law firm.

Before entering legal practice, Elizabeth worked in clinical trial research operations for a number of institutions, such as Columbia University and Icahn School of Medicine at Mount Sinai. She also was a clinical research associate for a global pharmaceutical company, where she was responsible for managing clinical trial sites participating in diabetes and obesity trials throughout the US and Canada and served as a subject matter authority for informed consents and institutional review boards. Elizabeth also coauthored scientific publications in both the obesity and oncology spaces.

## Education

Boston College Law School

JD, 2022

Stony Brook University

BS, 2016

Columbia University

Postbaccalaureate, premedical certificate, 2014

University at Buffalo

BS, 2010

## Admissions & Credentials

New York

## Memberships & Affiliations

Food and Drug Law Institute

Society of Clinical Research Associates