



Michelle D. Axelrod

Principal

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Michelle D. Axelrod is the Managing Principal of Porzio, Bromberg & Newman's New England office. Michelle has over 25 years of experience addressing legal and compliance issues impacting companies in the life sciences industry; 15 years as in-house counsel.

Michelle primarily counsels pharmaceutical, medical device, and biotech clients on legal and compliance issues related to product development and commercialization, and related clinical, medical, sales, marketing, patient support and reimbursement activities. Michelle reviews promotional content and medical communications, advises on fraud and abuse matters and related issues, provides direction regarding field and account management, and supports clients' compliance initiatives, including the development of policies/SOPs, training, and monitoring and auditing programs. Michelle also negotiates, drafts and reviews all types of contracts, including clinical trial and related agreements, HCP consulting/advisor/speaker agreements, external funding agreements, distribution agreements, agreements with health plans/PBMs, retail/specialty pharmacies, GPOs, wholesalers, and other healthcare entities.

Prior to joining Porzio, Michelle held the position of Assistant General Counsel at Sunovion Pharmaceuticals Inc., formerly Sepracor Inc. In this role, she served as the lead commercial and regulatory attorney supporting the development and commercialization activities for seven products. She also helped to build the company's compliance program.

Drawing from her in-house background and years of experience working with small, midsize, and large companies in multiple therapeutic areas, Michelle offers valuable insights to clients on corporate dynamics and provides innovative ideas to support business goals while effectively protecting companies and mitigating organizational risk. She maintains a practical approach, and understands the importance of collaboration between business units and the Legal and Compliance teams, to achieve business objectives.

Recognitions

- BTI Client Service All-Stars (2024)

News

- Life Sciences Principal Michelle D. Axelrod Recognized as 2024 BTI Client Service All-Star, 6/04/2024
- Porzio, Bromberg & Newman Named Winner of Financial Times Innovative Lawyers in Healthcare & Life Sciences Award, 12/05/2023

Michelle D. Axelrod Cont.

Articles

- Clinical Trial Recruitment: Who Are You Paying And What Are You Saying? – *Clinical Leader*, 7/15/2024
- Website Accessibility Claimants Targeting Pharmaceutical Companies, 11/05/2020

Events

- Puerto Rico Pharmaceutical Summit 2024, 2/06/2024
- Principal Michelle Axelrod Presented at ACI's 4th Annual Women Leaders In Life Science Law, 7/20/2017
- Principal Michelle Axelrod Presented at AdvaMed's 2017 Women's Executive Network Conference, 6/20/2017
- Porzio Attorneys Presented at CBI's 14th Annual Pharmaceutical Compliance Congress, 4/27/2017
- Porzio New England Healthcare Compliance Roundtable: Compliance Measurements, 4/07/2017
- CBI's Global Compliance Congress for Life Sciences, 11/16/2016
- Principal Michelle Axelrod to Present at AdvaMed's 7th Annual Advertising and Promotion of Medical Devices Conference, 11/11/2016
- ACI's 3rd Annual Conference on Women Leaders in Life Sciences Law, 7/29/2016

Speaking Engagements

- "Medical Device Compliance: Proactive Strategies for Effective Risk Management," AdvaMed, 1/23/2025
- "Cracking the Code of Data Privacy: Ethical Approaches to Handling Sensitive Information," Porzio's 8th Annual Ethics & Eggs CLE Seminar, 12/05/2024
- "Medtech Compliance Bootcamp," AdvaMed, 9/10/2024-9/11/2024
- "Medtech Compliance 101 – Mid-Year Check In," AdvaMed, 5/08/2024
- "Clinical and R&D Compliance –Emerging Trends and New Risk Areas," Informa Pharmaceutical Compliance Congress, 4/16/2024
- AdvaMed & Porzio Life Sciences MedTech Compliance 101 Bootcamp, 9/14/2022
- Incorporating Management of High-Risk Engagements into Your Compliance Program; Virtual HCP Engagement Strategies Conference, 10/20/2021
- "Operationalizing Compliance Guidance - Key Learnings for DOJ Updates, OIG Fraud Alert and Open Payments Enforcement Action," Speaker, Pharmaceutical Compliance Congress, 9/28/2021
- "Compliance Challenge: Federal, State and International Transparency, Disclosures and Reporting; Part 4 of Four-Part Series, Culture, Effective Compliance Program Development and Implementation, Government Expectations and Assessing Your Risk Profile," Medtech Compliance Virtual Bootcamp, 3/11/2021

Michelle D. Axelrod Cont.

- "Compliance Challenge: Grants, Donations and Other Funding; Part 3 of Four-Part Series, Culture, Effective Compliance Program Development and Implementation, Government Expectations and Assessing Your Risk Profile," Medtech Compliance Virtual Bootcamp , 3/09/2021
- "Compliance Challenge: Healthcare Professional Engagements; Part 2 of Four-Part Series, Culture, Effective Compliance Program Development and Implementation, Government Expectations and Assessing Your Risk Profile," Medtech Compliance Virtual Bootcamp, 3/04/2021
- "Compliance Framework; Part 1 of Four-Part Series, Culture, Effective Compliance Program Development and Implementation, Government Expectations and Assessing Your Risk Profile," Medtech Compliance Virtual Bootcamp, 3/02/2021
- A Look at Patient Ad Boards, Clinical Trial Consultants and Ambassador Programs; 17th Annual Pharmaceutical Compliance Congress 2020, Virtual/Online, August 13, 2020., 8/30/2020
- "What you say matters: Communication Pitfalls and Whistleblower Risks," AdvaMed Bootcamp MedTech Compliance 101/201, 10/21/2019
- Where Is the Line? Tackling the Overlap in Medical and Commercial Activities; CBI 5th Annual Life Sciences Compliance Congress for Specialty Products, Boston, MA, 9/12/2019
- Defining Key Terms and Congress Level-Setting; CBI Patient Support Services Congress at Philadelphia, PA, 6/19/2019
- Key Aspects of Planning and Executing Advisory Boards; Comprehensive Strategies for Managing HCP Interactions, Philadelphia, PA, 10/10/2018
- Shed Light on Regulatory and Compliance Concerns for Specialty Pharmacy Distribution; CBI's 4th Compliance Congress for Specialty Products, Boston, MA, 9/13/2018
- Retaining Women in the workplace; ACI's 4th annual women Leaders in Life Science Law, Boston, MA, 7/20/2017
- "Negotiating Your Career; AdvaMed's 2017 Women's Executive Network Conference, Cambridge, MA, 6/20/2017
- Elite CCO Exchange and Fireside Chat; CBI's 14th Annual Pharmaceutical Compliance Congress, Washington, DC, 4/27/2017
- Compliance Measurements; Porzio New England Healthcare Compliance Roundtable, Waltham, MA, 4/07/2017
- Best Practices to Successfully Implement Global Compliance in the Life Sciences Industry and Beyond; CBI's 3rd Annual Global Compliance Congress, London, UK, 11/16/2016
- Mock Promotional Review Group Panel Discussion; AdvaMed's 7th Annual Advertising and Promotion of Medical Devices Conference, Washington, DC, 11/10/2016
- "A Deeper Dive into the Compliance Landscape," AdvaMed MedTech Compliance 201, 9/21/2016
- "Compliance Boot Camp 101," AdvaMed MedTech Compliance 101, 9/19/2016
- Small Group Breakouts and Interactive Town Hall: Identifying Tactical Next Steps in the Quest for Professional and Personal Development; ACI's 3rd Annual Conference on Women Leaders in Life Sciences Law, Boston, MA, 7/26/2016

Michelle D. Axelrod Cont.

- Anti-Trust Guidelines Regarding Pricing and Contracting; Anti-Trust Attorney, ACI's Bio/Pharmaceutical Pricing and Contracting, Silver Spring, MD, 3/15/2016
- In-House Roundtable on Commercial Trends in Pharma: A Conversation on Where the Industry is Now and Preparing for Where It's Going; ACI's 16th Annual Forum on Fraud and Abuse in the Sales and Marketing of Drugs, Boston, MA, 3/10/2016

Practices

- Data Privacy
- Life Sciences Legal, Regulatory, and Compliance

Area of Focus

- Compliance and Regulatory Counseling
- Pharmaceutical, Medical Device, Biotech

Industries

- Life Sciences

Industry Focus Areas

- Medical Device
- Pharmaceutical

Media Mentions

- "Clients Single Out 296 Attorneys from 148 Firms for The Best Client Service," BTI Consulting *The Mad Clientist*, 6/06/2024

Bar Admissions

- Massachusetts, 2003
- New York, 1997

Education

- *University of Rochester*
B.A., Political Science and Women's Studies, 1993
cum laude
- *Brooklyn Law School*
J.D., 1996

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