

Melissa M. Hunt, J.D., LL.M.

Seattle, WA
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Profile

Top-performing corporate legal and Compliance professional with an extensive track record of success delivering the key leadership, strategies, and insights to maximize compliance for global companies within the life sciences sector. Possess strong analytical skills with the vision to see potential issues and employ effective solutions to mitigate/eliminate risks. Excel at building, training, and optimizing the performance of skilled teams. Adept at partnering with stakeholders across all areas and levels to build consensus for unified approaches to achieve key legal and compliance goals. Credentials include a Master of Laws (LL.M.) from Loyola University and Juris Doctor (J.D.) from William Mitchell College of Law.

Core Strengths

- Senior-Level Leadership
- Brand Attorney, Health Law & Compliance
- Legal Research & Writing
- Corporate Governance
- Compliance Monitoring & Reporting
- Risk Analysis & Management
- GDPR/HIPAA Data Privacy
- Cross-Functional Collaboration
- Advertising and Promotional Committee /Medical Review Committee
- Staff Training & Development
- Budget Management
- Policy and Procedure Management

Professional Experience

Arcus Biosciences – Remote

Senior Director, Health Law, 2023 to Present

Business Partner and Health Law Attorney who works with the business to provide legal advice for the day-to-day activities of a pre-commercial business.

Select Contributions:

- Work with the business on a daily basis on an array of vital legal matters for pre-commercial company, helping them with legal advice for various parts of the organization, including, but not limited to, clinical trials, market access, clinical trial patient recruitment, CRO agreements, and advisory boards.
- Worked with the business to put together a process for medical and commercial reviews.
- Provided health law advice for both healthcare professional, vendor, and clinical trial agreements.

Omeros – Seattle, WA

Head of Compliance and Brand Attorney, 2020 to 2023

Business Partner, Head of Compliance, and the Brand Attorney who works with the business to ensure that their day-to-day activities are done in a compliant and ethical manner.

Select Contributions:

- Work with the business on a daily basis on an array of vital legal and compliance matters for a \$ 73.8 million pharmaceutical brand including, but not limited to, disease state education, reimbursement, HIPAA and GDPR privacy laws, and promotion of products.
- Created and implemented an auditing and monitoring program.
- Chair of Compliance Committee which meets on a quarterly basis to discuss compliance matters to ensure that the company maintains an effective compliance program.
- Legal Reviewer for the both the Medical Review and the Promotional Review Committees.

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Advanced Sterilization Products – Everett, WA
Regional Director of the Americas, Legal, 2019 to 2020

Driving force behind all aspects of compliance across Latin America, the US, and Canada for Advanced Sterilization Products' portfolio.

Select Contributions:

- Consult on an array of vital compliance matters for a \$775M medical device brand including promotions, contracts, financial reporting, Anti-Kickback Statutes, Foreign Corrupt Practices Act issues, and global country codes.
- Architected and built out a high-performance compliance program for the US, Canada, and Latin America.
- Continually craft/refine policies and procedures for carrying out healthcare and corporate compliance investigations in addition to taking lead point for seeing compliance investigations through to resolution.

Seattle Genetics, Inc. – Everett, WA

Associate Director/Senior Manager, 2015 to 2019

Relied upon as a senior subject matter expert in legal and compliance matters including promotions, contracts, open payments reporting, global country codes, and much more. Continually ensured compliance protocols were in place and strictly enforced for the \$500M pharmaceutical company.

Select Contributions:

- Ramped up the commercial team for compliance with GDPR and was the legal and compliance liaison for the European office.
- Directed a skilled team executing comprehensive annual risk assessments and served as a strategic business partner for stakeholders, ensuring corrective & preventative actions (CAPA) were followed up on.
- Served as the compliance chief enforcer, spearheading and closing out compliance investigations.
- Negotiated with an industry partner to create a highly effective set of joint standards for co-promotions.
- Honored with three **Impact Awards** in 2016/17/18 for outstanding dedication to compliance as well as an Exceptional Values Award from the Commercial team.

Endo Pharmaceuticals, Inc. – Malvern, PA

Compliance Manager - Operations, 2013 to 2015

Built, trained, and optimized the performance of an 11-member team and exercised full oversight over aggregate spend projects/processes for the global company. Adeptly prioritized and allocated a \$500K operating budget for compliance.

Select Contributions:

- Designed/implemented corporatewide Integrity and Deferred Prosecution Agreement processes/procedures and played a key role in crafting/submitting the first year's report to the Office of the Inspector General.
- Created, implemented, and ensure follow through on CAPAs generated based on field and desk monitoring.
- Received the Spotlight and Above & Beyond Awards for exceptional compliance efforts.

Manager - Corporate Compliance (Subsidiary: American Medical Systems, Inc.), 2013 to 2015

Simultaneously oversaw compliance for a billion-dollar affiliate and its brand portfolio, providing guidance on areas such as Anti-Kickback Statutes, Stark & False Claims Statutes, Marketed Products Lifecycle Management (HHS OIG Guidelines), state & federal transparency, FDA Sample Reporting, and more.

Select Contributions:

- Created a dynamic compliance program in partnership with key business leaders from across all areas.
- Advised internal stakeholders on Fair Market Value and built/enforced an exception process including managing day-to-day operations, data & trend analysis, and system improvements.

Additional experience as Owner/Attorney (2009-2014), Schneider & Hunt PLLC; Compliance Manager/Sr. Compliance Specialist, Prime Therapeutics (2010-2012); and Specialist II: Compliance Operations (2009-2010), Boston Scientific,

Education & Credentials

Master of Laws (LL.M.) in Health Law, Loyola University – Chicago, Chicago, IL (2014)

Juris Doctor (J.D.), William Mitchell College of Law, St. Paul, MN (2009)

Bachelor of Arts in English, St. Olaf College, Northfield, MN (2002)

.Admitted to practice law in the State of Washington and Minnesota.

Honors

Pro Bono Work for 501(c)(3) organization | Recipient of Exceptional Value Award – 2019, 2018, 2017 | Polaris Award Recipient – 2010, 2011, & 2012 | First American to win Gregory K. Steele, Q.C. Prize - Fall of 2008
MSBA Elder Law Section Award for Student Services - Fall of 2008 | Minnesota Justice Foundation Recognition for Volunteering 50+ hours | Elder Justice Scholar - Spring of 2008 | Pro Bono Work for 501(c)(3) organization

Publications & Presentations

Author - *Back-to-Basics: Understanding the Distinct but Complementary Roles of Legal & Compliance*, Life Sciences Compliance Update – Pending Publication in October 2023

Guest Lecturer at Seattle University School of Law– Promotion within the Pharmaceutical Area and the First Amendment - 2022

Presenter & Panelist CBI's Washington, D.C. Aggregate Spend Conference – 2017

Presenter at CBI's Monitoring & Auditing Conference – 2017

Author - *It's a Brave New World, or Is It? CIAs & Their Ability to Create Change*, Life Sciences Compliance Update – 2016

Presenter at CBI's 6th Annual West Coast Compliance Congress – 2015

Presenter at CBI's Speaker Programs West – 2015

Presenter at the ACI Pharmaceuticals and Enforcement Conference – 2014

Author - *Grandparent Custody: The Need for a Uniform Third Party Petition for Custody*, Canadian Centre for Elder Law – 2008

Volunteer Experience

President of Seattle Chapter of the Healthcare Businesswomen's Association - 2023-present

Pro Bono work with QLaw of Seattle – 2020 -present]

Mentor for the Seattle Chapter of the Healthcare Businesswomen's Association – 2021-2022