




HELENA S. MARCHETTI

Counsel with eleven years in life sciences regulatory and FDA practice, advising biotech and medical device companies on product development, clinical trials, and post-market compliance. Recognized internal expert on combination products and software-as-a-medical-device frameworks.

CONTACT

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 Boston, MA

KEY SKILLS

- FDA regulatory strategy
- 510(k), De Novo, PMA submissions
- Software as a Medical Device (SaMD)
- Combination products
- Clinical trial and IND advising
- Warning letter and 483 response
- HIPAA and healthcare privacy
- Regulatory diligence for M&A
- Client training and CLE presentations
- Associate development and supervision

PROFESSIONAL EXPERIENCE

June 2020 - Present

Counsel, FDA and Life Sciences | Greymont Sayers LLP | Boston, MA

- Lead regulatory diligence on roughly 18 life sciences transactions per year, including a \$640M acquisition of a Series C diagnostics company.
- Advise on IND, 510(k), De Novo, and PMA submissions; primary author on FDA pre-submission packages for four SaMD clients.
- Run the firm's quarterly client roundtable on FDA digital health policy, attended by general counsel from 40+ companies.
- Manage warning letter responses and Form 483 remediation plans; closed out a three-site CAPA matter for a Class III device maker in 14 months.
- Mentor and supervise three associates; serve on the firm's professional development committee for the regulatory group.

February 2016 - June 2020

Senior Associate, Healthcare Regulatory | Donhauer Klein PC | Philadelphia, PA

- Counseled hospital systems and digital health startups on HIPAA, anti-kickback, and Stark compliance.
- Wrote enforcement-defense submissions to OCR and state AGs on data-breach matters affecting up to 280,000 patients.
- Built a fixed-fee compliance package for early-stage telehealth clients, used by 22 companies in two years.
- Co-authored two ABA Health Law publications on remote patient monitoring.

EDUCATION

- J.D., Harvard Law School, 2014
- Ph.D. Molecular Biology, Johns Hopkins University, 2011
- B.S. Biochemistry, Tufts University, 2005
- Bar Admissions: Massachusetts (2014), Pennsylvania (2016), District of Columbia (2018)