

Exponent®
Engineering & Scientific Consulting

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Professional Profile

Véronique Li, MBA, is a Senior Manager at Exponent with more than 15 years of experience in FDA compliance, medical device regulation, and healthcare strategy. She specializes in product development, regulatory pathways and submissions, interpretation of FDA policies and guidance, due diligence, and quality management mostly across the medical device industry.

Ms. Li has led more than 200 regulatory consulting projects involving pre-market submissions (e.g., 513(g)s, RFD(s), breakthrough designations, EUAs, Q-Submissions, IDEs, De Novos, 510(k)s, PMAs), due diligence assessments, compliance audits, and quality system evaluations, providing expert analysis and strategic guidance for medical device manufacturers, consulting firms, law firms, and private equity firms. Her work encompasses regulatory intelligence, post-market surveillance, labeling and promotional review, and FDA enforcement responses, with particular expertise in medical device clinical investigations and Quality Management System (QMS) compliance.

She has served clients by helping them address challenges related to FDA Form 483 and Warning Letter responses, regulatory pathway selection for novel technologies, Medical Device Reporting (MDR) and recall management, and mergers and acquisitions due diligence. Her consulting experience spans pre-submission strategy, investigational device exemption (IDE) submissions, 510(k) preparation, post-market compliance (e.g., registration and listing, UDI compliance), and corporate policy development for FDA-regulated products. Additionally, she has advised on Small Business Designations and drafted allegations of regulatory misconduct. Her experience expands across a wide range of medical products, including cardiac electrophysiology, combination products, dental, digital health, ENT, gastrointestinal, general surgery, general wellness, in vitro diagnostic, neurological, ObGyn, ophthalmic, pediatric, renal, respiratory, and transplant devices.

Ms. Li's consulting approach integrates regulatory intelligence monitoring, gap analysis, risk assessment, and cross-functional stakeholder engagement to deliver actionable, compliance-focused recommendations. She is certified in Quality Management Systems and Six Sigma Green Belt methodologies. Her expertise includes ISO 13485, Part 820 (Quality System Regulation), corrective and preventive actions (CAPAs), complaint handling systems, and data integrity assessment.

Before joining Exponent, Ms. Li served as a senior medical device regulatory expert at Hyman, Phelps & McNamara, where she advised senior executives on regulatory strategy and conducted due diligence on over 85 mergers and acquisitions. She previously worked at the FDA's Center for Biologics Evaluation and Research (CBER) and Center for Devices and Radiological Health (CDRH), where she served as Lead Reviewer and Policy Advisor. Earlier in her career, she was a healthcare consultant at PricewaterhouseCoopers and a Certified Technical Service Specialist at Abbott Laboratories (formerly St. Jude Medical). She earned her MBA from Boston University and her BSE in Biomedical Engineering from Case Western Reserve University.

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Ms. Li is a recognized thought leader in FDA regulatory affairs, having authored more than 50 publications analyzing FDA policies, guidance documents, enforcement actions, and regulatory trends for industry publications including the Food and Drug Law Institute (FDLI) Update Magazine and The FDA Law Blog. She co-authored a RAPS article with former FDA colleagues to provide guidance on career considerations and options after FDA. She regularly presents at FDLI training courses on investigational device exemptions, clinical investigations, and post-market compliance. She has contributed to a chapter to an American Bar Association publication on FDA regulation of digital health products and has served as adjunct faculty at The George Washington University.

Academic Credentials & Professional Honors

M.B.A., Health Sector Management, Boston University, 2011

B.S.E., Biomedical Engineering, Case Western Reserve University, 2006

Academic Appointments

Adjunct Professor, The George Washington University, Washington, DC, 2019–2023

Prior Experience

Senior Medical Device Regulatory Expert, Hyman, Phelps & McNamara, PC, Washington, DC, 2018–2026

Consumer Safety Officer (Data Manager), U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (CBER), Silver Spring, MD, 2017–2018

Biomedical Engineer (Policy Advisor), U.S. Food and Drug Administration, Center for Devices and Radiological Health (CDRH), Silver Spring, MD, 2015–2017

Biomedical Engineer (Lead Reviewer), U.S. Food and Drug Administration, Center for Devices and Radiological Health (CDRH), Silver Spring, MD, 2012–2015

Healthcare Consultant, PricewaterhouseCoopers (PwC), Boston, MA, 2010–2012

Certified Technical Service Specialist, Abbott Laboratories (formerly St. Jude Medical), Secaucus, NJ, 2006–2008

Publications

Li, V., "Inside Warning Letters: A Statistical Update." Food and Drug Law Institute Update Magazine, October 2025

Li, V., "Inside Warning Letters: A Statistical Update." thefdalawblog.com, October 2025.

Li, V., "Leading the Way: Highlights from the 12th Annual ACT Women Leaders in Life Sciences Law Summit." thefdalawblog.com, August 2025.

Li, V., "A Software Demo is Worth a Submission Full of Screenshots, But Is An Early Orientation Meeting Worth the Time?" thefdalawblog.com, July 2025.

Li, V., "To Meet or Not to Meet: Day 70 and Counting." thefdalawblog.com, July 2025.

Li, V., "Better Late Than Never: FDA Published FR Notices For De Novo Classifications Dating As Far Back as 2010." thefdalawblog.com, July 2025.

Li, V., "The RFD Process: Time for Reform?" thefdalawblog.com, June 2025.

Li, V., "Life after the FDA: Career paths for former regulators." Regulatory Focus, March 2025.

Li, V., "To 513(g) or not to 513(g)? That is the question." thefdalawblog.com, November 2024.

Li, V., "Where Have All the De Novo Summaries Gone? An Update." thefdalawblog.com, September 2024.

Li, V., "Long Time Passing: Where Have All the De Novo Decision Summaries Gone?" thefdalawblog.com, August 2024.

Li, V., "The Summit for Women Leaders in Life Sciences Law." thefdalawblog.com, July 2024.

Li, V., "Better Late Than Never – Unpacking FDA's Highly Anticipated (and Long Overdue) Guidance on Diversity Action Plans." thefdalawblog.com, July 2024

Li, V., "When Worlds Collide: The Theory of Real-World Evidence Meets Reality." thefdalawblog.com, May 2024.

Li, V., "FDA Grants A Registration Fee Waiver for Very Small, Broke Device Manufacturers." thefdalawblog.com, March 2024.

Li, V., "How to Run DMC? It's Tricky – FDA's New Draft Guidance Provides Updated Recommendations on How to Best Use Data Monitoring Committees in Clinical Trials." thefdalawblog.com, March 2024.

Li, V., "Why, Who, When, Where and More: New Draft Guidance on Notifying FDA about Discontinuance or Interruption in Manufacturing." thefdalawblog.com, March 2024.

Li, V., "FDA Issues Long-Awaited QMSR Final Rule." thefdalawblog.com, February 2024.

Li, V. "FDA Improves the Process for Filing Complaints About Medical Device Companies." thefdalawblog.com, October 2023.

Li, V. "FDA's New Draft Guidance on 510(k) Implant Devices: What You Need to Know." thefdalawblog.com, October 2023.

Li, V. "FDA Gives More Time to Comply With Certain DSCSA Requirements." Bioprocess Online, September 2023.

Li, V. "FDA Gives More Time to Comply With Certain DSCSA Requirements." Outsourced Pharma, September 2023.

Li, V. "FDA Gives More Time to Comply With Certain DSCSA Requirements." Pharmaceutical Online, September 2023.

Li, V. "Logistics Unwrapped: A Roadmap to Successful FDA Meetings in In-Person and Hybrid Formats." thefdalawblog.com, September 2023.

Li, V. "Lacks v. Thermo Fisher Scientific Inc. – An Extraordinary Event from More than 70 Years Ago That Led to a Lawsuit, Resulting in a Settlement." Food and Drug Law Institute Update Magazine, Fall 2023.

Li, V. "2024 Fall CDRH ELP Proposal Submission Period is Now Open Through September 5, 2023." thefdalawblog.com, August 2023.

Li, V. "Finalizing the Quality Management System Regulation – A High Priority for End of 2023." thefdalawblog.com, July 2023.

Li, V. "Helping FDA Help Itself: Voluntary Submissions of Allegations of Regulatory Misconduct." thefdalawblog.com, June 2023.

Li, V. "Minor Updates to FDA Pre-Submission Guidance With More to Come." thefdalawblog.com, June 2023.

Li, V. "'TAP Dancing' Towards Faster Device Commercialization: CDRH's Total Product Life Cycle Advisory ('TAP') Program." thefdalawblog.com, June 2023.

Li, V. "Update on CDER, CBER, and CDRH Meetings with Industry." thefdalawblog.com, June 2023.

Li, V. "FDA to Require Breast Density Notification Amongst Other Updates to Mammography Regulations." thefdalawblog.com, March 2023.

Li, V. "eMDR System Enhancements." thefdalawblog.com, March 2023.

Li, V. "QSMR Harmonization Curiously Missing from Spring 2023 Regulatory Agenda." thefdalawblog.com, March 2023.

Li, V. "FDA Publishes Final Rule to Amend and Reduce Regulatory Burden on Outdated and Duplicative Requirements as They Pertain to Radiological Health Regulations." thefdalawblog.com, February 2023.

Li, V. "FDA and Health Canada eSTAR Pilot is Open and Accepting Participant Requests." thefdalawblog.com, January 2023.

Li, V. "FDA's Recent Update to the Digital Health Policy Navigator." thefdalawblog.com, December 2022.

Li, V. "Is my Software a Medical Device? Use the Digital Health Policy Navigator." thefdalawblog.com, December 2022.

Li, V. "Discounts Available! Submit a Small Business Certification Request Today for a Reduced Medical Device User Fee." thefdalawblog.com, November 2022.

Li, V. "MedTech Conference Download." thefdalawblog.com, November 2022.

Li, V. "Like Everything Else, Medical Device User Fees Are Not Immune to Price Increases." thefdalawblog.com, October 2022.

Li, V. "Transition Plans for Covid-19 Products are Amongst CDRH FY2023 Priorities." thefdalawblog.com, October 2022.

Li, V. "Planning for the End of the COVID-19 Public Health Emergency." thefdalawblog.com, October 2022.

Li, V. "Electronic Submission Template for Medical Device 510(k) Submissions." thefdalawblog.com, October 2022.

Li, V. "Allegations of Regulatory Misconduct Against Medical Device Manufacturers: Greater Transparency Needed." thefdalawblog.com, October 2022.

Li, V. "Judge Rotenberg Education Center v. U.S. Food & Drug Admin." Food and Drug Law Institute, June 2022.

Gibbs, J.N., Li, V., and Mullen, A.B. "Chapter 2, FDA Regulation of Digital Health Care Products – Bringing Medical Devices to Market." American Bar Association, Health Law Section, 2021.

Li, V. "A Small Victory for Theranos: Judge Dismisses 4 Counts of Conspiracy and Wired Fraud Against Former Executives." thefdalawblog.com, March 2020.

Li, V. "CDRH Misses All Kinds of Goals." thefdalawblog.com, February 2020.

Li, V. "FDA Says that Theranos Discovery Strain is Causing Other FDA Enforcement Efforts to Take a Backseat." thefdalawblog.com, January 2020.

Li, V. "United States ex rel. Wood v. Avalign Technologies." thefdalawblog.com, January 2020.

Li, V. "The Theranos Saga Continues: Court Requires Government to Produce Documents." thefdalawblog.com, November 2019.

Li, V. "Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act." thefdalawblog.com, October 2019.

Li, V. "Patients Know Best: FDA Releases Draft Guidance on Patient Engagement in the Design and Conduct of Medical Device Clinical Investigations." thefdalawblog.com, September 2019.

Li, V. "FDA Issues Final Rule on Medical Device Classification Procedures." thefdalawblog.com, January 2019.

Li, V. "CDRH Introduces Third 510(k) Pilot in Less Than Two Months: This Time on OCT Devices." thefdalawblog.com, October 2018.

Li, V. "A Future Paradigm with Potential Broader Implications." thefdalawblog.com, May 2018.

Li, V. "Are You Talking? Because CDRH Says Its Listening, At Least if You Are In the Digital Health Space: Notes from a Two Day Workshop." thefdalawblog.com, February 2018.

Li, V. "FDA Issues UDI Guidance for Class I and Unclassified Devices." thefdalawblog.com, January 2018.

Speaking Engagements

FDLI/CDRH Introduction to Medical Device Law and Regulation In-House Virtual Training Course – Investigational Device Exemptions (August 19, 2021; October 20, 2021; August 9, 2022; December 7, 2023, June 5, 2024, July 16, 2024)

FDLI/USAMMDA Training Course Introduction to Medical Device Law and Regulation – Clinical Investigations (May 9, 2022)

FDLI Training Course Introduction to Medical Device Law and Regulation – Post Marketing Issues (November 17, 2022)

Project Experience

Medical Device Regulatory Submissions & Strategy

- Led regulatory pathway assessments for novel devices for multiple medical device manufacturers seeking FDA clearance; delivered strategic recommendations that accelerated time-to-market by an average of 4-6 months through Pre-Submission meetings and optimized submission strategies.
- Developed comprehensive 510(k) submission packages including substantial equivalence arguments, performance testing protocols, and biocompatibility assessments for Class II devices.
- Advised high level disinfectant company on De Novo classification strategy; crafted special controls recommendations and clinical validation protocols that supported successful market authorization and subsequent market clearances.
- Prepared Q-Submission requests for manufacturers navigating complex regulatory pathways; secured FDA agreement on clinical trial design and regulatory strategy.

Due Diligence & Mergers and Acquisitions

- Conducted regulatory due diligence on 85+ M&A transactions for private equity firms and medical device companies evaluating acquisition targets; identified compliance risks, post-market obligations, and hidden liabilities that informed deal valuations ranging from $50M to $500M+.
- Evaluated target company's product portfolios, regulatory submissions history, and quality system documentation during pre-acquisition assessment; suggested improvements to documentation and remediation efforts in response to critical 483 observations and pending FDA enforcement actions.
- Assessed manufacturing and quality systems compliance for portfolio companies post-acquisition; developed remediation roadmaps addressing Part 820 deficiencies and establishing scalable quality management infrastructure.
- Analyzed regulatory intelligence on competitive landscape and FDA policy trends for companies evaluating strategic acquisitions in digital health and combination products; delivered market opportunity assessments that informed corporate development strategy.

FDA Compliance & Enforcement Response

- Drafted comprehensive responses to FDA Form 483 observations and Warning Letters for medical device manufacturers facing significant compliance issues; negotiated with FDA officials and achieved case closure without consent decree in multiple high-risk enforcement situations.
- Prepared clients for FDA inspection and readiness assessments anticipating for-cause, routine, and surveillance inspections; conducted gap analysis of quality systems, corrective action procedures, and design control documentation that strengthened compliance posture.
- Advised device manufacturers on Medical Device Reporting (MDR) obligations following field safety concerns; developed reporting strategy, root cause analysis protocols, and corrective action plans that satisfied FDA requirements and prevented recall escalation.
- Represented clients in FDA meetings and correspondence regarding regulatory violations, product jurisdiction determinations, and compliance disputes; secured favorable outcomes through evidence-based advocacy and regulatory precedent analysis.

Quality Management & Post-Market Surveillance

- Assessed quality management systems against ISO 13485 and Part 820 requirements for manufacturers preparing for regulatory audits and certification.
- Designed complaint handling, CAPA, and post-market surveillance systems for startup medical device companies establishing quality infrastructure; created scalable procedures that supported growth from initial market launch through commercial expansion.
- Evaluated MDR reporting practices and adverse event trend analysis for established device manufacturer with complex product portfolio; streamlined reportability determination processes to improve reporting timeliness.
- Developed field action and recall management procedures for manufacturer addressing product quality issues; coordinated cross-functional response including health hazard evaluation, correction strategy, and FDA notification that minimized business disruption.

Clinical Investigations & IDE Strategy

- Advised on Investigational Device Exemption (IDE) applications and clinical trial design for significant risk devices requiring clinical data for PMA approval; developed study protocols, informed consent documents, and monitoring plans that secured FDA approval on first submission.
- Guided sponsors through FDA clinical hold situations by analyzing deficiency letters, developing response strategies, and revising protocols; achieved clinical hold lift and study resumption within 90-day timeframes.
- Reviewed clinical trial data and statistical analysis plans for pivotal studies supporting PMA submissions; identified endpoint definition issues and enrollment strategy gaps that could have jeopardized regulatory approval.
- Prepared diversity action plans and patient engagement strategies for clinical investigations following FDA's updated guidance on enrollment practices; implemented evidence-based recruitment approaches that improved demographic representation.

Digital Health & Software as Medical Device (SaMD)

- Assessed software classification and regulatory pathway options for artificial intelligence and machine learning-enabled medical devices; determined appropriate level of FDA oversight based on intended use, risk classification, and policy exemptions under 21st Century Cures Act.
- Advised digital health companies on software lifecycle documentation and cybersecurity requirements for 510(k) and De Novo submissions; assessed submission-ready documentation including software description, verification and validation protocols, and risk management files.
- Conducted regulatory intelligence monitoring on evolving FDA policies for clinical decision support software, mobile medical applications, and AI/ML-based devices; translated policy developments into actionable compliance strategies for digital health clients.

Regulatory Policy & Training

- Developed and delivered regulatory training programs on IDE requirements, 510(k) submissions, and post-market compliance for FDA trade associations and corporate clients; educated 500+ industry professionals through FDLI courses and in-house training sessions.

- Authored 50+ regulatory intelligence publications analyzing FDA guidance documents, enforcement trends, and policy developments for industry readership; provided thought leadership on QMSR harmonization, De Novo transparency, and medical device user fees.
- Taught graduate-level course on regulatory law for medical devices at The George Washington University for four academic years; mentored biomedical engineering students pursuing careers in regulatory affairs and quality assurance.