

Litigation Curriculum Vitae

Alan Donald, MS, MBA, RAC, FRAPS

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Expert Witness Profile

- 25+ expert witness projects in Federal and State courts
- Testified in depositions and at trial; authored multiple expert reports
- Retained exclusively by prevailing side in all cases
- Specializing in FDA medical devices, biologics, pharmaceuticals, diagnostics, software medical devices (AI/ML), and combination products
- Clients include Johnson & Johnson, Pfizer, Merck, Boston Scientific, Baxter, Zimmer, Smith & Nephew

Expertise

- FDA & International Medical Product Regulations
- Regulatory Submissions: 510(k), PMA, INDs, EUAs
- Quality Systems (development, audits, compliance)
- Clinical trials (design, implementation, international)
- Product safety, labeling, risk management
- Software as a medical device (AI/ML)

Representative Expert Witness Cases

- Pharmaceuticals: Vioxx, Rosiglitazone
- Medical Devices: cardiology devices, implants, pelvic mesh, breast implants, infusion pumps
- Diagnostics: COVID tests, genetic markers, HCG kits
- Healthcare Products: ethanol hand sanitizers

Court Experience

Federal and State Courts

Expert reports, depositions, courtroom testimony

Professional Background

President & CEO, Matrix Medical Consulting Corp. (1995–present)

- Regulatory and quality consulting for medical devices, biologics, and pharmaceuticals.
- Expert in FDA and international regulatory submissions, quality systems, and compliance.

Previous Roles (1980–1995)

- Senior Manager, Quality Assurance – Advanced Tissue Sciences (biotech, tissue engineering)
- Director, Regulatory Affairs – Advanced Bioresearch Associates (regulatory consulting)
- VP Operations – Tri-Stage, Inc. (dental implants)
- Director of Operations – Windsor Medical (insulin infusion pumps)

Education

BA Biology (Human Physiology) – Harvard University / Claremont McKenna College

MS Biochemistry & Cell Biology – San Diego State University

MBA (High Tech / Medical Products) – UC San Diego

Certifications / Honors

- Regulatory Affairs Certified (RAC), Regulatory Affairs Professionals Society (RAPS)
- RAPS Fellow (FRAPS), awarded 2010
- 15 years Professor, Master's Program in Regulatory Affairs (SDSU)

Selected Speaking Engagements

- FDA Medical Device Regulation (AI/Software) – Exploit Technologies, Singapore
- Global Regulatory Planning – SGInnovate, Singapore
- US FDA Regulatory Environment – JFIT, UC San Diego
- Medical Design & Manufacturing Executive Summit – Best Practices in Innovation & Compliance

Publications / Patents

- Patent: Miniaturized Chromatography Apparatus for Biomolecule Assay (#4,787,971)
- Publications in Journal of Biological Chemistry, Methods in Enzymology, and industry journals.