ALAN DONALD, MS, MBA, RAC, FRAPS

Expert Witness – FDA Regulatory, Quality Systems & Multidisciplinary Technical Expert

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PROFESSIONAL SUMMARY

Alan Donald is a highly experienced FDA regulatory and multidisciplinary expert with over 45 years in the medical products industry, including 30+ years as a consultant and executive. He provides independent, technically grounded expert analysis and testimony in complex matters involving medical devices, pharmaceuticals, biologics, diagnostics, combination products, and software/AI-based medical technologies.

Mr. Donald integrates three critical domains—FDA regulatory compliance, biomedical engineering/product development, and medical/scientific analysis—typically requiring multiple experts. This unified approach delivers cohesive, defensible opinions, streamlines case development, and reduces costs for counsel.

AREAS OF EXPERTISE

- **FDA Regulatory Compliance:** PMA, 510(k), IDE, IND, BLA, combination products, QSR/GMP, post-market surveillance, recalls, CAPA, risk management, labeling, and promotional claims.
- **Quality Systems & Manufacturing:** Design controls, process validation (IQ/OQ/PQ), supplier controls, sterilization/packaging validation, and failure investigations.
- **Product Development & Failure Analysis:** Cardiovascular/implantable devices, drug delivery, hemostatic technologies, regenerative medicine, diagnostics, and software/AI medical devices.
- **Scientific & Clinical:** Physiology, biochemistry, tissue-device interactions, pathology, analytical/clinical validation, stability, and toxicology.

EXPERT WITNESS EXPERIENCE

Alan Donald has been retained as an independent expert witness in over 25 matters involving FDA-regulated medical products since 1998. His engagements span complex civil litigation in both federal and state courts, providing objective, technically grounded analysis and testimony on regulatory compliance, quality systems, product development, manufacturing practices, failure investigations, and causation issues.

Mr. Donald's multidisciplinary background allows him to serve as a single integrated expert across FDA regulatory requirements, biomedical engineering/product design, and medical/scientific evaluation. This approach streamlines case development, reduces costs, and produces cohesive, defensible opinions.

- Comprehensive case evaluations and merit assessments; expert reports, deposition testimony, and trial testimony.
- Regulatory analysis involving PMA, 510(k), IDE, IND, BLA, combination products, QSR/GMP, MDRs, recalls, complaints, CAPA, and risk management.
- Failure analysis, root-cause investigations, product development, manufacturing practices, standards-of-care evaluations, and causation issues.
- Representative matters involving cardiovascular and implantable devices, hemostatic technologies, drug delivery systems, diagnostics, biologics, software/AI-based medical technologies, and combination products.
- Representative matters involving products manufactured by Pfizer, Merck, Johnson & Johnson, Boston Scientific, Baxter, Zimmer, and others.

PROFESSIONAL EXPERIENCE

Founder, President & Principal Consultant *1995 – Present*

Matrix Medical Consulting (Matrix Medical Services) | San Diego, California

Founded and led a specialized consulting firm providing integrated FDA regulatory, quality systems, and technical expertise to medical device, pharmaceutical, biologic, diagnostic, and combination product companies. Retained as an expert witness in over 25 litigation matters involving FDA compliance, product safety, manufacturing issues, root-cause failure analysis, and regulatory strategy.

Director, Regulatory Affairs *1993 – 1995*
Advanced Bioresearch Associates (ABA) | San Diego, California
Established and directed the Regulatory Affairs function. Managed regulatory submissions, IDEs, and clinical program compliance for novel biologic and medical device products, including breast implants and AIDS-related therapies.

Senior Manager, Quality Assurance *1990 – 1993*
Advanced Tissue Sciences, Inc. | La Jolla, California
Developed and implemented quality systems, process validation, and manufacturing controls for engineered human tissue products, including Dermagraft. Managed audits, inspections, and regulatory compliance activities.

Founder & Vice President of Operations *1987 – 1990*
Tri-Stage, Inc. | San Diego, California
Co-founded a medical device manufacturing company. Led operations, quality assurance, failure analysis, and regulatory affairs for dental implants and associated instruments.

Director of Operations *1984 – 1987*
Windsor Medical, Inc. | Enfield, Connecticut
Oversaw manufacturing, quality assurance, and regulatory compliance for portable programmable insulin infusion pumps and diabetic therapy products. Managed eight operating departments.

Regulatory Affairs / Reliability Engineering / Complaint Handling / Failure Analysis *1980 – 1984*
IMED Corporation | San Diego, California
Managed regulatory submissions, reliability engineering, complaint investigations, and failure analyses for infusion and implantable medical device technologies. Supported corrective actions and product improvements.

Director of Quality Assurance & Regulatory Affairs *1979 – 1980*
Pharmaco Inc.
Directed quality assurance and regulatory affairs activities supporting pharmaceutical manufacturing and compliance operations.

Operations, Quality Control & Biological/Sterilization Laboratory Director *1976 – 1979*
IVAC Corporation | San Diego, California
Managed operations, biological testing, sterilization validation, and quality control laboratory activities for infusion and diagnostic products.

ACADEMIC APPOINTMENT

Professor of Regulatory Affairs *2000 – 2016*
San Diego State University | San Diego, California
Taught graduate-level courses in medical device regulations, international medical regulations, diagnostics, pharmaceuticals, and combination products within the Master's in Regulatory Affairs Program.

EDUCATION

- MS, Biochemistry & Cell Biology – San Diego State University
- BA, Biology (Human Physiology) – Harvard University / Claremont McKenna College
- MBA, Executive Business Administration (High Tech/Medical Products) – University of California, San Diego

CERTIFICATIONS & HONORS

- RAC – Regulatory Affairs Certification (U.S.)
- FRAPS – Fellow, Regulatory Affairs Professionals Society (2010)
- NIH SBIR Grant Review Committee Reviewer (NIDA)
- Multiple peer-reviewed publications and one U.S. patent
- Frequent domestic and international speaker on FDA regulation and medical technologies