David L. Chesney, MSJ

Principal and General Manager,

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SUMMARY OF EXPERIENCE:

Mr. Chesney is the Principal and General Manager of DL Chesney Consulting, LLC. Previously he served 23 years with the FDA, and 21 years with PAREXEL International, including 19 years leading the Strategic Compliance Consulting group within PAREXEL Consulting.

At the FDA, he advanced from Investigator to Supervisory Investigator and Director, Investigations Branch, working in the Boston, Seattle and Philadelphia District Offices. In 1991, he was appointed the District Director, FDA San Francisco District Office, where he served until joining PAREXEL in 1995. At PAREXEL. Mr. Chesney provided compliance consulting and training services to clients worldwide. For 19 years, he led the Strategic Compliance Consulting group, and also personally provided regulatory enforcement related consulting services to the pharmaceutical, medical device and biologics industries, plus technical assistance to legal counsel in various privileged matters.

Mr. Chesney has a bachelor's degree in biology from California State University, Northridge and and postgraduate credits in biology from California State University, San Diego. He also holds a Master of Science in Jurisprudence (Pharmaceutical and Medical Device Law) and a Certificate in Health Care Compliance from Seton Hall University School of Law.

Primary Expertise

- Experienced in GMP, GCP, QSR and Pharmacovigilance compliance, both pre and post-marketing.

- Development of corporate regulatory compliance strategy; management controls for regulatory compliance; analysis and development of quality assurance organizations and quality systems; laboratory controls; failure and deviation investigations; investigation and resolution of data integrity issues; drug safety and compliance with pharmacovigilance requirements; management of responses to regulatory inspections and enforcement actions; representation of clients to the FDA and assistance with FDA communications; training in FDA compliance topics.

- Specialized experience in providing adjunct services to Legal Counsel such as strategy for avoidance of regulatory sanctions; vacating consent decrees; assistance in internal investigations, resolution of whistleblower complaints, due diligence assessments, and other privileged and confidential matters. Experienced expert witness (deposition and live courtroom testimony).

- Highly experienced trainer and public speaker as an expert on FDA inspection and enforcement.

PROFESSIONAL EXPERIENCE:

Principal and General Manager, DL Chesney Consulting, LLC
2016 - Present
Specializing in strategy level consulting services to senior management in the pharmaceutical and biotechnology industry in the areas of Good Manufacturing Practice, Good Clinical Practice and Pharmacovigilance compliance. Services include FDA inspection readiness and response to inspection observations; assessments of quality assurance systems and Quality Units; assistance to legal counsel and company leadership with FDA inspection outcomes, post-inspection correspondence and meetings, and remediation strategy development and implementation; training in GxP compliance areas and FDA inspection readiness, including education of executive management in understanding their responsibilities for compliance governance at the corporate level. Assistance to Venture and Private Capital companies with due diligence efforts surrounding product. facility and company acquisitions and investment opportunities. Highly experienced in providing adjunct services to legal counsel in privileged matters.

Vice President and Practice Lead, Strategic Compliance Services. PAREXEL Consulting, Waltham, MA
2004 - 2016

Personally provided consulting services and managed a group of over 50 subject matter experts who function as PAREXEL Consulting's subject matter experts in compliance strategy. The group is based throughout the US and in Europe. The focus is on GMP/GCP/GLP/QSR/MDR compliance, drug safety and post marketing reporting requirements, risk management, FDA communications and interaction, response to FDA enforcement sanctions such as Warning Letters and Consent Decrees of Permanent Injunction, data integrity assessments, and management controls for regulatory compliance .

Senior Director, Strategic Compliance Services, KMI, a Division of PAREXEL International, LLC, Waltham, MA,
1995 – 2004

Personally provided consulting services and directed a group of KMI Senior Compliance Consultants who function as KMI's leading experts in GMP, QSR, GLP and GCP compliance strategy and FDA inspection readiness.

FDA Experience

District Director FDA, San Francisco District Office, Alameda, CA
1991 – 1995

Directed over 180 FDA employees and managed all enforcement operations of the San Francisco District Office. Provided overall direction and management of FDA's inspection, compliance, laboratory analytical, public affairs, and administrative activities in Northern California, Nevada, Hawaii, and the Pacific Trust Territories. Represented the FDA before industry, professional, and academic groups as an expert on FDA inspection and enforcement matters. Coordinated Federal-State enforcement activities with FDA counterpart agencies at the State level. Served on the Field Advisory Committees to the Center for Biologics Evaluation and Research (CBER), Center for Veterinary Medicine (CVM), and the Office of Chief Counsel. Served as an Evidence Development Instructor for FDA at the national level.

Director, Investigations Branch, FDA; Mid-Atlantic Region (Philadelphia District Office) Philadelphia, PA
1988 – 1991

Directed a staff of approximately 50 investigators located in the states of Pennsylvania and Delaware. Participated in the development of the drug pre-approval inspection program. Completed FDA/ORA's Executive Development Program. Served as Evidence Development Instructor for the FDA at the national level.

Supervisory Investigator in Charge, FDA; Pacific Region (Seattle District Office) Portland, OR
1982 – 1988

Directed inspection and investigative activities of the FDA in Oregon and southern Idaho. Served as District level Evidence Development Instructor.

Supervisory Investigator, FDA; Northeast Region (New England District Office), Boston, MA
1977 – 1982

Supervised a group of FDA investigators and managed the biologic, medical device, and bioresearch monitoring (clinical compliance) programs.

Investigator, FDA; Northeast Region (New England District Office), Boston, MA
1972 – 1977

Conducted a wide range of investigations and inspections for the FDA, concentrating in drugs, biologics, GCP, GLP and medical devices.

EDUCATION:

Seton Hall University School of Law, Newark, NJ

- *Master of Science, Jurisprudence (Pharmaceutical and Medical Device Law), 2019*
- *Certificate in Health Care Compliance awarded 2008;*

California State University; San Diego, California
- *Graduate Study, Biology (two years full time)*

California State University; Northridge, California
- *Graduate Study, Biology (one year full time)*

California State University; Northridge, California
- *Bachelor of Arts in Biology (Chemistry Minor)*

ADDITIONAL / SPECIALIZED TRAINING:

Many years of FDA in-service training in several compliance areas: Food and Drug Law; Pharmaceutical Manufacturing; Pharmacology and Experimental Therapeutics; GCP; GLP; Blood Banking and Plasmapheresis, and a variety of related topics. (Complete listing available upon request.)

Completed the FDA/ORA Executive Development Program, 1990-91

LANGUAGE SKILLS:

English: Native
Spanish: Conversant but not fluent; good reading skills.

PROFESSIONAL ASSOCIATIONS:

- Parenteral Drug Association (Faculty, PDA Training and Research Institute)
- Food and Drug Law Institute (Instructor, FDLI *Introduction to Drug Law* course)
- Regulatory Affairs Professionals Society

PUBLICATIONS AND PRESENTATIONS:

Frequent public speaker at a wide variety of industry seminars and professional meetings for over 25 years (details available upon request). Multiple presentations for University of Georgia, Athens GMP conference; GMP by the Sea and other Pharmaconference events; Institute for Validation Technology, IPA Canada; FDA News Inspection Summit; PDA; ISPE; Southern California Chapter of AOAC, and other similar conference venues.

Faculty, PDA Training and Research Institute

Volunteer Instructor, *pro bono*, for the Food and Drug Law Institute program *Introduction to Drug Law*, 2014 - present

Published articles in several journals and newsletters including *FDLI Update*, Pharmaceutical Technology, BioPharm, ISPE and PDA Chapter newsletters, and the Journal of cGMP Compliance

Co-author of Chapter 14, *Review of FDA Inspections and Related Regulations* in "A Practical Guide to Food and Drug Law and Regulation", Food and Drug Law Institute, 2014

Contributing author to "Fundamentals of Regulatory Affairs, the RAPS preparation guide for the Regulatory Affairs Certification exam", 1999-2002

Principal Author, "Clinical Supplies Manufacture: GMP Considerations," Encyclopedia of Pharmaceutical Technology, Second Edition (Marshall Dekker Publications, 2011, web-based resource)

AWARDS:

- FDA Award of Merit, FDA's highest award for individual achievement
- Several FDA Group Recognition Awards