

# 3<sup>rd</sup> International Summit on **GMP, GCP & Quality Control**

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*David L Chesney*

Parexel International, USA



## Best practices for internal and supplier auditing

**N**arrative summary: This workshop will compare and contrast the requirements and expectations of the FDA, EMA, and Canadian health regulatory authorities pertaining to the conduct of internal audits and supplier audits. The regulatory requirements of these venues will be summarized and compared. Recent changes to the US Food, Drug and Cosmetic Act intended to strengthen control over the supply chain will be explained along with current FDA guidance for implementation of these changes. Time will be allocated for questions and open discussion among the participants.

### Learning objectives: Attendees will learn-

- Current regulatory requirements pertaining to internal and supplier auditing in the US, European Union and Canada
- Impact of recent changes to the US Food, Drug and Cosmetic Act pertaining to supply chain management and the implications of these changes for companies who are inspected by the FDA
- Examples of best practices for internal and supplier auditing including program management and evaluation of audit findings
- Variations in regulatory agency policies regarding access to audit reports during health authority inspections

## Biography

David L Chesney, Vice President and Practice Lead, Strategic Compliance Services for PAREXEL Consulting, works with PAREXEL clients in the pharmaceutical, biologics and medical device industries worldwide. He also directs PAREXEL Consulting's Strategic Compliance Services group. Prior to joining PAREXEL Consulting, he served 23 years with the FDA. Chesney 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, San Francisco District Office, where he served until joining PAREXEL in 1995. His expertise includes GMP, GCP, GLP, QSR and MDR compliance consulting and auditing. Chesney is highly experienced in the FDA enforcement process and specializes in helping clients avoid or mitigate enforcement sanctions. He has extensive experience providing adjunct services to client legal counsel, including FDA communication strategies, conduct of internal investigations, due diligence assessments and other privileged matters. Recently Chesney has completed corporate quality organization effectiveness assessments for major pharmaceutical companies, biotech companies, and virtual companies. Chesney frequently conducts briefing and training sessions for senior managers and executives in compliance topics and FDA inspection readiness. He is an experienced public speaker and has published articles in several industry publications such as Pharmaceutical Technology, Biopharm, RAPS Focus, and FDLI Update. He has authored or co-authored two book chapters, one in the current FDLI Practical Guide to Working with the Food and Drug Administration, and another on application of GMP to the production of investigational medicinal products. He has taught PDA TRI courses in inspection readiness and quality and compliance management for virtual companies. Chesney received his BA in Biology from California State University, Northridge. He subsequently completed postgraduate study in biology there and at California State University, San Diego, and has also received a Certificate in Health Care Compliance from Seton Hall University School of Law. He is an active member of the Parenteral Drug Association where he serves on the faculty of the PDA Training and Research Institute (TRI), the Food and Drug Law Institute (where he serves as a member of the Drugs and Biologics Committee), and the Regulatory Affairs Professionals Society.

[Dave.Chesney@parexel.com](mailto:Dave.Chesney@parexel.com)