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## Defining and managing a corporate quality culture

Defining and Managing a Corporate Quality Culture Commonly, companies who face regulatory compliance problems decide that "The culture needs to change" but few know what has contributed to their problems, or how to bring about the needed changes. This presentation will discuss the factors that often cause companies to face difficulties in establishing a corporate culture that supports quality and GMP compliance, and also the steps that a company can take to develop a strong, supportive culture of quality. The discussion will include:

- Five common factors that contribute to corporate quality culture problems
- Five steps that can be taken to promote a positive corporate quality culture
- A "prescription" for positive quality culture change

## 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 Technoology, 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.

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