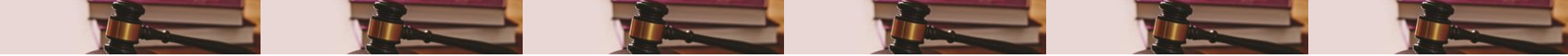

Leadership

FDA Expectations v. Industry Protections

R. Chase
Director, Lachman Consultant Services, Inc.
r.chase@lachmanconsultants.com

FDLI

Legal Notice

Most Responsible

Executives v. QCU

- Local escalation process to Executives ensure resources are provided to support and maintain the QCU and quality system
  - Not limited to annual reviews or management review meetings

Site v. Corporate

- Feedback mechanism to ensure lessons learned are applied across the organization
  - Corporate Responsibility and Corporate Culture

Management Oversight

FDA expects to see established plans for escalation to the highest levels of the organization

In remediation, FDA expects to see direct commitment by Executive Leadership through Global Quality Councils/Advisory Boards

Industry will try to manage quality at the lowest possible level. Roll up to regional level or to corporate quality only in extreme circumstances. Escalation plans rarely directly indicate notice to corporate leadership (CEO)

Issuing A 482/483

FDA Investigators ask for the most responsible individual at the site, if the CEO is at the site, it is expected they will appear to receive the 482/483

Industry prefers to have the primary quality representative accept the 482/483

Responses 483/UTL/WL

Responses signed by the CEO is one indication of the “responsibility” being understood

Industry stresses individual site responsibility and most often sends the response from the local or regional quality lead

Organizational Structure

FDA expects that the org structure is understood and can be documented – do org charts show responsibility

Also, FDA expects that the structure can be explained

Leadership at local sites may not be able to fully explain the corporate structure, the ownership of multiple entities or site locations or the relationship of DBAs

CORPORATE RESONSIBLITY

FDA expects that any 483 observations issued, and particularly any WL matters are shared across the organization and evaluated with corrective actions being taken where appropriate

Legal definitions of ownership, fractioning of oversight and DBAs may be used to try to lessen liability of Executive Leadership -- this may be used to justify lack of corporate wide corrective actions