Research, Development and Clinical Trials

Compliance Update: Morning Track II

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Preparing for the Next Wave of Change

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Morning Track II:

Research, Development and Clinical Trials Compliance Update

9:30 a.m.	Current Compliance Challenges	***Timothy Cleary, Esq.*** VP, Legal & Chief compliance Officer Sanofi Pasteur Inc.
10:00 a.m.	Assessing Future Regulatory and Compliance Developments: Complying Clinical Trial Reporting Obligations	***Theresa A. Toigo, MBA, R.Ph.*** Director Food & Drug Administration
10:30 a.m.	GAP Analysis: How we Get to Where we Want to be – Managing GCP Inspections Pre-Approval	***Robert F. Church, Esq.*** Partner Hogan & Hartson, LLP
11:00 a.m.	The Intersection of the False Claims Act and FDA's Authority over Clinical Trials	***Peter S. Spivack, Esq.*** Partner Hogan & Hartson, LLP
11:30 a.m.	FDA & Duke University's Clinical Trials Initiative	***Rachel Behrman, MD, MPH*** Director Food & Drug Administration

Recent Compliance Challenges for R&D

- Several notable enforcement actions against sponsors of clinical trials signal a compliance trend for R&D organizations
- Law enforcement officials and regulations publicize these actions to signal areas of concern and to serve as a deterrent
- These actions suggest that scrutiny of compliance standards for research, development and clinical trial oversite will continue

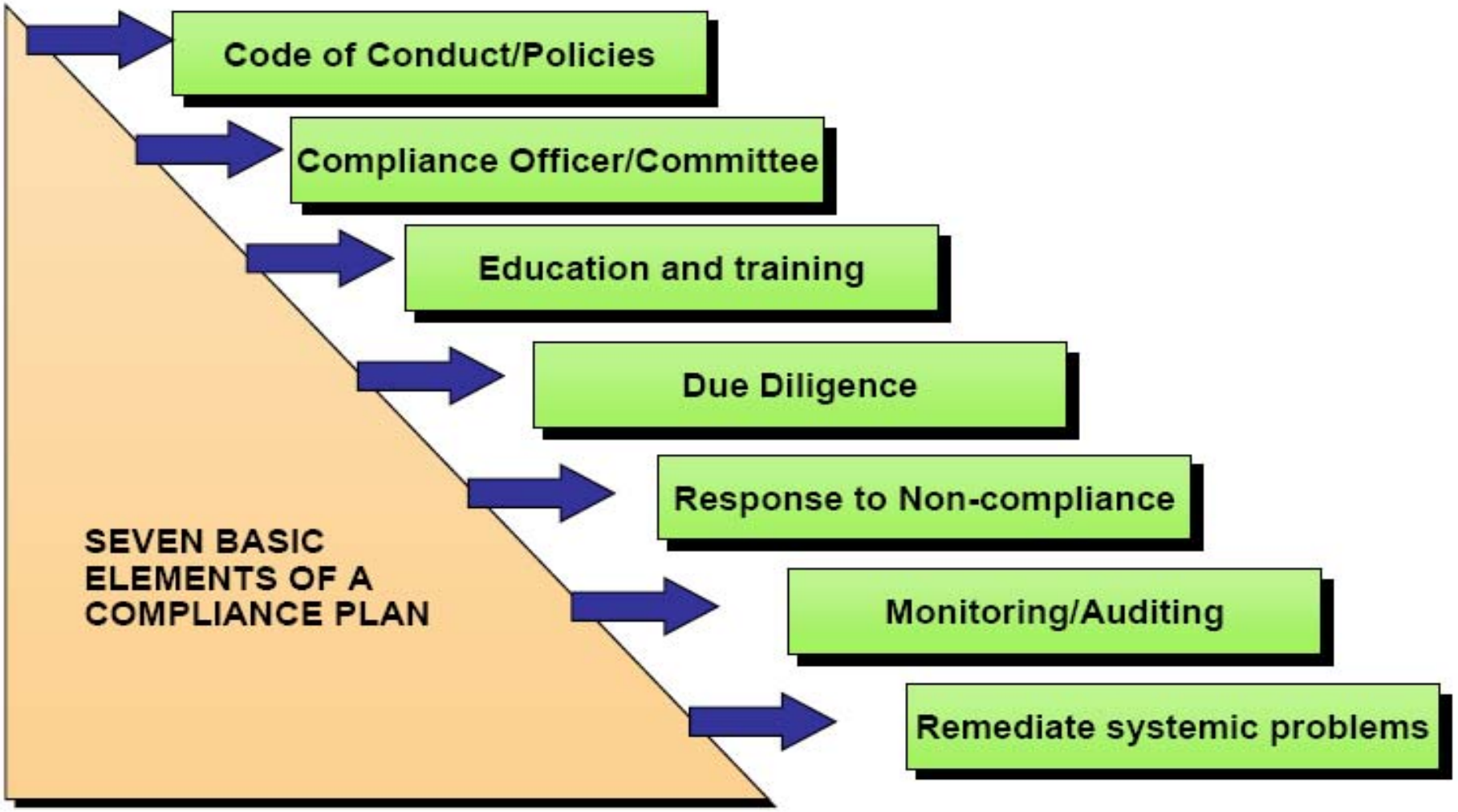
Examples

- Passage of the Federal Food and Drug Amendment Act of 2007 impacting post-approved clinical trials, safety labeling changes, risk evaluation and mitigation strategies and posting of clinical trial results
- Warning letter to sponsor of a clinical trial for observations relating to Good Clinical Practices
- Warning letter to another company for failure to file timely and orderly safety reports
- Pronounced Congressional interest in management and oversight of clinical trials, including enforcement actions against clinical trial investigators.
- Enforcement Initiative Panel with several US attorneys at a conference on managing legal risks in conducting clinical trials

Preparing for the Next Wave of Change:

So, in light of the potential for increasing focus on R&D and clinical development, what's a company compliance official to do?

Elements of an Effective Compliance Program



Sources: US Sentencing Commission Guidelines; OIG Compliance Guidance for Pharmaceutical Manufacturers

Areas for Compliance Consideration

Who has responsibility for compliance with R&D? Are all the compliance elements in place?

- Compliance with FDAAA?
- Well-established clinical trial management process?

  Note: *Pursuant to 21 CFR § 312.56(b), sponsor should promptly secure compliance if they discover an investigator not following clinical protocols*
- Screening for suitable CROs, IRBs, and clinical sites?
- Process for adverse event reporting?
- SOPs?
- Training and education?

Areas for Compliance Consideration

CONTINUED…

- Auditing?
- Oversight of Phase IV studies? Is marketing insured and to what extent? Potential for off-label promotion?
- Process to deal with serious unexpected adverse events and other issues impacting patient safety?
- Internal alert and response structure for patent safety issues or data integrity problems?
- Process to vet conflicts of interest?

Some Final Observations

- Need for compliance training and education oriented to a scientific mind
- Need to establish guidance on exchange of scientific information vs. “promotion”
- Need to ensure well-defined roles/responsibilities for CROs, IRB, and clinical investigators
- Need to ensure application of new PhRMA Code of Interactions with Healthcare Professionals as it applies to R&D

Some Final Observations

CONTINUED…

- Need to establish process to respond to instances of non-compliance within R&D organizations
- Need to engage senior management support for compliance within R&D