Advanced Issues in Clinical Compliance

Striking the Right Balance of Compliance within Clinical Development Across Corporate Compliance, QA, and Operations

November 11, 2009

PricewaterhouseCoopers

Background – R&D Compliance within the Industry

- Traditionally, pharmaceutical and biotech companies with US operations have established Corporate Compliance functions to address compliance risks associated with sales and marketing activities. Quality Assurance functions have typically focused their efforts on addressing FDA compliance within R&D and Manufacturing divisions.
- As the focus of OIG scrutiny shifts from sales and marketing to R&D, pharmaceutical companies are having to proactively take measures to mitigate overall compliance risk to their organizations. Some examples of these activities include:
  - Internal review and redesign of R&D compliance controls
  - Assessment of compliance governance between R&D line functions, Quality Assurance, and Corporate Compliance
  - Delineation of clear roles and responsibilities for R&D compliance controls design, auditing, monitoring and remediation

What function is ensuring that emerging R&D compliance risk areas are being addressed?

R&D compliance areas where oversight responsibilities may require greater clarity

- Clinical Trial Registration and Results Disclosure
- Payments to Investigators (including payments made by CROs)
- Third party audits for vendors contracted by R&D (e.g. CROs)
- Fair Market Value for physicians working for R&D (e.g. consultants for Drug Safety, R&D advisory boards, etc)
- Financial Disclosures / Conflicts of Interest
- Phase IV Studies / Outcomes studies
- FCPA

How is compliance around these activities being managed in your organization?

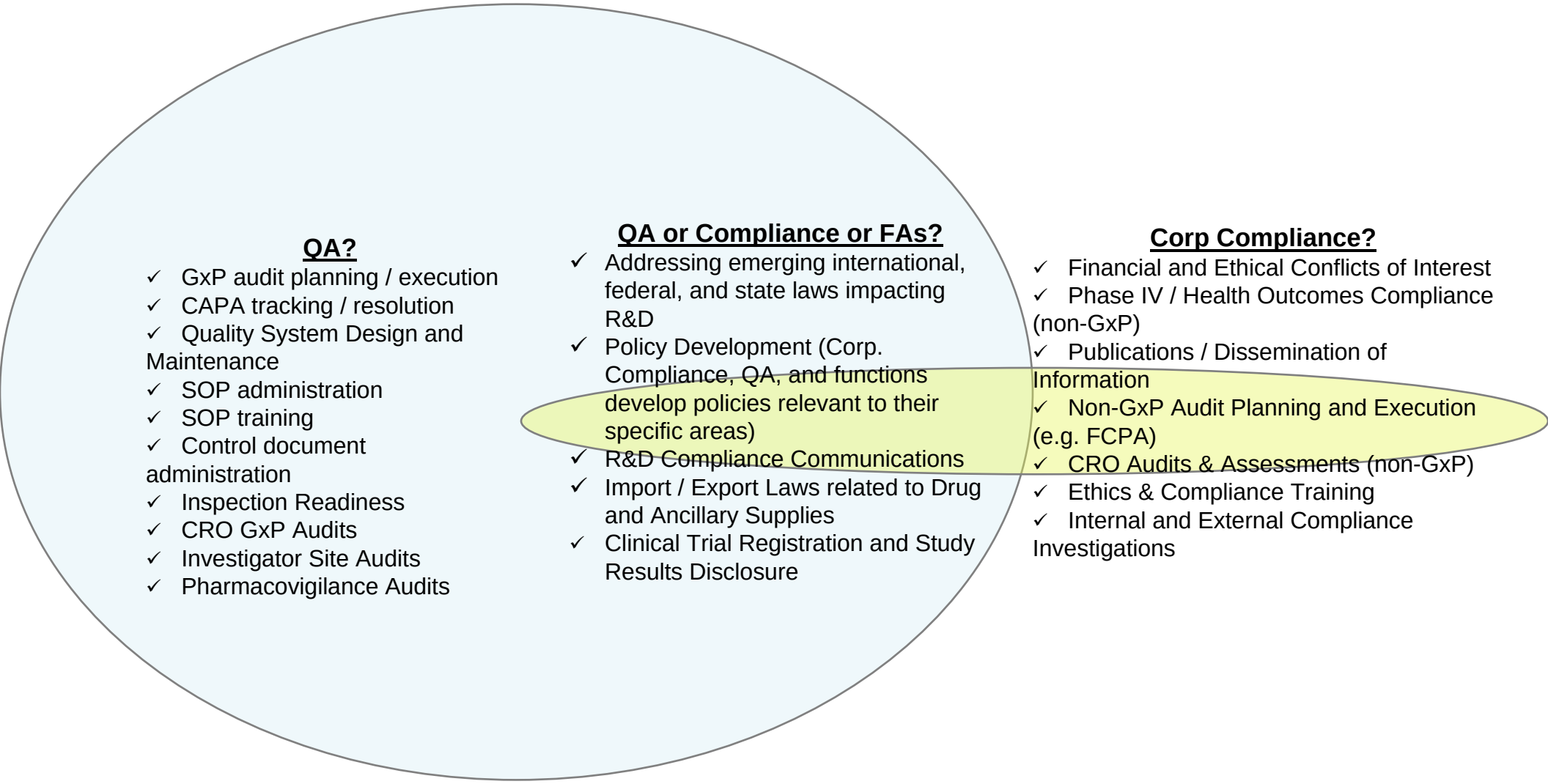
Different Models are in place to oversee compliance within R&D but gaps remain....

Corporate Compliance has no involvement in R&D and QA addresses only required GxP compliance requirements.

Corporate Compliance maintains peripheral involvement in R&D through assessment of activities where prescribers are paid and potentially influenced inappropriately – e.g. FCPA. QA addresses only required GxP compliance requirements.

QA assumes complete oversight responsibility for the R&D compliance infrastructure and supports the design, maintenance, and review / refinement of all compliance controls. Corporate Compliance does not play a role.

Compliance Activity Oversight Roles and Responsibilities Across R&D – Who Owns What????

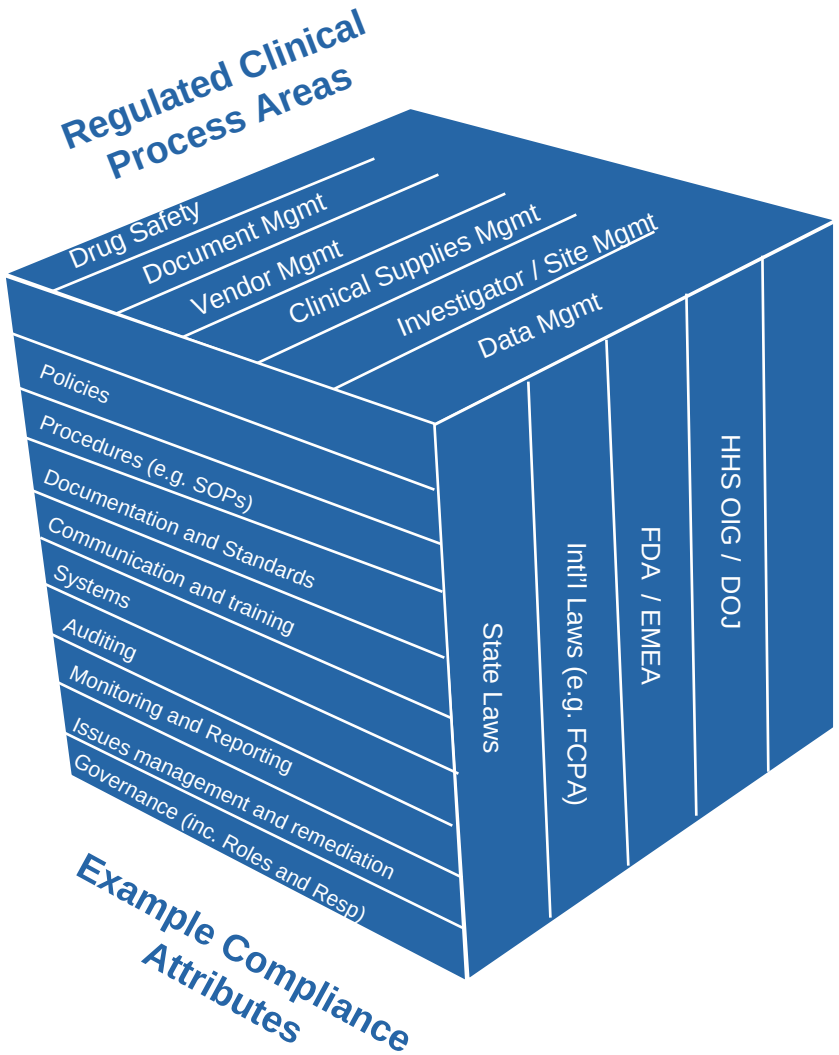


Key Questions to Identify the Right R&D Compliance Model for your organization

- What R&D compliance activities does QA currently oversee? What R&D compliance activities does Corporate Compliance currently oversee?
- What are the compliance challenges that are not being adequately addressed by QA or Corporate Compliance? What compliance responsibilities are placed on Clinical Development functions (that are not shared by QA or Corp Compliance)?
- Are there areas where compliance controls within R&D and functions outside of R&D should be harmonized?
- How are R&D processes and compliance controls (policies, SOPs, training, documentation) currently managed – who is / should be responsible for aligning changes in R&D process with the required updates to compliance controls?
- Are there any R&D compliance metrics in place to ensure compliance with regulatory compliance requirements? Who is / should be responsible for assessing these metrics?
- Is there a corporate compliance governance committee structure in place for the company? Are potential R&D compliance issues raised to this committee?

Approach to Assigning Compliance Oversight Responsibilities across R&D

- Determine scope of all existing R&D activities that are regulated by process area
- Assign compliance oversight accountability / responsibility to functional area based on compliance attributes
- Identify appropriate compliance governance structure in alignment with overall corporate compliance structure
- Agree upon future state governance structure to ensure R&D compliance needs are comprehensively addressed and risks are evaluated / mitigated proactively



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