Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

Compliance Programs for Research and Development Organizations

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Agenda

I. Making the case for compliance considerations in the R&D environment
II. Examining the Compliance requirements in Business Processes – Developing an Improvement Plan
III. Getting to action beyond the Improvement Plan

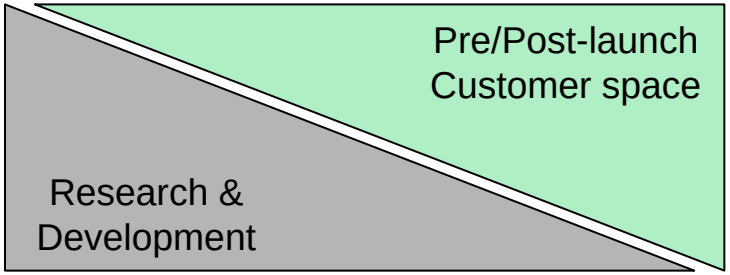
Drug development model

Traditional drug development model – blockbuster/FIPCo

Rules

ICH
FDA
EMEA

Good
Regulatory Practices:
GRP
GLP
GCP
GMP



Push

DDMAC
Safety Surveillance

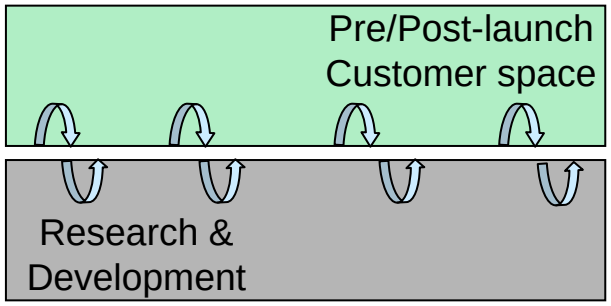
Good
Promotional Practices
Pharmacovigillance

Transformation development model – targeted medicine/FIPNet

As we engage the customer earlier in targeted development, the GXP Practices still apply

and

the compliance requirements from the customer interface **now apply as well.**



Pull

Business Integrity

- Corporate Integrity Agreements
- Sarbanes-Oxley accounting
- Foreign Corrupt Practices Act
- PhRMA code of conduct
- Privacy
- FDA reform - risk management
- Clinical trial registry
- Grants/donations transparency

Example areas of focus in CIAs

Requirements for written Policies and Procedures addressing:

Payments	• Consultant or other fee-for-service arrangements entered into with HCPs or HCIs and all events and expenses relating to such engagements or arrangements, ensuring that the arrangements and related events are used for legitimate and lawful purposes.
Payments	• Sponsorship or funding of grants (including educational grants) or charitable contributions.
Publications	• Authorship of any articles or other publications about therapeutic areas or disease states that may be treated with Government Reimbursed Products.

Examining the Compliance Requirements in Business (R&D) Processes

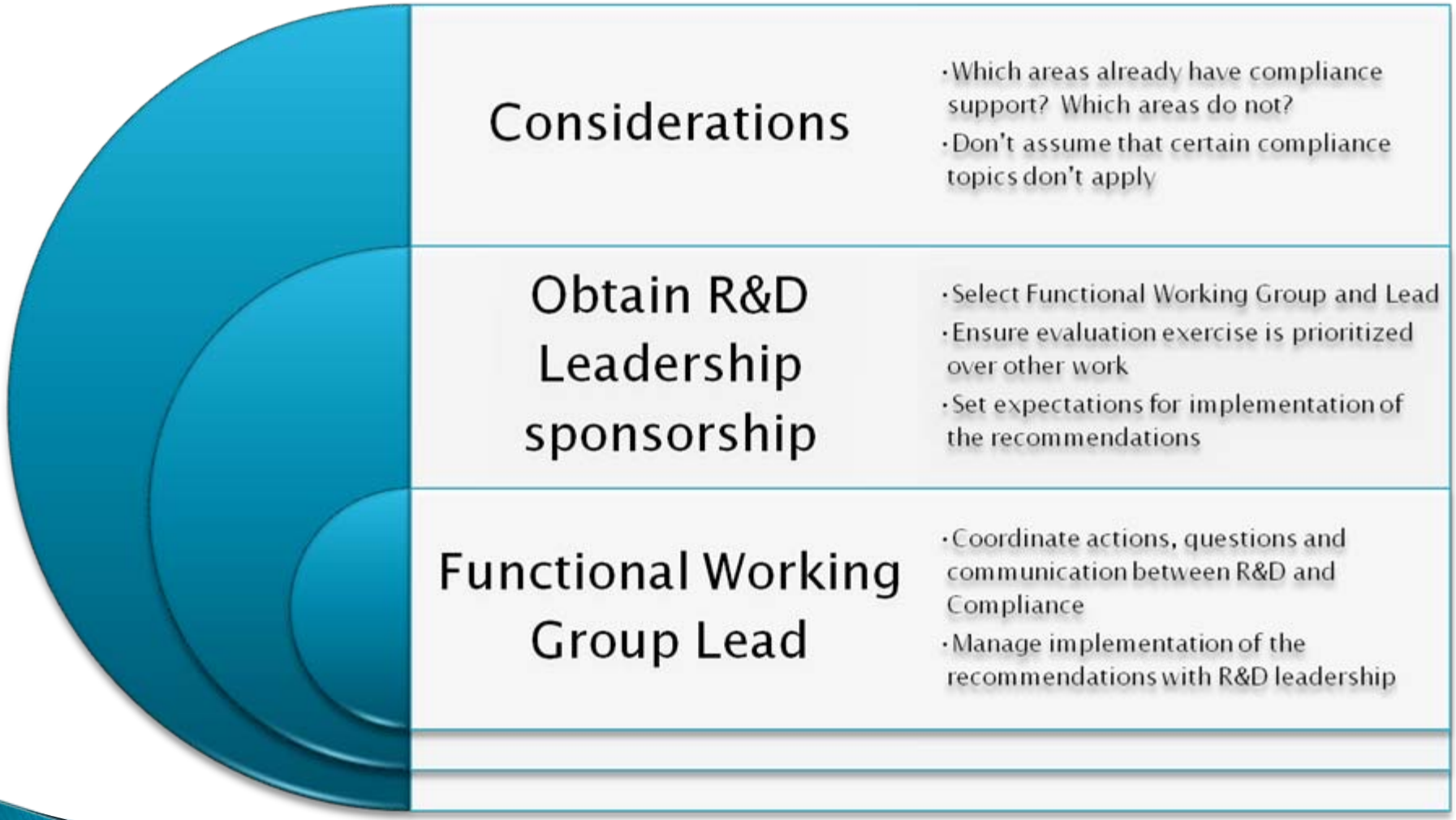
1. Identify the relevant Policies for R&D
2. Prioritize the Policies that are of greatest concern
3. Select the R&D areas to evaluate
4. Identify the impacted processes/ activities
5. Develop your Assessment Plan and Identify the Gaps
6. Close the Gaps

1 – Identify the relevant Policies for R&D

Using your organization's current list of Policies, identify those with a scope that includes R&D:

2 – Prioritize the Policies that are of greatest concern

3 – Select the R&D areas to evaluate



4 – Identify the impacted processes/ activities

Prioritized Compliance Topics (Policies)

R&D Areas

	Anti-Corruption	Business Meals	Grants & Donations	Meetings & Events w/ HCPs	Payments to HCPs	Scientific Disclosure
Biology						
Chemistry						
Drug Disposition						
Pharmacology						
Toxicology						

~ Activities / Processes ~

Activity/ Process Identification Example

Pre-Clinical Activities during which Business Meals could occur:

- **Collaborations** – Interactions with an external organization where a contract is in place
- **Scholarly** – Interactions for general scientific advancement rather than company specific projects or objectives – lack of explicit contract with external party
- **CRO** – Interactions with contract research organizations
- **Procurement** – Interactions with routine vendors of reagents, supplies, or materials
- **Hiring/Staffing** – Interactions with candidates for employment

Activity/ Process Identification Example

Prioritized Compliance Topics (Policies)

R&D Areas

	Anti …	Business Meals	Grants …	Meetings …	Payments …	Sci…
Biology		• Collaborations • Scholarly • CRO • Procurement • Hiring/ Staffing				
Chemistry						
Drug Disposition						
Pharmacology						
Toxicology						

The Compliance Program Model

Compliance and Ethics Seven Element Model

5 – Developing your Assessment Plan and Identify the Gaps

- The Assessment Plan is a mapping of the R&D activities and processes to the OIG 7-Element Compliance Model.
- Using our earlier example, we would map the Biology Business Meal situations to the OIG 7-Element Compliance Model.

	Collaborations Scholarly CRO	Procurement	Hiring/ Staffing
Owner	?		
Policies & Procedures	?		
Training	?		
Communication	?		
Monitor & Audit	?		
Discipline Process	?		
Corrective Actions	?		

5 – Developing your Assessment Plan and Identify the Gaps

- Owner
  - Is there a R&D Area group or person who takes responsibility for this compliance topic in this R&D Area?
- Policies & Procedures
  - Are there local area procedures that provide specific guidelines for this compliance topic?
  - Is it clear how to apply the procedures to different situations?
- Training
  - Is there adequate training for this compliance topic?
  - Are the appropriate personnel being trained in this topic?

5 – Developing your Assessment Plan and Identify the Gaps

- Communication
  - Is Leadership actively communicating the importance of compliance for this compliance topic?
  - Are there adequate avenues for personnel to ask questions and get answers on this compliance topic?
- Monitoring & Auditing
  - Is the R&D Area routinely assessing their performance with respect to this compliance topic?
  - Is the Compliance department routinely monitoring the R&D Area's performance with respect to this compliance topic?
  - Is the process understood for gathering the data and assessing compliance with this compliance topic?
- Discipline Process
  - Are the consequences of non-compliance understood?

6 – Close the Gaps

- List out the identified gaps
- Complete analysis of gaps
- Develop Improvement Plans for the prioritized items
  - Sort into Near Term Plans and Longer Term Plans
- Track progress on the Improvement Plans

Title	Functional Group	Status	Owner	Description	Resolution	Completion Date	Target Completion Date	Progress Update	Evidence

- Review progress with R&D Leadership Sponsors

Getting to Action beyond the Improvement Plan

- Develop compliance topic SMEs in business areas
  - Especially important in R&D where you want scientists to have awareness, but not be administrative experts
  - SMEs can reduce risk by serving as point persons
  - Use this role for self-assessments and to raise the level of awareness
- Secure a seat at the table in various leadership teams where you can have influence
- Share case studies that generate learning discussions
  - Articles from the media
  - Anonymized workplace situations
  - Press releases/reports from government agencies

Getting to Action beyond the Improvement Plan

- Keep a diary of questions asked/answers provided and analyze periodically
  - Provides insight on where the organization may need help
    - Topic ideas for quick reference guides, lunch 'n learn, newsletters, FAQs
    - Example: Create a travel aid for scientists attending a conference. Include information regarding data disclosure, AE reporting, company rules for meal expenses
  - Provides content for shared learning amongst your Compliance staff
- Analyze your R&D data from the company hotline
- Review monitoring reports for serious findings
- Talk periodically with your corporate auditors
- Compare notes with your Quality and HR colleagues

Questions?