

Building an Effective Compliance Program in Healthcare Products R&D

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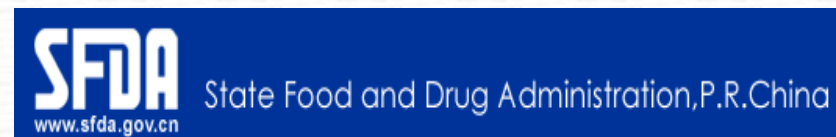
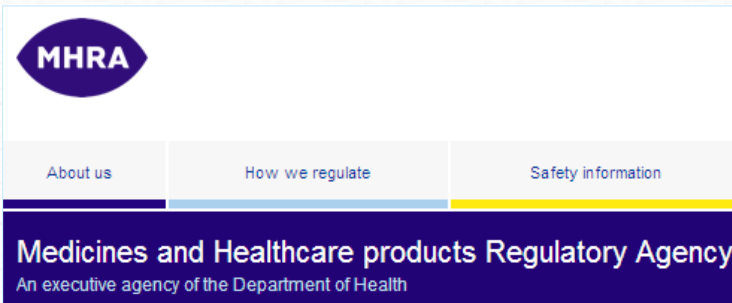
Agenda

- Summary of Current Enforcement Environment
- Perspectives on Building Effective Compliance Programs in R&D
- Panel Discussion – Practical Lessons and Tips
- Q&A



Enforcement Environment

Scrutiny by Health Authorities



Enforcement Environment

Investigations by Government Agencies



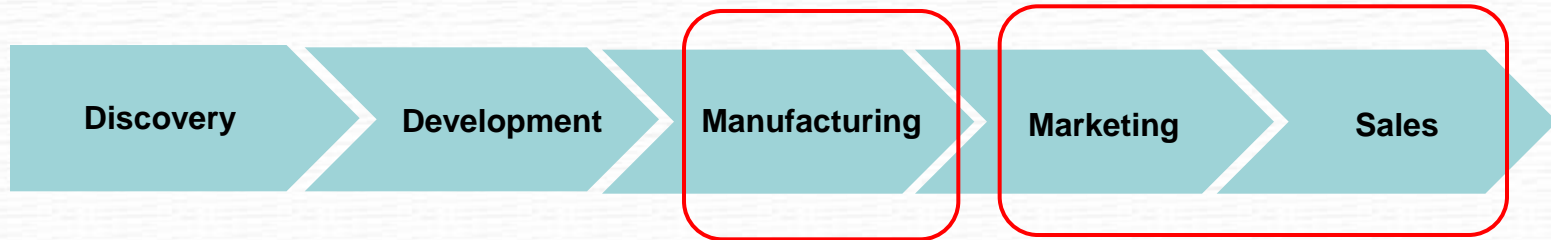
Enforcement Environment

Pharmaceutical Industry Value Chain



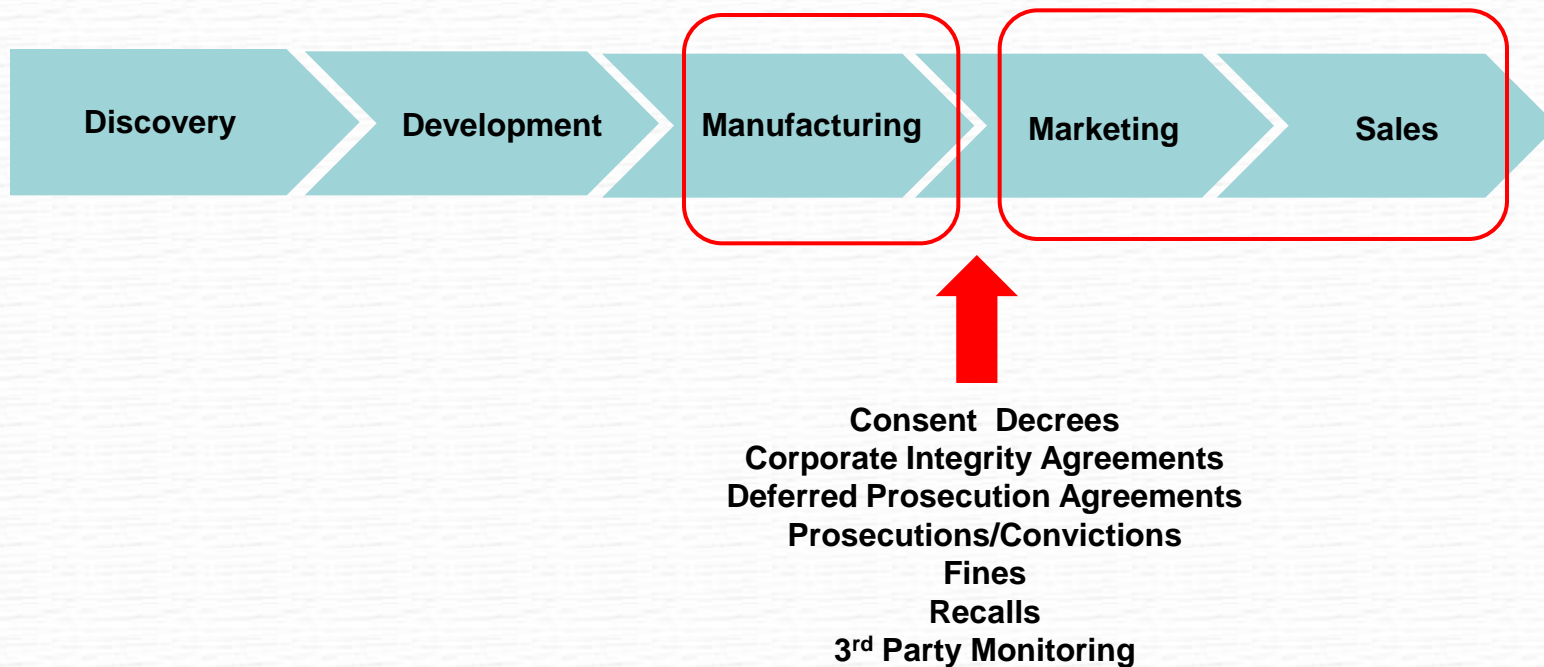
Enforcement Environment

Investigations by Government Agencies Across the Pharmaceutical Industry Value Chain



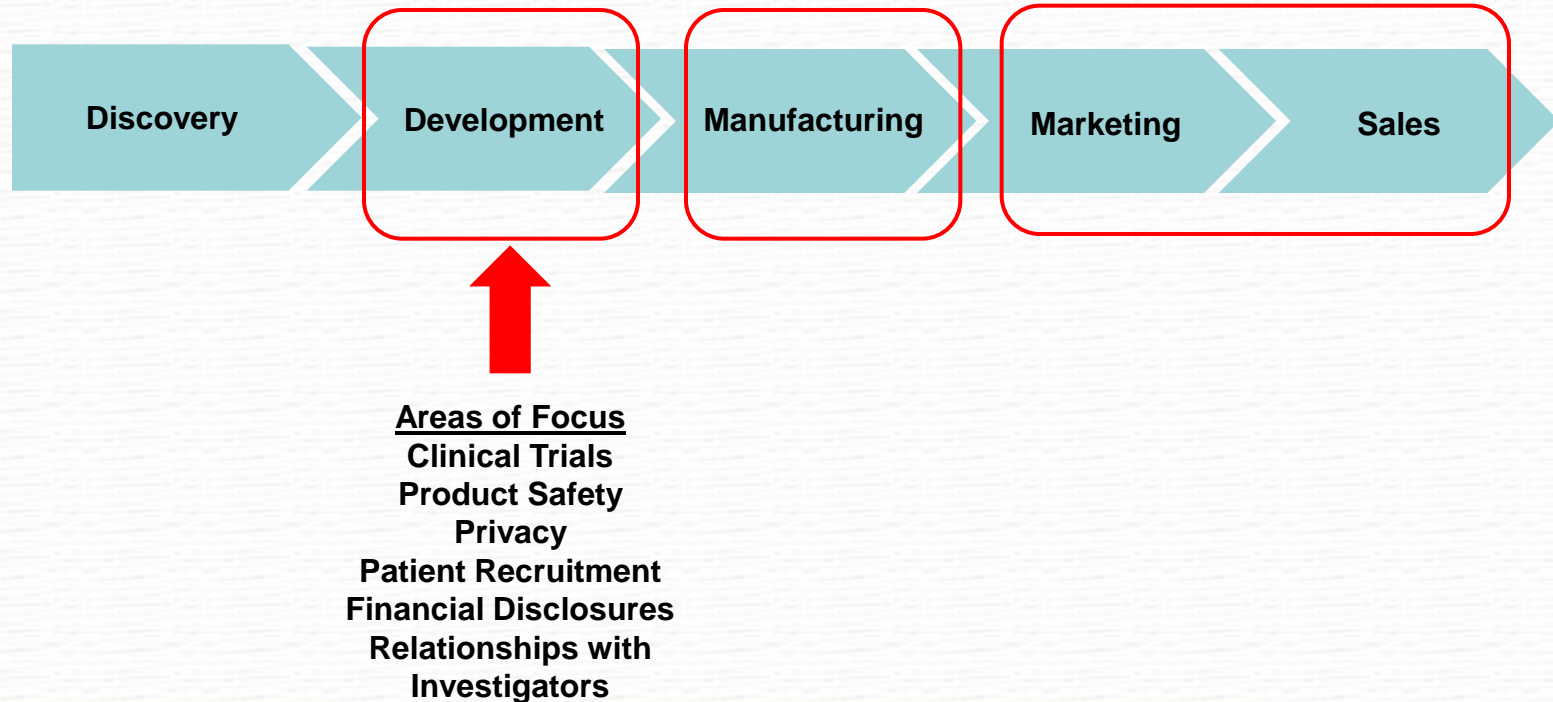
Enforcement Environment

Risks of Non-Compliance



Enforcement Environment

Investigations by Government Agencies Across the Pharmaceutical Industry Value Chain



Common Observations from Inspections and Investigations in Development

- Failure to secure investigator compliance
- Failure to submit progress reports to Health Authorities
- Inadequate safety analyses and reporting
- Failure to notify Health Authorities, investigators or IRBs
- Inadequate accountability for investigational materials
- Failure to obtain detailed and fully-executed Investigator Agreements
- Failure to obtain FDA or IRB approval
- Inadequate monitoring
- Unqualified study monitors
- Incomplete corrective action



Potential Risks

- Warning Letter
- Consent Decree
- Corporate Integrity Agreement
- Deferred Prosecution Agreement
- Criminal action
- Civil action
- Reputational damage
- Fines and penalties
- Loss of license to do business



Perspectives on Building Effective Compliance Programs in R & D



Strategy

Design, implement and enhance the compliance program:

- Follow government and industry guidance
 - OIG Compliance Program Guidance for Pharmaceutical Manufacturers
 - PhRMA Guidance
 - Leading Industry Practices
- Include R&D activities in the scope of the compliance program



Strategy

Utilize Available Resources



**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Office of Inspector General

**OIG Compliance Program Guidance for
Pharmaceutical Manufacturers**

U.S. Department of Health & Human Services
Office of Inspector General

OIG Home > Fraud >

Corporate Integrity Agreements

Strategy

Utilize Available Resources



U.S. Department of Health & Human Services
Office of Inspector General

Reports: Office of Evaluation and Inspections Reports
Subject Index 

Strategy

Utilize Available Resources



PRINCIPLES ON
Conduct of CLINICAL TRIALS
.....
Communication of
CLINICAL TRIAL RESULTS

Strategy

Utilize Available Resources



Panel Discussion Practical Lessons and Tips



Effective Compliance Programs

Key Elements

- Policies and Procedures
- Compliance Officer and Compliance Committee
- Training and Education
- Communication
- Risk Assessments
- Monitoring and Auditing
- Response and Corrective Actions
- Disciplinary Guidelines



Effective Compliance Programs in R&D

Considerations for Compliance Program Design

- Expectations
 - Enforcement agencies
 - Stakeholders
- Leading practices in R&D
 - Pharmaceutical
 - Biotechnology
 - Medical device
- Challenges



Effective Compliance Programs in R&D

Policies and Procedures

- Expectation
 - Written standards of conduct, policies, procedures and protocols that verbalize the company's commitment to compliance
- Leading practices in R&D
- Challenges



Effective Compliance Programs in R&D

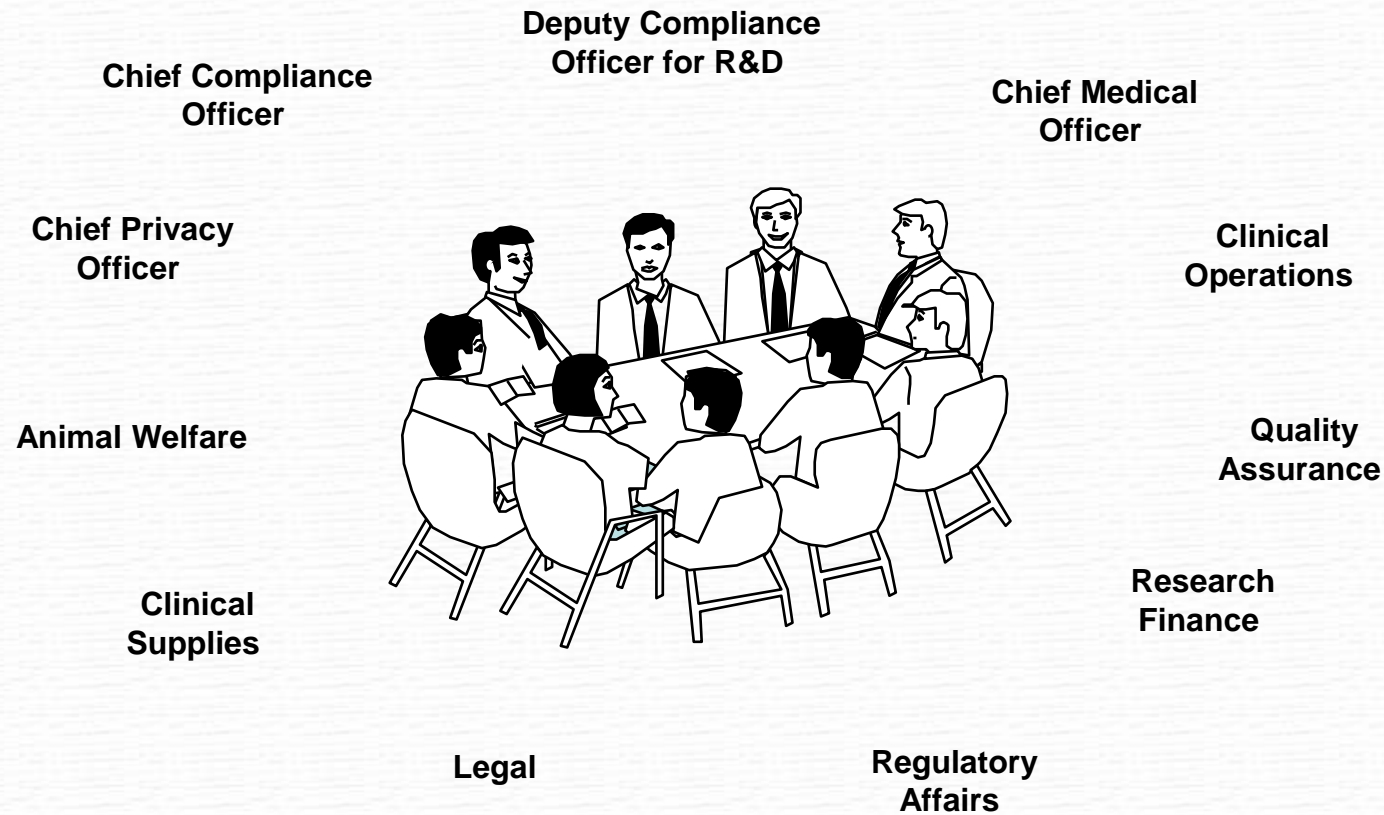
Compliance Officer and Compliance Committee

- Expectation
 - Designation of a compliance officer and other appropriate bodies charged with the responsibility for developing, operating, and monitoring the compliance program
- Leading practices in R&D
- Challenges



Effective Compliance Programs in R&D

Compliance Committee in R&D



Effective Compliance Programs in R&D

Training and Education

- Expectation
 - Development and implementation of regular, effective education and training programs for all affected employees and contractors
- Leading practices in R&D
- Challenges



Effective Compliance Programs in R&D

Communication

- Expectation
 - Creation and maintenance of an effective line of communication between the compliance officer and all employees and contractors
- Leading practices in R&D
- Challenges



Effective Compliance Programs in R&D

Risk Assessments

- Expectation
 - Periodically assess the risk of criminal conduct
 - Take the appropriate steps to design, implement, or modify the compliance program to reduce the risk of such conduct
- Leading practices in R&D
- Challenges



Effective Compliance Programs in R&D







Risk Assessment Tools – Compliance Scorecard

Compliance Area	Effectiveness	Adequacy vs Compliance Standards					Risk Rating	Leading Practice	Priority for Corrective Action
		Quality System	Process	Policies & SOPs	Organization	Training			
Clinical Protocols	2	3	3	2	3	3	Minor	No	Low
Protocol Deviations	2	1	1	2	1	2	Critical	No	High
Clinical Investigator Fraud	3	3	3	2	3	3	Minor	Partial	Low
Corrective Action Follow-up	1	1	2	1	1	2	Critical	No	High
Privacy & Data Protection	2	2	2	2	2	2	Minor	No	Medium
Safety Reporting	1	2	1	1	2	2	Major	No	High
Vendor Management	1	3	3	1	2	1	Major	No	Medium



Effective Compliance Programs in R&D

Risk Assessment Tools – Compliance Gap Analysis

Priority for Action			
Regulatory Risk	 High If not corrected, likely to generate a regulatory authority observation (e.g., FDA 483), may be in risk of warning letter or official action	 Med If not corrected, may generate a regulatory authority observation (e.g., FDA 483)	 Low If not corrected, may or may not generate a regulatory authority observation (e.g., FDA 483)
Leading Business Practice	 No Does not follow leading practices	 Partial Opportunity for higher efficiency	 Yes Matches leading practices



Effective Compliance Programs in R&D

Monitoring and Auditing

- Expectation
 - Use of audits and/or other risk evaluation techniques to monitor compliance and identify problem areas
- Leading practices in R&D
- Challenges



Effective Compliance Programs in R&D

Monitoring and Auditing are Different

- Monitoring
 - Act of overseeing progress and ensuring that activities are conducted in accordance with policies, procedures and applicable regulatory requirements
- Auditing
 - Systematic and independent examinations of activities to determine the activities were conducted according to a specific plan , following approved procedures, and applicable regulations



Effective Compliance Programs in R&D

Response and Corrective Actions

- Expectation
 - Development of policies and procedures for the investigation of identified instances of noncompliance or misconduct
 - Prompt response to detected offenses, initiation of corrective and preventive measures, and reporting to authorities as appropriate
- Leading practices in R&D
- Challenges



Effective Compliance Programs in R&D

Disciplinary Guidelines

- Expectation
 - Development of policies and procedures addressing non-employment of individuals/entities excluded from participation in federal healthcare programs
 - Enforcement of disciplinary action against employees and contractors who violate company requirements
- Leading practices in R&D
- Challenges



Q & A



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