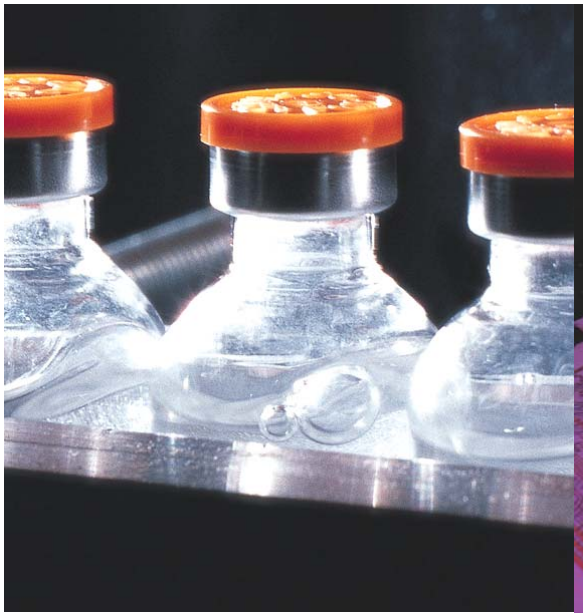
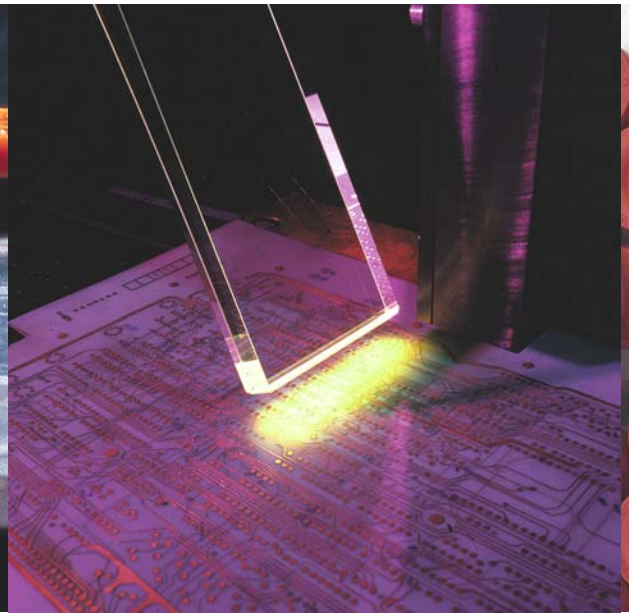
PRICEWATERHOUSECOOPERS


Pharmaceutical Congress Spring 2003

Preconference Symposia

Compliance 101 for Pharmaceutical Manufacturers

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June 8, 2003

Agenda

- Introductions & Objectives
- Overview of Industry Practices
- Approach to Compliance Risk Assessments
- Case Example for an Assessment of a Risk Area

Introduction to Presentation

"Given the wide diversity within the pharmaceutical industry, there is no single "best" pharmaceutical manufacturer compliance program. The OIG recognizes the complexities of this industry and the differences among industry members."

- OIG Compliance Program Guidance for Pharmaceutical Manufacturers

Presentation Objectives

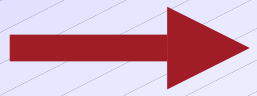
Explore Practical Initiatives to Consider in Implementing a Compliance Program

- Focus of Discussion
  - Seven Elements of an Effective Compliance Program
  - Pharmaceutical Industry Practices
  - Methodology for Conducting Compliance Risk Assessments
  - Off-Label Sales and Marketing Activity

Presentation Objectives

Explore Practical Initiatives to Consider in Implementing a Compliance Program

- Standards and Procedures
- Oversight Responsibility
- Education and Training
- Lines of Communication
- Monitoring and Auditing
- Enforcement and Discipline
- Response and Prevention



Pharmaceutical Industry Practices

Pharmaceutical Industry Practices

Scope of Compliance Function

- Responsibility for compliance in a highly regulated industry
  - Legal
  - Regulatory Affairs
  - QC/QA
  - Finance
  - Others
- Determine scope of responsibility for the compliance function and establish operating rules for interacting with compliance-related departments

Pharmaceutical Industry Practices

Standards and Procedures

- Codes of Conduct
  - Focus on business risks, ethics, regulatory requirements and legal issues
  - Utilize examples of acceptable/unacceptable behaviors and often include FAQs
  - Translated into multiple languages for global distribution
  - Distributed to employees during new hire orientation and frequently shared with suppliers, consultants, temporary employees and customers
  - Receipt and certification process

Pharmaceutical Industry Practices

Standards and Procedures

- Identification and Mitigation of Risk
  - Reliance on Legal and Internal Audit departments for identification of risk areas and the development of mitigation policies
  - Update and delivery of training to address new risk areas
- Policies and Procedures
  - Trend towards centralization for policies and procedures with increased use of company intranet sites to facilitate access and manage distribution
- Performance Evaluations
  - Few companies include compliance in performance evaluation

Pharmaceutical Industry Practices

Oversight Responsibility

- High-Level Management
  - Boards of Directors have formal responsibility for the compliance program
  - General Counsel typically has overall senior management responsibility for the compliance program
- Organizational Structure
  - GC as Compliance Officer in many companies with delegation of day to day responsibility to a member of the legal department
  - Small number of organizations with CO and Compliance department independent from Legal

Pharmaceutical Industry Practices

Oversight Responsibility

- Compliance Committee
  - Comprised of senior managers from business units and functions including Legal
  - Committee roster may differ during design and implementation of compliance program vs. day to day operations
  - Formal policies and procedures are in development
- Update Meetings and Reporting
  - Board, designated committee of Board, or the CEO receives an annual update on the compliance program

Pharmaceutical Industry Practices

Education and Training

- Basic Training for Employees
  - Training on the Code of Conduct for new hires
  - Records and logs for new hire training are maintained
  - Policy training in risk areas for appropriate personnel (e.g., sales, marketing, contracting)
  - Trend towards computer-based training using common and customized modules
- CIA Training Requirements
  - See specifics for 3/4 hour and 90 minute training programs

Pharmaceutical Industry Practices

Lines of Communication

- Communication Mechanism
  - Hotline/Helpline in place and administered by third-party
  - Informal or no procedures for logging, evaluating, investigating or resolving compliance-related reports
  - Many organizations track reported issues
  - Formal non-retaliation or non-retribution policy linked to the hotline
  - Most organizations respond to issues by delegating the matter to the appropriate department (e.g., HR, IA, security)

Pharmaceutical Industry Practices

Monitoring and Auditing

- Strong traditional Internal Audit function
- Limited resources to address compliance monitoring and auditing
- Many companies outsource monitoring and auditing for 1-3 years with objective to develop internal capability
- Initial focus of audits:
  - Code of Conduct
  - Training
  - Compliance with policies and procedures in risk areas

Pharmaceutical Industry Practices

Enforcement and Discipline

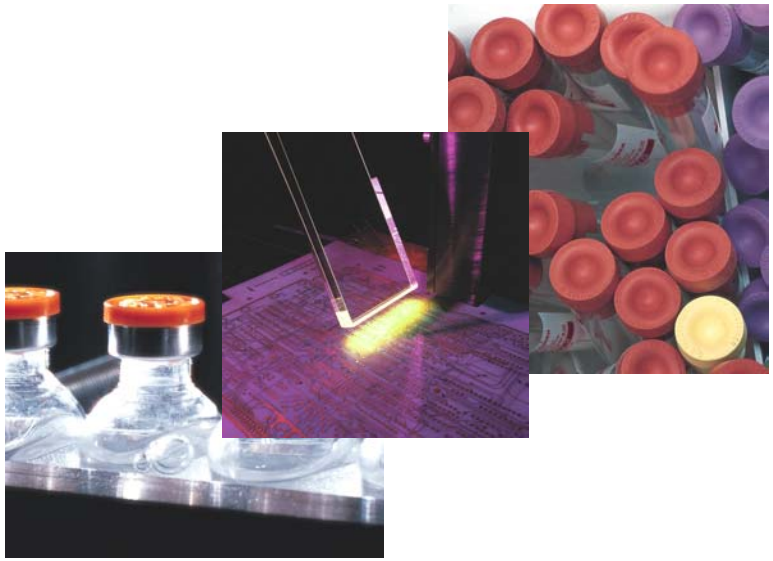
- Disciplinary Policies
  - Formal discipline policies in place, but few are tied to compliance program or Code of Conduct
- Reporting of Suspected Violations
  - Formal policy to report to immediate supervisor, CO, or hotline
- Background and Sanctions Check
  - Criminal background checks for new hires
  - Increased use of HHS/OIG List of Excluded Individuals/Entities and GSA List

Pharmaceutical Industry Practices

Response and Prevention

- Responding to Detected Offenses
  - Informal processes at many companies
- Corrective Action Plans
  - Informal processes

Compliance Risk Assessments



Elements of the Value Chain Are Potential Sites for Compliance Risk Assessments

Pharmaceutical & Healthcare Products Value Chain

- Discovery Research
- Investigator and Patient Recruitment
- Study Monitoring
- Data Management
- Pharmacoeconomics and Health Outcomes
- Analytical Testing
- Toxicity Testing
- Partnerships
- Outsourcing Suppliers

- Market Research & Study Services
- Marketing Support
- Promotional Materials
- Advertising
- Sales Organization
- Event Management
- Training & Education
- Databases
- Contract Sales
- Co-promotion Agreements

- Manufacturing and Packaging
- Specialized Delivery Systems
- Packaging Supplies
- Raw Material Supplies
- Plant Maintenance
- Engineering and Construction
- QA / QC Testing
- Contract Manufacturing
- Logistics
- Waste Management

- Professional Services
- Transportation/Travel
- Communications
- Insurance
- Legal
- Accounting
- Energy
- Training

Human Resources Support, Benefits, & Compensation

Information Technology

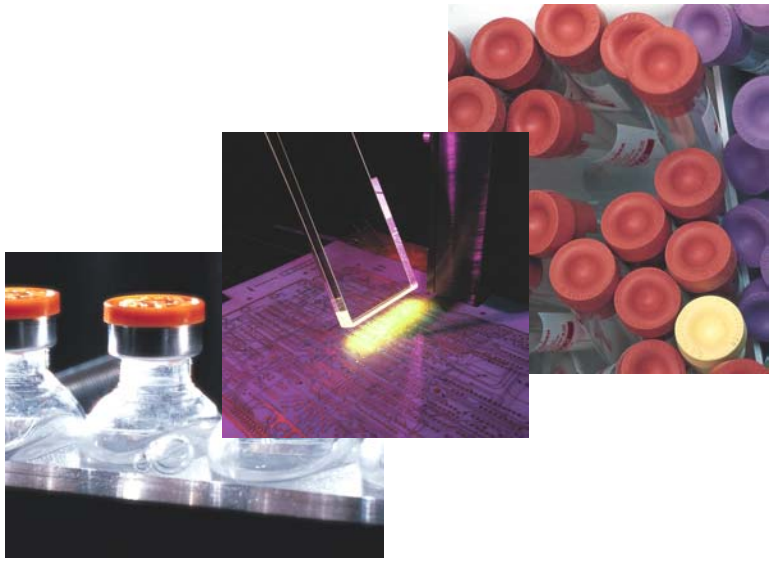
- Hardware / Software
- Web Hosting
- Support Services
- e-Business Applications

An Approach to Conducting Compliance Risk Assessments

Risk Assessment Process

4-6 Weeks

Case Example – Off-Label Activity



Case Example for Risk Assessment

Off-Label Sales and Marketing Activity

- Areas to Consider for Review
  - Strategic, business unit and marketing plans
  - Customer call lists and sales representative call reports
  - Sales incentive compensation programs
  - Exhibit booths at professional meetings
  - Line extension clinical trials (company-sponsored and customer-initiated)
  - Publication plans

Case Example for Risk Assessment

Off-Label Sales and Marketing Activity

- Areas to Consider for Review (Continued)
  - Opinion leader, thought leader and consulting agreements
  - Advisory Boards
  - Financial/non-financial support for patient advocacy groups
  - Product websites and chat rooms
  - US prescriber access to non-US product websites with additional indications for use

Contact for Additional Information

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