

Monitoring and Tracking in Companies with Small Compliance Departments

The Seventh Annual
Pharmaceutical Regulatory and
Compliance Congress Best
Practices Forum

Retta M. Riordan, Moderator
Business Ethics & Compliance Officer
Organon USA Inc., Roseland, NJ

Thomas Glavin
Vice President and Deputy Compliance Officer
Shire Pharmaceuticals Inc., Wayne, PA

Scot Steinheiser
Senior Manager, Corporate Compliance
Astellas US LLC, Deerfield, IL

Advantages & Disadvantages of Monitoring with Small Compliance Departments

- Monitoring is one of the 7 Elements of a corporate compliance program
- Various challenges facing Small Compliance Depts.
 - Resources—Human and financial
 - State of IS/Finance systems for tracking
 - Decentralization of Data
 - Priority overload
- No small department exception in the 7 Elements

Advantages & Disadvantages of Monitoring with Small Compliance Departments (cont'd)

- But there are distinct advantages, too
 - Nimble
 - Flexible
 - Know everyone, and everyone knows you
 - Can track manually, if necessary
 - Less bureaucratic
 - Less siloed—people are used to wearing many hats and working as teams

Magic Bullets?

- Setting Monitoring Priorities
- Human Resources Challenge
- Financial Resources Challenge
- Handling the Data
- What to do with Monitoring Results
- Fixing the Problem
- Viewing the Results as an Opportunity
- Training, Training, Training

Setting Priorities for Monitoring at a Small Company

- How do you determine what to monitor?
 - Conduct a risk assessment
 - Mine the CIAs
 - Review OIG Guidance
 - Listen to statements of government officials
 - Review OIG Work Plans and Semi-Annual Reports
- How do you prioritize the programs/practices you have identified?
 - Rolling cycle
 - Greasy wheel
 - Gut feel
 - Follow the money
 - Constantly reassess and reprioritize, as necessary

Resource Challenges—Human

- Problems:
 1. Not enough people in small compliance dept. to monitor targeted programs/practices
 2. You cannot be everywhere
- Possible Solutions:
 1. Use personnel not in the compliance function
 - Legal, Regulatory, Medical, Audit, Sales/Marketing Operations
 - Lead without authority
 2. Buy external help
 - Consulting company
 - Law firm

Resource Challenges—Financial

- Problems:
 1. Not enough heads to do it
 2. Not enough \$ to pay to have it done
- Possible Solutions:
 1. Combine/Share budgets
 - Legal
 - Finance/Audit
 2. Make the business case for involvement of other functions/departments
 - Program Efficiencies
 - Accountability and Control

Decentralization of Disparate Data in Sm(all) Companies

- Systems and Silos
 - Expense Reporting
 - Promotional Spend
 - Speaker Program Attendance
 - Department tracking inconsistent
- Sales Representatives + Warehouse + Vendors = Headaches all around

Decentralization of Disparate Data in Sm(all) Companies (cont'd)

- Magic button or digits to aggregate data
- Staffing limitations
- Annual Certifications

After the Storm (Post-Monitoring Phase)

- What is uncovered must be addressed
- Avoid Analysis Paralysis
- Active Coaching
- Positive Remedial Action
- Plan Additional Training

After the Storm (Post-Monitoring Phase) (cont'd)

- Update Policies and Procedures as needed
- Adjust systems or processes to fill the gap
- Further investigation may be warranted
- Coordinate disciplinary action with Department Management and Human Resources

Disclaimer

The views expressed and ideas presented in this session are those of the speakers and are not necessarily shared by the presenters' employers. Any examples provided are hypotheticals and should not be attributed to any individual company.