Promotional Compliance Monitoring: Past, Present, and Future

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Promotional Compliance Monitoring Defined

- Monitoring is the ongoing, near-time analysis of data sources to proactively identify, trend and respond to potential compliance “signals”
- Monitoring is distinct from auditing, which is typically retrospective and often limited by time, frequency and scope
- Monitoring results inform corrective action plans, including full-scale compliance investigations, policy changes, enhanced training and communications, additional monitoring, focused audits and other programmatic responses

Promotional Monitoring in new CIAs

Allergan CIA Excerpt

i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program and/or FDA authorities implicated;

ii. a description of Allergan's actions taken to correct the Reportable Event; and

iii. any further steps Allergan plans to take to address the Reportable Event and prevent it from recurring.

iv. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities and/or FDA authorities implicated.

Allergan shall not be required to report as a Reportable Event any matter previously disclosed under Section III.G, above.

I. Notification of Communications with FDA. Within 30 days after the date of any written report, correspondence, or communication between Allergan and the FDA that materially discusses Allergan's or a Covered Person's actual or potential unlawful or improper promotion of Allergan's products (including any improper dissemination of information about off-label indications), Allergan shall provide a copy of the report, correspondence, or communication to the OIG. Allergan shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed off-label matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

J. Field Force Monitoring and Review Efforts.

To the extent not already accomplished, within 120 days after the Effective Date, Allergan shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor sales representatives' interactions with HCPs and HCIs relating to Government Reimbursed Products. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales representatives' interactions with HCPs relating to Government Reimbursed Products and to identify potential off-

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Pfizer's Promotional Monitoring Program: Promotional Quality Assurance (PQA)

Mission Statement

Promote Pfizer's commitment to integrity by proactively monitoring and analyzing U.S. **promotional** activities to identify potential **compliance signals** and providing Pfizer legal and business colleagues with **real-time** information supporting decision-making and **legal risk** mitigation.

High-Level PQA Process

RAMP™
Risk Assessment and Mitigation Planning

Prioritize Products and Identify Focus Areas

PQA
Promotional Quality Assurance

Conduct targeted monitoring, review and escalate findings

Responsive and Corrective Action

Respond to identified issues as appropriate

The PQA Story: Past

Launch of state-of-the-art monitoring program

Multiple Data Sources

- Email
- Sampling Records
- Call Notes
- Verbatim Records
- Other Records

Robust Review and Escalation Process

Collaboration with
- Legal
- Compliance
- Data Owners

Formalized reporting and escalation

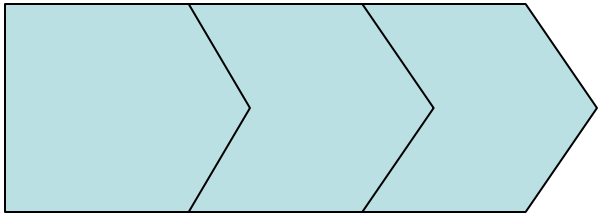
Strategic Staffing Model

Team background:
- Legal
- Pharmacy
- Nursing
- Audit
- Sales
- Quality Assurance
- Technology

The PQA Story: Present

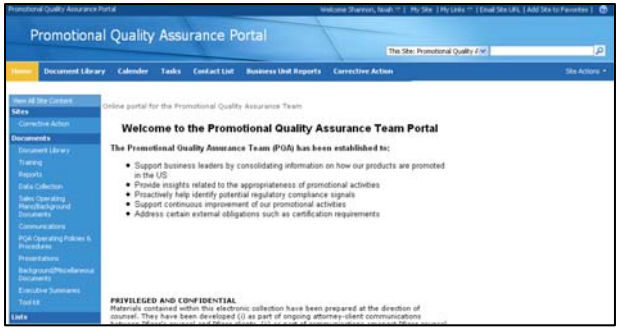
Continuous Improvement: Process and Technology

Process



- Refinement of review and escalation process
- Updated reporting
- Product On-boarding

Technology



- Enhanced records review platform
- Data sharing and trending
- Process automation

The PQA Story: Future

New Data Sources and Monitoring Approaches

Sources

- Prescriber and Diagnosis Data
- Healthcare Professional Payment Information
- Social Media

Approaches

- Integration across data sources
- Enhanced geographic trending
- Statistical and regression analyses

PQA Success Factors

- Strong, regular collaboration with Compliance, Legal, and Business Colleagues
- Development of product-specific expertise
- Effective leveraging of existing technologies and data sources
- Continuous process improvement
- Transparency in communication
- More informed certifications

Questions?