Industry Perspectives on Surveillance Inspections – Can They Deliver Greater Value?

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Surveillance Inspections

"Recipe for a successful inspection = one that adds value and encourages manufacturing quality"[1]

[1]2015 GPhA CMC Workshop, Compliance and Inspection, Office of Regulatory Affairs; Ellen Morrison; June 10, 2015

Current State of Surveillance Inspections

* Provides confidence to stakeholders that drug products are manufactured according to requirements and regulations
* Provides an opportunity for industry to learn
  - Within a firm based on observations from regulators
  - From failures of others shared publicly by regulators

Current State of Surveillance Inspections

* Lack of incentive for proactive enhancement of manufacturing quality
  - Stick versus carrots
* Limited use of risk-based approaches by regulators
  - Risk is not evenly distributed across the industry
* Inefficient use of industry and regulator resources
  - Lack of harmonization of standards across regulators
  - Lack of consistency within regulatory agencies

Ideal State

* The goal is to assure product quality
* Requires two fundamental elements
  - Risk is understood and mitigated
  - Risk prevention and product quality are promoted and incentivized
* Requires a holistic, collaborative approach between industry and regulators

Example-FDA's Case for Quality

* Center for Device and Radiological Health
* Key objectives
  - Align FDA's compliance focus to address industry quality gaps
  - Enhance transparency and visibility of Agency data to drive quality
  - Increase industry engagement

Leveraging the Case for Quality- Understand and Mitigate Risk

* Regulators could collaborate with industry to identify the most significant quality risks and align their focus on these
  - Focus on enforcement of compliance or on delivering quality?
  - Role of metrics?
* Once risk areas are understood, perform a diagnostic to determine
  - Allocation of resources
  - Level of consistency required in regulator's knowledge and oversight of key risk areas

Benefits

* Broadens the assessment of risk beyond specific establishments[1] to issues and trends
* Redirects focus of inspections and other oversight from compliance to assurance of product quality
* Makes efficient and effective use of resources

[1]FDASIA Section 705 instructs FDA to inspect drug establishments in accordance with a risk-based schedule

Example-Aviation Safety Reporting System

* Developed by FAA, replicated in many countries and by the railroad industry and firefighters
* Objective is to improve the aviation system and protect life
* Receives and analyzes voluntarily submitted incident reports from anyone in the aviation industry
  - May describe unsafe occurrences and/or hazardous conditions
  - Voluntary, confidential and non-punitive
  - One of the world's largest sources of aviation safety information

Aviation Safety Reporting System

* Used to mitigate risk and promote learning
  - Alert messages regarding imminent hazards are sent to those in positions of authority in the aviation industry
  - Less urgent information is shared in multiple ways
  - A public, searchable database is maintained
  - Proven to improve aviation safety
- Regulators could develop a similar system for product quality information

Incentivizing Product Quality

* Potential incentives include
  - Fewer/shorter inspections
  - Firm-managed change control
  - Accelerated product approvals
* Could be introduced in a variety of ways
  - Risk prevention/reduction plan
  - Quality maturity model

Example-Seafood HACCP

* Implemented in the 1990s for seafood producers
  - Similar program being piloted by USDA with poultry and meat producers
* Requires the manufacturer to identify risks, develop mitigation plans and verify effectiveness
* FDA inspections focus primarily on the adequacy of the plan
  - Results in shorter and/or less frequent inspections for high-performing firms
  - Has reduced food-borne illness

Quality Maturity Model

* Could be developed collaboratively by industry and regulators
* Firms could self-report and be evaluated during inspections
* Progressive incentives could be offered as the firm moves through the stages of maturity
* Could inform the development of ICH Q12

Surveillance Inspections

* Can add greater value if
  * Informed by a collaborative evaluation and understanding of risks to product quality
  * Compliance focus is aligned to identified risk areas
  * Used as a tool to incentivize product quality