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

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“Recipe for a successful inspection = one that adds value and encourages manufacturing quality”

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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.
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
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
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
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

Example-Aviation Safety Reporting System
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