

Quality Metrics

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Background

- The problem of subjectivity in inspection findings
- Limitation on “compliance-oriented” measure
- FDASIA Sections 705 706
- Vision of global data sharing
- Transition from a mandatory program to a pilot

FDA's Stated Goals

- Help develop compliance and inspection policies and practices
- Use in risk-based site selection model
- Predict and mitigate drug shortages
- Encourage manufacturing innovation

FDA's Metrics

- Lot Acceptance Rate
- Product Quality Complaint Rate
- Invalidated OOS Rate

FDA's Intended Use

- Establish a signal detection program
- Identify drug shortage risks
- Improve the effectiveness of inspections
- Work with firms on early resolution of potential quality problems
- Use metrics as an element in post-approval manufacturing change reporting program (to encourage innovation)
- FDA recognizes self-selection bias

Quality Metrics Reporters List

- Tiers depending on how much information is reported
- FDA indicates that actual data will not be public

Public comments

- Legal authority?
- Voluntary list as a form of compulsion?
- Confidential information
- Compliance cost
- Achieving a higher tier in reporting creates a bias toward companies with fewer products
- Metrics are complex and cannot be standardized
- Diverts attention from other Key Performance Indicators