Quality Metrics, current experiences and considerations

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Agenda

- Quality metrics in TRD today

- Industry challenges with quality metrics

- Approach to support the risk-based inspection program in Sections 704 to 706 of US FDASIA

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Quality metrics in TRD today

Key Quality Indicators and Right-First-Time Metrics

- Metrics are composed of Key Quality Indicators and right-first-time metrics

KQIs

- Deviations, CAPAs, OSS/OOE, Complaints
- SOPs and forms overdue for periodic review
- Training completion rates
- Quality Module implementation
- Inspection activity
- Recalls
- Reject rates

RFT

- Batch record review
- Analytical record review
- Technical documents
- Master documents

- Weekly monitoring of metrics at the working group level

- Monthly data collection and reporting to site management, to Global TRD, and then to Development division

- Reviewed by management in Quality Review and Management Review meetings throughout the year

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Industry challenges with quality metrics

- Targets
  - Do they make sense?
  - Achievable for everyone?
  - Do they drive bad behaviors?

- Reporting
  - Discrepancies due to duplicative efforts
  - Are different sites measuring the same way?
  - Right-First-Time: How do you accurately define what is not RFT?

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Getting to a future metrics state to support FDASIA

"White paper" written to support the risk-based inspection program in Sections 704 to 706 of US FDASIA

- Metrics proposed
  - Leading indicators (predictive of future performance)
  - Lagging indicators (identifies or signifies past up-to-present performance)

- Pilot program established to develop the definitions and approach

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