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
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
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?
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