Value of Quality Metrics

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Background

- 8 Business Units
- 74 Manufacturing plants worldwide
- 50+ Distribution Centers
- 20+ design centers
- Global product presence
- ~45k Associates worldwide
- Billions finished medical devices and IVDs produced and distributed annually
- Enormous volume of data

Key Reasons for Initiating a Quality Metrics Process

- Gather, Consolidate, Analyze and Interpret complex and large volume of relevant quality data
- Enable timely identification of quality issues
- Provide unbiased pathways for management escalation
- Enable appropriate initiation of corrective actions
- Provide management with information for resource allocation
- Timely assessment of risk and need for field corrective actions
- Influence organizational focus, culture and behaviors – create environment of accountability

Types of Metrics Tracked

- Customer Satisfaction
  - Customer Complaints
    - Number of complaints received monthly
    - Normalized complaint rate
      - Could be normalized over units sold, installed instruments, tests per instrument, cycle count ….
  - Complaint investigation process performance
    - Customer complaint turn around time (initiation to closure)
    - % of complaints over 60/90 days
    - Oldest complaint open
  - Reliability
    - Mean Time Between Failures
    - Service Repair Effectiveness
    - On time Maintenance

Types of Metrics Tracked

- Manufacturing Process Performance
  - Quality Yield
    - % of Batches/Instruments produced without non-conformances
  - Number of non-conformances generated
  - % Non-conformances open > 30/60 days
  - Number of deviations initiated
  - % Deviations open > 30/60/90 days
- Calibration
  - % Calibration on time
  - % OOT
  - % OOT with product impact

Types of Quality Metrics Tracked

- Quality System Performance
  - CAPAs
    - CAPAs % on Time Completion
    - CAPA Effectiveness
    - Average days open
  - Internal Audit
    - Schedule Compliance
    - Time Observations Closure
  - Adverse Event Reporting
    - Number of Adverse Events Reported
    - % Reported on Time
  - Training
    - % on time Training
  - Field Actions
    - Number Risk Assessments Initiated
    - Risk Assessments open > 30 days
    - Number of Field Actions Initiated
  - Supplier Performance
    - Supplier Audit Schedule Compliance
  - Process Validation
    - Process Validation Schedule Compliance

How Metrics are Reported

- Data is organized by key product lines, manufacturing plants and in line with business and department organizational structure
- Goals are established based on historical or desired performance
- Frequency of reporting is predefined based on types of data tracked:
  - Most monthly, some quarterly, weekly or bi-weekly
- Separate reports are generated for complex data
  - Complaints, CAPA, Non-Conformances, Internal and Supplier Audit

How Metrics are Reported

- Metrics are structured with increasing granularity and timing at lower levels to enable appropriate visibility, accuracy and support timely decisions

	Corporate	Unit	Plant
Complaints	Rate (G,Y,R)	CPM	Product A Received
			Product A CPM
		CPS	Product B CPS
			Product B Received
			Product B Trend
	TAT (G,Y,R)	% > 30/60/90 Days	% > 30/60/90 Days (A)
			% > 30/60/90 Days (B)
		Oldest Open	Oldest Open (A)
			Oldest Open (B)
Frequency	Quarterly	Monthly	Weekly

Examples of Quality Goals and Report Structure

Scorecard Metrics	May 2016	Apr 2016	Mar 2016	Goal	Alert Limit	Action Level	FY15 - Q3	FY15 - Q4	FY16 - Q1	FY16 - Q2	12 Month Average
BDDS Overall											
Calibrations (% Overdue)	1%	0%	2%	<6%	6%-7%	>7%	3%	2%	1%	2%	N/A
Calibrations (Out of Tolerance) > 30 days	2	4	3	<30 Days	N/A	≥30 Days	6	3	**36**	3	N/A
CAPA (% Effectiveness)	100%	**84%**	100%	≥95%	N/A	<95%	N/A	N/A	**92%**	100%	N/A
CAPA (% Overdue)	**3.4%**	**4.9%**	**4.6%**	<3.0%	3.0-5.0%	>5.0%	**3.4%**	0.7%	**3.4%**	**4.6%**	2.6%
CAPA (Average Days Open)	163	147	159	<181	181-364	>364	N/A	N/A	145	159	N/A
Complaints (Average Days Open)	39	36	34	<46	46-59	>59	37	43	32	34	N/A
Complaints (Average Days to Close)	44	40	33	<46	46-59	>59	43	**52**	**47**	33	**46**
Complaints per Million (CPM)	6.1	6.5	5.8	<7.0	7.0-7.8	>7.8	5.8	6.7	6.1	5.8	6.0
Compleints per System (CPS)	0.0234	**0.0252**	**0.0288**	<0.0248	0.0248-0.0264	>0.0264	0.0224	0.0227	0.0227	**0.0288**	0.0207
Deviations (% Overdue)	2%	1%	2%	<11%	11%-20%	>20%	3%	6%	3%	2%	3%
Deviations (Average Days to Closure)	69	65	73	<91	91-180	>180	46	50	52	73	63
Internal Audits (Compliance to Schedule)	N/A	N/A	**88%**	>95%	80%-95%	<80%	96%	100%	100%	**88%**	N/A
Internal Audits NC Aging >6 months)	**22%**	**28%**	**17%**	<10%	10%-19%	>19%	**13%**	4%	0%	**17%**	**10%**
%QN over 60 days	**11%**	**10%**	**12%**	<10%	10% - 15%	>15%	**14%**	7%	5%	**12%**	**11%**
RTFT	98.7%	98.7%	98.5%	>96.3	95.3-96.3	<95.5	97.4%	97.0%	97.0%	98.5%	97.7%
Training (% Compliance)	99%	99%	99%	≥95%	N/A	<95%	98%	98%	98%	99%	99%
Validations (% Compliance to Schedule)	N/A	N/A	94%	>89%	51%-89%	<51%	98%	97%	**85%**	94%	N/A
PM Compliance (Completion %)	**87%**	**87%**	**88%**	≥90%	80% - 90%	<80%	N/A	N/A	N/A	**88%**	N/A
PM Compliance (On-time %)	**46%**	100%	**89%**	≥90%	80% - 90%	<80%	N/A	N/A	N/A	**0%**	N/A
Infantile Failure Rate	11%	11%	N/A	TBD	TBD	TBD	N/A	N/A	N/A	N/A	N/A

* Simulated data

Quality Metrics Implementation Process

- Quality metrics reporting process is documented in the SOP
- Goals are formally established based on statistical analysis of historical performance or desired results
- Goals are reviewed as needed and at a minimum on annual basis
- Goals are formally approved and records retained
- Calculation method is determined and documented
- Spreadsheets used to collect and interpret information are validated and controlled
- Designated individuals are responsible for gathering, compiling and reporting metrics
- Minimum distribution list is established
- Reporting frequency is defined in the SOP
- Response to underperforming measures is defined in the SOP (Escalation to MR, Risk Assessment Initiation triggers, CAPA, etc…)