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

<table>
<thead>
<tr>
<th>Complaints</th>
<th>Corporate</th>
<th>Unit</th>
<th>Plant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rate (G,Y,R)</td>
<td>CPM</td>
<td>Product A Received</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Product A CPM</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CPS</td>
<td>Product B CPS</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Product B Received</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Product B Trend</td>
</tr>
<tr>
<td>TAT (G,Y,R)</td>
<td>% &gt; 30/60/90 Days</td>
<td>% &gt; 30/60/90 Days (A)</td>
<td>% &gt; 30/60/90 Days (B)</td>
</tr>
<tr>
<td></td>
<td>Oldest Open</td>
<td>Oldest Open (A)</td>
<td>Oldest Open (B)</td>
</tr>
<tr>
<td>Frequency</td>
<td>Quarterly</td>
<td>Monthly</td>
<td>Weekly</td>
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</table>
## Examples of Quality Goals and Report Structure

### Scorecard Metrics

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

*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 an 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…)