
Roche Pharmaceutical Quality Metrics

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Agenda

- Roche Pharmaceutical Quality Metric “White Paper”
- Current
- Next Steps

Roche Pharmaceutical Quality Metric Position

Pursuant to the FDA's request for recommendations...

- Roche's Quality Metric Position is intended to address two main areas
 1. **Product Quality Performance**
 2. **Site Manufacturing Quality Performance**
- Intent has been to:
 - keep it simple and objective,
 - promote the right behaviors,
 - provide potential for regulatory flexibility, and
 - align with business metric needs,
- Roche Quality Metric Position was developed with Genentech / Roche SME input, active involvement in various industry group metric workshops, and submitted to the FDA in December 2013.
- Roche remains active with industry group efforts to align and influence the developing FDA Quality Metrics Program.

Primary Recommendations to the FDA and Industry

1

Start with a smaller set of objective metrics that are most readily definable and in place for firms across the industry,

2

Establish a pilot program to evaluate the ability to gather, analyze and use the initial set of metrics, and

3

Expand over time to include more predictive leading metrics to help drive the industry to a culture of planned, predictable performance and enhancing manufacturing quality.

Proposed Initial Quality Metrics

Metric	Rationale
<p>Batch Rejection Rate (%) Definition: Number of rejected batches / total number of batches dispositioned during the period (x 100)</p>	<ul style="list-style-type: none"> • System: Production, Packaging & Labeling Indicator • Generally collected
<p>Confirmed Out of Specification Rate (%) Definition: Number of confirmed OOS results / total number of batches tested during the period (x 100)</p>	<ul style="list-style-type: none"> • Production, Laboratory System Indicator • Generally collected
<p>Critical Complaint Rate (%) Definition: Number of critical complaints / total number of complaints during the period (x 100)</p>	<ul style="list-style-type: none"> • Quality System Indicator • Strong link to product quality

Proposed Future Quality Metrics

Metric	Rationale
<p>CAPA Effectiveness Rate (%) Definition: Number of effective CAPAs / total number of CAPAs assessed for effectiveness during the period (x 100)</p>	<ul style="list-style-type: none"> • Production, Packaging & Labeling Indicator • Drive increased capability in root cause analysis
Metric	Rationale
<p>Process Capability Definition: To be developed</p>	<ul style="list-style-type: none"> • Production, Quality Indicator • Drive increased capability in product quality & process knowledge
Metric	Rationale
<p>Quality Culture Maturity Assessment Definition: Survey based index based on Roche's Engrained Quality criteria</p>	<ul style="list-style-type: none"> • Quality System Indicator • Drive appropriate behaviors and mindset

Other Metrics Being Considered...

Metric	Metric
<ul style="list-style-type: none">Lot Acceptance Rate	<ul style="list-style-type: none">Recurring Deviation Rate
<ul style="list-style-type: none">Recall Rate	<ul style="list-style-type: none">Media Fill
<ul style="list-style-type: none">Stability Failure Rate	<ul style="list-style-type: none">Environmental Monitoring
<ul style="list-style-type: none">Invalidated (Unconfirmed) OOS Rate	<ul style="list-style-type: none">APQR Adherence to Plan
<ul style="list-style-type: none">Rework / Reprocessing Rate	<ul style="list-style-type: none">Critical Investigation Rate

Questions



Doing now what patients need next