Key Performance Indicators – Quality Operation
cME (QA) and Smart-QC (QC Laboratories)

In Red Key Performance Indicators generated by cME (QA) and Smart-QC (QC)

#	Focus Area	cME - KPI Examples QA Operation	Smart-QC KPI Examples QC Operation
1	Compliance	• Investigation Open above 30 days; New vs. Closed / Closure TAT • Regulatory Commitments • Complaints • **Activities based KPI (e.g. daily audits, clearances, swabs) & Failures / observations while performing these activities.**	• OOS Rate / Investigations • OOS Closure TAT • **Stability Test On Time %**
2	Right First Time	• **Right First Time (by area / product)** • **RFT by QA tech / by Owner** • **Breakdown of documentation errors**	• Retest Rate
3	Financial & Efficiency	• Overtime Rate • **Reviewer's efficiency** • **QA Techs Earned Hr. vs. Actual Hrs.** • Budget Variance • **QA Tech Workload vs. QA Tech Availability %** • **% of Time Spent On QA VA vs. Non-QA Activities**	• Overtime Rate • **Analyst Earned Hr. vs. Actual Hrs.** • **Analyst weekly efficiency %** • Budget Variance • **Cost per sample** • **Cost per product** • **Instrument utilization**
4	Customer Service	• **Release cycle time** • Schedule Adherence • **Reviewer cycle time / Mfg./Pkg. response time for documentation errors** • Investigations / CAPA closure Turn Around Time	• **Sample turn around time / Cycle Time** • **On Time Delivery / Schedule Adherence** • **Backlog**
5	People / Training	• Cross Training • Turn-over / Hiring • Safety	• **Cross Training Score** • Turn-over / Hiring • Safety
6	New Product Introduction	• **Quality of the Batch Record**	• **Retest Rate / Turn-around time**