

5th International Summit on

GMP, GCP & Quality Control

August 12-13, 2016 Toronto, Canada

Turning the FDA quality metrics into a proactive quality improvement tool

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In July of 2015 the FDA issued draft guidance – Quality Metrics. In this guidance the FDA informed the industry that it plans to have all firms that manufacture an API or drug product for distribution and sale in the United States to submit data that the Agency will use to calculate defined quality metrics. In reality, the FDA will be requiring the firms to review the type of data that they should have been reviewing since the 1978 release of the current GMPs. The FDA indicates that they will use the data and calculated metrics to plan a risk based inspection schedule. The firms should take this opportunity to use to identify systemic problems and monitor the effectiveness of elements of the quality system. However, if the firms collect and submit the data and calculate the same quality metrics that the FDA will be calculating in the time frame discussed in the draft guidance, they will be evaluating data up to a year old and the indicators will be lagging. Pharmaceutical firms should establish programs that proactively use the data they will have to collect for the FDA, the calculated metrics, and other appropriate data as leading indicators of problems and apply the enablers of the Pharmaceutical Quality System: Quality Risk Management and Knowledge Management to support the elements of the Pharmaceutical Quality System: Process Performance and Product Quality Monitoring, Corrective Action/Preventive Action (CAPA), Change Management System, and Management Review to support their program of continuous improvement.

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Maintenance: An overlooked source of value added improvement

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One of the most overlooked opportunities for value add improvement in functionally mature operational quality systems is within the realm of maintenance. It seems that somehow, we don't particularly view maintenance as a value added best practices activity. Rather, it is often viewed as a "chore" that has to be done and documented. At best, it is viewed as a method to minimize operational downtime, but not as an activity that adds value and increases productivity and quality. Recalls and nonconformance from sterility barrier failures, foreign material contamination, incomplete bonding, sterilization aberrations, lost productivity and efficiency from process downtime, employee injury, part non-conformance, and significant remediation activity from regulatory non-compliance are all potential results of a "less-than-robust" maintenance program. Making the effort "up-front" to establish robust and validated time to failure based preventive maintenance processes rapidly pays for itself in improved regulatory compliance, less operational downtime, reduced costs of operation, improved product quality, and improved quality of work life for those using well maintained tools.

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