Utilizing Lean Sigma Methodologies to Improve Bioanalytical Workflow.

INTRODUCTION:
- Manufacturing and other business sectors have utilized Lean Sigma methodologies to apply the “scientific method” to common quality and efficiency problems.
- Celerion utilizes the “scientific method” not only in the delivery of top quality bioanalytical results, but also to improve our operational efficiency and effectiveness.
- High-level thought process utilized for this project: Define – Measure – Analyze – Improve - Control

DEFINE:
- The goal of this project was to minimize the time from the start of sample analysis to batch acceptance.
- Improving this area of the value stream would enable Celerion to better meet our customers drug development milestones and react quickly when unforeseen changes arise (Figure 1).
- Two areas of focus were identified using the customer perspective.

MEASURE:
- Cross-functional teams put together to address these focus areas.

ANALYZE (FOCUS AREA #1):
- Team used a timeline diagram to capture all potential reasons.
- Instrument capacity identified as a primary potential cause for this issue.
- Summarized data from the scheduling systems to better understand the current utilization against overall capacity.
- Data was compiled from over 250 batches and averaged out over a standard 24-hour day to visualize the instrument usage (Figure 4).
- Bulk of batches are delivered to the instrumentation team in the afternoon.
- Data does not include method development or maintenance which normally occurs on first shift.
- Based on the current state process, there was still instrument capacity in the early afternoon as well as very early in the morning.

ANALYZE (FOCUS AREA #2):
- Separate team met to address the lag from instrumentation end to baseline integration.
- Current state process involved analysts completing data integration steps.
- These most of the batches were completed on instrumentation in the middle of the night or early morning, the data would not be processed until later in the day when the analysts were available.

IMPROVE (FOCUS AREA #1):
- Pugh Concept Selection tool used to identify best solution against goals for this process step.
- The tool allowed for a consistent and objective point of view as the team moved toward solution element generation.
- Multiple proposals were ranked against weighted goals.
- Addressed the process bottleneck in the late afternoon.
- This would reduce the non-value added wait time and ensure the quick decisions could be made on data from the previous day’s batches.

IMPROVE (FOCUS AREA #2):
- The short-term solutions developed from this exercise incorporated a shift schedule with the extraction analysts and instrument operators.
- New process resulted in reducing the non-value added steps by over 50%.
- New process significantly increased the department’s production.

CONTROL:
- Solutions developed from these two focus areas worked together to streamline the entire bioanalytical workflow.
- Daily meetings alleviated as new communication tools were developed to accommodate these process improvements.
- The data was available earlier in the day so that decisions could be made immediately.
- Several Sigma methodologies within Celerion, we have been able to match our abilities to produce quality bioanalytical products to operational practices by ruthless tag team decision making steps thereby helping our customers get drugs to market sooner.

Figures 1-8 are provided as supplementary materials for the complete documentation of the project.