Utilizing Lean Sigma Methodologies to Improve Bioanalytical Workflow.

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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" now not only in the delivery of top quality bioanalytical results, but also to improve our operational efficiency and effectivity.
- High-level thought process utilized for this project: Define – Measure – Analyze – Improve - Control

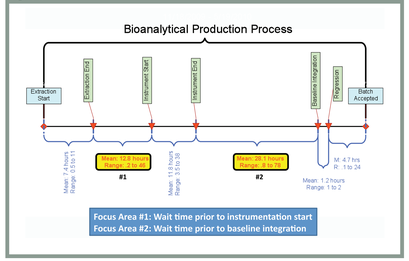
DEFINE:

- **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**
- **Cross-functional teams put together to address these focus areas**

MEASURE:

- Map created to visualize the work shifts, position capacity, and timing of various steps in the process
- Key personnel groups were plotted on this map against the batches and data steps *(Figure 2)*
- Majority of the extraction and data management work was completed on first shift while the instrumentation of batches was completed on second shift
- A bottleneck can be observed when the extracted batches are delivered to instrumentation
- Delayed timing of the data management process (i.e. baseline integration) due to the reliance on analysts to complete this task at some point in their workday

Figure 1.



ANALYZE (FOCUS AREA #1):

- **Team used a fishbone diagram to capture all potential reasons** *(Figure 3)*
- **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 time 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**

Figure 2.

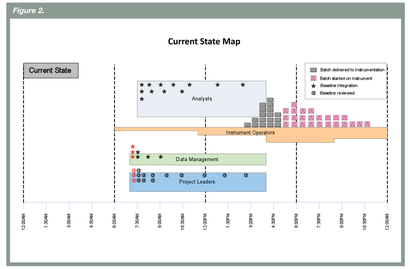
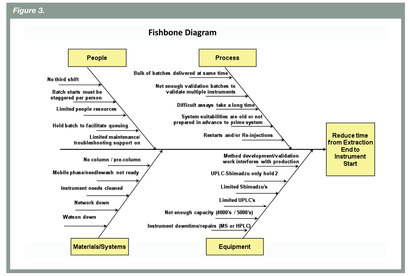


Figure 3.



ANALYZE (FOCUS AREA #2):

- **Separate team met to address the time from instrumentation end to baseline integration**
- **Current state process involved analysts completing data integration steps**
- **Since most of the batches were completed on the instruments in the middle of the night or early morning, the data would not be processed until later in the day when the analyst were available**

IMPROVE (FOCUS AREA #1):

- **Ranked the list of potential causes using a simple Cause & Effect matrix**
- **Team identified potential solutions to the highest ranked causes** *(Figure 5)*

Figure 4.

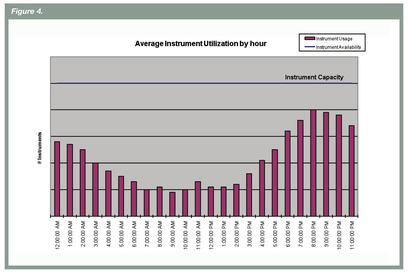
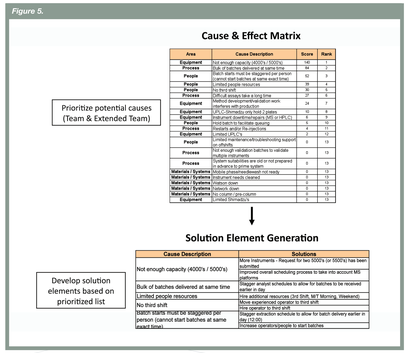


Figure 5.



- **The short-term solutions developed from this exercise incorporated a shift schedule with the extraction analysts and instrument operators**
- **Addressed the process bottleneck in the late afternoon by spreading out the delivery time of batches into instrumentation**

IMPROVE (FOCUS AREA #2):

- **Pugh Concept Selector tool used to identify best solution against goals for this process step**
- **This tool allows for a consistent and objective point of view as the team moved toward solution element generation**
- **Multiple proposals were ranked against weighted goals to determine best option** *(Figure 6)*
- **Led the team to develop a process change in which one data management employee worked an early shift to complete the baseline integration step before the rest of the department arrived**
- **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**

Figure 6.

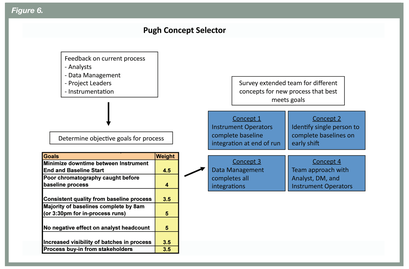
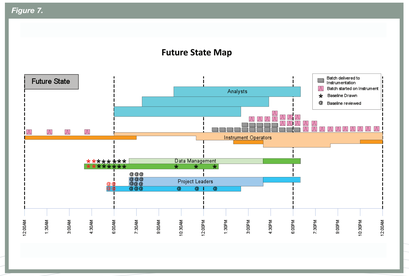


Figure 7.



CONTROL:

- **Solutions developed from these two focus areas worked together to streamline the entire bioanalytical workflow**
- **Daily meetings eliminated as new communication tools were developed to accommodate these process improvements**
- **Allowed the analysts to focus more time directly on value-added steps for our customers** *(Figure 7)*

CONCLUSIONS:

- New process resulted in reducing the non-value added steps in the process by over 50% *(Figure 8) (Figure 9)*
- Batches were able to be instrumented much quicker and the data was available earlier in the day so that decisions could be made immediately.
- By using Lean Sigma methodologies within Celerion, we have been able to match our abilities to produce quality bioanalytical products to operational practices by cutting lag time from decision making steps thereby helping our customers get drugs to market sooner

Figure 8.

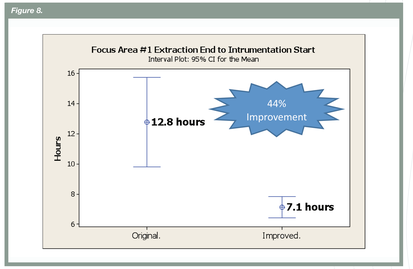
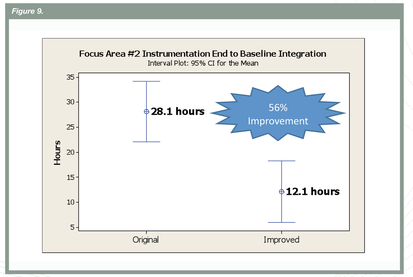


Figure 9.



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