Empower! Enable! and Control?*

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The quality control laboratories at Eli Lilly and Company's Clinton Laboratories manufacturing facility have been pursuing continuous quality inprovement since 1985, through an emphasis on customer service, measurement, leadership, teamwork, total involvement and an organized approach to problem solving. These laboratories have implemented many improvements during this time frame, including design and construction of a raw materials analysis area, reorganization of the laboratories into 'work cells', reduction of cycle time for numerous assays, improved training systems. Continous quality improvement also means continuous change. In the world of quality control continuous change is not always seen as positive, and championing quality improvement in this environment can be restrictive but not impossible.

The focus of improvement in our laboratories includes improving the work environment and the elimination of 'non-value adding' activities, not just the technical improvements usually associated with laboratory quality. Improving the work environment or changing the physical organization of the laboratory can result in improvements in technical measures, such as reduction of cycle time and reduced assay variability. Our guidelines for quality improvement activities are:

1. The activity must focus on the laboratory aim which is 'Absolute Credibility'.
2. The activity or proposed improvement may not jeopardize the current level of customer service.
3. The proposed change must be data based.
4. Any changes which affect a Good Manufacturing Practice (GMP) quality system must be implemented by using an approved change control process.

These guidelines created an environment where many of the laboratory staff became involved in solving problems and recommending countermeasures. Under these guidelines, any problem could be addressed. There were no barriers too great to be challenged. The laboratory was empowered.

The supervisory staff of the laboratory began attempting to manage the laboratory as a team and formed the Lab Management Team (LMT). In earlier days, chemists or technicians would bring problems to a supervisor, who would then paternalistically take responsibility for solving the problem (or not). The new expectations for supervision were to turn the proposal back over to the originator and challenge them with solving the problem on their own. The originators were given encouragement and were offered guidance in data based problem solving. Some of the management philosophies during this period were:

1. Shared responsiblity.
2. De-emphasizing the classical roles of supervisor, chemist and technician.
3. Management by walking around (MBWA).
4. Mistakes are valuable learning opportunities.

The LMT periodically reviewed the progress of teams and individuals who were working on improvement activities in an attempt to support and assist with the elimination of barriers. Their goal was to enable quality improvement through leadership and by 'walking the talk'. Very quickly, however, the task of supporting improvement activities and managing the routine laboratory business became overwhelming and, at best, the quality improvement activities received nothing more than 'moral support' from the LMT. In this environment only those tenacious few with very strong commitment persevered and many improvement opportunities faded. They needed more guidance than the LMT realized or that the LMT could provide.

The LMT was commited to an environment of shared responsibility, never-ending improvement, respect or people empowerment and job ownership. The team believed in its staff, who demonstrated that they are technically talented and very hard working. So what happened? The LMT needed to take into account the diversity of the laboratory staff. Some techicians openly expressed that they did not want the additional responsibility that comes with being empowered. They wanted to continue to depend on supervision for decision making. They were also being asked to take on the personal risk involved in taking responsibility for others, for making their own ideas a success, for trying something new and, finally, to challenge management. Not everyone was comfortable with taking on these responsibilities. Regardless of how hard the LMT worked at creating an environment which encouraged empowerment, they could not make empowerment risk-free.

The progress of several empowered individuals was slowed to a crawl by jealously, drained resources on high profile projects, failed recognition, the 'not invented here' syndrome and the perception by their peers of sycophancy. It was obvious that the traditional approach was not going to yield the results that the LMT was looking for.

As a result, the LMT chose to commission a new team to address a problem with unacceptable assay cycle time for a bulk drug substance and requested that they create a control system for the analysis of the product. A team leader was dedicated to this problem for several months and the measure of success for the team leader was to be the involvement of the entire staff of the laboratory where this product was assayed. The staff worked on four different shifts and consisted of approximately 25 people.

The control system consisted of a flow chart, which mapped out the steps of the laboratory process. Quality indicators for the process were identified and critical measurement points (process indicators) were established to predict the outcome of the quality indicators. As the data was collected, small problems became apparent and the team implemented countermeasures to solve them. The entire staff was included in brainstorming possible countermeasures to other problems which were then used to effect further improvements. The control system led to an 80% improvement in cycle time of all assays from an average total of 146 to 30 h. This cycle time includes a bioassay which incubates for 18 h.

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This effort came closer to total involvement than any other previously. It had a stronger sense of teamwork and created breakthrough improvement. There was much more direction given to this team and much more control present at all times. The control was not exerted by supervision, but by the control system. The control system pointed out areas of weakness and non-value adding steps. It incorporated data at every step, all of which contributed to the quality indicators so that improvements were immediately noticed in the over-all quality of the laboratory activities. The LMT's biggest mistake was that it viewed control as undesirable, old-style management. But the team was stuck in a paradigm in which control meant control people. A control system which incorporates data provides more focus and direction than is possible with supervisors acting as control people.

The role of a laboratory analyst was created and learned over many years. The early guidelines used by the LMT for quality improvement were an attempt to empower analysts to go beyond the traditional role. The LMT expanded the maximum expectation for analysts and kept these expectations simple in order to encourage participation in improvement activities. Within these guidelines 'the sky was the limit' and this was a dramatic departure from past expectation. Indeed it was so dramatic that analysts experienced a feeling of 'can I really do this?', which is riskier than a feeling of 'now I can do this!'. Control systems are a mechanism through which the minimum expectations of an analyst are expanded. The role of the analysts was no longer 'run assays' but became 'manage a control system', which incorporated all aspects of the laboratory process (sample receiving, record retention, paper flow, data verification, result reporting, as well as running assays). Control systems enabled empowerment by providing direction and enhancing analyst ownership of the entire laboratory process.

The LMT's next step was then to replicate this success throughout the quality control laboratories. Much like the development of the first control system, the replication of control systems required a process and teamwork. There were several learning points from the first team's experience. The original team required direction, training and coaching. As a result, the LMT developed a timeline to provide the team building, control system and statistical training, as well as the recognition the teams would need to flourish.

The LMT also identified all of the major systems in the laboratory and prioritized them by importance. They selected four focus areas to develop the next phase of control systems. Information was shared with all laboratory employees. Each shift provided a volunteer representative to work on a Control System Development Team (CSDT). The cross shift team members worked together with their customers to develop the control system for their area. The CSDT then proceeded to collect data to drive improvement in their areas. The original team is now working with its customers to develop a master control system in production which will drive control systems across many areas of the plant.

All of the teams are currently collecting data and implementing countermeasures to achieve improvement. Independent improvements which are not associated with a control system are still encouraged as the laboratory continues on the never-ending journey towards excellence.

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