Continuous improvement in laboratory management is a constant and universal goal for pharmaceutical companies and their suppliers. However, the daily demand of meeting production schedules and keeping instruments maintained and calibrated while assuring regulatory compliance leaves little time for improving processes. A strong, company-wide plan for continuous improvement has been the key to streamlining the quality control operation at Boehringer Ingelheim Chemicals, Inc. (BICI), located in Petersburg, Virginia. It resulted in reducing instrument downtime by 50 percent, ensuring compliance with regulatory guidelines, and shortening time-to-market to near “just-in-time” levels. There also was an unexpected benefit: the ability to apply integrated life cycle management principles for ongoing improvement.

BICI manufactures active pharmaceutical ingredients (APIs) and drug intermediates. In 2007, the QC laboratory management team set out to significantly increase productivity and reduce costs as part of a Six Sigma commitment to continuous improvement.

The following objectives were defined:
- “Let chemists be chemists” by freeing them up from performing routine instrument maintenance tasks
- Reduce instrument downtime
- Streamline the process for complying with regulations

The challenge

The Petersburg QC lab contains more than 500 instruments from multiple manufacturers, which were being serviced and maintained by an in-house service team and multiple manufacturers’ service representatives. The latter required several service contracts, creating an administrative burden as well as operational complexity. In addition, Operational Qualification (OQ) using each manufacturer’s protocol was performed for each instrument, necessitating the filing and tracking of many regulatory compliance documents. The paper-based, manual system added to delay, administrative overhead, and tedium.

After examining a number of alternatives, BICI decided to replace its traditional in-house service model with an integrated service delivery (ISD) program that addressed the organization’s needs more completely.

Choosing the right service model

In recent years, four main instrument service models have been in use depending on each lab’s requirements: in-house, service consolidator, independent service provider, and OEM. Each choice offers advantages and drawbacks, which BICI weighed carefully.

- The in-house model generally offers the fastest response time and flexibility to work around laboratory schedules, since service personnel are on site. The tradeoffs are the high cost, the administrative load, and the necessity to stay current on the newest technologies.
- Service consolidators use actuarial tables to reduce service contract spending 15 to 25 percent compared to other models. There can be tradeoffs in terms of risk, quality, and convenience, since these firms are incented to perform only the bare minimum service at the lowest cost in order to maintain their thin margins.
- Outsourcing to independent service providers is generally the lowest-cost option. The tradeoff is that these vendors tend to have competencies only in specific areas and often lack the quality control processes, parts supplies, and operational infrastructures to support larger labs in mission-critical environments like ours.
- In the OEM service model, having each instrument serviced by its manufacturer falls at the high-quality/low-risk end of the service model spectrum. However, using the OEMs typically costs more, may be administratively challenging to work with, and often results in response times of days, not hours.
Most recently, the concept of an ISD model, which is a blend of the others, has been emerging. This model typically pulls together the benefit of on-site, high-caliber resources with the administrative and operational back-office efficiencies to manage services across all of the lab's systems. After investigating our options, we decided to implement an ISD tailored to our unique QC environment.

The Laboratory Resource Management solution

Our management team worked with Agilent Technologies to design a Laboratory Resource Management (LRM) solution to address our current business requirements while providing us with the commitment to adapt to future needs. Agilent recommended an expert-level, on-site service engineer to provide same-day response to service events and flexibility in coordinating and delivering scheduled servicing around the lab’s planned and ad hoc activities. An on-site inventory of high-use parts was established to increase the likelihood of same-day repairs.

BICI used Six Sigma principles to set the parameters of the new LRM program, but found that a black belt needn’t be assigned to the project to obtain the efficiency gains. A new set of metrics was implemented and a continuous monitoring system was put in place to verify performance at a high level of detail for BICI management. If a specific incident deviates from the service target, the system facilitates root-cause analyses. Thus, BICI acquired the ability to set very tight standards and measure against them.

Increased productivity for bench chemists

BICI conducted a follow-up survey after the new system had been in place for 12 months. It revealed that the amount of time that bench chemists spent troubleshooting equipment was reduced by 22 percent for chromatography systems, 25 percent for other analytical systems such as UV/IR/AA and dissolution systems, and about 6 percent for ancillary apparatuses such as balances and pipettes. Chemists also cited increased productivity due to assistance and training from the on-site service engineer, resulting in more proficient use of the instrumentation systems and equipment. The end benefit to the bench chemists was more time to spend on the quality control of products as well as on methods development to increase the efficiency and capabilities of the lab.

Reduced instrument downtime

Reducing the amount of instrument downtime due to repair and maintenance was another key goal of this initiative. Through improved operator training and a robust maintenance program, BICI experienced a 26 percent reduction in the incidence of unscheduled downtime of chromatography equipment and a 33 percent reduction for other analytical systems attributable to the new LRM program. And the efficiency gains carried through into the scheduled maintenance events themselves, with reductions in scheduled maintenance downtime of 54 percent for chromatographic systems and 50 percent for other analytical systems. Nearly all scheduled maintenance and operational qualification activities were completed as scheduled.

Real-time troubleshooting, the expertise of the service engineer, and the immediate availability of service parts all contributed to increased instrument availability and service efficiency. When unplanned service events occurred, the Agilent solution paid big dividends: Greater than 75 percent of all repair events were resolved in the first service visit and 95 percent of all repairs were completed within two days. This translated into a 51 percent reduction in the amount of time required to repair chromatography systems and a 33 percent reduction for other analytical...
equipment. These results far exceeded our expectations and have impacted our lab chemists positively, enabling them to spend substantially more time focused on their analyses and allowing us to move closer to our goal of just-in-time inventory management.

**Improved compliance process**

At BICI, our previous compliance process comprised a myriad of OQ procedures from each manufacturer of QC lab instrumentation. Qualification was carried out manually, adding considerable delay, tedium, and overhead to the process. We were able to automate this function by adopting the Agilent Enterprise Edition Compliance system. In addition to increasing efficiency, stakeholders had higher confidence in the reporting accuracy, including regulatory audit readiness.

One of the biggest realized benefits from the new compliance solution was the substantial reduction in time spent on compliance qualification report reviews. Report review tasks that used to take up to three hours per report in the past now can be completed in less than 30 minutes each—an 80 percent reduction. Over the course of a year, approximately 200 hours of Ph.D. chemist time was saved, making this high-value talent available for what it was hired to do. Instrument downtime due to compliance testing also was reduced. Downtime due to compliance qualification was decreased by 55 percent for HPLC and GC instrumentation, 46 percent for other analytical techniques, and 17 percent for equipment such as balances and pipettes. The automated reporting system also allowed BICI management to track trends, compare performance through a library of searchable PDF reports, and provide a strong scientific basis for operational decisions. The result is compliance reporting in which we have a high level of confidence, regardless of changes in the regulatory environment.

**Cultural factors**

One key concern was how readily this major change would be accepted by our QC lab staff. People are by nature resistant to change, and this is amplified in the QC lab environment. Internal and external customers rely on the lab to provide highly reproducible QC data, using methods and procedures that rarely change. BICI was careful to involve lab personnel early in the process and engage in an open dialogue with them. There was initial resistance and skepticism when the new ISD model was introduced; however, resistance ceased to be a concern once benefits began to be realized. About half the staff reported increased familiarity with chromatographic instrumentation after implementation of the new service model and more than 40 percent noted that they spend less time on service activities.

**Laboratory administration**

The BICI QC operation was able to reduce the number of service contracts it carried by 70 percent, freeing up 280 hours per year of purchasing team time. In addition, our in-house service team now spends 67 percent less time in support of the QC function. The in-house service team also now helps identify other process improvement opportunities at the site.

**Continuous process improvement**

BICI created a business process excellence team to identify methods to improve customer-facing business performance. The team knew that productivity could be improved and, as a result of the relationship with Agilent, they have identified a number of time wasters and designed a highly effective solution. BICI chemists now have significantly more time to spend at the bench, instrument downtime has been cut as much as 50 percent, and other productivity benefits have been identified. Most importantly, the mechanism is in place to facilitate continuous process improvement to accommodate future needs.

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