

BioBenchmarkSM Biopharmaceutical Operations Benchmarking Study

QUALITY CONTROL

The Quality Control (QC) environment in all organizations is inherently complex. Each company approaches analytical testing differently, with different structures, a different number of laboratories, and a wide variety of personnel responsibilities. As a result, the design of the benchmark for the laboratories focused on the business process, or sample, perspective. The study examined how companies were structured to support product release, in-process testing, raw materials, facility monitoring, and stability, rather than capturing data for a comprehensive comparison of specific laboratories.

The study placed a particular emphasis on product testing, one of the key QC functions that impacts the ability of a company to release product in a timely manner.

OVERALL IMPRESSIONS

In general, there are significant opportunities for improvement in the industry's laboratories, according to the study results. Traditionally, the focus on laboratories has been more on the science of testing than on the manufacturing aspect of the environment. A QC testing laboratory can be viewed as a complex production line handling a large mixture of samples with differing priorities and processes. In general, there is very limited measurement of operational efficiencies and ongoing performance in biopharmaceutical laboratories. The study results indicated that most laboratories do not have very good standards for resource planning, and scheduling in multi-product environments requires a significant time commitment from analysts and supervisors.

RESULTS

Organization

One of the key challenges facing a QC group as it matures is determining the best organizational structure it should take. Small companies can be successful with only one or two laboratories providing most of the testing support (often supplemented with outsourced testing). As companies grow, the need to specialize and focus laboratory resources becomes vital to maintaining control of the testing volume.

The study results clearly reflected that most laboratories eventually arrive at a technology-based structure, with laboratory names such as microbiology, bioassay, immunoassay, and biochemistry.



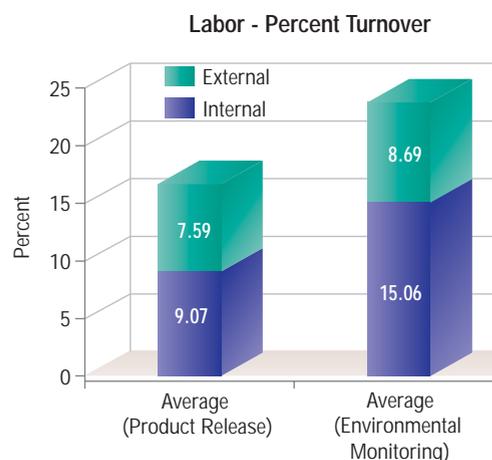
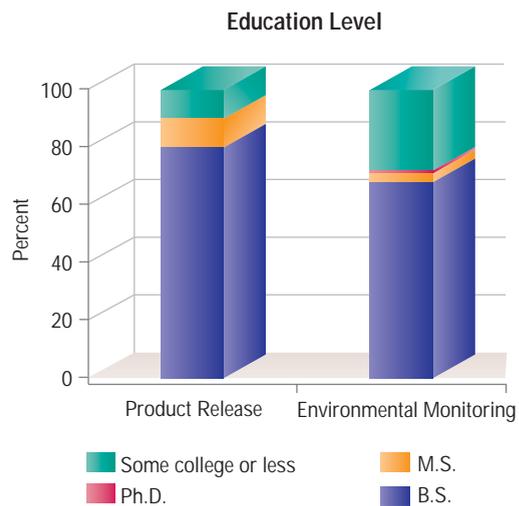
Centralizing similar testing functions to a dedicated set of analysts and equipment appears to be the best way to maximize resources (both instruments and laboratory). However, prioritization, scheduling, and sample management can become issues in this environment. For instance, since stability and product-release samples are very similar, they often compete for the same resources, and determining which sample receives priority testing can be complicated. Additionally, understanding the chain of custody and the ownership of a certain lot's testing can be difficult and frustrating for a company working to release the lot. This can result in a lack of accountability for release time, since many laboratories "own" the sample simultaneously.

The study revealed that a common QC organizational model is a hybrid structure, which is primarily technology-based with some specialization. Often times there were companies with biochemistry, microbiology, and bioassay laboratories, along with a separate raw materials or stability laboratory (to prevent the conflicts previously discussed). One structure seen in traditional pharmaceutical companies has QC, or laboratory testing, as part of the manufacturing organization.

Without exception, all biopharmaceutical companies in the study preferred their laboratories were part of the quality unit, reporting to a vice president of quality.

Staffing

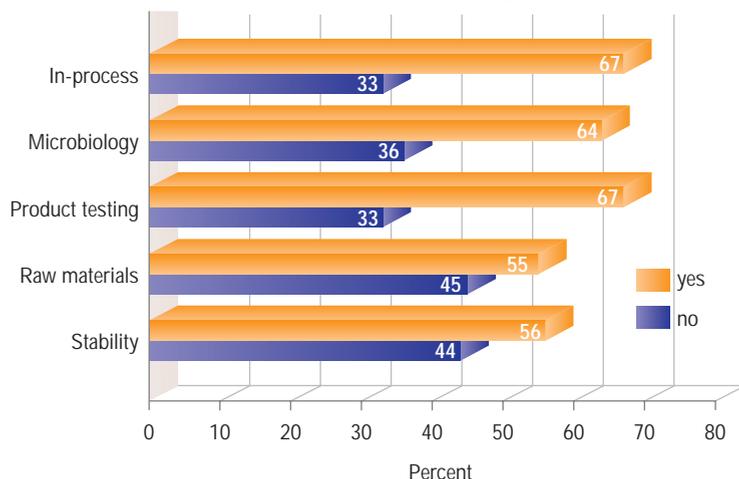
Turnover in laboratories, like most areas within biotechnology companies, is a challenge. Many companies are finding it difficult to maintain enough qualified laboratory resources to support the operation. The turnover rate for analysts supporting product release is about 17%, demonstrating the challenge of keeping a properly skilled workforce in place. Analysts supporting environmental monitoring (EM), often from the microbiology laboratory, churn at even a higher rate, al-



though many companies commented that EM feeds other laboratory operations.

The hiring trend in laboratories is not changing as in manufacturing – 90% of laboratory analysts supporting product release have bachelor degrees or higher. The opportunity in laboratories, both for retention purposes and for job satisfaction, is to follow the model practiced in manufacturing and other industries: By converting testing to a standardized, repetitive process, the need to hire highly educated individuals is reduced. This model works successfully at many reference laboratories and is a possible future model for biopharmaceuticals as well. In fact, some study participants commented that they are considering bringing lower-skilled individu-

Sample Types using LIMS



Product Sample Turnaround Times

	Average	Minimum	Maximum	(Standard Deviation Percent)
Sample cycle time (days)	29.2	17.5	45.0	(36%)
Percent retest rate (for all reasons – out of specifications, out of trend, laboratory error) (days)	11.6	2.0	20.0	(61%)

als into the laboratory, assuming they can quickly adapt to the environment.

One strategy laboratories can implement to improve the efficiency of their analysts is to increase their bench time for testing. Companies in the study average only approximately 56% analyst availability for product-related sample testing because the analysts get involved in support (cleaning, reagent prep), validation, and methods transfer activities. The best-in-class companies achieve analyst utilization of 75% and higher. They achieve this rate by establishing focused support roles for easier-to-hire, more cost-effective technicians, and offloading time-consuming tasks from the more valuable analysts. Relying on support staff to perform non-vital activities in all facets of QC is a key opportunity for most companies in this industry.

SYSTEMS

A Laboratory Information Management System (LIMS) is used by about two-thirds of the companies in the study, primarily to track product samples and facility monitoring efforts. Most companies without a LIMS currently are in the process

of evaluating and purchasing a system. Of all support IT systems for operations, LIMS is often the first to be implemented at most companies. Although the system is capable of instrument interfacing, data archival, training management, and other advanced functions, the majority of companies use it solely to manage sample status and final results.

Average product sample turnaround times vary dramatically among study participants. Product release test time is often the bottleneck for the release process – ranging between 9 days and 45 days – with most companies averaging just less than one month for testing. Since many of the participating companies test similar products for release (monoclonal antibodies), the wide range of numbers suggests they have an opportunity to revisit their current methods and decide which testing is vital for assuring product quality.

Another performance measure is retest rate. Again, the reported performance from the study participants indicates that many companies have opportunities to greatly improve their ability to test correctly the first time.