QUESTIONS OF QUALITY

The Good, The Bad, and The Ugly

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The cost of quality in chromatography can be divided into prevention, appraisal, and failure.

I am sorry to disappoint film fans looking for a discussion about Clint Eastwood's contribution to law and order through the ages, but this month's column is about the cost of quality. Quality is often thought of as dimensionless and intangible; however, it is one of the main factors that control how a chromatography laboratory is perceived by its customers. The four main areas for consideration are

- cost of analysis
- level of service
- timeliness
- quality.

Never thought of your laboratory in this way? Just analyse samples, don't we?

Imagine you want to analyse some samples: would you use a laboratory that charged the highest prices? Was not consistent delivering results? When you got the results you needed to request a large number of reanalyses? The report was not understandable? Of course you would be rather unwilling to send your samples to a laboratory with a performance record like this (if you did want to send them to such a laboratory, there is not much hope for you!). However, if you happen to work in a laboratory like this, life can be quite exciting — allegedly.

I would like to focus on quality, or more specifically, the cost of quality. For the purpose of definition, the cost of quality is simply the activities you must perform to ensure that customer requirements are met. This is a very loose definition; however, it allows this factor to be widely applicable and to cover many situations. The concept that quality costs money is explicit in this definition, and the degree depends on the customers and their requirements. In regulated industries, such as pharmaceuticals and agrochemicals, the ultimate customer is the licensing authority that provides mandatory requirements. Other companies work to a voluntary quality scheme, such as ISO 9000 or ISO Guide 25. With these, a quality scheme has a set of guidelines determined by ISO but is implemented by the company itself. In these instances, the customer is the individual or organization that receives the chromatographic services of the laboratory.

THE GOOD, THE BAD, AND THE UGLY

In the cost-conscious environment that we all work in, how can the cost of quality be controlled? This is where the title of this month's column comes in.

Prevention of failure (The Good): the cost of trying to prevent or reduce the potential for poor analysis and failures.

Appraisal of failure (The Bad): the cost of assessing the level of quality achieved through internal quality checks by levels of supervisors and managers, and external checks by quality assurance departments. This topic specifically excludes the normal quality controls that should be taken throughout an analysis as part of the standard scientific demonstration or external quality-assurance schemes, such as an inter-laboratory comparison of performance.

Failure (The Ugly): the cost of reanalysis and correcting mistakes. This has an intangible cost if the mistakes are discovered by the customer, because the credibility of the laboratory suffers and this can take a long time to restore.

The cost of quality increases as you progress from prevention, through to appraisal, and to failure. However, the implementation time is the inverse of this (i.e., it is quicker to spot a failure than to prevent one). Confused? Read on …

THE GOOD: PREVENTION OF FAILURE

The best way to avoid the cost of quality is to train chromatographers: knowledge and motivation prevent failure, increase overall quality, and cut the cost of quality. Training should use a combination of academic knowledge, acquired practical skills, on-the-job training, and specific training courses. This process will take time. Therefore, it is a relatively slow process to make prevention work well. However, it is the best approach if the cost of quality has to be contained effectively. If a "right-first-time" approach is adopted, an investment in training is essential.

Of course, when organizations want to reduce their costs, what is one of the first targets? Yes, you've guessed right — the training budget! If less money and effort are put into prevention, then appraisal and failure costs will be higher — a fact often not realized by laboratory managers or accountants. A better approach is to cut the capital budget and concentrate on ensuring the staff are effective (i.e., they are doing work to a higher quality standard). This approach to cost cutting will reduce the overall cost of quality.

Note the combination of knowledge *and* motivation presented above. Chromatographic and analytical knowledge by itself is not always sufficient. A chromatographer with good knowledge of the work he or she is performing can still make mistakes because his or her motivation is not high. This can be summarized as "can do" versus "will do." The individual above can do the task, but will not do it if he or she is not sufficiently motivated. This makes it vital that a role of the organization and management involves keeping the morale and motivation of staff high. Sometimes, in organizations that are undergoing change, this is not

always done, leading to lower-quality work and an increase in the cost of quality.

Trained staff should be backed up by a good-quality system, regardless of the quality standards that are adopted by, or enforced on, the organization. Key procedures are documented in standard operating procedures (SOPs). The prime requirements are that these procedures are easy to understand, are explicit in their information and, above all, can be read and followed. It is amazing how common it is to be given a centimetre-thick pile of paper when one asks to see an SOP. Ask yourself, would you read this and understand the contents? Unlikely. Would you refer to this to solve a minor problem? Even more unlikely. How many SOPs are there in your organization that are only read when written and when reviewed? Don't send me answers — I have a good idea!

A good SOP should be a relatively short document covering a specific task or related tasks rather than a whole operation. Instead of writing it in a typical scientific style, which tends to be passive, try an active style which is less wordy and more easily understood. Contrast these two examples:

- Withdraw 3 mL of the 0.2 M acetate buffer and transfer the contents to a tube containing the sample.
- Pipette 3 mL of the 0.2 M acetate buffer into the sample tube.

Which version do you prefer — the direct or indirect version? Imagine a whole SOP written in the indirect style...

When chromatographers are not well trained and procedures are poorly documented, laboratory management can always rely on senior staff and the quality-assurance group to spot mistakes. This leads us to appraisal schemes that determine the cost of quality.

THE BAD: APPRAISING QUALITY

After the initial chromatographic analysis, data analysis, and calculations, the draft results or even a draft report will be reviewed by one or more supervisors or managers. Furthermore, in regulated industries, in which the data will be used for submissions, a quality assurance unit will audit the report. In this instance, we have a number of layers of checking, covering the original analysis. The purpose is to detect errors in a chromatographic analysis before the report or results are declared final.

Having worked for a number of years in chromatography laboratories in various organizations, it is important for me to state that I agree that results should be checked. It is important to have one check within the laboratory to ensure the accuracy of results and see that no problems have occurred. However, with properly trained staff, multiple checks should not be necessary, but they can be difficult to eliminate (the checks, not the staff, I hasten to add). Again, the amount of checking within a laboratory can be reduced by training staff properly.

External quality checks are often the result of a regulatory decree or the requirement of an individual quality scheme, and there is little the organization can do but comply. From experience, the members of the quality unit will have a good idea of which chromatographers produce good quality work and those who do not. However, the main problem with appraisal is that there is little change in quality because there is usually little motivation to achieve better performance. The attitude can be summarized as "why bother, those above will put it right — that's what they are paid to do." However, as chromatographers have more work to do in higher productivity laboratories, or in organizations that have been down-sized or had layers of management reduced, that is exactly the task they do not perform because they assume that their staff are well trained. This leads to increased failures.

THE UGLY: REWORKING AND CORRECTING MISTAKES

Words beginning with "re" feature prominently in this section. All those little tasks you just love to do, such as reanalysis, resampling, repeating, rerunning, and recalibrating. The highest cost of quality occurs when the sample analysis fails and has to be reanalysed or reworked completely. Causes of reanalysis can come from a variety of sources, such as instrument failure (run out of solvent, air bubble in the pump), column failure (it will last one more run), or detector failure (what noisy baseline?). These are entirely preventable causes of failure which are overcome by training, knowledge, and motivation of chromatographic staff.

There are many other problems or sloppy errors that should be easily prevented — have you ever forgotten to add the internal standard to an analytical run? This is a silly error that is usually not found until the chromatographic analysis, but requires the re-extraction of the whole batch. This can cause delays in obtaining the results and can also delay other analyses, as well as reducing productivity. Hence, there is a need to reduce this type of error to a minimum and improve overall laboratory productivity and effectiveness.

To help overcome the problems that cause failure, the reasons for these problems must be analysed and understood. Staff motivation could feature in the equation when the causes of problems are analysed. Another possible area is poor planning, resulting in the laboratory becoming a chronic bottleneck because staff are always processing work when it becomes urgent, rather than working to preplanned work schedules. Training can also be an issue that may overcome high levels of rework and improve quality.

Don't forget the analytical process: We have looked at the cost of quality from the perspective of the chromatographic laboratory. However, the laboratory is not just four walls; samples have to come from outside parties — the customers. If the whole process is not considered, the cost of quality will remain relatively high. Remember from Questions of Quality columns earlier this year, sampling and decision making take place outside the chromatography laboratory (1,2). This means that at least one key element of the analytical process is often outside the laboratory's direct control, but not outside its influence. The laboratory should involve its customers in the sampling aspects and must know the customers' reporting requirements.

Automate routine tasks wherever possible: To improve efficiency within the laboratory and the laboratory's effectiveness within an organization, paper and manual operations should be reduced, or even eliminated. Given that labour costs within a laboratory can comprise up to 70% of the total budget, automating the routine, error-prone tasks can improve speed and turnaround time, as well as reduce the cost of quality.

The bottom line: If you invest in prevention of failure through training, what's in it for the laboratory? In a well-trained and organized laboratory, the failure rate should be in the order of 0–5% of the work performed. When the emphasis is on appraisal of failure through quality control or quality assurance schemes, the rate is higher, in the range of 10–30% of the work. In a badly run laboratory, with no emphasis on training or quality control, failure rates can be in the order of 40%.

From the customer's perspective, which laboratory would you choose?

REFERENCES

(1) R.D. McDowall, *LC•GC Int.* **8**(2), 89–91 (1995).
(2) R.D. McDowall, *LC•GC Int.* **8**(7), 384–385 (1995).

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