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Executive Summary

The purpose of this paper is to assist organisations and those undertaking external quality assessments of those organisations, who may be comparing the benefits of, and resources required for, internally organised and externally administered proficiency testing (PT). Specifically it considers those organisations operating outside the scope of ISO/IEC 170251 (e.g., mid-sized to large food producers with plant laboratories).

The paper will cover the purpose of PT, the inherent benefits of an external, independent PT provider, and how internally organised PT may achieve those benefits. Understanding associated costs is an important consideration in the determination of the most appropriate PT solution. Therefore, this paper will also consider resource requirements of both internal and external PT provision and how to optimise the use of each to ensure the intended value is realised.

Finally, it will examine the requirements for internally organised PT solutions from the perspective of an external quality assessor/auditor, to ensure equivalence to independently organised PT services.

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Introduction

For commercial, contract, or third-party laboratories in the food and beverage industry, appropriate accreditation is often a key requirement of doing business.

However, for laboratories within a food manufacturing organisation, for instance a plant laboratory or even a research and development laboratory, the need for accreditation and its associated quality assurance requirements is not as clearly understood.

For laboratories seeking accreditation there is a cost associated with implementing an appropriate quality assurance system, as well as the costs charged by the accreditation body. This implementation cost needs to factor in the number of quality control and assurance tools that must be utilised, such as reference materials and PT, as well as staff time.

However, routine use of these tools is in fact essential not only for accredited facilities, but for any competent laboratory undertaking testing, regardless of its accreditation status. PT programs, in particular, underpin a laboratory's entire quality assurance system, enabling performance to be evaluated against other laboratories. This comparison helps assess the accuracy of a laboratory's measurement processes and thus the reliability of their measurement results, supporting continued product safety and quality.

Food manufacturers with several laboratories may consider implementing an internal PT program themselves, or may decide to participate in PT programs managed and operated by external PT providers. A number of key questions need to be answered in order to make such a decision:

- What are the benefits of an internally run PT program compared to those of an independent external PT program, or indeed of one that is accredited?

- What are the cost implications of conductingPT programs internally compared toparticipating in an external PT program?

- What requirements need to be implemented foran internally managed PT program to provide alaboratory with the same level of confidence inthe validity of their measurement results as canbe provided by an external PT program?

- How should an internal PT program beassessed by a third party to ensure that it isbeing competently managed and organised?

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Background

A Review of Proficiency Testing (External Quality Assurance)

"A PT scheme is a system for objectively evaluating a laboratory's performance by the use of external means, and includes a regular comparison of a laboratory's measurement results with those of other laboratories."

The primary objective of participating in PT is to help assess the accuracy of the laboratory's routine testing. Food manufacturers undertake routine testing in order to make critical decisions based on their measurement results. If unreliable measurement results are produced, this can lead to poor or inappropriate decisions, potentially impacting the trade of the product, the health and safety of consumers, and the reputation of the organisation and its brands.

In order to ensure accurate measurement results by their laboratories, a Quality Manager may choose to participate in an external PT program or may endeavour to develop a program internally, solely for their own laboratory group. If the latter is selected, they may still decide to outsource the management and organisation of the specific internal program (often called a closed program) to an external and independent PT provider. Regardless of the choice made, the principles and requirements outlined in the international standard ISO/IEC 170432, should guide the program. ISO/IEC 17043 is the internationally recognised competency standard for proficiency testing providers, and is the standard used by accreditation bodies to assess PT providers. Every component of a laboratory's quality assurance system needs to meet appropriate requirements; therefore, this would equally apply to any PT program implemented, whether it is internal and private, or external and independent.

The requirements outlined by ISO/IEC 17043 are therefore critical to ensure a PT program is effective and provides reliable laboratory performance assessments; all organisations providing PT programs need to establish procedures to meet these requirements. Guidance includes test material preparation and qualification to ensure that materials are homogenous and stable, so that the challenge for each participant is comparable; any PT program should be able to demonstrate that the test materials used are of sufficient quality. Additionally, ISO/IEC 17043 includes provisions for screening for collusion, whether or not intended, and for data anomalies such as multi-modal datasets or issues with a particular method.

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What is ISO/IEC 17043?

ISO/IEC 17043 is the international competency standard for proficiency testing (PT) providers.

- It identifies minimum requirements to ensure that the provision of PT is effective, valid, and impartial;
- Both technical and management requirements are covered;
- Technical requirements include planning, test material selection, homogeneity and stability assessment, reporting, statistical assessment, and performance evaluation;
- Management requirements include management systems, document control, staff training, subcontracting and purchasing, customer service, complaints/appeals, and controlling and preventing non-conforming work.

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Operational Considerations

There are several factors to consider when deciding to establish an internal PT program or to engage with an external PT provider.

These include test material appropriateness, staff time and expertise, and most certainly cost. While the cost of participating in an external PT program can vary considerably, an internal program has a number of costs that should be quantified as well:

To be effective, a PT program must be carefully planned and documented. For each round of the PT program testmaterials must be acquired, appropriately prepared, and assessed for sufficient homogeneity and stability. This assessment requires laboratory resources and technician hours;

▪The test materials then need to be distributed to the participating laboratories, which may be within a single country or could be spread throughout the world. When the distribution includes international shipping, specialised logistics support may be required;

▪Instructions must be developed and provided to ensure all laboratories follow the same general set-up process, so that results are comparable;

▪There must be a mechanism in place for efficient and reliable reporting of results from the participating laboratories to the PT provider that prevents collusion and falsification of results;

▪The reported results must be analysed and performance evaluations undertaken according to the principles outlined in the international standard ISO 135283, and a report produced and shared with the participants. The process of analysing the data to ensure reliable performance evaluations are derived can be a time-consuming step if appropriate software is not available. Many external PT providers have the advantage of having dedicated custom software systems designed for this purpose, which can produce comprehensive reports quickly, and often provide interactive trending tools for participating laboratories;

▪Inevitably, some allowance must be made for troubleshooting anomalies in the analysis and evaluation process;

▪Finally, when an organisation chooses to implement an internal PT program to satisfy accreditation or certification requirements, they must also support the preparation and facilitation of any audit of that program by accrediting or certifying bodies.

While the cost of participating in an external PT program can vary considerably, an internal program also has a number of costs that should be quantified as well.

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The international standard ISO/IEC 17025 mandates that a laboratory should ensure the validity of its measurement results by a comparison of their results with those of other laboratories.

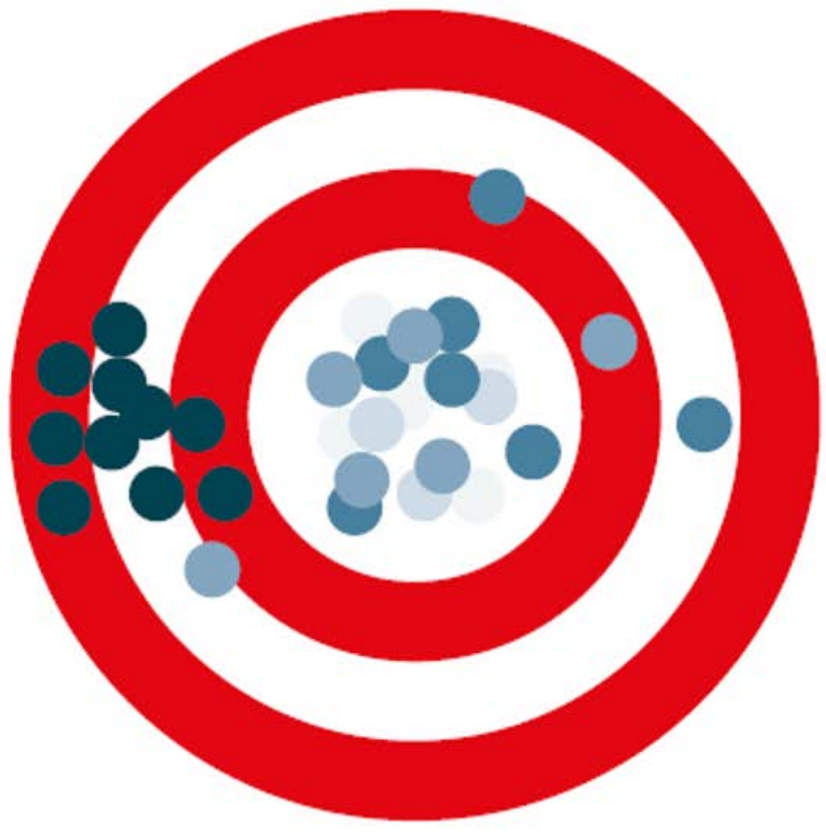
It raises the question of whether an internally organised PT program provides a sufficient independent comparison of measurement results: while such a program does provide a comparison between laboratories, these all belong to the same organisation. This can reduce variance, resulting in a comparison that inherently lacks the breadth and rigor of one that also includes measurement results from laboratories in other organisations.

Typically, an internal program, or indeed an externally organised closed PT program, includes only the measurement procedures used by the multi-site organisation which can cause Quality Managers to miss inherent biases or errors that would be revealed if measurement results were compared to a more global dataset. These similarities can restrict the scope of PT results and insight, limiting understanding of the organisation's actual performance. There is even a risk of assuming the organisation's group of laboratories performance is good, when, in fact, a more encompassing review may reveal that other laboratories or measurement methods are actually performing better.

Ideally, a PT program includes many measurement methods with a multitude of variances, so that information is generated on the relative performance of internally used procedures alongside a range of alternative approaches, including potentially newer technology. This broad perspective, typical of external PT provision, helps provide a comprehensive account of strengths and weaknesses in an organisation's measurement processes, not only ensuring accuracy, but identifying areas where new measurement methods could be beneficial.

Externally organised PT programs also provide increased assurance of confidentiality, which is an essential tenet of PT. The potential lack of "blindness" of the process within an internal PT program, from the test material composition to the participants submitted measurement results, can compromise the integrity and validity of the performance evaluation. While visibility of any of these factors cannot be assumed in an internal PT program, the arms-length position of an external PT provider guarantees this essential confidentiality in a way that is much harder to implement internally.

The arms-length position of external PT programs also minimises more subtle opportunities for bias. Identified issues have the potential to be more easily dismissed or justified in an internal PT program than when raised in external and independent PT reporting. The independence of external programs also sets boundaries on what can be adjusted in the course of an annual PT cycle; these boundaries can be harder to enforce in an internal program, when all interested parties may share goals or reporting lines.



Internal PT showing good agreement

Results compared to external labs

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Finally, many Quality Managers may not have experience running a PT program. Staff responsible for the management and organisation of external, accredited PT programs are required to have both initial and ongoing training. They also review datasets on a daily basis, building expertise and a perspective that is difficult to achieve for staff organising an internal PT program. With this seasoned view, this staff is better equipped to spot and troubleshoot issues that could impact the usefulness of performance assessments.

The individual and cumulative experience of staff at accredited external PT providers also supports the inclusion of 'non-routine' analyte challenges in their programs, including high and low analyte concentrations, different matrices, the presence of interferants, etc., in order to fully assess the performance of participants.

It is frequently outside the 'routine' that errors occur, and experienced PT providers who work more regularly outside the boundaries of everyday testing may be more adept at including these types of challenges. Internal PT programs can accomplish this as well, by considering the full spectrum of necessary test material variation in order to have increased confidence in the performance evaluations provided.

Internally designed and managed PT varies significantly in its execution, from fully accredited programs to ones that run simply as a visual audit process.

One international food and beverage company runs a well-established internal PT program accredited to ISO/IEC 17043. At the other end of the spectrum, another organisation describes their internal PT program as, "just watch[ing] the technicians perform the analysis once in a while." A third organisation runs separate regional PT programs, due to localised measurement methods and product types, and the difficulties in managing international logistics. There is clearly a marked difference in what is considered an adequate internal PT program and, without standard requirements for operation, they cannot be considered equivalent to each other, and certainly not equivalent to an external PT program accredited to ISO/IEC 17043.

An internally managed PT program certainly can be effective and may be the right choice to meet an organisation's needs. If it is the right choice, it should be executed according to the requirements of ISO/IEC 17043. There should be appropriate independence of staff organising the program within the organisation to ensure objectivity, as mandated by the standard. It is also advisable to benchmark the program's performance against an external source on a regular basis. In many cases, an organisation that wishes to have an internal PT program may determine, on assessment of the conditions for successful PT, that it is most efficient to outsource the management and organisation of their program to an external PT provider, as a closed PT program.

Closed vs. Open Proficiency Testing (PT)Programs

Many PT providers offer both open and closed PT programs.

Open PT programs are available to any laboratory who wishes to participate:

- They are designed to be more general in nature, with matrices and analytes that will appeal to a broad range of laboratories;
- They provide a global peer comparison across a wide range of methods

Closed programs are designed specifically to an organisation's desired requirements:

- They are available only to those laboratories designated by the organisation;
- They may use the organisation's own products or analytes that are specific to those products;
- The organisation can designate longer analysis times, specific measurement methods, or special approaches to evaluation;
- These can be considered internal PT programs that also have all the benefits of being managed and organised by an external PT provider.

From the Perspective of a Quality Assessor/Auditor

Shifting the focus to that of a quality assessor/ auditor examining whether an organisation is meeting requirements for PT participation through an internal PT program; what needs to be considered?

First, competency to successfully execute the program must be assessed. When an external PT provider is used, the measure of their competency is whether they are operating to the requirements of the international standard ISO/IEC 17043, and indeed whether they have been independently accredited to this standard by a national accreditation body. It follows that an internally orchestrated PT program should be held to the same standard requirements of competency. While some internal PT programs may be assessed, and subsequently accredited, to ISO/IEC 17043, the majority are assessed by other auditors (if at all, who are often not familiar with the requirements of ISO/IEC 17043 and its statistical counterpart ISO 135283).

An auditor should review evidence that demonstrates conformity to the requirements of both of these international standards. This will include ensuring that test materials are fit for purpose and that the evaluation and assessment of participant performance conforms to appropriate statistical principles. Auditors should also ensure there are documented processes in place to screen for data anomalies, collusion and falsification of measurement results reported by laboratories. Finally, they must be able to ascertain the validity of the internal PT program in the absence of external data and review.These extra reviews will add to the scope of an assessment of organisations using internal PT programs, and additional time should be allocated for the evaluation. Quality assessors or auditors will require training on the relevant international standards, and auditing checklists and protocols will need to include documentation of performance against the requirements of these standards.

While some internal PT programs may be assessed, and subsequently accredited, to ISO/IEC 17043, the majority are assessed by other auditors (if at all), who are often not familiar with the requirements of ISO/IEC 17043 and its statistical counterpart ISO 13528.

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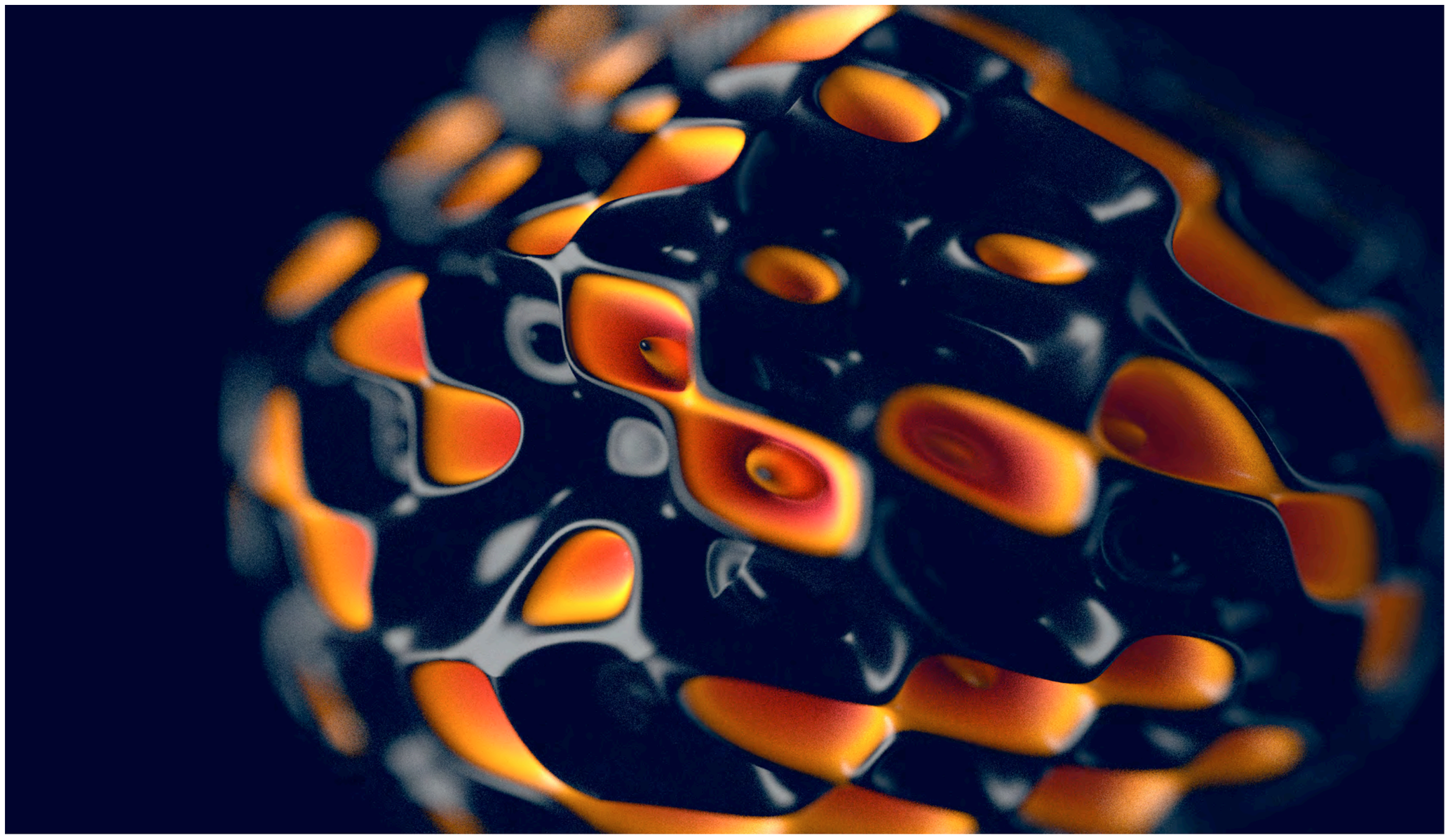
Case Study

International food & drink producer



Situation

A major international food and drink producer organised a number of internal Proficiency Testing (PT) programs for in-house and supplier laboratories. The programs were organised by three full time staff members at their headquarters, and executed with support provided by additional staff from their regional network of thirty-five laboratories around the world.

The internally organised PT programs used their own brand products for test materials, which provided items identical to those encountered in every day testing, making it robust for quality assurance and also for keeping costs contained.

Management of the programs by an internal resource of only three full time staff members presented a number of challenges. These included difficulties in distributing test materials to some regions and countries; limited IT investment in the PT management system; and no documentation produced to control and communicate the internal PT program.

Other concerns included achieving sufficient participation and, in some rare cases, laboratories discussing results.

Action

- The organisation collaborated with two external, accredited PT providers, to design replacement closed PT programs supplemented by open PTprogram participation, managed for all sites;

- Worldwide logistics now managed by the external providers;

- Data management is optimised on tailored, dedicated reporting system with continual enhancements and on-going support;

- In addition, they also continue to maintain an internal PT program, which is also accredited to ISO/IEC17043.

Outcome

- Reliable and regular test material distribution;

- Sufficient participation numbers, ensuring no round cancellations;

- Secure online result reporting, increased validity of data and reduced opportunity for collusion;

- Reduced pressure on internal resource;

- Program documentation provided as part of the PT providers' ISO/IEC 17043 accreditation ensuring clear instructions and communication.

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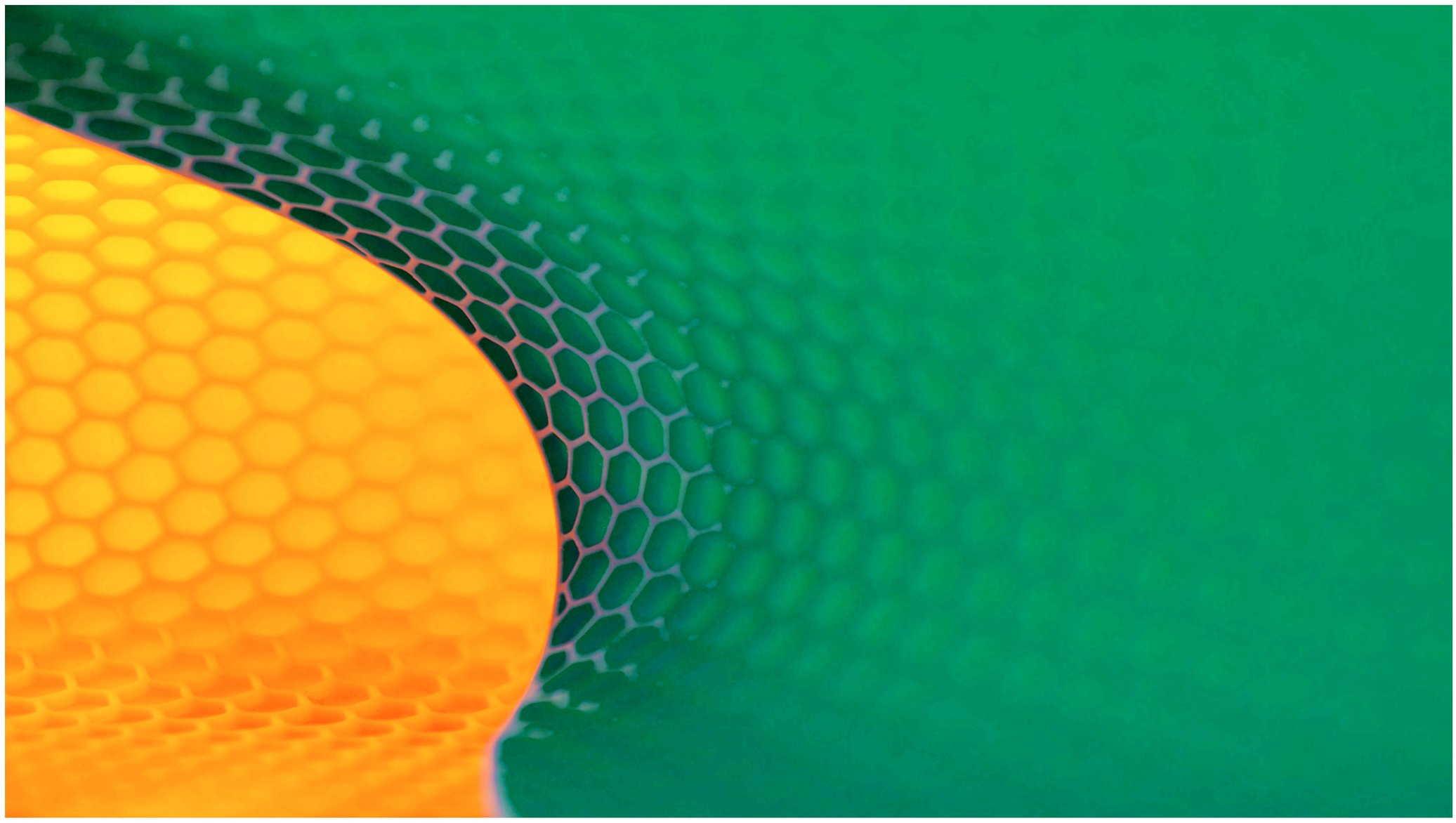
Case Study

International food producer



Situation

This high-profile international food producer previously organised a number of internal Proficiency Testing (PT) programs for all their laboratories (in-house and supplier).

Only a few of those laboratories are accredited to ISO/IEC 17025, so this feedback and oversight is all the more critical in understanding the capabilities of the laboratories and instilling confidence in their measurement results. The organisation was concerned that due to internal resource constraints in a number of departments, the internal PT program integrity was at risk.

There was also a lack of flexibility within technical operations, resulting in the same test material matrices being provided for each round and no process in place to retest if a laboratory performed poorly. Distribution challenges also meant laboratories in certain countries were unable to take part in some rounds due to logistical issues.

In addition, as IT resources were required outside the organisation's core area of competency, this meant limited support and updates for the system to enhance data management and reporting.

Program logistics, costs, and data management had become unmanageable, while comprehensive PT coverage of the business was increasingly critical.

Action

▪ Enrolled a number of laboratories in an existingexternally organised, open PT program;

▪ Worldwide logistics now managed by theaccredited, external PT provider;

▪ Data management optimised on tailored reportingsystem with continual enhancements and on-goingsupport;

▪Test material matrices are varied and additional testmaterials available for re-tests.

Objectives

▪Reliable and regular test material distribution;

▪ Secure online result reporting and increased validityof data;

▪ Reduction on internal resource pressure;

▪Increased consistency of PT results across productionnetwork with a harmonised way of working globally;

▪All costs upfront with no hidden costs for logistics andIT;

▪External stakeholder recognition due to participation ina PT program accredited to ISO/IEC 17043.

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Conclusion

The organisational decision of whether to manage a PT program internally, to outsource a customised closed PT program to an external provider, or to participate in an externally managed open PT program, has to be carefully made.

Many organisations will make this decision based on cost, but some may not accurately evaluate the true expense of planning and running an internal PT program that meets the necessary requirements to ensure that performance evaluations are fit for purpose. There are many aspects of managing a PT program, from design, production and quality control of test materials, to statistically analysing measurement results from the participating laboratories and producing appropriate performance evaluations, each of which needs to be costed appropriately.

The choice to use internally provided PT could be the more cost-effective solution for some organisations, but not for all. All cost implications must be carefully considered, taking into account both time and effort (and associated expense), to ensure the purpose of PT participation is achieved. Any PT program should also include evaluation by accrediting, certifying or other oversight bodies to ensure that it is fit for purpose. This external assessment provides assurance that the PT program, whether internal or external, is being implemented appropriately so that it provides reliable performance assessments for the laboratories participating, and that it has been designed and executed with independence and objectivity.

Organisations shouldn't use an internal program operating without independent oversight as a substitute for robust, thoughtfully organised and professionally executed program, and certification or other outside bodies shouldn't accept the two as equal.

About the Author

Heather Jordan

Heather Jordan is Director of LGC AXIO Proficiency Testing Operations, North America. She is responsible for the operations, customer service and sales of the full LGC AXIO Proficiency Testing portfolio in the USA and Canada, including proficiency testing schemes in a diverse range of analytical fields, covering the food industry, animal feeds, water, soil and contaminated land, pharmaceuticals, forensics and consumer safety.

Heather joined LGC in February 2017, following more than six years as the Director of Food Operations at the American Proficiency Institute (now part of the LGC Group). She has had a career dedicated to quality, with roles including Quality and Compliance Management and Client Relations Management, in addition to time spent as VP/Director for Quality Assurance at Priority Solutions International/Thermo Fisher Scientific.

Heather has presented on the topic of proficiency testing at IAFP and the Food Microbiology Symposium. She has also co-authored posters on various aspects of proficiency testing, which have been presented at AOAC, ASM, Eurachem and IAFP, as well as publishing a co-authored article in International Food Hygiene.

Heather brings her experience in operations management, client services and food quality assurance to LGC AXIO, to ensure that organisations are able to make effective decisions in deploying proficiency testing as a critical quality management tool.

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Throughout this paper references are made to LGC AXIO Proficiency Testing schemes. For more information and the specification of these schemes and relevant samples please visit lgcstandards.com/pt

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About us

LGC AXIO provides proficiency testing schemes with localised support across a truly global network to over 13,000 laboratories in more than 160 countries, conducting over 1,700 proficiency tests each year. At LGC AXIO we operate proficiency testing schemes across the food, beverage, environmental, clinical, pharmaceutical, consumer safety, forensic and petroleum sectors. Your laboratory will get the support it needs in demonstrating the effectiveness of your quality system through our secure web-based data reporting and analysis tool, PORTAL.

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