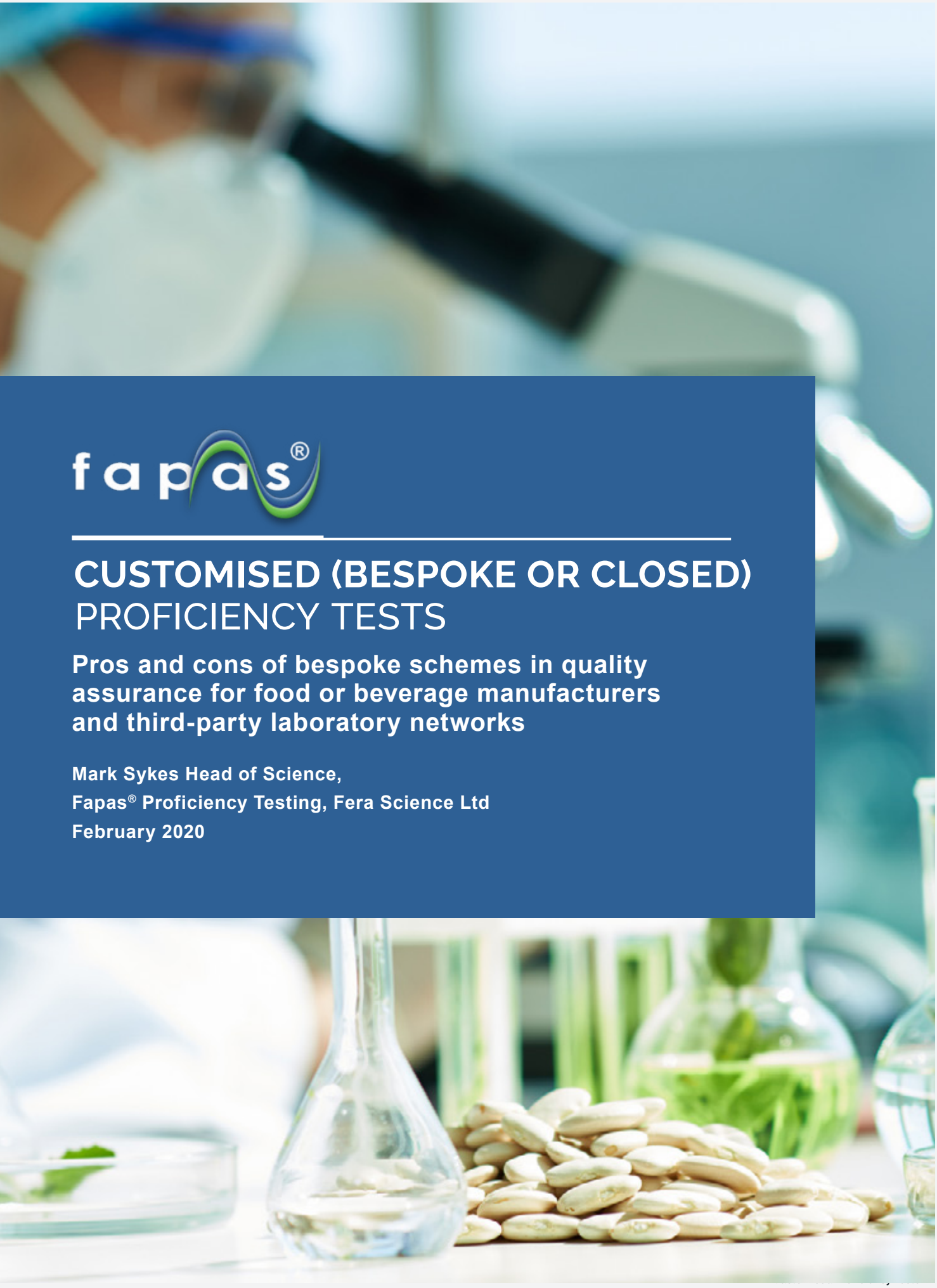

CUSTOMISED (BESPOKE OR CLOSED) PROFICIENCY TESTS

Pros and cons of bespoke schemes in quality assurance for food or beverage manufacturers and third-party laboratory networks

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February 2020

Routine, scheduled proficiency tests serve a valuable and cost-effective role in laboratory quality assurance. There are many different tests available to cover a wide variety of analyte and matrix combinations.

Sometimes, however, no scheduled proficiency test is quite right for the laboratory or company and something uniquely designed is required to address more specific questions of performance. This is where a bespoke or customised proficiency exercise needs to be commissioned.

This paper details how this may be achieved according to eight models that Fapas® has actually undertaken for key clients. The paper looks at the benefits of each model and the risks of not undertaking a bespoke test where it is needed.

Interlaboratory comparisons are a common means by which a laboratory can compare its performance to other laboratories. This is usually achieved simply and cost-effectively by taking part in a scheduled proficiency test (PT) organised by a professional PT provider. Such a PT will be efficiently managed and completely confidential. If that participating laboratory is independent, there is usually no other route by which it can make that comparison. However, the laboratory may not be independent but belong to a network of connected laboratories, under the ownership of a larger organisation.

The organisation might be national or international, or a third-party testing organisation with many varied clients. Perhaps the organisation is a food or beverage manufacturer with a global market and multiple manufacturing sites in many countries world-wide. Especially in the latter situation, the umbrella organisation needs an interlaboratory comparison that is a closer match to their products and specific analytical challenges, providing the quality manager with oversight of all their laboratories' PT results. In this situation, the organisation might plan their own PT. After all, how difficult can it be?

The answer, as many organisations find out, is "really quite difficult". If running PT was easy, professional PT providers would not be required. This paper sets out why organisations should entrust their interlaboratory trials to a professional PT provider such as Fapas®.

Open / Closed / Bespoke / Custom terminology

An 'open' PT is one that is advertised on the Fapas® website and is open to any laboratory to register.

A 'closed' PT is one that is not advertised on the Fapas® website and registration is undertaken on behalf of the organisation's laboratories by Fapas®. Additionally, a closed PT might invite laboratories not associated with the organisation to also take part to increase the statistical power of the data.

'Bespoke' and 'custom' are interchangeable terms for the purpose of this document. These terms mean that the PT is undertaken according to the client's specifications in agreement with Fapas®.

Inter-laboratory or intra-organisation?

A PT is defined as a comparison of performance between two or more laboratories; it is therefore 'inter-laboratory'. A comparison of laboratories under the ownership of a single organisation is still inter-laboratory but also within the whole organisation; it is therefore 'intra-organisation'. An intra-organisation PT will (with the express permission of the laboratories taking part) release the performance assessments to the parent organisation. This necessitates disclosure of the laboratory identities which would ordinarily remain confidential to the PT provider.

There are several models by which this can work:

1. Coordinate participation in a scheduled Fapas® PT by registering the organisation's laboratories for the specified PT. Fapas® will produce a bespoke report of the intra-organisation component. This is cost-effective and works where there are fewer laboratories under the organisation which will take part. Those laboratories are then being compared against an international population, as well as each other.

   The disadvantages are that it is the routine Fapas® material (not specific to the organisation) and has to be scheduled according to the Fapas® programme timetable.

2. Take part in a scheduled Fapas® PT (as in (1) above) but have an additional sample just for the intra-organisation part of the PT. This means that only the laboratories under the organisation will receive an additional sample which is not part of the advertised PT. This provides not only a subset of data for the organisation compared to the other laboratories taking part but also a unique subset relating just to the additional sample. The additional sample could be similar to the scheduled sample or different. This approach provides a unique level of information to the organisation, with the associated extra data, but the additional sample is dispatched at the same time, saving on shipping costs. Again, a bespoke report for the parent organisation is provided which will include assessment of the additional sample.

3 Fully bespoke test material (TM) production and PT. The organisation commissions Fapas® to manage the entire PT which is closed and involves only the laboratories belonging to the organisation. All specifications about the PT are agreed with the organisation and it is only for the organisation's purposes. Fapas® takes responsibility for co-ordinating all aspects of the PT. There is a formal contracting process and it may seem an expensive option but, typically, it is the most cost-effective way to obtain the necessary information required by the organisation.

4 Fully bespoke but the TM comes from the organisation and Fapas® runs the PT. This scenario is similar to (3) above but the commissioning organisation provides the test material (ordinarily, Fapas® would source the material). The material could be in bulk form (Fapas® would then prepare individual test samples from the bulk) or it could already be provided from the organisation in individual test sample form. The advantage is that the test material is exactly to the organisation's specification, for example taken directly off production line. This can also be combined with (3) above, so that the organisation provides their bulk standard material and Fapas® spikes with levels of certain analytes (typically contaminants) to an agreed specification.

5 Test material production only. This is a test material produced by Fapas® according to the organisation's specifications. It is characterised for homogeneity (and for stability, if requested). The test materials may then be distributed by Fapas® to the organisation's laboratories or to a single point of contact for onwards distribution by the organisation. The responsibility of Fapas® stops there – there is no PT co-ordination, no data analysis or performance assessment and no report.

6 PT co-ordination only. The organisation manages the test material production and shipping. In some cases, the organisation wants to be responsible for test material production and shipping to its laboratories. This might be used where the test material is commercially sensitive or particularly valuable. Fapas® can advise on homogeneity testing, if necessary. Otherwise, Fapas® will co-ordinate the 'soft' components of the PT such as website results submission, data analysis and reporting.

7 Taking on the co-ordination of a PT that has previously been run by the organisation. This is similar to any of the above scenarios but the organisation has a prior history of running the PT itself and simply wants another PT expert to take over its management. The reasons for this might be due to cost, loss of expertise within the organisation, or increasing size/complexity that means it's more effective to out-source the PT.

8 Non-PT interlaboratory comparison. Fapas® has also undertaken collaborative trials for method performance studies which are not PTs (but operate in a very similar way). In this situation it is sometimes easier for results submission to not use the Fapas® website interface but to return results by other mechanisms. The Fapas® website interface is much preferred but complexity of data and/or lack of familiarity by laboratories might dictate an alternative. This non-PT comparison is often the choice for complex analytes, typically where there is no established standard method, or particularly challenging matrix/analyte combinations are required.

9 A model we haven't yet thought of or we haven't been commissioned to attempt.

NB. All of the models above (except 9, of course) have actually been operated by Fapas® for various different clients. No further details are given here for reasons of client confidentiality.

Performance testing

Performance assessments in the form of a z-score will still be a part of an intra-organisation PT. However, the organisation has the opportunity to specify different limits of satisfactory performance (standard deviation for proficiency assessment) to the ones that Fapas® would ordinarily use. The default situation would be that Fapas® uses our knowledge and experience to define the performance limits unless otherwise specified. If the performance limits are not known, or there is no known precedent, then Fapas® can advise accordingly. The goal is to always agree and set performance limits which are fit-for-purpose.

Method dependency

The majority of PTs are intended to be independent of method, i.e. participants should use their own routine method. Occasionally an open PT will specify a particular method to be used, if it's important to the interpretation of results. A bespoke PT has the option to specify the exact method to be used. This typically involves corporate standard methods for which the commissioning organisation will provide the reference to the laboratories.

In some situations, part of the objective of the PT is to determine if there is any method dependency. This might involve asking laboratories to analyse the material using two or more different methods and/or to capture pertinent details of the methods being applied. Fapas® can then analyse the data according to the different method parameters and determine if there is any significant difference. In this context, 'significant' has a statistical meaning for which Fapas® can advise.

Short-term reaction and long-term trending

Something's wrong – let's fix it!

It's very tempting to react to the outcome of a single PT without fully realising the implications. Ideally, long-term trends should be monitored in a laboratory before making any judgements and this in turn requires multiple sets of data from multiple PTs. A PT has to start somewhere, however, and an extreme result (a z-score > ±3) is still a good indicator that a method or process needs investigating.

Fapas® is aware that there is a growing trend for laboratories to carry out a quality investigation if they receive a z-score of > ±2 but not > ±3. Whilst this is seen as good practice, it is not a requirement of ISO 17025 and it should be noted that the statistics employed by PT providers mean that there is a 1 in 20 probability that such a result is correct within the distribution of data. This is why these results are referred to as 'questionable'.

Long-term trending of data can be performed by the parent organisation or Fapas® can be commissioned to assist with this. Probably the most laborious part of the process is extracting the data. Since the data all reside in the Fapas® database, it's most efficient for Fapas® to download the data into a spreadsheet-compatible format that Fapas® agreed with the parent organisation for further interpretation either by Fapas® or the organisation itself.

Risk mitigation and product recalls

Proficiency testing can be regarded as an unnecessary expense – it does not generate profit for an organisation and takes some time away from profit-generating processes in the laboratory. However, laboratory analysis is undertaken for one purpose only – to provide information upon which commercial decisions will be taken. Such decisions might be to release valuable stock to market, for example, or the decision to recall stock if a breach of food safety is discovered. PT can provide the validation of the analytical results and improve confidence that the right decisions can be taken. The costs of allowing product to market which is not fit-for-purpose can result in recalls, the cost of which can be astronomical for an organisation and certainly many orders of magnitude more than the cost of PT.

In 2018, and using data gathered in 2012, the FDA estimated the cost of recalls to the food industry was around $7 billion, by taking the number of recalls involving the FDA per annum (700) and multiplying by the average direct costs of a recall ($10 million in 2012). In more recent surveys, global food companies have reported involvement in recalls costing over $100 million. This demonstrates the additional costs associated with recalls, because it is not just the recall itself that costs the organisation money; there is associated collateral costs in terms of potential fines, loss of reputation and sales, damage to brand value, and potential litigation.

www.foodsafetymagazine.com/magazine-archive1/junejuly-2018/the-costs-of-foodborne-illness-product-recalls-make-the-case-for-food-safety-investments

Post-PT service

The service that Fapas® provides does not just stop when the final report is issued. Further interpretation of data may be required or investigation into the root cause of problem areas. Fapas® has access to technical expertise covering a wide range of analytical applications that we can call on to assist with root cause analysis.

Additional R&D requirements

Bespoke test materials which are similar to the existing Fapas® portfolio will not require any development and, due to the market-leading range of Fapas® PTs, this is normally the case. Occasionally, test materials, which have different analytes or matrices or concentrations of analytes, might require some research and development time to ensure that a fit-for-purpose material can be produced. This is more likely where complex or new analytes are required, and standard methods are not readily available. This aspect will be priced and timetabled separately to the actual PT and Fapas® will advise on all aspects of the process.

Conclusion

The benefits of coordinating a group of laboratories to participating in PT are clear. The organisation can efficiently and cost-effectively monitor the analytical capability of their internal and external laboratories from a central point, saving time and money on conducting audits of the laboratories which might otherwise be necessary.

Laboratories can be compared directly, as they are testing the same PT material at the same time, and the global quality team can target resources to where they are needed based on objective performance in the PT rounds.

Whilst the headline costs can seem to be high at first glance, it is virtually nothing when compared with the direct and indirect costs associated with product recalls Perhaps the question from the board of directors should not be ‘can we afford to do a coordinated PT programme?’ to ‘can we afford NOT to do a coordinated PT programme?’

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PROFICIENCY TESTING

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Revision Date: 3 February 2021 Revision No: 01