Increase confidence with method validation and supplier accreditation

After obtaining ISO 17025 accreditation of its quality control laboratory, Yannick Bichot of Bio-Rad outlines the process, the challenges and the benefits – including an interview with two key participants.

CONSUMER DEMAND for food quality and safety take a prominent place in our society. For all players in the food chain, this translates into the implementation of systems and processes aimed at controlling risks and striving for very high quality products placed on the market.

From a microbiological point of view, the control of risk requires the establishment of acceptance or rejection criteria, involving controls using analytical methods of detection or enumeration of microorganisms. These methods, made compulsory most of the time by local or international legislation, can be described in international standards or alternative methods. The development of these alternative methods meets both the specific needs of certain sectors, such as reducing the time required to deliver results, and more general needs such as optimising analysis flows or automating laboratories.

In order to ensure that these alternative methods have equivalent performance to the reference methods, different benchmarks for method comparison have been developed, such as ISO 16140-2:2016 or AOAC validations. As part of these validations, comparison studies are conducted by independent expert laboratories within evaluation structures composed of independent technical experts. Concretely, alternative methods that are candidates for validation are characterised on the basis of a set of exhaustive technical criteria in order to demonstrate their equivalence with the reference method. The main criteria evaluated include:

- Sensitivity/specificity
- Relative limit of detection
- Inclusivity/exclusivity
- Relative trueness (for quantitative methods)
- Accuracy profile (for quantitative methods).

The reproducibility of the alternative method is also evaluated through an interlaboratory study involving several evaluation laboratories.

In addition to method validation, accreditation allows user laboratories to choose a supplier adapted to their needs. ISO 17025 accreditation is now widely adopted by food and water microbiology laboratories. More recently, the application of this standard by the quality control laboratories of culture media suppliers has become a strong recommendation of some national accreditation bodies. This ISO 17025 approach is demanding and complementary to other supplier certification systems such as ISO 13485 or ISO 9001.

In June 2020, Bio-Rad obtained ISO 17025 accreditation of its quality control laboratory from Cofrac. Louis-Marie Roque, Cofrac auditor and independent consultant, and Jean-Michel Plancq, Bio-Rad Quality Manager, explain how this approach was implemented, the challenges encountered and the benefits for customers using Bio-Rad methods in an interview (below) with Yannick Bichot, Business Unit Marketing Manager, Food Science Division, Bio-Rad Laboratories.

Q: You recently accompanied Bio-Rad in its ISO 17025 accreditation process. What was your role?

LMR: My role was to help Bio-Rad in its accreditation process according to the ISO 17 025 standard, more specifically for the technical part. The culture media preparation unit was already operating with rigor; the work consisted of resuming the processes to comply with those of ISO 17025.

Q: Can you describe how ISO 17025 applies to a method provider in water and food microbiology?

LMR: Accreditation is recognition of the competence of a body to perform the services specified in its scope (of accreditation). For a manufacturer of a method in water and food microbiology testing, it allows its customers to guarantee the conformity of the controls carried out for batch release. It is a guarantee of seriousness and competence which is validated by independent experts.

Q: Do you consider ISO 17025 as a key accreditation for a manufacturer and do you think this standard is a 'must have' for now and the coming years?

LMR: Quality control certificates issued by a manufacturer under ISO 17025 accreditation provide irrefutable proof that these controls are in conformity. In a world where customer requirements are becoming more important, being able to deliver products with quality control under accreditation is a guarantee of seriousness and confidence. Accreditation is recognised worldwide thanks to multilateral recognition agreements and will become an essential element in the future.

Q: What are the benefits for a laboratory to use an ISO 17025 accredited supplier?

LMR: Accreditation is a sign of trust. It allows a laboratory to trust its accredited subcontractor and to lighten its own internal laboratory controls. The ISO 17025 standard in its chapter 6.6 states that: 'The laboratory shall ensure that it only uses suitable products and services, when they are provided by external providers and have an influence on laboratory activities'. If the provider is not accredited, the laboratory must monitor the products and services to ensure their performance. In the case of an accredited provider, these controls can be greatly reduced. The accreditation of the service provider will allow the laboratory to take this competence into account and to consider it in its risk analysis.

Q: What was your perception of Bio-Rad as a company and more specifically the global quality management system?

LMR: The audit of Bio-Rad made it possible to realise that the level of quality requirements was already included in the structure. Admittedly, certain subtleties of the ISO 17025 standard were not considered, particularly with regard to the formalisation of the acceptance criteria for staff training, but on the whole, the rigor, traceability and a concern for continuous improvement were already present. Bio-Rad obtained its accreditation (from its first initial audit, with little deviation) for the control of culture media according to the ISO 11133 standard, which requires a very large number of skills.

Q: Why is quality so important to Bio-Rad?

JMP: Bio-Rad is a company which promotes strong customer relationships based on understanding and meeting their requirements, responding to their feedback and providing support.

Q: How is the activity of the quality control laboratory organised?

JMP: The laboratory has built its own quality system which evolves within the existing system using a large part of the existing documentation. This integrates the new requirements of the standard and the documents issued by the French Accreditation Committee.

In concrete terms, the laboratory has its own management review and internal non-conformity declaration process. The metrology, sampling and results reporting procedures have been adapted and strengthened and operating procedures (or methods) have been developed.

Q: Can you explain how this new accreditation is complementary to the other ones?

JMP: As previously mentioned, the accreditation of the laboratory is fully integrated into the existing quality system and the specificities implemented are considered as strengths and not constraints. It allows us to be more efficient as well as ISO 13485 certification and compliance with GMP.

Q: You are used to accreditations for clinical diagnostics products, the ISO 17025 was the first for food and water testing products - what were the most challenging points for this implementation?

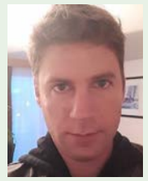
JMP: Standard 17025 has similarities with quality management standards such as 13485 and with GMP, however, some aspects were completely unknown to us. For example, the approach on the selection of methods and their validation, the rendering of results or test reports. The use of the Cofrac logo makes us proud and also responsible because our approach is part of the continuity.

Conclusion

Certification processes allow the selection of methods where performance has been characterised and which meet the international regulations in force. Accreditation of a suppliers' quality control laboratories increases confidence and facilitates the implementation of methods in user laboratories. These two approaches, which complement each other, are a solidification of competitiveness for food and water microbiology labs.

Yannick Bichot

Yannick Bichot is the Business Unit Marketing Manager, Food Science Division at Bio-Rad Laboratories in France. He spent five years in a French veterinary laboratory during the BSE crisis. Since 2005, he has been working at Bio-Rad in Food Microbiology and Veterinary Testing in different technical and marketing positions. He is a member of the AFNOR Agri-food Validation Commission and technical reviewer for NF Validation Technical Board. He is also a member of the AFNOR/V08B French standardisation commission for food microbiology test methods.



Louis-Marie Rocque

With an engineering degree in molecular biology, Louis-Marie Rocque founded an agri-food analysis laboratory specialising in research into GMOs. He has been a Cofrac assessor since 2009 within the field of water and food microbiology, molecular microbiology in GMOs, and animal health. He is also an active member of the AFNOR T90D commission (water microbiology), convenor of the ISO WG17 commission (PCR in water), and an expert within Afnor Validation. Louis-Marie has been a quality consultant for four years and is now the manager of a start-up in molecular biology.

Jean-Michel Plancq

Jean-Michel Plancq trained as a biochemist and has spent most of his career at Bio-Rad. He successively held the positions of Quality Control Manager then Production Manager before joining the Quality Assurance department in 2000. He participated in the launch of the first AIDS screening tests in 1985 and the BSE test in 2001. Jean-Michel also developed the Site System Quality System for the Steenvoorde manufacturing plant in accordance with the Medical Device Single Audit Program (MDSAP) and US GMP. He is now Quality Assurance Manager of the plant.