The Molecular Laboratory's Guide to ISO 15189

Fine tuning your quality control strategy for accreditation.

Quality controls are undoubtedly an essential part of laboratory life and play a key role in improving the quality of patient test results. But many labs still rely on in-house or in-kit quality controls out of the mistaken belief that independent controls are too costly or not worth the investment. However, this is about to change. With ISO 15189 already mandatory across laboratory disciplines, this regulatory requirement is on its way to global molecular labs in the very near future. And the requirement for auditing that comes with it will mean that a quality assurance policy is no longer just 'nice to have', but necessary.

With that in mind, molecular laboratories around the world are reconsidering the way they manage quality controls, and are now integrating independent third-party controls to their workflow. **The benefits of this are clear.** But why does ISO 15189 mean this needs to happen?

What is ISO 15189 and what does it mean for your laboratory?

ISO 15189 is a standard that signifies competent, impartial, and accurate functioning of a medical laboratory. To achieve compliance, laboratories must pass assessments under their national accreditation body, demonstrating that they meet the requirements in their discipline.

How does this affect you?

This standard is important for all areas of healthcare, promoting standardisation of practices and traceability in a highly technical field with lives at stake. More specifically, ISO 15189 can provide a helpful foundation for laboratories looking to develop their quality management system and assess their own competence. It will also be used to confirm this competence by regulating authorities, and accreditation bodies, particularly in areas where auditing has become mandatory.

Even in areas where compliance is not yet required, having ISO 15189 accreditation is an international token of quality, integrity, confidence, and aptitude, providing a distinct advantage over other laboratories that haven't yet made the leap.

Why independent controls?

Aside from minimising patient harm, reputational damage, and all the costs associated with retesting, quality assessment is a key component of achieving ISO 15189 accreditation – and that's where independent quality controls come in.

While some molecular laboratories are under the impression that in-kit controls provided with their assays suffice, accreditation agencies recommend that independent third party controls should be used in complement to monitor system performance. This is also recommended for Laboratory-Developed ("home brew") Tests.

And the UK accreditation service, UKAS say the swap is **already delivering ROI**[1] for the laboratories who've made the move, thanks to operational cost saving resulting from the newly gained improved performance.

> Laboratories producing their own "home brew" testing carry the risk of ***"contamination, inadequate equipment or failings in processes that must be rigorously managed"***[2].

What is the optimal path to ISO 15189 accreditation for molecular laboratories?

There are three factors that auditors look for when deciding which laboratories meet the standards for ISO 15189 accreditation:

- Traceability at all stages of the production process
- Proof of training and employee competence (particularly surrounding performing assays)
- Proof of the performance of the method used to conduct quality assurance

While this is simple in principle, there are many potential roadblocks that could prevent a laboratory from meeting these criteria. The main concern revolves around implementing all the stages of the quality management system across the entire laboratory. Doing this in one area of laboratory activity can be simple, but standardising processes across all operations requires a far greater amount of human and material resources, from increased metrology to the recruitment of a quality engineer.

So, how can laboratories achieve this?

There are several significant changes that some laboratories may need to make to achieve accreditation. Molecular laboratories who wish to become ISO 15189 compliant would need to:

- Establish an initial method verification file
- Prove continuous monitoring of method performance using a mixture of internal and independent quality controls
- Perform a regular review of non-conformities and demonstrate a pattern of analysing them to establish a plan of improvement
- Set up internal audits to ensure compliance

Laboratories able to demonstrate all of the above are better equipped to achieve accreditation and gain the associated benefits before ISO 15189 becomes mandatory to global molecular labs.

How Bio-Rad can help

As a market leader with over 70 years of performance providing cutting edge, reliable, innovative healthcare products, we are well equipped to help your laboratory reach its full potential, reduce the risk of patient harm, and achieve ISO 15189 accreditation.

We're proud to offer:

- Best-in-breed independent quality controls and third-party assessment of test systems
- Liquid, stable, multi-analyte liquid products that are ready to use straight from the box
- Intuitive and automated management solutions to improve laboratory efficiency
- Peer-group comparisons to boost reliability
- Outstanding customer service and technical support whenever you need it

[1] The Biomedical Scientist – 'Is your lab ready?' (https://thebiomedicalscientist.net/science/your-lab-ready)
[2] ISO – 'Medical Laboratory Testing: How can we trust the results?' (https://www.iso.org/news/ref2617.html)

Discover how Bio-Rad's innovative Quality Control offerings can give your laboratory a competitive advantage and help minimise the risk of patient harm today. Request an informal chat with a Bio-Rad specialist to discuss your options or receive a free sample.