Contract Services

Bespoke quality assurance products for in vitro diagnostic (IVD) device manufacturers
Improve regulatory compliance and quality assurance for your in-vitro diagnostic devices

All players in the field of genomic testing are required to comply with the new European Regulation on in vitro diagnostic medical devices (IVDR) which came into force in May 2022.

In vitro diagnostic IVD manufacturers have a phased full compliance window from 2025 (low-risk devices) to 2027 (high risk devices). Non-compliance with IVDR will make it highly unlikely that a manufacturer will be able to distribute their IVD device in the EU market.

EMQN CIC has exclusively developed bespoke products to help manufacturers of IVDs meet the regulatory requirements of IVDR and ensure improved quality assurance for their devices.

In Vitro Diagnostic Regulation (IVDR)

One of the major additions to the IVDR, defined in Article 78, is the requirement for the device manufacturer to undertake systematic and proactive post-market surveillance (PMS) to collect and review experience gained from the IVD device performance in real-world use.

The implementation of IVDR and CE marking of new IVD’s is expensive, and time consuming. This adds an additional cost premium to any new IVD device and evidencing PMS in a reliable, independent and cost-effective manner can be difficult. Although these regulations are not mandatory for research use only (RUO) kits, there is utility in developing quality assurance models in advance of new RUO’s being adopted in a wide range of laboratories.

An approach to PMS that is increasingly gaining traction is the participation of IVD device manufacturers in Proficiency Testing (PT) / External Quality Assessment (EQA) activities, since they allow for blinded and independent assessment of a tests’ performance on real clinical, or artificial reference, materials. The real-world performance of the assay can then be benchmarked against alternative approaches used by the other participant laboratories.

A disadvantage of this approach, primarily due to the complexity of the genomic testing process, is that most EQA schemes are only run once or twice each year. Additionally, the gold-standard for EQA schemes is to
assess the whole clinical pathway, including the analytical and clinical reporting processes.

**A new mechanism of support has been developed by EMQN CIC to allow IVD device manufacturers to routinely collect PMS information, supplementing the data from other activities including EQA scheme participation.**

For further information on the IVDR watch this webinar hosted by the European Society of Human Genetics.

**What can we do for you?**

We can support your PMS activities through the provision of bespoke quality assurance ring trial activities, designed specifically for your IVD device. These include:

- **Multiple sample distributions** per year (up to 4) to ensure regular external assessment of assay performance.

- **Bespoke artificial reference materials** (solid tissue and/plasma based matrices) containing both single or low number of pathogenic variants (up to four variants), and defined variant allele frequencies (VAF’s) used to mimic patient samples.

- **Restricted access to the ring trial for the laboratories that purchase your IVD device.**

- **Individual laboratory** feedback of the results to participating laboratories, along with a comprehensive Laboratory feedback report summarising the results containing anonymised laboratory participation data.

- **Manufacturers feedback report**, including aggregated results and data collected during the trial e.g., additional information on the methods employed by the laboratories, pre-analytical procedures and results etc. This report may also contain data detailing the performance of each participant laboratory (where the sponsor has obtained the consent of the laboratory to share this data).

- **A long term (3 year) commitment** to provision of the service for your company.
About us

EMQN CIC is a life sciences company based in Manchester, UK which supports genomics diagnostic laboratories, and IVD manufacturers and other partners, to provide accurate and reliable clinical tests.

We are a UKAS accredited proficiency testing provider (# 4367).

Contact us today

Scan the QR code to find out more.

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