# Primerdesign's quality control: The what's and why's of ISO certification

Quality is paramount to Primerdesign's success and reputation. It is critical that customers are confident in the quality and performance of our products. By promoting a culture of improvement, accountability and by maintaining certifications to ISO 13485 and ISO 9001 our aim is to use our knowledge and expertise in qPCR to provide the very best kits in all areas of need. We are proud to adhere to international certification when designing, manufacturing and supplying real-time PCR kits, reagents and PCR instruments.

**What are harmonised standards and why do we use these?**

The International Organization for Standardization (ISO) develop and publish international standards as part of a list of harmonised standards by the EU. Harmonised standards are recognised standards that have been confirmed to meet EU legislation. Harmonised standards provide defined guidelines for best practice within a company. They facilitate companies such as Primerdesign in developing reliable, stringent processes and enabling consistent quality of products, whilst keeping errors to a minimum. For example, the ISO standards that Primerdesign abide by are required to maintain certifications, which allow access to regulated markets.

**What standards are we certified to and why?**

**Primerdesign is certified to ISO13485 and ISO9001**. ISO13485 details the requirements for a quality management system specifically related to medical devices. Certification to this ISO standard demonstrates Primerdesign's ability to consistently meet customer and regulatory requirements in relation to the supply of medical devices. Primerdesign is involved in all stages of the life cycle of the medical devices including the design, development, production and storage. This allows us to be in total control of the product and make sure everything is maintained to the highest quality. Primerdesign is also certified to ISO9001. This ISO standard details the criteria for the development of a quality management system to provide products or services according to customer needs. This standard promotes Primerdesign in developing specific key areas such as a strong customer focus, continual improvement, communication, leadership and an efficient processed approach. All of which helps us to ensure customers are receiving exemplary service.

**What are the benefits of being certified?**

ISO 9001 and ISO 13485 allow Primerdesign to supply you with a vast array of products which have all been rigorously tested and validated in house, so we can ensure we are meeting all requirements. This rigorous internal evaluation of our products helps us enable you in achieving precise and reproducible results.

*Examples of how certifications are beneficial to us and to you:*

- As part of our post-market surveillance activities, the design of our genesig qPCR Detection Kits are periodically reviewed and updated to ensure they detect the most recently published sequences. We can, therefore, have the utmost certainty on the detection capabilities of all our kits.
- Limited batch to batch variation. For example, each vial of oasig Lyophilised Master Mix will be manufactured in exactly the same way according to strict, controlled procedures. This way we can ensure each batch is as good as the last. Again, enabling precise and reproducible results.
- Use of procedures that are stringent, formalised and reviewed enable Primerdesign to ensure all reagents are of the highest quality in terms of specificity, longevity and purity.

**How do we ensure that we meet the product standards day to day?**

We have a Quality Management System (QMS) in place, which is a body of regulations that provides control over the complete lifecycle of products. This covers products through conception, design, manufacturing, marketing, distribution and post-market activities. Our quality system is aimed at providing good quality products in areas of

clinical and research needs. The QMS provides us with clear statements and correct processes to follow in all aspects of our work. Using standard operating procedures (SOPs) and controlled documents provides consistent controlled steps for staff on how to complete certain tasks, which ensures that product quality is consistent.

**How do we get audited, what happens when?**

For our certifications to ISO13485 and ISO9001, we are annually reviewed by our notified body, the British Standards Institute (BSI). An audit is conducted over a number of days where the QMS is rigorously checked against the harmonised standard. Our customers also come and review our system to ensure that we can meet specified standards for specific work requirements and approve Primerdesign as a supplier of expert qPCR solutions. If you have any further questions about the quality systems we have in place at Primerdesign, please do not hesitate to **contact us**.