Making quality personal: The Thermo Fisher Scientific approach to Quality Assurance

Quality assurance (QA) doesn't stop at the doors of the QA team – it's everybody's job to make sure products are safe, efficient, and fit for purpose.

Carissa Courtney, Thermo Fisher Scientific's director of quality for the EMEA region, explains the company's QA processes, and, crucially, why they matter.

Safety: Everyone's number one concern

Quality assures compliance, and compliance assures safety – which is our number one priority at Thermo Fisher Scientific.

Our microbiology products are used to diagnose illness, guide treatment decisions, ensure food is free of dangerous pathogens, and ensure drug products are safe before they leave manufacturing facilities.

The stakes are high. We know mistakes can put lives at risk and we take this responsibility very seriously.

Global standards

To us, quality means consistency, and we do everything in our power to make sure our customers receive same high standard product of every time they order.

Like all manufacturers, we adhere to a range of different standards and regulations relating to the specific products we supply. In the UK, we work to ISO 35485 standards for our in vitro diagnostic medical devices, for example, and ISO 17025 where we manufacture prepared culture media.

In addition, we also have Medical Device Single Audit Programme (MDSAP) accreditation, which allows us to sell our products into multiple regions, including the United States, Canada, Australia, Brazil, and Japan. It means we are audited every year, to ensure we are compliant with regulations in every market we operate in.

But assuring quality means more than adhering to the rules.

Above and beyond

Our QA programmes have several branches, all with a common aim: making sure standards are met, that any issues are identified, rectified, and never repeated, and that any room for improvement is spotted and exploited.

The quality systems management teams looks at our quality manuals and documents to ensure they continually meet the legal standards, as well as the standards we apply to ourselves.

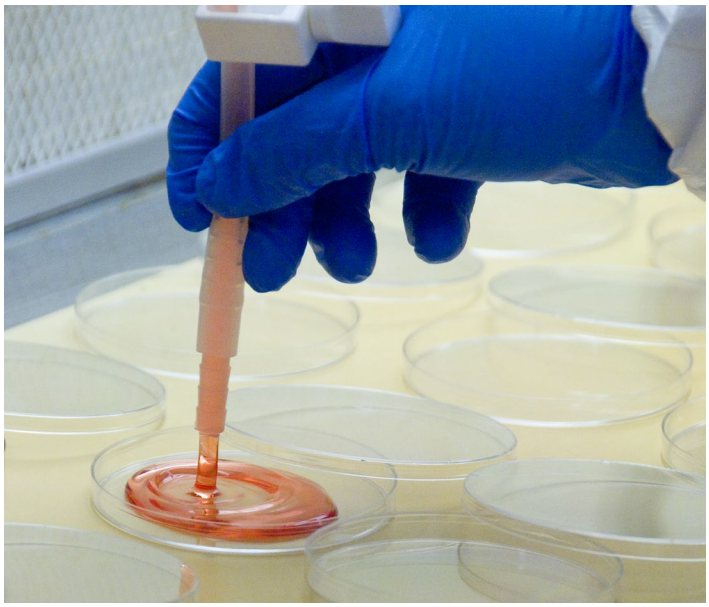
Quality engineering look at the consistency of manufacture, and, when things go wrong, they put the corrective and preventative actions (CAPAs) and processes in place to make sure it doesn't happen again.

We have a number of processes to alert us to quality issues, including internal monitoring systems which are accessible to all. When something doesn't seem right, or we identify a possible improvement, the information is fed into our QA system and risk assessed.

This might result in product or process improvements – both of which boost the quality of our offerings.

Despite all our best efforts, sometimes we will receive customer complaints, and these are assessed by the relevant team, whether that be technical or QA. A thorough investigation might result in a vigilance process, a CAPA, or, in some cases, a report to the regulatory agencies.

Whatever the outcome, every customer complaint is an opportunity to review and improve our processes.



Getting it right first time

Quality control, or putting samples of our products through their paces to make sure they perform as intended, is the "last gate" before products are sent to the customer, but when the QA processes are right, it plays a supporting, rather than a starring role.

At Thermo Fisher, we put a lot of work into making sure our products are as efficient and as safe as they can be before they are shipped, but we also know how important it is to know we can quickly identify and rectify issues if they arise.

Because to us, quality is personal.

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