

Trust and mistrust

Since time immemorial, trust has been the backbone of society. It was necessary to trust one's neighbour and the community where one lived in order to combat enemies and to survive. Soldiers in an army and players on a football team must place trust in each other to reduce the chance of defeat.

However, when nations state: "In God we trust" (US), implying that all others need to be watched, this suggests that mistrust now rules. Closed-circuit television cameras in the streets, public and private buildings are numerous; controls before money can be withdrawn from banks; controls in universities, from the police and the now numerous private security men, are becoming an increasing part of everyday life. We also see it in the pharmacy sector.

Manufacturing practice standards (Good Manufacturing Practice – GMP) were raised in the 1960s and 1970s. They were put in place as a consequence of serious tragedies. The aviation industry, which has a fine history of quality implementation, was used as the benchmark. At first, the standards were focused on quality control but were soon widened to encompass quality assessment and management. At the beginning of this century, the quality of working and environmental conditions was considered, as has been the most important issue of risk analysis. After implementation of GMP, other quality systems have followed such as good laboratory practice (GLP), good clinical trial practice (GCTP) and good pharmacy practice (GPP), in order to achieve universal standards. They are all summarised by the collective term GxP.

There is no doubt that raised standards in production facilities, equipment and documentation of basic processes has improved quality; in the case of basic processes this was particularly necessary. It became possible to see what was done and also how to work in a time-efficient way. The regulatory drug authorities adapted the improvements and published guidelines to show how improvements could be implemented. GMP was set as a framework for what should be considered. However, it is not enforceable by law and practitioners could argue that in order to meet a quality need, their procedures need to differ from GMP. It has been said for some time that "GMP is common sense in a structured way". GMP became an intellectual process to achieve better quality and safer practice.

This benefited all, including the products, management, personnel, customers and authorities. GMP should be at hand always, everywhere, but the procedure should be built into the process.

It quickly became apparent that use of GxP was a way to compete in the commercial field by using quality to promote and sell. Some companies fulfilled GMP but also adopted new procedures to benefit not only quality but also commercial interests. Soon the industry was driving the process. GMP was implemented for every conceivable incident and precautions taken. GMP was no longer common sense and it became obvious that "common sense is not so common". The drug supervision authorities followed but they do not lead the process. GMP became even more complicated. Even small ideas required not only GMP procedures but also qualification and validation, processes that take months and years to accommodate. Procedures, laboratories and controls must be certified, which was the start of a new commercial side of GMP, using a certified partner. The ideas were incorporated into all GxP and created much longer timelines for a process to undergo, as well as enormous costs.

Today, chemical analysis, which was once done routinely, must now be performed in a certified laboratory. Monitoring, which is the responsibility of the sponsor of a clinical trial, has to be done by certified monitors; even certified monitoring companies have now come into being. This makes procedures more time-consuming and increases documentation so that GMP has now been described as "a great mountain of paper". Inevitably, the costs have increased dramatically.

GMP is here to stay; it is highly valuable to all and an absolute necessity. It is the mistrust in GMP and GxP as a whole that we do not want to see. All GMP must be based on sound risk assessment and handling. Today, the cost of GxP prohibits the testing of an idea or a new therapy on individual patients. It is not even affordable to give patients special treatments for rare diseases because of costs and obstacles from GxP. This is not what is wanted or what should be told to patients.

EJHP Science urges readers to report their experience and development of quality practices.

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