What exactly is Quality Culture ?

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Previous articles (see: Quality Culture in the Pharmaceutical Industry: Benefits and Challenges) discussed the benefits and challenges of a quality culture, so what exactly is a quality culture? Siegfried Schmitt, Parexel's vice president of technology, said regulators and industry are debating the concept of a culture of quality and how to implement it.

Q Various presenters at recent conferences have mentioned the concept of 'Quality Culture,' yet we cannot find this term in the applicable regulations and guidances. Can you tell us more?

A The subject of a quality culture and how to measure its maturity has been discussed and published about for years, perhaps most notably through the cooperation of FDA with the University of St. Gallen, Switzerland. Quality is, of course, fundamental for achieving compliance with the laws and regulations governing healthcare products. Thus, companies need to have the organization, the processes, procedures, facilities, and systems in place that will assure quality of their products and services.

The argument by some is that this should include a culture of quality. The debate is still ongoing, and there is at present no agreement amongst the stakeholders (i.e., industry and regulators) about this concept; particularly how it could be measured or enforced.

That said, there are plenty of examples of how quality can be measured every day in any pharmaceutical company. The following are just some examples that show a lack of quality culture.

In a particular company, all staff are trained at least annually in good manufacturing practice, which includes good housekeeping and good documentation practice. Staff in the manufacturing area follow the instructions and the training, as do the operators in the analytical laboratories. Warehouse staff on the other hand, regularly fail to document activities (such as sampling), do not perform checks (e.g., if wooden pallets are heat treated) yet document them as being done, and place goods in aisles and corridors instead of the allocated storage locations. Why is one group behaving so differently from the others? Rumors have it that the warehouse team is resistant to change. A cultural thing? Possibly.

A manufacturing site had been manufacturing for the local market for many years without any issues with the local regulators. As part of an initiative to manufacture for a wider market, consultants were asked to perform a compliance assessment against regulations of specific overseas markets. This assessment identified a number of non-conformances and, therefore, the need to improve and upgrade the facility. The effort was estimated to cost several million US dollars. The site management team listened to the recommendations and dismissed them as being unreasonable. Their argument was that what is good for our people will be good enough for others. A question of culture? Very likely.

An international company manufactures a product in two locations. The process is the same, yet the batch records are 50 pages on one site and 500 pages on the other. Despite a global quality system and well-trained staff in either location, there is this significant difference in detail in the operating instructions. Could that be culture-driven? Potentially.

As professionals in the industry, we all assume that we know what is right when it comes to quality, but can we be as certain when it comes to culture? If it were easy, the regulators would certainly have codified this in the laws and regulations by now.

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