Poles Apart
Drug Discovery and Equipment Qualification

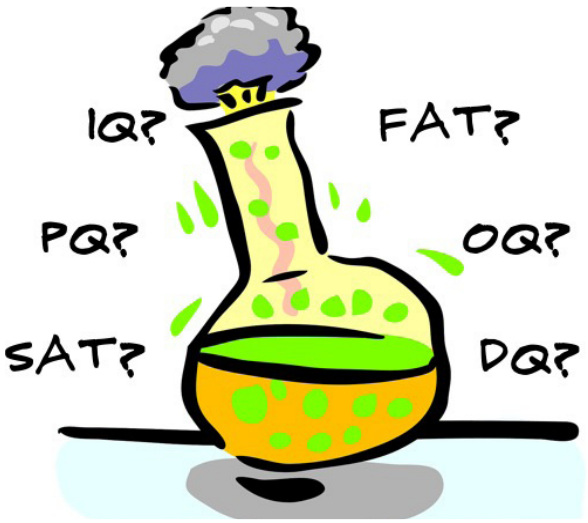
Equipment qualification is a regular occurrence in facilities operating under GMP or GLP regulations. Many drug discovery units consider the concept to be far less attractive and tend to avoid qualification activities. Two very different views on the same topic – reliability and performance of technology.

Equipment is not everlasting. It may break down completely or it may perform below required standards. In case of a complete breakdown, the reaction is identical in regulated and non-regulated facilities – call the service. As far as tracking and detecting performance deficiencies is concerned, regulated and non-regulated facilities deal with the matter differently. The former run regular qualification activities, the latter argue why this would be a waste of time.

„Equipment will not last forever.“

“Our equipment is far too complex for that!” is a frequently used argument which is a bit annoying once you think it through. Firstly, regulated equipment like an automated production line for sterile medicinal products is qualified on a regular basis and is at least as complex as the equipment mostly found in drug discovery. Secondly, drug discovery as such is one of the most complicated and complex activities. Expecting potential success in the overall process but claiming unmanageable complexity of a sub process like qualification is somewhat contradictory.

„Complexity is no excuse.“



Waste of Time

“The impact of qualification on resources would be too high!” is another rationale used in the context. This view frequently originates in uncritical and poorly reflected transfer of established quality regulations (GLP, GMP) to drug discovery units. Results are often rather absurd, for instance qualification of magnetic stirrers or filing cabinets. Any drug discovery scientist who experienced such a GxP dominance is unlikely to desire a repetition. However, this view on qualification confuses the impact of mismatched procedures with the positive effect of qualification processes as such.

Qualification processes require some planning to generate value for drug discovery units. Risk assessment is the first step. What would be the impact of equipment opera-

ting below the required standards? How high is the risk of equipment operating below required standards? How likely is the detection of equipment malfunction during routine processes? Such a systematic assessment focuses qualification activities on equipment and parameters that really matter and leaves the unimportant ones alone.

The next step is a smart definition of the qualification activities to prevent waste of resources through over engineering. “Black box qualification” is a technique that frequently allows to kill several parameter birds with one qualification stone. Hiring external qualification expertise should be considered as well.

Bottom Line

At discovery’s bottom line, important equipment may fail to operate according to required standards, potentially compromising the overall success. Due to the technology level of modern drug discovery, dangerous malfunctions will happen rather sooner than later. Establishing feasible and manageable processes to detect those and to prevent disastrous impact is possible and should be considered a necessity, not a luxury.

„Equipment Malfunction will happen.“