Wrestling with a Pig in Mud

„Arguing with a QA manager is like wrestling with a pig in mud. After a while you realise the pig enjoys it.“

So far, this unique wrestling competition has not made it to the Olympics, which is probably a pity since the discipline would make quite a splash in the Olympic wrestling arena. However, participants of QA mud wrestling belong so far to a highly selected subgroup of the Life Science Industry, consisting of the QA team in one corner and members of manufacturing or development teams in the other.

Emerging QA Focus Drug Discovery

Drug Discovery Units experiencing Attention from Corporate QAs

At least until recently, but things seem to be changing. All of a sudden, we observe an increasing number of Drug Discovery units experiencing rather unexpected and largely unwanted attention from company QA, receiving messages like “GLP standards in your labs would be a jolly good idea, don’t you think so?” Well, mostly the Drug Discovery scientists do not think so and express their opinion quite clearly and unmistakably, but QAs seem to be persistent.

What is the driving force behind this determination “to boldly go where no QA has gone before”? Well, apart from looking for new spheres of influence, the allegedly deficient quality of preclinical data, which has been discussed for a while now, might play a role. Once companies focus on Drug Discovery quality, there seems to be just a short step to the conclusion “We have quality issues, we have quality systems – let’s (mis)match both”.

Badly Matched - Established Quality Systems and Discovery

(Mis)-Matching Quality Systems and Quality Issues

Unfortunately, GLP or GMP standards do not necessarily guarantee overall quality of discovery results in terms of fitness for an intended research purpose. They generate a gap free chain of data, from the very beginning over execution till the end. They introduce rules and methodologies like written procedures, training or technical maintenance which will have a positive impact on data quality. They set up a rigid frame work to control operations. But from a discovery point of view, they are not the perfect quality tool.

To begin with, GMP and to some degree GLP are designed for routine processes and this origin is clearly observable. The GMP typical amount of process related documents and forms is manageable for processes running again and again for years but appears completely impractical from the perspective of a fast moving discovery process. Time consuming equipment qualification, running through extensive design, installation, operational and performance phases with the occasional FAT and SAT in between is fine for manufacturing equipment used for a decade but a nightmare waiting to happen for discovery labs simply trying to purchase a new centrifuge.

GxPs Designed for Routine Processes

Next problem is the expectation built into GxPs that processes will strictly run along a pre-defined path. This shows quite clearly in technical terms like “Study Plan” for GLP or “Out of Specification” for GMP. Unfortunately, once GxP controlled processes leave their pre-defined path, complicated and time consuming activities enter the game, like deviation management, amendments or CAPA, to name just a few. Since finding the unplanned and unspecified is a usual occurrence in Drug Discovery (one might state the unexpected is what research is about), discovery pushes the GxPs quite often into uncharted waters, where the lack of charts is compensated by time consuming “correction” procedures and an additional helping of forms to fill.

GxPs Expect Processes to Follow a Pre-defined Path

Motivation from the benefit or added value which could be gained from quality activities is another factor to keep in mind. One important benefit generated by GxP compliance is acceptance – data, results, reports or products pass the review of government bodies without any issue. Consequently, the rational driving GxP systems is frequently “We have to because the regulations/regulators require it.” Unfortunately, this kind of benefit does not motivate Drug Discovery at all. Therefore, discovery scientists frequently experience GxP driven quality activities as an added workload without any value for those working on it. Quite a pity, because to the right mind-set (which is not the regulators-require-it mind-set), quality activities offer a multitude of opportunities to generate benefit and added value for Drug Discovery.

In general, imposing existing quality systems on Drug Discovery is not a smart move. The GxPs and the specific quality requirements of Drug Discovery fit like a foot and a glove – not very well. On the other hand, the significance of quality in drug discovery is hardly debatable, so simply riding out the storm is not a viable option. We always counsel Drug Discovery units to take the bull by the horns, to enter the driver seat of quality processes. Smart and discovery specific application of existing tools like process mapping, risk analysis, risk management or user requirement analysis paves the ground towards a quality system that delivers substantial benefits and added value. Existing quality systems should be considered as a reservoir of ideas and concepts, which may work in discovery as well, provided they are adapted smartly. And QAs can indeed support with their expertise and experience, provided their willingness to deep-dive into science as well.

Discovery Units Need to Take an Active Role in Establishing Quality Systems

And as far as the mud wrestling competition with QA is concerned, some sort of team sport might be a better picture. Maybe American football – mud plays a major role as well and the image of tackling together quality topics in Drug Discovery might create the right team spirit.