Case study - Extending the Quality System

In the past, pharmaceutical companies have been using medical devices to deliver their drugs in either single-entity combination products or procedure packs. After a major ruling by the FDA, pharmaceutical companies have been made aware of the regulations impacting the device constituent part. Therefore, the Pharmaceutical Quality Systems had to be updated accordingly.

The task

The client assigned the team of Avanti Europe with the overall project lead for the update of the existing Pharmaceutical Quality System to implement the relevant parts of the Medical Device Directive.

The case

Having Avanti Europe assigned to the task, the team started with a assessment of the existing Pharmaceutical Quality System (PQS) and mapped the interfaces out. The interfaces had to be connected to the Medical Device Directive for which a project estimate was created. As the project leader from Avanti Europe was aware of the upcoming changes in the directive, i.e. the update to the Medical Device Regulation 2017/745, the project estimate included the advice to update and align to the MDR. The time line given by the client was aggressive and undiscussable as a Health Authority audit was already scheduled.

The project plan was discussed with the client and agreed upon the different milestones. In parallel, an initial training of the impacted staff was planned, organized and conducted to manage the expectations and prepare the change in understanding of combination products. This initial introduction to combination products and the medical device understanding raised eyebrows at the staff as they understood the medical device constituent part as functional packaging, so far. The sheer myriad of regulations for the "functional packaging" led to a lot of questions and unfortunately only a few early adopters.

The PQS extension progressed and the first new SOPs had been subject to training. Again, the staff was called to the training facility and, on the basis of the initial training, led through the regulations and the newly created SOPs. Needless to say, that the initial few SOPs raised a lot of questions before the jigsaw of SOPs showed the bigger and broader picture of combination products as used by the company.

The main focus was set on development of the medical device constituent part being interwoven with the pharmaceutical development, the updated risk management procedure and the newly created usability SOP. The latter especially led to many discussions and explanatory lecture-like trainings to make this "new aspect" to the pharmaceutical staff clear. Confused and confounded with clinical trials and patient training in the beginning, it became through continuous training and explanations along to the new product development

project within that company apparent to the staff. Usability engineering was a new animal in the zoo of development tools and very important for home-use drugs (other than following the oral route).

Apart from the new or updated tools used during product development, the vigilance process had to be updated as well with major impact on the process. In fact, a totally new process had to be created to include triage and analysis of device constituent part related feedback to render it compliant to the regulations. Again, this involved training and Q&A-sessions to manage the change.

The very skilled project team and an excellent stakeholder management led to the point that the management of expectations and the change was successful. From that handful of early adopters, the team could win the interest of the entire involved staff on the importance and procedures for combination products. In fact, the team even had quest speakers from the senior management involved in the training sessions to make the point clear in its importance.

Thanks to the skilled team and the excellent communication with the staff, the audit passed with recommendations, but no findings.

The learning

1. This case study shows very impressively that the most fundamental factor of success is an experienced team with the ability to understand the situation fast and empower with empathy the project team and the client.

2. Very stringent management of stakeholders, expectations and training led to the success of the project. The concurrent development of a combination product enriched and boosted the learning of the new topics and processes.

3. Passion for the topic and understanding of a heterogenous team led to the success of the client's project. The entire team, whether internal or external collaborators identified themselves with the project and acknowledged and respected each other as experts in their individual fields.

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…reaching far beyond conventional consultancy as we are supporting companies with "hands-on" expertise. Our experts provide tailored service in order that along to the product, the know-how is delivered as well. We call it the "end-to-end" approach which delivers superior service quality also as experts in Quality Assurance and Regulatory Affairs.