Case study - The mission impossible made possible

Avanti Europe was assigned with the lead and end-to-end development of a novel, connected drug delivery system for a new drug entity. The drug product had just started to being used in a phase I clinical trial with an utterly aggressive time line.

The task

The client assigned the team of Avanti Europe with the overall project lead for the device constituent part as well as the Quality Engineering, Quality Assurance, Development and Human Factors Engineering tasks.

The case

Prior having the novel drug entity in the phase I clinical trial, the company evaluated different existing drug delivery systems readily available on the market, but it seemed that none of these was capable of delivering the drug in the defined formulation and in the specified time. Further, it was clinically relevant to gather information on the use of the device as well as transmit data to a local emergency team. With the onboarding of the Avanti Europe development team, an initial analysis of the status quo was made and the internal team briefed. Training of the client initiated immediately to bring the client and project team to the same understanding and knowledge basis. As a result of the analysis and training, the Pharma Quality System had to be extended to implement the device constituent aspects and render the PQS compliant to 21 CFR 4 as well as EU MDR regulations.

In fact, the time line given by the client was so aggressive that the PQS extension was established concurrent to the development and with a little head start, just enough to release the SOPs prior starting the defined development step. As the demanded development time line was so stringent, only a very experienced team could have managed to bring the initial vague specification of the drug product to a functional drug delivery prototype within 9 months of development work. Starting from a draft Quality Target Product Profile, not only the PQS extension had to be established, implemented and trained, but also the entire device constituent part development had to be brought to the prototype level for meeting the next milestone. The milestone for the prototyping was reach on time and verified by audit without any finding.

From the functional prototype meeting the key functions and characteristics, the design was refined to meet user acceptance, safety and effectiveness. As the development of the drug delivery devices was done concurrent to the drug development, close collaboration and superior communication was mandatory. To balance the uncertainty from the drug development but also from the device development, a risk-based approach and risk-aware development was crucial.

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Even though there were a plan B and C in place, the reality of the formulation change at the very late stage of device development struck the team hard. Drawings, specifications, designs and simulations had to be updated based on the new formulation impacting the viscosity of the drug product and thus, affecting the drug delivery time, forces, frictions and many more. Whatsoever, the risk-awareness and preparedness of the entire project team made it possible to update all of the impacted properties and deliver a verified and risk-mitigated device for phase II clinical trial.

During the phase II clinical trial, the device development team worked on setting up the infrastructure for connecting the device to a secured cloud and negotiating with suppliers on quality and supply agreements. Software programming for retrieving anonymized data for emergency alerting and product vigilance was carried out and concluded with software validation.

The entire development, from initial assessment based on draft QTPP and market research on potential drug delivery devices was concluded on time to meet the deadline of having a verified and validated drug delivery device ready for phase III clinical trial. The entire timeline was set by the company to 2.5 years, and the team concluded the task successfully and on time in 3 years, thanks to a delay in the phase II clinical trial.

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 and risk-aware development with no shortcuts and many plan B's and C's paid it out in the end, even though the major change in the formulation happened at a very late stage. Thanks to the prepared "disaster recovery plan" of the development team, the risk hit hard, but didn't endanger the project at its fundamentals

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 product and acknowledged and respected each other as experts in their individual fields. Apart from all this, the team fused to an organism itself, helping each other out in cases of work overload and restrictions. Neither was the project leader too good to help with logistics nor was the development engineer in supporting human factors test organization.

Avanti Europe is…

…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 a design engineering house.

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