New Concept for Equipment Qualification and Process Validation at Medicoat

Degree programme: MAS Medical Technology

Complex equipment and processes like vacuum plasma spraying (VPS) of orthopaedic implants need tailored qualification and validation (Q&V) methods to optimize the use of the company's resources.

Medicoat AG is a Swiss company acting in the coating of orthopaedic implants with titanium and hydroxyapatite, the contracted manufacturing of implants and the production of hydroxyapatite powders. In its three subsidiaries, one in Switzerland and two in France, the company coats several implants of different manufactures. All these processes and the necessary equipment require a considerable qualification and validation (Q&V) effort. Since they have different activities and backgrounds, its three subsidiaries currently have different approaches regarding Q&V methods. This sometimes represents difficulties for the synergy between the subsidiaries and demands additional and sometimes unnecessary work. The objective of this thesis is to develop a concept that will unify the methods for qualification and validation and explain this in one single critical path.

The first step to realize this concept is to analyse from which stakeholders the inputs for a concept should come. Once this is done, a literature search will tell what exactly the requirements are and what the guidelines actually say about qualification and validation. Inputs from employees and an analysis of the current methods and quality systems of all subsidiaries will clarify the situation in the company and the weak spots. After that, a validation review will be used to analyse the situation from the customer's point of view. Finally, a seminar about process validation in the medical devices industry will offer the opportunity to analyse the requirements for this process from the point of view of a notified body. These inputs will then be enough to summarize the weak spots using a gap analysis. A new concept can then be sketched using a workflow and detailed in the form of master documents, process instructions and templates. Feedback and acceptance of this new concept will be accessed during conversations and interviews with the strategic stakeholders. At the end, a brief simulation of how long a qualification and validation process would take with the new concept will be performed for different projects using a project plan. The expectation is that the feedback from the stakeholders will be positive and future Q&V projects could be concluded within a maximum of six months.

The results show that the regulations and guidelines do not define how qualification and validation must be performed. They rather determine that the process must exist and be properly documented. This tendency can also be observed when consulting with the notified body. It was observed that the company has no significant non-conformance regarding QV, but has improvements to make regarding its documentation and especially integration between the subsidiaries. A workflow for the new concept has shown that it is possible to separate machine from process and to have, respectively, a separation between qualification and validation. Besides the workflow, the new concept was presented in the form of a process instruction containing the critical path for QV and making reference to created templates and process documents which are crucial for the understanding of this thesis. The feedback from the employees was positive and all qualification and validation simulated projects presented a planning below six months' duration. Qualification and validation is a wide subject and can be interpreted in different ways. It is, however, very important that the key elements and persons within a company are oriented in the same direction. There is more than one correct way of performing validation. However, there are ways more suited depending on the process and the available resources. Defining the most important and obligatory items and leaving the details up to the judgement of the project leader presented itself here as the solution to increase compliance, maintain flexibility and improve the synergy between the subsidiaries. The implementation of this concept could save a lot of resources for Medicoat.

Thomas Spring