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Editorial

Quality by Design: An Interface between Effort and Success

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While designing a formulation the major concern of a formulator is to achieve the best degree of quality in the final product. Before FDA launched Current Good Manufacturing Practices, the quality of a product was only defined using the quality control tests or more specifically Quality by Test (QbT). In case of pharmaceuticals, the product is defined on the basis of its quality. So, the quality of pharmaceutical product should be determined by a more effective and a comparably easy method. For this, FDA generalized the concept of Quality by Design (QbD), which was based on the conceptual understanding of how the attributes of a production process or the attributes of the material used in the specific process affecting the quality of the end product that is the final required product. The application of Quality by Design (QbD) in pharmaceutical drug development loop is now a thrust area for the regulatory authorities as well as the industry views.

It is better to design a process that ensures the quality of the product then formulating, optimizing and testing the product which tends to deterioration of the raw materials as well as wastage of time. This is where the QbD finds its role and importance. QbD is a holistic, scientific and a risk based approach which defines the range of working parameters for a unit operation along with continuous monitoring of the process parameters and establish a relation between the input and output parameters which in order yields a quality product. ICH Q8 defines QbD as "a systematic approach to development that begins with pre-defined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management, which is in accordance with FDA's current drug quality system ideology of quality cannot be tested into products; it should be built-in or should be by design".

The approach of QbD comes into function by four basic elements that are QTPP (Quality Target Product Profile), CQA (Critical Quality Attributes), CMA (Critical Material Attributes) and CPP (Critical Process Parameters). During a quality by design process the determination of CQAs and CMAs is important which govern the process design and process understanding. The CMAs are for the input materials such as the drug itself, excipients and the in process materials whereas the CQAs are for the output materials.

The implementation of the QbD in a pharmaceutical process needs good understanding of the process as well as the target product. The desired performance attributes of the product are defined and QTTP is established. The critical factors or process and materialistic properties are identified that is the CQAs. The possible CMAs and CPPs are identified. Once the elements are identified a DoE (Deign of Experiment) is established. A DoE is a structured, organized method to establish relationship between the factors affecting the process and its output. The DoE links and establishes relations between the CMAs, CPPs to CQAs and provides the information required for the execution of the process. Afterwards a process Design Space should be defined, leading to an end product with desired QTPP. ICH Q8 defines the Design Space as "the multidimensional combination and interaction of input variables (e.g. material attributes) and process parameters that have been demonstrated to provide assurance of quality". If the changes of the factors are made within the design space then it is reported that there is no need to handover the supplements to revise the acceptance criteria to FDA.

To keep the process under stabilized conditions there is a need to continually monitor the process affecting factors and process itself. To ensure continuity and quality maintenance various tools are employed in the process of QbD which are DoE, Risk Assessment and PAT (Process Analytical Technology) which use real time measurements or rapid measurements to ensure that the quality governing factors stay in the underlying limits. The PAT functions by designing, analyzing and controlling all the factors that either directly affect the process or influence other factors that govern the quality of the end product. Hence, when all these technologies and approaches are used in co-ordination they lead to a process design that is already calibrated to manufacture quality products and therefore the name "Quality by Design".

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