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Applications of quality by design (QbD) and its tools in drug delivery

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Quality by Test (QbT) was the only way to guarantee the quality of drug products before FDA launches current Good Manufacturing Practice (cGMP) [1], which is an approach without clear understanding of the processes. In order to solve this problem, FDA generalized Quality by Design (QbD) in the field of pharmacy [2]. In pharmaceutical industry, QbD brings cost-efficiency and simplicity of manufacturing process into reality. Several tools are utilized to make QbD system easily applied to pharmaceutical field, namely design of experiment (DoE), risk assessment and process analytical technology (PAT). QbD is based on the thorough understanding of how materials and process parameters affect the profile of final products. The following parameters are defined to describe those characteristics: Quality target product profile (QTPP); critical quality attributes (CQAs); critical material attributes (CMAs) and critical process parameters (CPPs) [3].

The applications of DoE and PAT in pharmaceutical field are discussed in detail in this review. DoE combines parameters such as CPPs, CMAs and CQAs into QbD system, which is a reasonable method to determine the relationship between the input and output of a process. In addition, full factorial design, Plackett–Burman (PB) screening design, fractional factorial statistical design, central composite–face centered–response surface design and Box–Behnken design can be used to establish a design space (DS) for a given process to guarantee the quality of final products. In addition to DoE, PAT is also an important tool of QbD; by obtaining technological and material parameters online, it plays a role in real-time monitoring of pharmaceutical process without interruption. In order to achieve successful PAT implementation, there are three-step-process (namely design, analyze and control) and four PAT tools in the design and optimization of drug formulations and manufacturing process; the four PAT tools are as follows: (1) multivariate tools for design, data acquisition and analysis; (2) process analyzers; (3) process control tools; and (4) continuous improvement and knowledge management tools. In conclusion, with the assistance of DoE and PAT together with other QbD tools, thorough understanding of pharmaceutical process can be achieved and stable quality of products can be assured.

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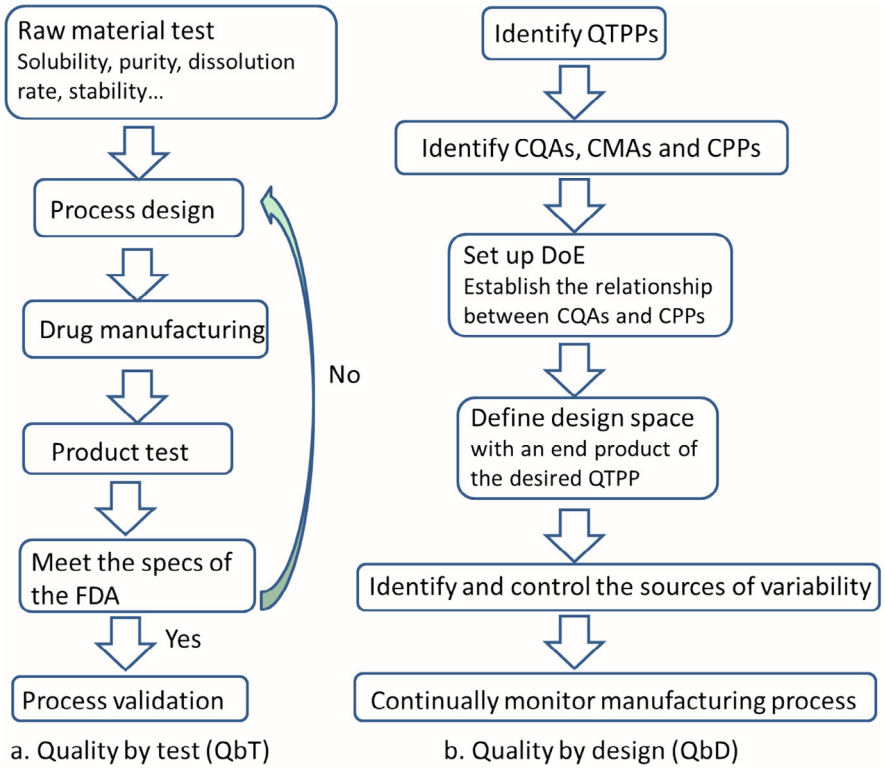

Fig. 1 Comparison between QbT and QbD.

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