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Review on Quality by Design (QbD): A Concept for Development of Quality Pharmaceuticals

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Abstract: Quality by design (QbD) is the best key to build a quality in all pharmaceutical products. QBD is emerging to increase the promise of providing safe and effective medicines to customers and promises to improve the efficiency of product quality. Under this concepts of be throughout design and growth of product, it is important to identify desire product performance report [Target Product Profile (TPP), Quality Target Product Profile (QTPP)] and identify Critical Quality Attributes (CQA). To recognize the impact of raw material [Critical Material Attributes (CMA)], Critical Process Parameters (CPP) on the CQAs and identification and control sources of changeability. The plan of pharmaceutical development is to design a quality products and its manufacturing process always deliver the future performance of the product. The base of Quality by design is ICH Guidelines Q8 for Pharmaceutical for development, Q9 quality risk management, Q10 for pharmaceutical quality systems.

Keywords: Quality by Design(QbD), ICH guidelines, Quality Target Product Profile, Process Analytical Technology

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