

Pharmaceutical Quality by Design: An Overview

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Regulatory science based pharmaceutical development and product manufacturing is highly recommended by the authorities nowadays. The new concept quality by design (QbD) is mostly preferred nowadays and is strongly recommended by regulatory agencies (the Food and Drug Administration, FDA, in USA, and the European Medicines Agency, EMA, in EU). According to the current regulatory science philosophy, QbD is one of the key elements of the various pharmaceutical developments. Experiments in pharmaceutical technology should use the QbD concept in order to achieve a time- and cost-saving process ensuring a high-quality product. The philosophy of the QbD concept can be summarized as a systematic, scientific, risk-based, holistic and proactive approach to pharmaceutical development so as to ensure the predefined quality.

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