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Quality by Design (Q-b-D) for Biopharmaceuticals

The principles and practices of Quality by Design (QbD) for biopharmaceutical manufacturing processes are here now, with regulatory authority expectation for market approval submissions to include at a minimum the quality target product profile (QTPP), critical quality attributes (CQAs) and critical process parameters (CPPs).

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Understanding Pharmaceutical Quality by Design

Quality by design (QbD) is an innovative product development process approach using both existing knowledge and emerging science to identify key “quality” issues (in regulatory jargon, the chemistry/manufacturing/control (CMC) of a medicine) in order to address or predict their impact on product attributes and ultimately patients’ health.

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