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Comparative analysis of Quality by Design (QbD) platforms

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In order to improve the quality of a drug product, International Conference on Harmonization (ICH), United States Food and Drug Administration (USFDA) and European Medicines Agency (EMA) and Japanese Pharmaceuticals and Medical Devices Agency (JPMDA) have suggested a various guidelines and Quality by Design (QbD) platforms. To this end, the main objective of this research is to conduct comparative analyses among those platforms. In addition, this research proposes a new QbD platform and its associated guideline. This is proposed QbD platform includes six steps: Quality Target Product Profile (QTPP), Critical Quality Attribute (CQA), Risk Assessment (RA), Design Space (DS), Control Strategy (CS), and Life cycle Management (LM). In addition, this research also provides a number of statistical design and analysis methods, such as Quality Function Deployment (QFD) for CQA procedure, Failure Mode and Effect Analysis (FMEA) for the RA procedure, Design of Experiment (DoE) and Response Surface Methodology (RSM) for design and operating spaces generation in the DS procedure and robust design optimization methods to reduce process variability. Finally, this research demonstrates possible solutions for existing scale-up problems for commercial pharmaceutical manufacturing processes.

Recent Publications

1.Chae Kim M C, Le T H, Bao C, Kim J T, Chun H S, Shin S, Lee H J (2017) Robust optimization for the simultaneous enhancement of nitric oxide inhibition and reduction of hepatotoxicity from green tea catechins. *Food Sci Biotechnol*: 1-10.

2.Choi G, Le TH, Shin S (2016) A new multidimensional design space identification method for a quality-oriented drug development process. Total Quality Management & Business Excellence, 27:7-8, 804-817.

Biography

Sangmun Shin has his expertise in quality by design and its associated statistical analyses in pharmaceutical science. He has also developed a number of robust design estimation and optimization methods in order to find the robust factor settings for various manufacturing and pharmaceutical processes. Improvement of pharmacokinetics and pharmacodynamics evaluation precision is his new research direction.

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Notes:

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