

Quality risk management system

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How often does this happen with you?

Your product is developed and ready for scale-up... and there is a last minute change of manufacturing site!

Reasons provided could be one or many of the following- "Our Operations is way too loaded" or "We are running back orders, hence can't take up more" or "Getting this manufactured at a contract location works better for our bottom line." These reasons are absolutely valid for business, but they create havoc among product developers i.e. R&D personnel.

The situation aggravates further when R&D finds out that, their process was developed using an "Octagonal" blender, while the manufacturing site has only a "V" blender. Further, there is no time to procure and qualify a new blender... and there is no way that "Filing date" can be moved ... WoW...!!

Such situations are when QRMS (Quality Risk Management Systems) are the only scientific saviours!

This paper captures use of QRMS to situations such as above and similar, practical and commonly occurring scenarios within the pharmaceutical industry.

Theoretically, QRMS can be applied to both (a) regulators and (b) manufacturers. This paper, however, shall cover aspects of QRMS as applied to the latter.

As QRMS is an overall and continuous process of minimizing risk to product quality throughout its life cycle, QRMS is therefore, applicable both proactively and retrospectively.

This paper shall cover- both proactive and retrospective aspects of QRMS, Verification of a QRM plan, Risk Management tools and Real- life case studies.

Following case studies are being discussed at length-

(a) Proactive QRMS:

- I. Quality-by-design (QbD) during drug- product development.
- II. QbD during stability studies.
- III. Risk Analysis prior to a process scale-up.

(b) Retrospective QRMS: Internal audits, CAPA etc.

Biography

Shruti U. Bhat has completed Ph.D. in Pharmaceutics & Industrial Pharmacy, from University of Mumbai, India and a MBA from ITM- Southern New Hampshire University USA. She has over 17 years of work experience with Strategy Design & Implementation of QRM and other Business Process Improvement tools within the Pharmaceuticals and Life science industries at large. Shruti has published over 50 scientific papers and reviews in reputed journals and has over 30 patents to her credit. She is Chief Operations Officer at Innoworks Inc. a Canadian Management Consulting firm.

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