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8<sup>th</sup> International Conference and Exhibition on  
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## Quality risk management in pharmaceuticals

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Every product or process has associated risks. Zero risk reduction is not a realistic goal nevertheless protection of patient by managing this risk in the quality system and manufacturing process is being given prime importance in the pharmaceutical industry. Quality Risk Management (QRM), a systematic process that assesses risk to the quality of a drug product across the lifecycle. QRM gives a company the ability to maintain compliance while also identifying product issues that could be harmful to the consumers, some being susceptible patients. One of the primary principles of QRM states, “the degree of rigor and formality of quality risk management should reflect available knowledge and be commensurate with the complexity and/or criticality of the issue to be addressed.” Therefore, a QRM framework can be applied to all levels of potential risk to the safety of a product, and it does not have to be done in a long, arduous process. With this in mind, quality risk management can and should be integrated into the daily operations of any company that wants to maintain a focus on product integrity and patient safety. Assessing, reviewing, and rating risks can then become a natural reaction to product and operation issues. ICH Q9 and FDA guidance document on quality risk management provides a detailed information for the use of risk management tools in pharmaceutical product development and manufacturing quality decision making. Effective quality risk management can facilitate better and more informed decisions, can provide regulators with greater assurance of a company’s ability to deal with potential risks, and might affect the extent and level of direct regulatory oversight.

### Biography

Rashid Mahmood has Master Degree in Analytical Chemistry and MS in Total Quality Management. He has 15 years of experience of Pharmaceutical Quality Operations and has participated in many international conferences as a keynote speaker. He has presented various talks in USA & China on Cleaning Validation, cGMP Guidelines, Quality Risk Management, Role of Mass Spectrometry in Pharmaceuticals and on new Drug Delivery Systems. Currently he is working as a Senior Executive Manager Quality Operations for Surge Lab.(Manufacturer of Microencapsulated APIs, Liquid & Dry Powder Parenterals) which is the best export oriented company of Pakistan.

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