Review Form 1.7

Journal Name:	**Journal of Pharmaceutical Research International**
Manuscript Number:	**Ms_JPRI_99152**
Title of the Manuscript:	**Implementing a Risk-Based Approach to Quality Management System ISO-13485 Processes in Compliance with EUMDR 2017/745 for Medical Device Industry**
Type of the Article	**Original Research Article**

General guideline for Peer Review process:

This journal's peer review policy states that **NO** manuscript should be rejected only on the basis of '**lack of Novelty'**, provided the manuscript is scientifically robust and technically sound.
To know the complete guideline for Peer Review process, reviewers are requested to visit this link:

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PART 1: Review Comments

	Reviewer's comment	**Author's comment** *(if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)*
Compulsory REVISION comments **1. Is the manuscript important for scientific community?** (Please write few sentences on this manuscript) **2. Is the title of the article suitable?** (If not please suggest an alternative title) **3. Is the abstract of the article comprehensive?** **4. Are subsections and structure of the manuscript appropriate?** **5. Do you think the manuscript is scientifically correct?** **6. Are the references sufficient and recent? If you have suggestion of additional references, please mention in the review form.** **(Apart from above mentioned 6 points, reviewers are free to provide additional suggestions/comments)**	**1. Yes. Application of risk techniques allows problems to be solved before they impact the product, in addition to improvement in process efficiency when attention is placed on higher risk issues and requirements are dialed down for lower risk items** **2.Yes** **3.Yes** **4.No. Focus is distracted by repeated display of information. Rearrange introduction to avoid repetition. Historical view and benefits of ISO-13485 and EUMDR 2017/745 in medical devices are good start to involve as beginning of introduction. Then definition of risk based approach and it's implementation importance in compliance with EUMDR 2017/745 of medical devices.** **5.Yes** **6.Yes**	
Minor REVISION comments **1. Is language/English quality of the article suitable for scholarly communications?**	**1.Yes** **Good research work but you need to present information in simpler framework such as points or diagram and not in a narrative style to avoid distracts the reader focus.** **Rearrange introduction with the following subsections:** **Historical view and concentrated definitions of ISO-13485 and EUMDR 2017/745 for Medical Device industry.** **Benefits of ISO-13485 and risk-based approach to QMS.** **Replace the explanation with a chart whenever possible.**	
Optional/General comments		

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PART 2:

	Reviewer's comment	**Author's comment** *(if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)*
Are there ethical issues in this manuscript?	*(If yes, Kindly please write down the ethical issues here in details)*	

Reviewer Details:

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