Review Form 1.7

Journal Name:	**Journal of Engineering Research and Reports**
Manuscript Number:	**Ms_JERR_119393**
Title of the Manuscript:	**Methods for Medical Device Design, Regulatory Compliance and Risk Management**
Type of the Article	**Review 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)**	Indeed, it appears that the manuscript might be interesting for the practitioners and scientists to read in light to the fact that the paper under discussion is a scientific paper concerned with the medical device technology. Therefore, the ability to meet specified safety, efficacy, and quality requirements by the compliance of design controls and medical device regulations is deemed as relevant. In today's setting there is a demand for documentary study for design controls and compliance as the regulatory environments both nationally (health-policies-of-states, FDA regulations) and globally (ISO standards) continue to develop and expand. **Yes** **NO** **Yes** **yes** **yes**	
Minor REVISION comments **1. Is language/English quality of the article suitable for scholarly communications?**	Authors should ensure that grammar and sentence completeness are thoroughly checked.	
Optional/General comments	Adding to the above, the text division into parts is believed to make it possible to read through as ideas and arguments proceed from one point in a logical manner. Each section might entail delivering the details regarding one of the aspects linked with the creation of the medical device or information on the guidelines. To turn stated facts actual, it is needed to add existing links or references on sources of information regarding the rules and procedures, for instance, Premarket Notification 510(k), Premarket Approval (PMA), Medical Device Reporting (MDR). Elaborate each activity you have listed out in your model of medical device development with action methods or practices to detail your strategy (for example verify the design; build a mock-up; evaluate the results; and on and on). To heighten the focus on the role of risk management practices in relation to the intended devices, it is suggested the following ideas be pondered: described relation between the mentioned devices and the various stages of regulation compliance, as well as the development of the device. Despite being quite extensive, the paragraph could have been shortened with more focus put on the areas of IEC 60601-1 that have specific relevance to the manuscript. Thus, possible filtering of content may help to enhance its effectiveness and message coherence. There are certain words and phrases associated with the standard which are defined in a rather crude way; certain concepts are introduced in a somewhat manner. Periodically, you may want to refer readers to certain aspects of medical device standards, so using brackets with brief descriptions can help those who may not understand all the details. A brief discussion of the points mentioned above can help explain the measures necessary to enhance the argumentation of the given paragraph with a focus on the relevance and significance of the IEC 60601-1 standard in medical devices.	

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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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