

Review Form 1.7

Journal Name:	Journal of Advances in Medical and Pharmaceutical Sciences
Manuscript Number:	Ms_JAMPS_119790
Title of the Manuscript:	Enhancing Safety and Compliance in Syringe Manufacturing: A Study of Risk Management Strategies Based on ISO 14971
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)
<p>Compulsory REVISION comments</p> <p>1. Is the manuscript important for scientific community? (Please write few sentences on this manuscript)</p> <p>2. Is the title of the article suitable? (If not please suggest an alternative title)</p> <p>3. Is the abstract of the article comprehensive?</p> <p>4. Are subsections and structure of the manuscript appropriate?</p> <p>5. Do you think the manuscript is scientifically correct?</p> <p>6. Are the references sufficient and recent? If you have suggestion of additional references, please mention in the review form.</p> <p>(Apart from above mentioned 6 points, reviewers are free to provide additional suggestions/comments)</p>	<p>The quality standards is crucial in the medical device industry.The ISO 14971 standard provides a systematic framework for identifying, evaluating, and controlling risks in the medical device industry.The manufacturing processes of syringes must adhere rigorously to stringent standards to prevent and control risks.</p> <p>Yes</p> <p>Yes, comprehensive</p> <p>Yes ,appropriate</p> <p>Yes with little addition</p> <p>insufficient</p> <p>Risk management for medical devices and the new BS EN ISO 14971</p>	
<p>Minor REVISION comments</p> <p>1. Is language/English quality of the article suitable for scholarly communications?</p>	<p>Yes</p>	
<p>Optional/General comments</p>	<p>1- what are the decide of risk acceptability levels.(each process). 2- what are the effective way to control risk during syringe manufacture (used soft plastic or glass components) 3- If risk cannot be completely eliminated ,what is the best option in each process 4- Addition, the Risk Management Review before it ships market and added to the risk management file. 5- show the local regulations and effect on product.</p>	

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)
<p>Are there ethical issues in this manuscript?</p>	<p><i>(If yes, Kindly please write down the ethical issues here in details)</i></p>	

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