

Review Form 1.7

Journal Name:	Journal of Pharmaceutical Research International
Manuscript Number:	Ms_JPRI_101387
Title of the Manuscript:	Regulatory Compliance in the United States: A Comprehensive Analysis of USFDA Guidelines and Implementation Strategies
Type of the Article	Original Research Article

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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>Yes</p> <p>Yes</p> <p>Yes</p> <p>No</p> <p>Partly yes</p> <p>No</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>The topic is relevant, but the manuscript lacks sufficient background for this review besides being repetitive.</p> <p>The authors should address the background or problem statement along with references for instances for non-compliances, penalties, recalls. It would be better if the authors could present these in order of their frequency of occurrence.</p> <p>What is the source of the non-compliances as mentioned under challenges? It has not been explained in the manuscript.</p> <p>The regulatory structure can be presented as the figure. One of the objectives is to give an overview of the regulatory framework in the United States. The same has not been addressed adequately. The information provided is already known. Any new insights would have added value to the manuscript. Bottlenecks if any could have been discussed?</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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