

Review Form 3

Journal Name:	Journal of Pharmaceutical Research International
Manuscript Number:	Ms_JPRI_122642
Title of the Manuscript:	FDA Warning Letter Trends: A 15-Year Analysis
Type of the Article	

Review Form 3

PART 1: Review Comments

Compulsory REVISION comments	Reviewer's comment	Author's Feedback <i>(Please correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)</i>
Please write a few sentences regarding the importance of this manuscript for the scientific community. Why do you like (or dislike) this manuscript? A minimum of 3-4 sentences may be required for this part.	This article provides only the frequency of drug recalls, without adequately classifying the non-conformities. While it suggests the need for improvements, it does not clearly define the specific areas requiring attention. With some enhancements, the article could serve as a valuable guide for quality assurance scientists.	
Is the title of the article suitable? (If not please suggest an alternative title)	Yes	
Is the abstract of the article comprehensive? Do you suggest the addition (or deletion) of some points in this section? Please write your suggestions here.	Add 2 lines of conclusion	
Are subsections and structure of the manuscript appropriate?	There is lack of data presentation. Please follow the journal format.	
Please write a few sentences regarding the scientific correctness of this manuscript. Why do you think that this manuscript is scientifically robust and technically sound? A minimum of 3-4 sentences may be required for this part.	There is a significant lack of data presentation in this article. The non-conformities should be classified, and the data should be presented using graphical representations to enhance clarity and understanding. It is suggested to briefly outline the drug recall process, emphasizing that recalls occur when a product violates safety standards and poses potential health risks. To reduce the frequency of recalls, write the approaches needed for reducing recalls. It's important to highlight serious recall issues, such as contamination and mislabeling, which have had significant impacts on human populations, leading to adverse effects and even fatalities. You note the increasing number of recalls from foreign manufacturers, potentially due to the FDA's stringent policies however it is possible negligence on the part of these manufacturers. It would be beneficial to link the rise in recalls with the approval of new therapeutic substances, although the article should avoid specifying whether this trend is increasing in terms of ratios. If the FDA recall ratio is rising, identifying the most concerning sector is critical. Additionally, mentioning recent FDA policy changes, including stricter regulations and inspections, particularly for foreign manufacturers, would help explain the current recall trends. Overall, while the article offers valuable insights, improving data presentation and better classifying non-conformities would make it more effective.	
Are the references sufficient and recent? If you have suggestions of additional references, please mention them in the review form.	Please follow the journal format.	
Minor REVISION comments Is the language/English quality of the article suitable for scholarly communications?	Improve in some spacing spelling and grammars.	
Optional/General comments	NA	

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PART 2:

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

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