

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 Article

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PART 1: Review Comments

Compulsory REVISION comments	Reviewer's comment	Author's Feedback (Please correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)
<p>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.</p>	<p>This manuscript is important for the pharmaceutical professionals, consultants and other regulatory professionals as it provides a comprehensive analysis of FDA warning letters that includes analysis of trends of warning letters and focus overtime by the US FDA inspectors. This article provides insight and concern related to quality systems and integrity of data those are now evolving as compliance challenges faced by the pharmaceutical industry. The detailed analysis of geographic distribution identifies these quality issues across the countries dealing pharmaceutical products. I value this manuscript for its thorough analysis and clear conclusion.</p>	
<p>Is the title of the article suitable? (If not please suggest an alternative title)</p>	<p>The title is suitable as the title rightly represent the focus of the content discussed in this article.</p>	
<p>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.</p>	<p>The article is mostly comprehensive, but it can include following:</p> <ol style="list-style-type: none"> 1. Major observations and trends based on countries/region 2. Major observations based on types e.g. Drugs, Device, etc. 3. Include graphical presentation 	
<p>Are subsections and structure of the manuscript appropriate?</p>	<p>Yes, the subsections and structure of the manuscript are appropriate and flow a logical flow of information.</p>	
<p>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.</p>	<p>Please find few sentences regarding the scientific correctness of this manuscript:</p> <ol style="list-style-type: none"> 1. This manuscript has been written in an appropriate and logical flow of information with the inclusion of quantitative and qualitative analysis. 2. This manuscript is scientifically analysing FDA warning letter trends from 2005 to 2021 3. The manuscript incorporates recent data until 2021 though it lacks data of 2022 to 2023. 	
<p>Are the references sufficient and recent? If you have suggestions of additional references, please mention them in the review form. :-</p>	<p>Yes, the references are sufficient and recent. However, it can include data of 2022 and 2023:</p> <ol style="list-style-type: none"> 1. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters 2. https://www.thefdagroup.com/blog/2019-fda-warning-letter-inspection-observation-trends 3. https://www.gmp-journal.com/current-articles/details/the-fda-warning-letter-report-2023.html 	
<p>Minor REVISION comments</p> <p>Is the language/English quality of the article suitable for scholarly communications?</p>	<p>Language and English quality of the article are mostly suitable. However, some complex sentences need to be simplified, e.g.</p> <ol style="list-style-type: none"> 1. However, this surge also raises questions about the agency's capacity to maintain consistent oversight across all areas during times of heightened focus on specific issues." 2. This trend aligns with the agency's stated goal of enhancing public health protection through rigorous oversight 	
<p>Optional/General comments</p>	<p>The manuscript provides a thorough and insightful analysis of FDA warning letter trends over 15 years, highlighting significant shifts in regulatory focus and compliance challenges. However, some sections would benefit from clearer language and more concise phrasing to improve readability and scholarly impact.</p>	

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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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