Review Form 2

Book Name:	**Advanced Sterile Compounding: Current Standards**
Manuscript Number:	**Ms_BPR_ 3781**
Title of the Manuscript:	**Advanced Sterile Compounding: Current Standards**
Type of the Article	**COMPLETE BOOK**

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)*
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 manuscript is highly valuable to the scientific community as it provides a comprehensive overview of the essential practices needed for ensuring adherence to USP Chapter 797 standards in compounding facilities. It highlights practical strategies, from risk assessments to environmental monitoring, which are crucial for maintaining patient safety and operational efficiency. The manuscript's emphasis on both theoretical knowledge and practical application provides a well-rounded approach that can benefit professionals in the field. Its clear synthesis of current practices, challenges, and solutions makes it a useful resource for improving compliance and fostering a culture of continuous improvement within compounding operations.	
Is the title of the article suitable? **(If not please suggest an alternative title)**	If the current title accurately reflects the focus on implementing and maintaining USP 797 standards in compounding facilities, it should be suitable. However, if the title needs refinement, a more specific alternative could be: **"Ensuring Compliance with USP Chapter 797: Best Practices for Safe and Sterile Compounding"** or **"Implementing and Sustaining USP 797 Standards in Compounding Facilities for Patient Safety"**. These suggestions emphasize the main themes of adherence, best practices, and patient safety	
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.	If the abstract provides a clear overview of the manuscript's main points—such as the importance of compliance with USP 797, the steps for assessment and implementation, and strategies for ongoing adherence—it should be comprehensive. However, here are some suggestions to enhance the abstract: 1. **Include Key Points on Challenges and Solutions**: Briefly mention common challenges faced during the implementation of USP 797 and potential solutions to make the abstract more balanced. 2. **Highlight Emerging Trends**: Add a note on any technologies that can support USP 797 compliance, such as automated monitoring systems or data analytics. 3. **Emphasize the Impact on Patient Safety**: Make sure the abstract underscores the importance of patient safety as a primary outcome of following USP 797 standards. 4. **Mention Stakeholder Roles**: Acknowledge that compliance extends to leadership, quality assurance teams, and policymakers, highlighting their collaborative role.	
Are subsections and structure of the manuscript appropriate?	The subsections and structure of the manuscript appear to be logical and organized, focusing on key areas such as risk assessment, training, environmental monitoring, and compliance strategies. However, here are some suggestions to enhance the structure: 1. **Logical Flow**: Ensure the subsections follow a natural progression. For instance, start with identifying risks and challenges, move on to implementation strategies, and conclude with monitoring, assessment, and continuous improvement.	

	2. **Highlight Key Areas**: Consider adding separate, clearly labeled subsections for critical topics such as "Gap Analysis," "Environmental Monitoring," and "Competency Assessments" if not already done. This will make the manuscript more reader-friendly. 3. **Avoid Repetition**: Check if any points are repeated across sections. Consolidate similar ideas into single subsections to improve clarity and reduce redundancy. 4. **Add Practical Insights**: A "Best Practices" or "Practical Recommendations" section could help provide actionable takeaways, enhancing the manuscript's utility for the audience. Overall, while the structure is generally appropriate, small refinements in organization and labeling could improve readability and coherence.	
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.	The manuscript appears to be scientifically robust and technically sound as it is well-grounded in established regulatory guidelines, particularly USP Chapter 797. It demonstrates a thorough understanding of essential practices such as environmental monitoring, risk assessments, and competency evaluations, which are critical to maintaining sterile compounding standards. The inclusion of practical insights, such as the use of containment engineering controls (C-PECs) and regular personnel training, aligns with current best practices in pharmaceutical and healthcare settings. By addressing both theoretical and practical aspects, the manuscript provides a comprehensive and accurate depiction of the requirements necessary to ensure compliance and patient safety.	
Are the references sufficient and recent? If you have suggestions of additional references, please mention them in the review form. **-**	The references cited in the manuscript are generally sufficient and cover a broad range of sources relevant to USP Chapter 797 and sterile compounding practices. They include guidelines, historical perspectives, and recent studies, which add depth to the manuscript. However, a few references could enhance the paper further: 1. **Consider more recent studies** on the impact of technology-assisted compounding systems to reflect advancements in automation and safety improvements. 2. **Incorporate global perspectives or non-U.S. guidelines**, such as those from the European Pharmacopoeia or WHO, to provide a more comprehensive view of sterile compounding standards. 3. **Additional references on training programs** and their long-term outcomes could strengthen discussions around competency assessments and education. For instance: • **ISMP's updated guidelines on sterile compounding** might provide additional practical insights. • A study comparing compliance rates in different facility types (rural vs. urban) might add a new dimension to the discussion. Including such references could make the manuscript more globally relevant and reflective of recent advancements in the field.	

Review Form 2

Minor REVISION comments **Is the language/English quality of the article suitable for scholarly communications?**	The language quality of the article is generally suitable for scholarly communication, with clear and concise descriptions of technical concepts. However, there are areas that could benefit from slight refinement to enhance readability and professionalism: 1. **Clarity and Precision**: Some sentences are lengthy or overly complex. Breaking them into shorter sentences would improve readability. For example, rephrasing complex ideas into simpler terms without losing technical depth can aid comprehension. 2. **Grammar and Syntax**: While overall acceptable, a thorough proofreading could catch minor grammatical inconsistencies, such as subject-verb agreement or misplaced modifiers. 3. **Scholarly Tone**: The manuscript maintains a formal tone, but some sections could benefit from more scholarly phrasing. Avoiding colloquialisms and ensuring consistent use of technical terminology would strengthen the academic quality. 4. **Consistency**: Ensure uniformity in the use of tenses and citation styles throughout the document to maintain professionalism. Overall, the article is well-written, but targeted edits can further enhance its suitability for a scholarly audience.	
Optional/General comments	**Abstract** • Emphasize the **reason for reviewing current standards**, such as addressing challenges, incorporating new technologies, or mitigating emerging risks. • Condense the list of processes (e.g., identification, measurement, dilution, mixing) to allow room for broader content coverage. • Define the acronym **"CSPs" (Compounded Sterile Preparations)** when first introduced, even if the audience is familiar. • Identify the **target audience** (e.g., pharmacists, regulatory professionals) and highlight the **practical implications** (e.g., improved compliance, patient safety). • Strengthen the **concluding sentence** by emphasizing the significance of updating standards in sterile compounding practices. **Introduction** **"The Sterile Compounding Crisis: A Call for Reform"**: • The section is well-structured with effective subheadings. • Improve **conciseness**: For example, streamline the explanation of the link between drug shortages and sterile compounding. • Provide **specific examples or actionable steps** for broad solutions, such as strategies to mitigate drug shortages. • Avoid redundancy in terms like **"rigorous surveillance systems"** and **"robust adverse event reporting system"**. • Conclude with a remark tying strategies to **measurable outcomes**, such as improved compliance or reduced patient harm. **Sterile Compounding: A Critical Overview** • This section is thorough and integrates regulatory updates effectively. • Condense explanations of detailed points, such as **risk-based categorization**. • Briefly connect training and environmental monitoring measures to their **direct impact on patient safety**. **Responsibility of Personnel Compounding** • Highlight the critical role of the **Designated Person** and **multidisciplinary involvement** effectively. • Condense repetitive points on sterility and quality checks.	

	• Streamline language for clarity and focus on the **insights** regarding expanding USP standards to other disciplines. **CSP Microbial Contamination Risk Levels** • The explanation of updated microbial contamination risk levels (numerical categories) is effective. • Be more concise when comparing category-specific requirements. • Elaborate briefly on conditions that exempt **immediate-use CSPs**, ensuring practical clarity. **Beyond-Use Dates (BUDs)** • Simplify overly detailed sentences, such as: Original: "BUDs for CSPs are determined by the shorter of the stability or sterility limits..." Revised: "BUDs depend on the shorter of stability or sterility limits, considering drug, diluent, and container factors." • Ensure clarity while maintaining technical precision. **Pharmacy Compounding–USP <797> Risk Level Assessment** • Be concise when describing CSP categories to avoid redundancy. • Provide **examples of CSPs** for each category to better illustrate the differences. • Emphasize the **practical implications** of extended BUDs for patient care and pharmacy operations. **Immediate-Use CSPs** • Avoid redundancy regarding bacterial lag phase and competency policies. • Use bullet points or subsections for easier readability. • Include examples of **scenarios** where the changes are beneficial, such as critical care emergencies. **Requirements for Immediate-Use CSPs** • Consolidate overlapping points about **aseptic procedures** and **training**. • Use bullet points for clarity and quick reference. • Emphasize evidence-based compatibility and strict timelines for safety and efficacy. **Aseptic Practices for Compounding** • Summarize key points for quick reference. • Consider using **flowcharts or diagrams** to visually represent critical procedures. **Personnel Training and Competency Testing** • Include specific examples of **training scenarios** or common challenges faced by personnel. • Provide actionable tips for addressing these challenges. • Summarize key training goals to reinforce understanding and retention. **USP Chapter 797 Personnel Training Requirements**	

	• Clearly state the **purpose of media-fill tests** upfront.
	• Simplify descriptions of **sampling and incubation protocols** to improve readability.
	
	797 Compliance: Essential Documentation Review
	
	• Specify types of **corrective actions** or procedures to document deviations.
	• Highlight the importance of periodic **audits** of documentation to ensure compliance and effectiveness.
	
	Evaluating Institutional Adherence to USP Chapter 797 Standards
	
	Provide actionable steps under key areas:
	
	1. **Gap Analysis**
	  ○ Conduct initial assessments using tools like ASHP.
	  ○ Review all 64 'should' statements to identify weaknesses.
	2. **Facility Classification**
	  ○ Define compounding risk levels (low, medium, high) and establish corresponding SOPs.
	3. **Training**
	  ○ Implement dynamic/static smoke tests and regular competency checks.
	4. **Environmental Monitoring**
	  ○ Align air and surface sampling with risk-based assessments.
	5. **Documentation**
	  ○ Ensure clarity and include implied details (e.g., sample protocols, deviations).
	6. **Policy Updates**
	  ○ Update policies regularly based on data trends. Assign oversight responsibility.
	7. **Compliance Improvements**
	  ○ Upgrade materials (e.g., stainless steel for better durability).
	
	Suggestions for Enhancing the Conclusion
	
	1. **Continuous Improvement**: Emphasize ongoing assessments and audits.
	2. **Call to Action**: Urge the adoption of proactive training and documentation strategies.
	3. **Beyond Compliance**: Highlight safety, quality, and patient outcomes.
	4. **Emerging Trends**: Reference new tools (e.g., automated monitoring, analytics).
	5. **Stakeholder Role**: Stress collaboration among leadership, quality teams, and policymakers.	

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)*	

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