



Esther Gerteis

VP Medical & Regulatory Affairs

TRiCares GmbH

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Optimizing Regulatory Submissions:

The Crucial Role of Soft Skills and Documentation Presentation Quality

Agenda

- Regulatory Agencies: Partners, Not Opponents
- Understanding Regulatory Perspectives
- Effective Document Presentation

Regulatory Agencies: Partners, Not Opponents



Dispelling Misconceptions about Regulatory Agencies

1. Patient Safety First:

- Regulatory agencies prioritize patient safety above all else. Their main goal is to ensure that any new device or drug is safe and effective for public use.

2. Not Here to Block Progress:

- Contrary to popular belief, regulatory bodies do not aim to hinder innovation. They are not looking to block advancements or impose unnecessary hurdles. Their regulations are in place to safeguard public health.

3. Communicate Clearly and Convincingly:

- When preparing your submission, focus on crafting a clear and compelling narrative. Present your trial data and evidence in a way that demonstrates the safety and efficacy of your device or drug.
- Use plain language that can be understood by someone who may not be an expert in the specific disease, procedure, or your product.

Regulatory Agencies: Partners, Not Opponents



Dispelling Misconceptions about Regulatory Agencies

4. Understand Their Perspective:

- Remember that regulatory agencies may not have in-depth knowledge of the disease you are addressing, the specific procedure or treatment, or your innovative device or drug. It's your job to educate them through your submission.
- Provide comprehensive background information and context to help them understand the significance and potential impact of your work.

5. Collaboration Over Confrontation:

- Approach interactions with regulatory agencies as opportunities for collaboration. View them as partners who share your commitment to patient safety and innovation.
- Be proactive in addressing any concerns they may have and be open to feedback.

Regulatory Agencies: Partners, Not Opponents



Dispelling Misconceptions about Regulatory Agencies

6. Highlighting the Benefits:

- Emphasize the potential benefits of your device or drug for patients. Show how it can improve outcomes, quality of life, or address unmet medical needs.
- Use real-world examples or case studies if available, to illustrate the positive impact of your product.

Conclusion:

Regulatory agencies are crucial allies in the journey to bring new medical innovations to market. By understanding their role and priorities, and by communicating clearly and effectively, we can work together to ensure that safe and effective treatments reach those who need them most.

Regulatory Agencies: Partners, Not Opponents



Emphasizing Collaboration and Partnership in the Regulatory Process

1. Fostering Collaboration:

- Approach regulatory interactions with a mindset of collaboration and partnership. Treat regulatory agencies as valuable partners who share your goal of bringing safe and effective treatments to patients.

2. Respect and Clarity:

- Show respect for the regulatory agencies by going the extra mile to make your documents clear and accessible. Remember, well-organized and easy-to-read documents reflect your respect for their time and expertise.
- Avoid complex cross-referencing. Instead, repeat important information when necessary to ensure clarity. This practice helps reviewers by minimizing the need to jump back and forth between sections.

3. Creating a Smooth Narrative:

- Strive to write your submission as a smooth, coherent story. A well-structured narrative helps reviewers follow your logic and understand your data without unnecessary difficulty.
- Make each section and paragraph flow logically to the next, maintaining clarity and focus throughout your document.

Regulatory Agencies: Partners, Not Opponents



Emphasizing Collaboration and Partnership in the Regulatory Process

4. Prioritize Ease of Reading:

- Focus on creating documents that are easy to read and understand. Break down complex data into digestible pieces, using clear headings, bullet points, and summaries where appropriate.
- Ensure that critical points are easily identifiable and supported by clear evidence.

5. Proactive Communication:

- Don't hesitate to reach out to regulatory agencies if you have questions about how best to present your data. They can provide valuable insights into their preferences and expectations.
- Engaging in proactive communication demonstrates your commitment to transparency and collaboration.

6. Tailoring Your Submission:

- Tailor your submission to meet the specific needs and preferences of the regulatory agency. This might include following specific guidelines, formats, or styles they prefer.
- **Be flexible and willing to adapt your approach based on their feedback and requirements.**

Regulatory Agencies: Partners, Not Opponents

Emphasizing Collaboration and Partnership in the Regulatory Process

Conclusion:

Building a strong partnership with regulatory agencies is essential for a successful approval process. By prioritizing respect, clarity, and proactive communication, you can facilitate a smoother and more efficient review process. Remember, the goal is to make it as easy as possible for regulatory reviewers to understand and support your submission.



Understanding Regulatory Perspectives



Exploring Regulatory Agencies' Objectives

1. Assuring Maximum Patient Safety:

- Again, the primary task of regulatory agencies is to ensure the highest level of patient safety during clinical trials and beyond. Their regulations and requirements are designed to protect patients from potential harm.

2. Reliance on Expert Opinions:

- Regulatory agencies depend heavily on expert opinions to inform their decisions. These experts provide critical insights into the safety and efficacy of new treatments.
- While agencies cannot simply overwrite these expert opinions, they value thorough and well-reasoned responses to such feedback.

3. Communicating Your Perspective:

- When responding to expert opinions, it is crucial to clearly present your perspective. Ensure that the regulatory agency understands your viewpoint and the rationale behind your data and methodologies. At the end they decide not the expert.
- **Engage in open and respectful dialogue to help them see the merits of your case.**
- Remember, the regulatory agency makes the final decision about your submission, not the expert. Don't be discouraged by seemingly "stupid" questions; you never know who raised them or why. Use these opportunities to explain your data clearly to the agency.

Understanding Regulatory Perspectives



Exploring Regulatory Agencies' Objectives

4. Facilitating Direct Discussions:

- Regulatory agencies are open to discussing your submissions directly. By communicating effectively and respectfully, you can address any concerns they may have and facilitate a smoother approval process.
- Be proactive in seeking opportunities for direct conversations, as this can help resolve misunderstandings and expedite the review process.

5. Not Your Enemies:

- Remember, regulatory agencies are not adversaries. They share your goal of advancing patient care through safe and effective treatments.
- Approach interactions with a collaborative mindset, aiming to work together towards common objectives.

Understanding Regulatory Perspectives



Discussing Strategies to Align Submission Approaches with Regulatory Expectations

1. Be Honest:

- Be upfront about any issues or gaps in your data. If you made a mistake in your submission, apologize. Nobody is free of mistakes, and they will appreciate your honesty and excuse. Transparency builds trust and shows your commitment to patient safety.

2. Explain Your Rationale:

- Clearly explain why you believe your device or drug is ready for a trial, despite any issues. Provide a well-reasoned argument supported by your data.

3. Seek Solutions Together:

- Engage the agency in finding solutions. Collaborate to address concerns and develop a path forward. You might be surprised by the support and guidance you receive.

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Understanding Regulatory Perspectives



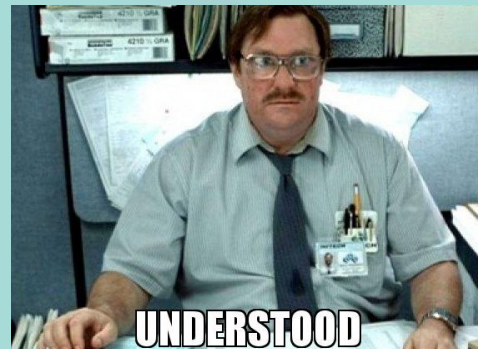
Discussing Strategies to Align Submission Approaches with Regulatory Expectations

4. Partner Up:

- View regulatory agencies as partners, not adversaries. Foster a collaborative relationship to work towards the common goal of patient safety and effective treatments.

Conclusion

Aligning your submission approach with regulatory expectations requires honesty, clear communication, and a collaborative mindset. By being transparent about challenges, explaining your rationale, seeking solutions together, and partnering up with regulatory agencies, you can foster a productive relationship that ultimately benefits patient safety and advances medical innovation.



Effective Document Presentation

Highlighting the Importance of Clear Communication in Submissions



1. Follow Agency Guidelines:

- Read and understand the guidelines for submissions from each regulatory agency. Adapt your submission to meet the specific requirements of each country.
- Use the prescribed folder structure and file naming conventions, including version numbers and dates.

2. Use Simple Language:

- Write in clear, simple English. Use straightforward sentences to ensure your message is easily understood by non-native speakers.

3. Introduce Your Company:

- In your initial submission, include a brief introduction about your company. Provide context about who you are and your mission.

Effective Document Presentation

Highlighting the Importance of Clear Communication in Submissions



4. Responding to Questions:

- When you receive questions from the agency, repeat the question in your response and provide your answer directly below. Avoid referencing other documents or paragraphs; include the relevant text in your response.

Conclusion

Effective document presentation is crucial for successful regulatory submissions. By following agency guidelines, using simple language, introducing your company, and responding clearly to questions, you enhance the clarity and accessibility of your submission. This approach not only facilitates a smoother review process but also strengthens your collaboration with regulatory agencies, ultimately contributing to the advancement of patient safety and medical innovation.



Effective Document Presentation



Sharing Best Practices for Organizing and Formatting documents to Improve Readability and Comprehension

1. Formatting Tips:

- Do not use block alignment in small columns for improved readability.
- Ensure adequate spacing between lines to enhance clarity.
- Avoid using overly small or fancy fonts; opt for legible and professional fonts.
- Utilize bullet points or tables wherever possible to organize information efficiently.
- Index all paragraphs for easy reference, even in PDF format.
- Make your document searchable in PDF format for accessibility.

2. Structural Elements:

- Include a table of contents and a table of figures to guide readers through the document.
- Provide an overview of all abbreviations used in the document and reintroduce them when first used in the main body.
- Define key terms and concepts in a dedicated paragraph or section, as applicable.
- Reference all sources used in a bibliography to ensure transparency and credibility.

Effective Document Presentation



Sharing Best Practices for Organizing and Formatting documents to Improve Readability and Comprehension

3. Numeric and Visual Elements:

- Number tables, figures, and graphs sequentially in the right order for easy reference.
- Avoid using bold, underlining, or different colors excessively; maintain a professional appearance.
- Repeat the header of tables spanning multiple pages for clarity and coherence.

4. Document Metadata:

- Number the pages and include a header and footer describing the document's purpose.
- Ensure clear file naming conventions, including version numbers and dates, for easy identification and tracking.
- Use short file names; some submission systems may not accept long file names due to folder structures with many subfolders, such as those used by Swissmedic, for example.

Conclusion

Effective document organization and formatting are essential for conveying information clearly and comprehensively in regulatory submissions. By adhering to best practices, including clear structuring, concise language, and meticulous attention to detail, you can enhance the accessibility and usability of your documents, ultimately facilitating smoother review processes and regulatory approvals. Incorporating these strategies fosters transparency, professionalism, and credibility, positioning your submissions for success in the regulatory landscape.

Effective Document Presentation



Sharing Best Practices for Organizing and Formatting documents to Improve Readability and Comprehension

1. Submit Redline Documents:

- Include redline versions of important documents, showing changes between iterations.
- Redline versions highlight modifications, making it easier for reviewers to identify alterations.
- Only highlight substantive changes in redline documents.
- Accept writing errors and small editorial changes without highlighting them.
- By focusing on significant alterations, regulatory agencies can prioritize reviewing substantive changes.

2. Table of Changes:

- Provide a table detailing changes, including old and new text, paragraphs, or figures, along with reasons for the changes.
- This table enhances transparency and aids in understanding the evolution of the document.

3. File Naming and Cover Letter:

- Ensure file names only differ in version number and date between iterations; include "rdl" or "redline" in the file name for redline versions.
- State each document's complete file name in the cover letter, along with its location if applicable.

Effective Document Presentation



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- State each document's complete file name in the cover letter, along with its location if applicable.

5. Version Control Across Agencies:

- When transitioning from version 1 to version 4 at one agency, provide all interim versions with respective redlines and tables of changes.
- This comprehensive approach ensures consistency and facilitates regulatory review processes.

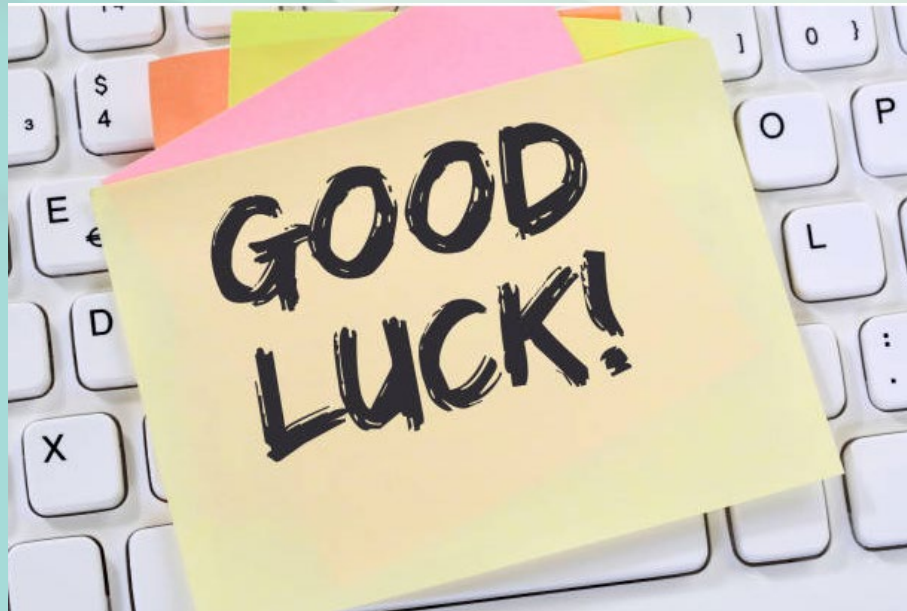
Conclusion

Incorporating redline documents and tables of changes into your submissions enhances transparency, expedites regulatory review, and demonstrates your commitment to regulatory compliance. By focusing on substantive changes and providing clear documentation, you facilitate efficient communication with regulatory agencies and ensure a smoother submission process.



Optimizing Regulatory Submissions

So - Good Luck with your next Submission



Please do not hesitate and reach out to me if you have any questions...