

Compliance Writing After the Inspection – November 19, 2024

Judith Meritz



Speaker Introduction

JUDITH MERITZ

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Ms. Meritz has over 30 years' experience representing Life Science companies, specializing in strategic planning and compliance mediation concerning the FDA and other international regulatory agencies. She has held key regulatory and legal positions for companies including Medtronic, Covidien, Henry Schein and the American Red Cross. She has served as the key player in interactions with the FDA and drafted inspection responses to numerous FDA 483's.



Agenda



— **Key Elements of a Good Response**



— **Crucial Information to Include in Response**



— **Do's & Don'ts**



— **Effective Word Choices & Red Flags**



— **How to Disagree with Inspector Observations**



— **Best Practices for Documentation and Communication**



Elements of a Well Written Response



Key elements to include in Response:



1. Your company's understanding of FDA concerns
2. The corrective actions you believe should be taken
3. Time schedule for completing corrective actions

Do not stress:



1. Statements that inspector had the facts all wrong
2. Or that the FDA does not understand your business
3. Excuse that other companies are acting in this manner

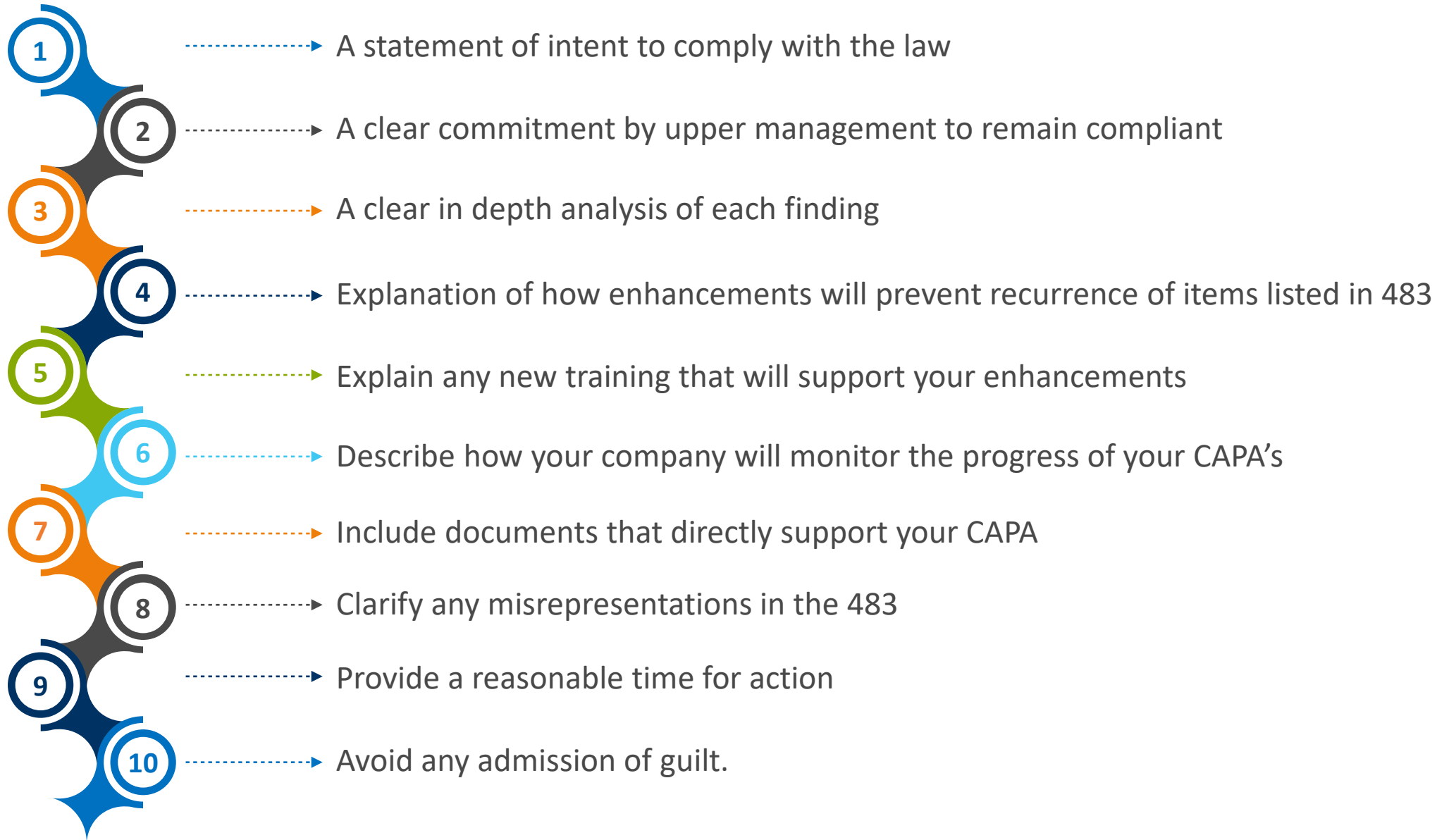


Examples of Don't Communications

“I have discussed the retrospective review with the team, and they have decided not to take this action, even though they would be intentionally ignoring the regulation”

“Well, so much for keeping this quiet. People in the field are now receiving reports. We will now be forced to come up with a definitive plan”

TEN Elements of an FDA 483 Response



Word Choices

1

Avoid inflammatory language

2

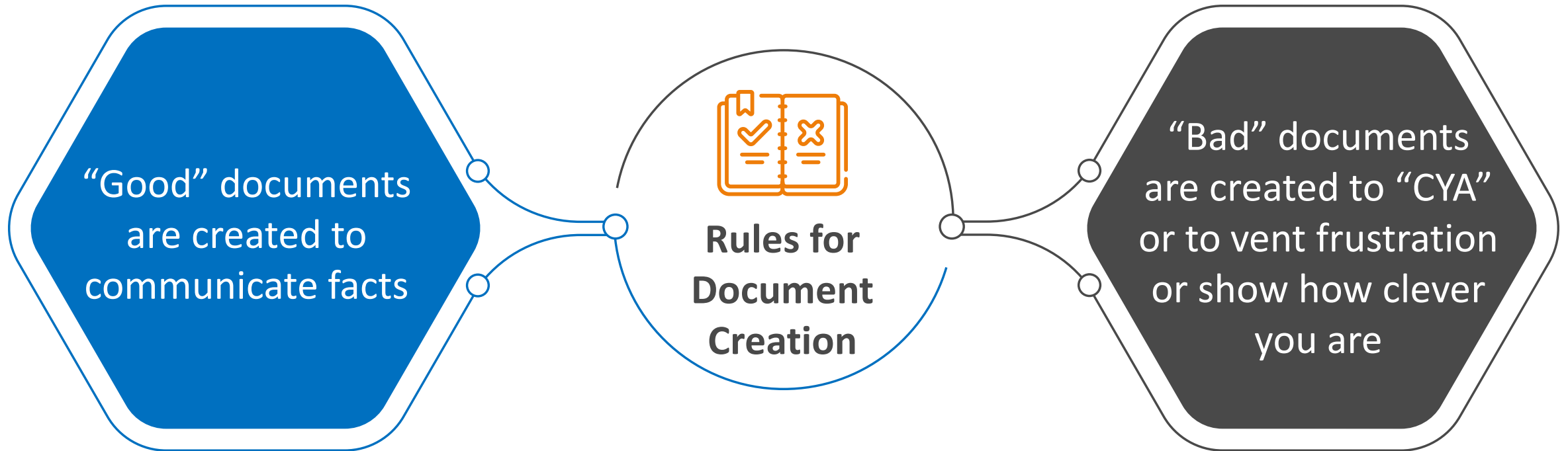
Avoid cliches

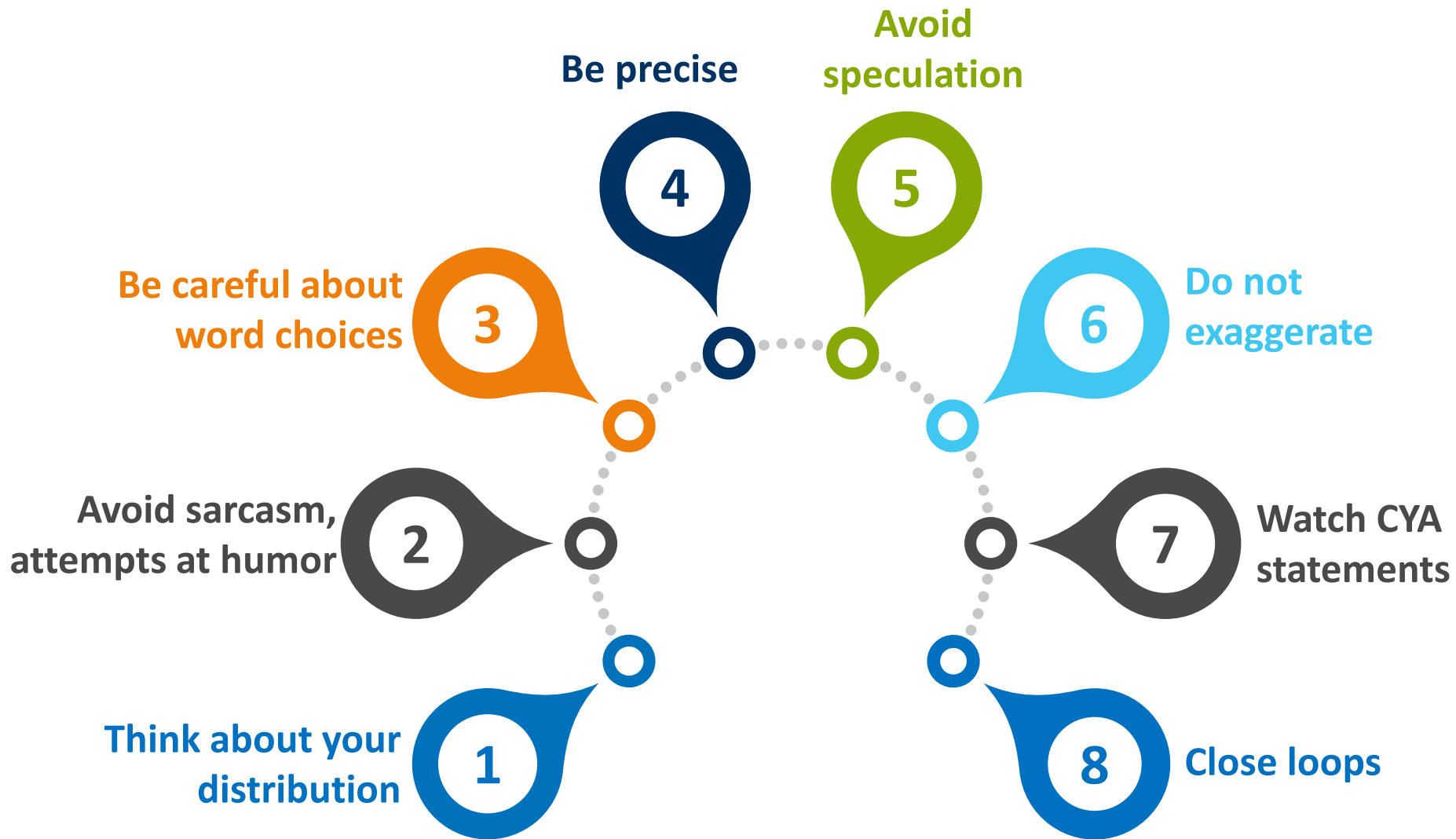
3

Avoid Flip comments

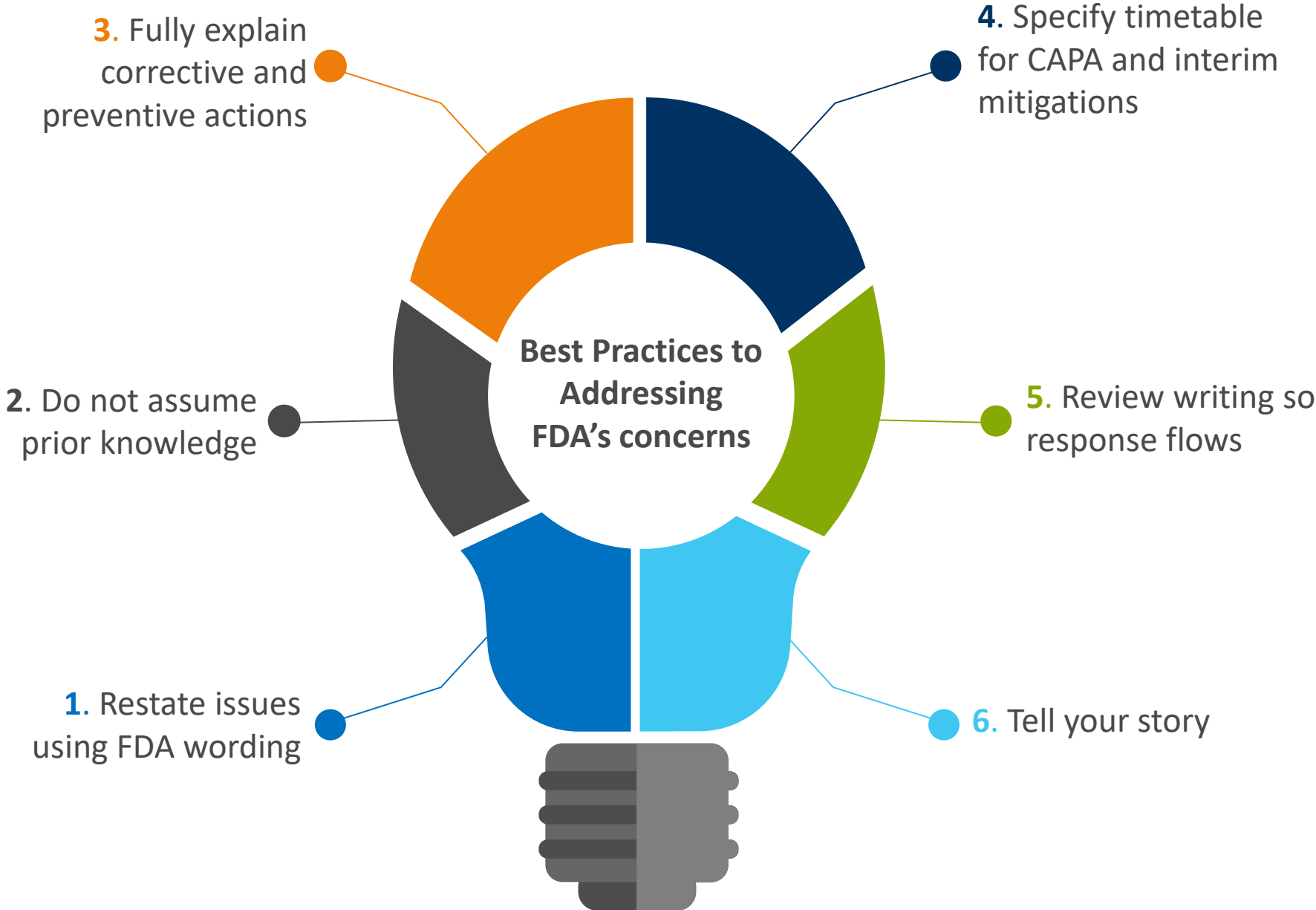
4

....Be careful with words like always, never, stupid, wrong to do, defective, fooled, on purpose





Conclusion



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THANK YOU




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