



HORIZONS


Think. Challenge. Excel.

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Top Ten Mistakes not to Make when Meeting with the FDA


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***PLEASE NOTE: THERE IS NO AUDIO FOR THIS PRESENTATION**



Types of FDA Meetings

- Industry Requested
 - Introductory
 - Informational
 - FDA 483 response
 - Warning Letter response
- FDA Requested
 - Regulatory Meeting
 - Food, Drug & Cosmetic Act “305 Meeting”
 - Bioterrorism Act Hearing



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Group Activity FDA Meeting Role Play

- Company Requested Meeting
- Respond to FDA-483
 - QSR issues
 - MDR issues
- Company Attendees
 - Reg Affairs Manager
 - MDR Consultant

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Group Activity FDA Meeting Role Play

Discuss Learnings from Role Play

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How to Avoid Ten Common Mistakes...

1. Understand FDA's Role
 - Not your consultant
 - You are ultimately responsible
 - Your business pressures may not be appreciated
 - Law enforcement responsibilities
 - Objective assessor
2. Respect FDA's Role
 - Public health focus
 - Busy schedules
 - FDA are people too!

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How to Avoid Ten Common Mistakes...

3. Meeting Management
 - Agenda
 - Industry attendees
 - FDA attendees
 - Pre-meeting materials
 - Presentation format and technology
 - Time management
 - When to say, "Good Bye"!

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How to Avoid Ten Common Mistakes...

4. Preparedness

- Understand the issues
- Understand company position
- Know the regulatory landscape
- Company participants on same page
 - Meeting objectives
- Roles clear
 - Company officials
 - Consultant(s) ?
 - Attorney(s) ?

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How to Avoid Ten Common Mistakes...

5. Clarity of Message

- Succinct, to the point, consistent
- Logical !
- Scientifically supported when necessary
- Seek feedback from FDA
- Avoid disproportionate focus on financials/dilutive metrics

6. Flexibility/Anticipation

- Anticipate possible FDA reactions
- Be flexible in reacting

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How to Avoid Ten Common Mistakes...

7. Open-mindedness
 - Listen to FDA's perspective
 - Do not minimize FDA concerns
8. Commitments
 - Exercise care
 - Don't over commit precipitously
9. Company Impression
 - Assure that FDA understands that you "get it"

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How to Avoid Ten Common Mistakes...

10. Follow-Up
 - Tie up loose ends/clarifications promptly
 - Provide ongoing feedback/updates

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Conclusion

- Understand and be respectful of FDA's role
- Strive for clear, common understanding of issues
- Do not minimize FDA concerns
- Be open-minded and flexible
- Have logic for your position

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Conclusion

- Give FDA confidence of your understanding, ability and willingness to take appropriate action

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**Blessed are those who can laugh at
themselves, for they shall never cease to
be amused.**

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