

BRF Interview Questions: External Stakeholders

Q1. First, do you have any general comments about BRFs that you've seen that you would like to offer before I ask specific questions?

Q2. Information on FDA decisions – How important is it to you to understand FDA's regulatory decisions on new drugs and biologics?

- Over the past few years, how often have you sought information about FDA's regulatory decisions on specific new drugs and biologics?
- [If they do seek out information] Where have you typically looked to find this information?
- [If they do seek out information] How have you used the information you have found?

Q3. Key Takeaways – Thinking about the BRFs that you have read, what were the biggest “takeaways” for you?

- Did anything in the BRFs surprise you?
- After reading the BRFs, did you have any further questions about how FDA came to its decisions?

Q4. Clarity – How clearly is the content presented?

“Clear” is defined as key points are stated explicitly, sequenced logically, and chunked logically; you can follow the logic underlying the regulatory decision.

- On a scale of 1 to 4, where 1 is not at all clear and 4 is very clear, how would you rate the clarity of the BRFs you have seen?
- In what ways is the content presented clearly?
- In what ways can the clarity be improved?

For example:

- ✓ *To what extent are key points stated explicitly?*
- ✓ *To what extent is content related to each key point chunked together?*
- ✓ *To what extent are key points presented in a logical sequence?*
- ✓ *To what extent can you follow the logic underlying the regulatory recommendation?*

Q5. Understandability – How understandable are the BRFs that you have read?

“Understandable” is defined as simplest words and sentence structures are used, and terms are used precisely.

- On a scale of 1 to 4, where 1 is not at all understandable and 4 is very understandable, how would you rate the understandability of the content presented in the BRFs you have seen?
- In what ways is the content understandable?
- In what ways can the understandability be improved?

Q6. Usefulness – To what extent are the BRFs useful to you?

- On a scale of 1 to 4, where 1 is not at all useful and 4 is very useful, how would you rate the usefulness of BRFs for your purposes?
- How have you used or how do you plan to use BRFs?
- How useful is the BRF for these purposes?
- How can the usefulness of BRFs be improved?
- How else would you like to use the BRF [if it contained the needed information]?
- How would the BRF need to be adjusted to accommodate these uses?

Q7. Is there anything else that you would like to add about the BRFs you have seen?