BRF Interview Questions: Applicant

Q1.   First, do you have any general comments about the BRF that you would like to offer before I ask specific questions?

Q2.   [If the application received an approval] On its Approved Drug Products page, FDA makes the BRF available in one or more of the following documents: primary clinical review, Cross-Discipline Team Leader summary memo, Division Director summary memo, and Signatory Authority summary memo. In which document or documents did you read the BRF?

Q3.   In reading the BRF, what were your key "takeaways"?

   ➢   Did anything in the BRF surprise you?
   ➢   After reading the BRF, did you have any further questions about how FDA came to its decision?

Q4.   Clarity – How clearly is the content presented in the BRF?

   "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 content presented in the BRF?
   ➢   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 is the BRF?

   "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 BRF?
   ➢   In what ways is the content understandable?
   ➢   In what ways can the understandability be improved?

Q6.   Usefulness – To what extent is the BRF 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 the BRF for your purposes?
   ➢   How have you used or how do you plan to use the BRF?
   ➢   How useful is the BRF for these purposes?
   ➢   How can the usefulness of the BRF 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 BRF?