

## Research Quality Assurance Specialist Interview Questions

1. Tell me about an experience in which you analyzed information and evaluated results to choose the best solution to a problem.

2. What factors do you consider when providing technical review of data or reports that will be incorporated into regulatory submissions to assure scientific rigor, accuracy, and clarity of presentation?

3. What is the most challenging part of interpreting regulatory rules or rule changes and ensuring that they are communicated through corporate policies and procedures?

4. What have you found to be the best way to maintain current knowledge base of existing and emerging regulations, standards, or guidance documents?

5. Share an experience you had in dealing with a difficult person and how you handled the situation.

6. Tell me how you organize, plan, and prioritize your work.

7. Share an experience when you applied new technology or information in your job. How did it help your company?

8. Share an example of a time you had to gather information from multiple sources. How did you determine which information was relevant?

9. Please share an experience in which you presented to a group. What was the situation and how did it go?

10. How would you rate your writing skills? (Ask for an example that demonstrates great writing skills.)

11. What are some long-range objectives that you developed in your last job? What did you do to achieve them?

12. Share an experience in which your attention to detail and thoroughness had an impact on your last company.

13. Provide an example of a time when you were able to demonstrate excellent listening skills. What was the situation and outcome?

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14. Walk me through how you would coordinate, prepare, or review regulatory submissions for domestic or international projects.

15. In your experience, what is the key to developing a good team? (Look for how they build mutual trust, respect, and cooperation.)

16. Describe an experience when you reviewed product promotional materials, labeling, batch records, specification sheets, or tested methods for compliance with applicable regulations and policies.

17. What is the most challenging part of coordinating efforts associated with the preparation of regulatory documents or submissions?

18. Tell me about the last time when you prepared or maintained technical files as necessary to obtain and sustain product approval.

19. Share an example when you effectively advised project teams on subjects such as premarket regulatory requirements, export and labeling requirements, or clinical study compliance issues.

20. Describe what methods you use to determine the types of regulatory submissions or internal documentation that are required in situations such as proposed device changes or labeling changes.

21. Provide a time when you were able to identify a complex problem, evaluate the options, and implement a solution. How did the solution benefit your employer?

22. Provide a time when you dealt calmly and effectively with a high-stress situation.

23. Share an experience when you coordinated recall or market withdrawal activities.

24. How do you stay up to date on adverse drug reactions and file all related reports in accordance with regulatory agency guidelines? Share an example.

25. Share a time when you willingly took on additional responsibilities or challenges. How did you successfully meet all of the demands of these responsibilities? (Make sure the candidate is a self-starter and

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can demonstrate some initiative.)

26. Describe an experience when you communicated with regulatory agencies regarding pre-submission strategies, potential regulatory pathways, compliance test requirements, or clarification and follow-up of submissions under review.

27. What have you found to be the best way to escort government inspectors during inspections and provide post-inspection follow-up information as requested?

28. Share an experience in which your understanding of a current or upcoming problem helped your company to respond to the problem.

29. Tell me about the last time you monitored or reviewed information and detected a problem. How did you respond?

30. Describe effective ways to identify relevant guidance documents, international standards, or consensus standards and provide interpretive assistance.

31. Share an example when you effectively recommended changes to company procedures in response to changes in regulations or standards.

32. Describe a time when you successfully persuaded another person to change his/her way of thinking or behavior.

33. Name a time when your patience was tested. How did you keep your emotions in check?

34. Tell me how you obtain and distribute updated information regarding domestic or international laws, guidelines, or standards.

35. Share an experience in which your willingness to lead or offer an opinion helped your company.

36. Give me an example of when you thought outside of the box. How did it help your employer?

37. What have you found to be the best way to monitor the performance of your work and/or the work of

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others? Share a time when you had to take corrective action.

38. Name a time when you participated in internal or external audits.

39. What kind of experience do you have writing or updating standard operating procedures, work instructions, or policies?

40. Provide an experience that demonstrates your ability to manage time effectively. What were the challenges and results?

41. Name a time when your creativity or alternative thinking solved a problem in your workplace.

42. Share an effective approach to direct the collection and preparation of laboratory samples as requested by regulatory agencies.

43. Provide an example when you were able to prevent a problem because you foresaw the reaction of another person.

44. What have you found to be the best way to prepare responses to customer requests for information, such as product data, written regulatory affairs statements, surveys, or questionnaires?

45. Provide an experience in which you were sensitive to someone's needs or feelings. How did your helpfulness affect your work environment?

46. Provide an experience in which your ability to actively find ways to help people improved your company or your own work ethic.

47. Share an experience in which personal connections to coworkers or others helped you to be successful in your work. (Make sure candidate works well with others.)

48. Have you specialized in regulatory issues related to agriculture, such as the cultivation of green biotechnology crops or the post-market regulation of genetically altered crops?

49. Describe methods you have found helpful to monitor national or international legislation on

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ozone-depleting substances or global warming.

50. Walk me through how you determine the effects of legal requirements related to the production, supply, or use of ozone-depleting substances or equipment containing such substances.

51. What is the most challenging part of determining requirements applying to treatment, storage, shipment, or disposal of potentially hazardous production-related waste.

52. Name a time when you effectively determined regulations or procedures related to the management, collection, reuse, recovery, or recycling of packaging waste.