

Biogen Specific Teaching Material

Quality – GDP (Good Documentation Practice) Rules





Questions & Answers

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1. Name some synonyms for 'good' (in the context of Good Documentation Practices).

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1. Sample answer: accurate, error-free, meticulous, complete, legibility

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2. What format(s) do records get completed on?

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2. Records can be in paper-based, electronically-based and/or photographic media form(s).

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3. What types of documentations are there?

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3. There are basically two types of documentation: (1) regulations (instructions, requirements) and (2) protocols or reports.

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4. What should you do if you do not understand how to fill out part of a document?

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4. If you don't know how to do something, just ask.

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5. What colour ink should be used for documenting?

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5. You should use a black or blue ink colour pen or print.

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6. What is the in-company standard for indicating a date?

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6. Day-Month-Year

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7. What is a synonym for 'indelible' ink?

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7. Another word for 'indelible' is permanent.

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8. What do you do when a field does not required an answer?

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8. Where a field does not required an answer, you need to indicate it with N/A.

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9. If you make a mistake on a form, you can just erase it. (true or false?)

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9. False. If you make a mistake on a form, you must cross it out (single line strike-through) and initial and date the correction.

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10. Which time format do you need to use in forms?

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10. You need to use the 24-hour standard (e.g. 20:00 for 8 PM)

Thank you for your attention!

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