

Biogen Specific Teaching Material

Quality – Data Integrity





Questions & Answers

1. What is "ALCOA"? An abbreviation, an acronym or a mnemonic?

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1. ALCOA is a mnemonic.

2. The role of MHRA audits on Approved Bodies is to make sure they are fulfilling their obligations according to GxP and ALCOA, in keeping with data integrity. (true or false?)

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2. True.

3. The MHRA uses adequate quality and risk management systems to ensure that data be collected and stored in a secure manner. (true or false?)

3. False. Manufacturers need to use adequate quality and risk management systems to ensure that data be collected and stored in a secure manner, not the MHRA.

4. Only original, legible, error-free records are accepted by regulatory bodies. (true or false?)

4. False. Certified copies of documents are also acceptable, provided they be signed and dated by the original author.

5. 'Legible' means that the hand-writing or print is decipherable and easy to read. (true or false?)

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5. True.

6. Name at least three (3) synonyms for 'accurate'.

6. Some synonyms for 'accurate' are: correct, error-free, faultless, authentic, precise, meticulous.

7. Name a few synonyms for the word 'integrity'.

7. Some synonyms for 'integrity' are: honesty, purity, honour, morality, trustworthiness, reputability.

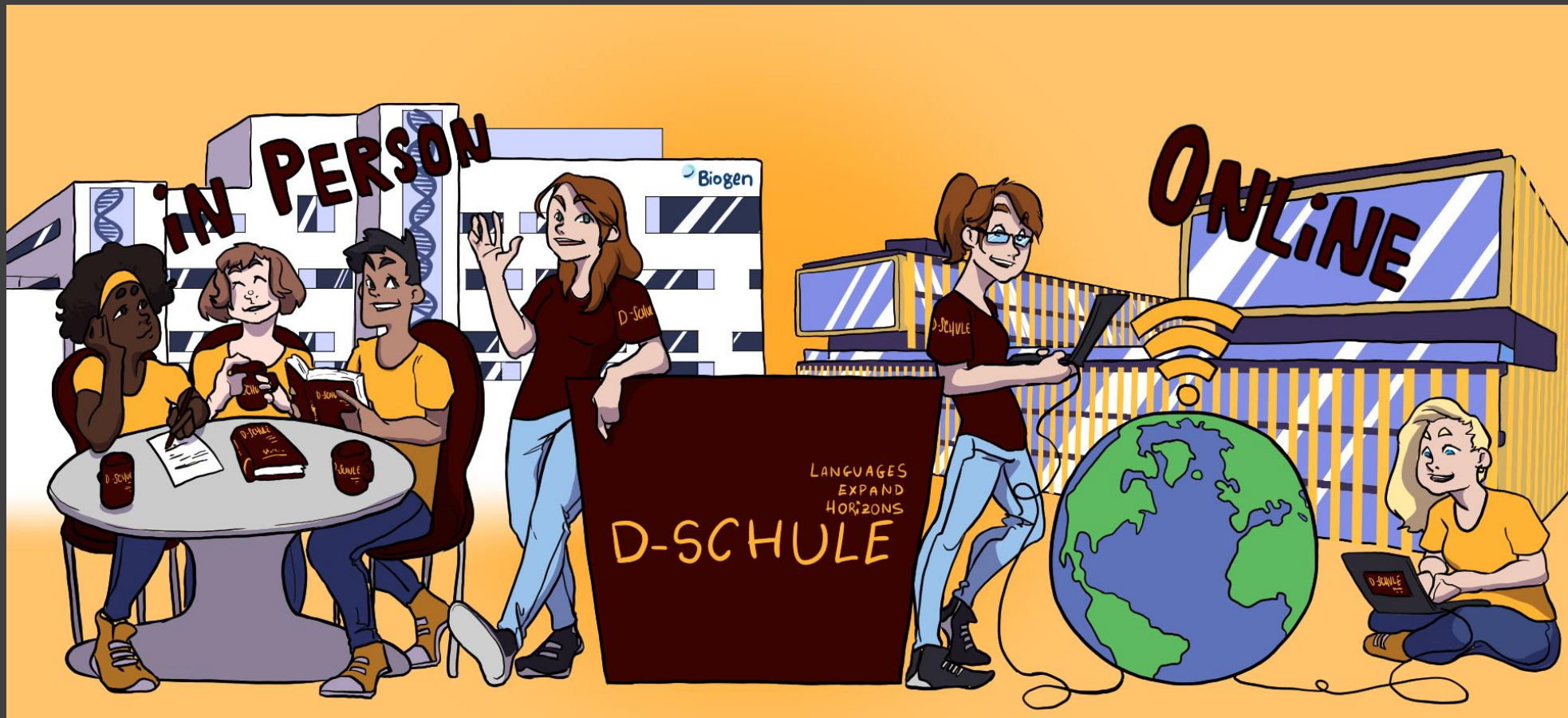
8. What does the acronym MHRA stand for?

8. MHRA stands for Medicines and Healthcare products
Regulatory Agency.



Thank you for your attention!

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