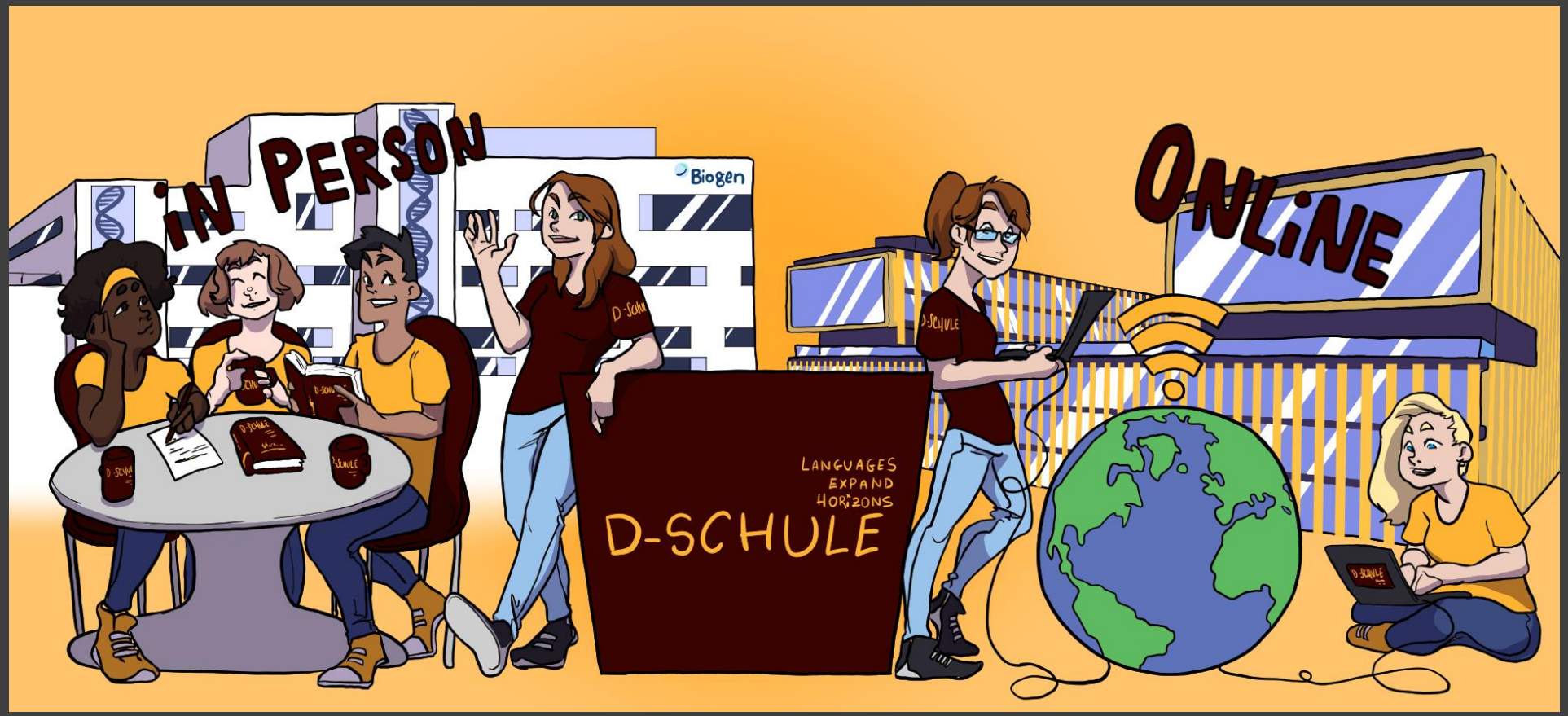
Biogen Specific Teaching Material

Good Manufacturing Practice Regulations



Questions & Answers

1. What is Good Manufacturing Practice (GMP)?

Good Manufacturing Practice Regulations

1. GMP is a set of (regional) guidelines that assure quality production processes and environment in the production of drug compounds (incl. cosmetics, food and animal feed).

2. What does adherence to the cGMP regulations assure?

2. The identity, strength, quality and purity of the product.

3. What is the main reason quality assurance plays a central role in pharmaceutical production?

3. The main reason quality assurance plays a central role in pharmaceutical production is its direct impact on consumer health.

4. What consequences might a pharmaceutical company face if it did not comply with cGMP regulations?

4. If a pharmaceutical company did not comply with cGMP regulations, it could result in any of the following: product recalls, fines, jail time, health issues.

5. Name at least three (3) aspects which GMP regulations delineate?

5. Possible answers: Record-keeping, personnel qualifications, sanitation, cleanliness, equipment verification, process validation, compliancy of process handling.

6. What does the C in cGMP stand for?

6. The c (in cGMP) stands for 'current'

7. The GMP was put in place to assure proper regulatory measures are followed after a product goes to market. (true of false?)

7. False. The GMP was put in place to assure proper regulatory measures are followed BEFORE a product goes to market.

8. Why would the consumer be at risk without GMP?

8. A consumer generally does not have the proper means of identifying whether a product is safe or effective.

9. On a global level, which bodies of authority are involved in devising GMP?

9. There are four bodies involved: The European Commission, the Pharmaceutical Inspection Co-Operation Scheme (PIC / S), the U.S. Food and Drug Administration (FDA), and the International Council for Harmonization of Technical Requirements.

10. Good Manufacturing Practice (GMP) are practices required to conform to guidelines recommended by agencies that control what?

10. The sale, manufacture, licensing and authorisation of drug compounds and medical devices

11. The identity, strength, quality and purity of a product lies in how close to the cGMP regulations are adhered to. (true or false?)

11. True. The identity, strength, quality and purity of a product lies in how close to the cGMP regulations are adhered to.

12. Due to strict GMP regulations, a product can now claim to cure, mitigate, treat, or prevent, a disease on its labeling. (true or false?)

12. False. The FDA prohibits any claim on labelling that any product can cure, mitigate, treat, or prevent, a disease.

Thank you for your attention!

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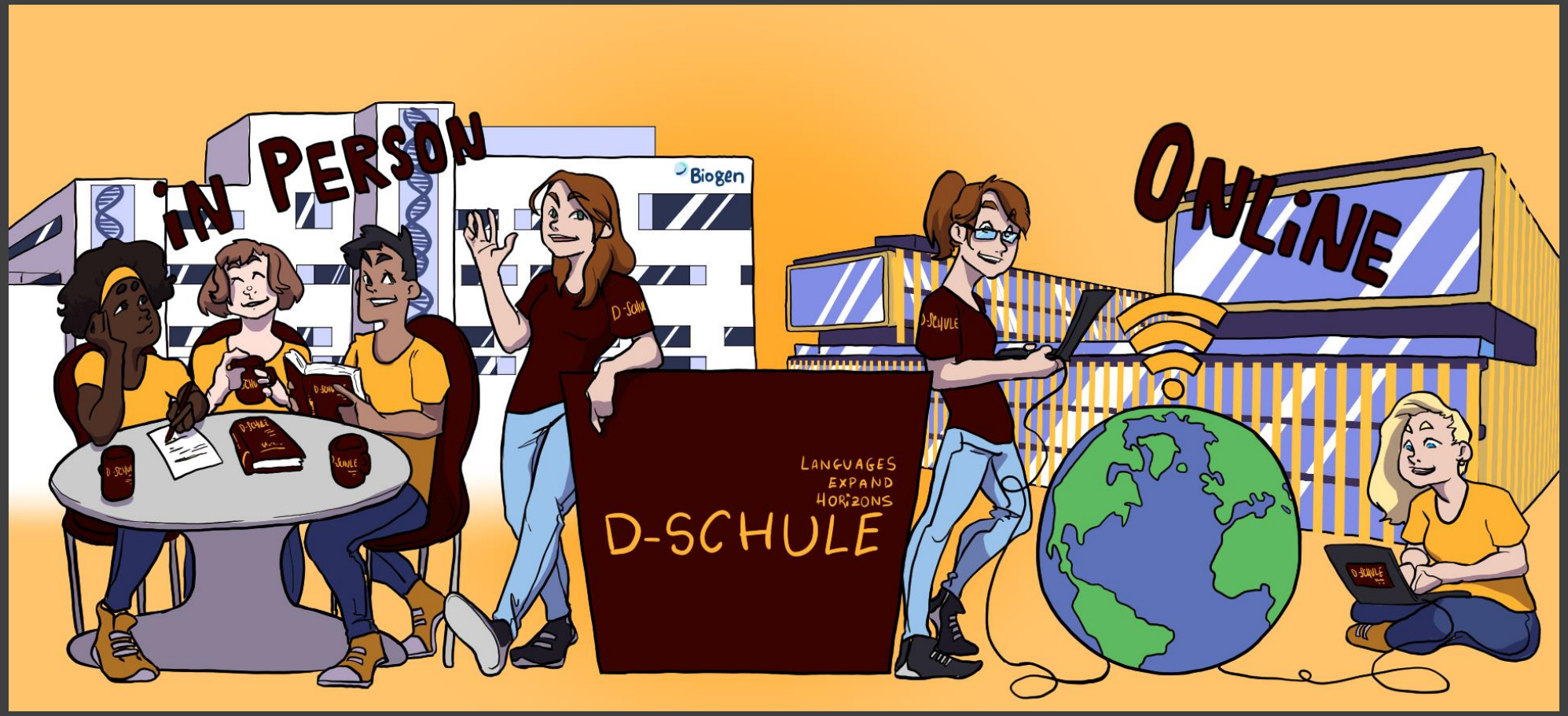

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