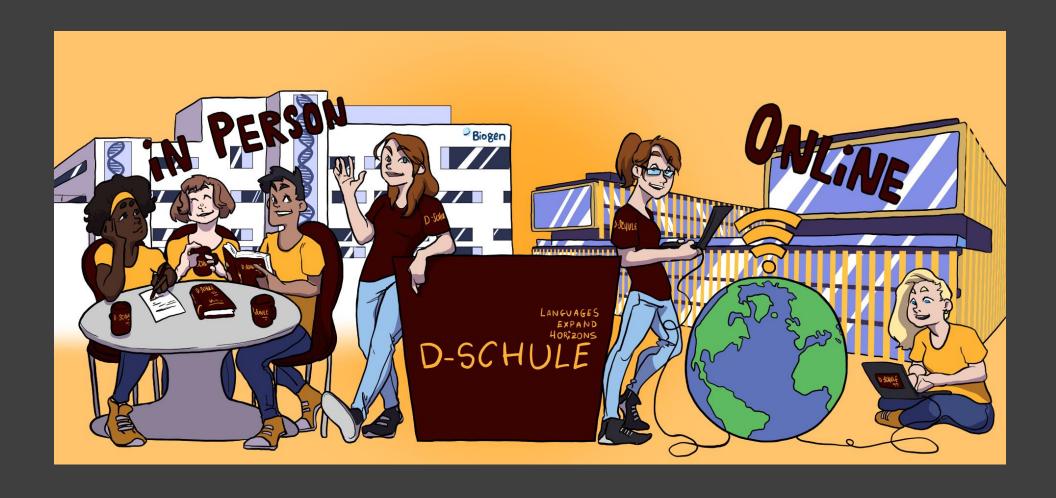
# Biogen Specific Teaching Material



# Questions & Answers

1. All countries worldwide follow the same legal directives for water sanitation and management. (true of false?)

1. False. Only Europe and the USA (and possibly China) apply strict legal standards (with the possibility of law enforcement).



2. In 2017, a revised monograph for Water for Injections (WFI) was introduced and approved for what purpose?









4. Which areas of the body can water (i.e. WFI) be injected?





5. Name at least two possible uses for potable water in the early stages of the production of pharmaceutical products.

5. Possible answers: Washing of equipment, rinsing of containers and in analytical reagents.

6. Which body of literature states the requirements or guidance of water for pharmaceutical use (WPU)?

6. You find it in national, regional and international pharmacopoeias.

7. When both dose and monomer levels exceed the given official limits (i.e. for Acrylamide & Epichlorohydrin), what must a public water system (such as Swiss TPH) do?



8. What do the following symbols stand for: Fe, Cu, Se and Pb?

8. Fe = iron, Cu = copper, Se = selenium, Pb = lead



9. Who is expected to carry out testing the quality of potable water used for pharmaceutical purposes?

9. The manufacturer must carry out the testing.

10. Water's unique properties, which allow it to dissolve, absorb or suspend many different compounds, through its polarity and hydrogen bonds, makes it .....





11. Which type(s) of water approved by the European Drinking Water Directive are used in the production of today's pharmaceutical products?

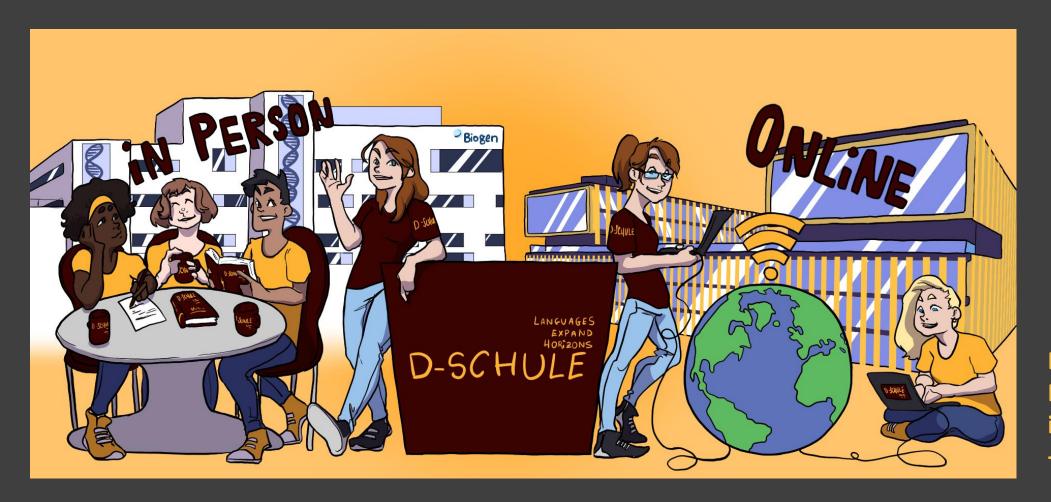


12. WFI is only available as prescribed medication. (true of false?)



# Thank you for your attention!

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