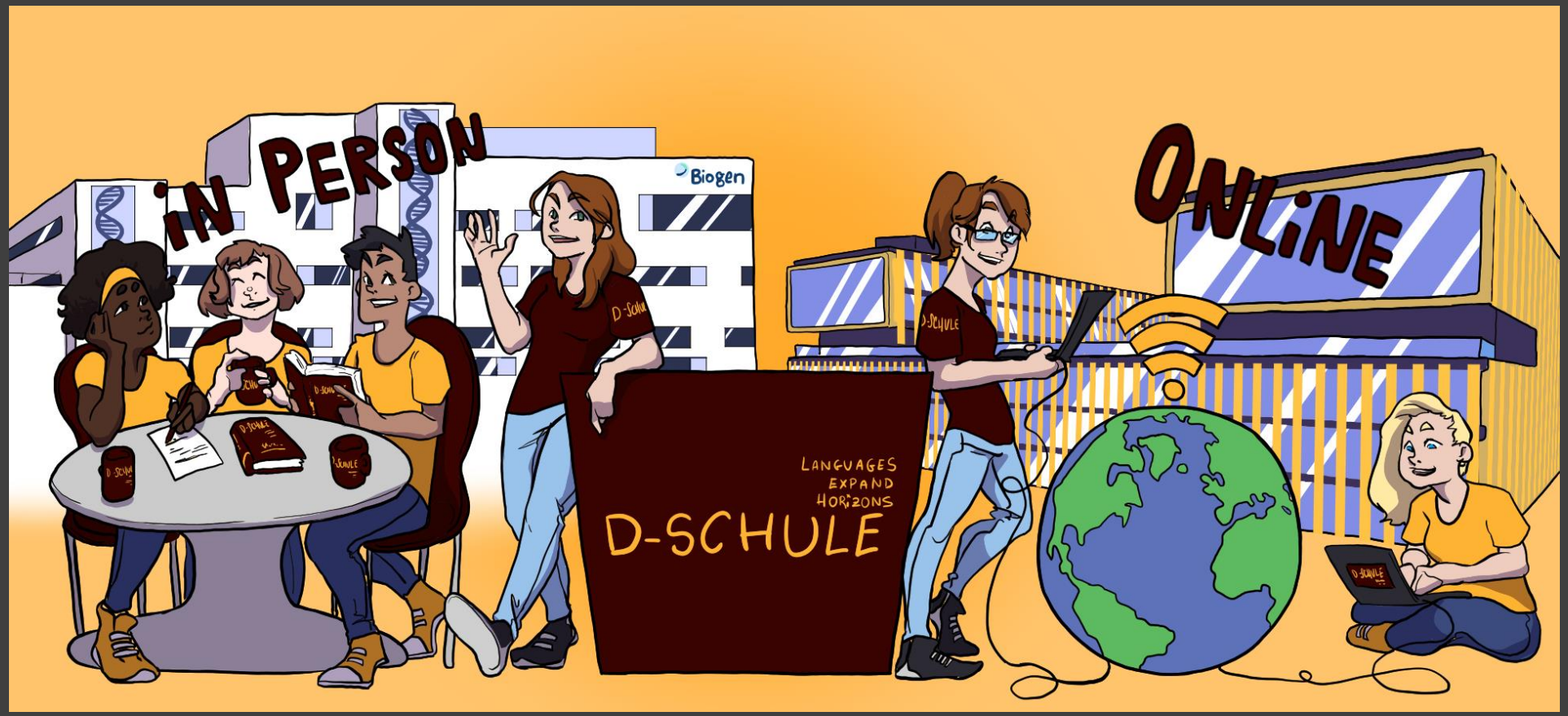
Biogen Specific Teaching Material

Cleaning and Disinfection – Regulatory Requirements



Questions & Answers

1. According to the FIFRA, what must be registered before sales or distribution of food and drug products?

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1. Any substance or mixture of substances intended to prevent, destroy, repel or mitigate any pest or microorganisms (incl. those in living humans and animals) must be registered with the FDA.

2. What standard statement appears on all registered pesticide and germicide product labels under the “Directions for Use” heading?

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2. The label reads: “It is a violation of federal law to use this product in a manner inconsistent with its labeling.”

3. Which authority regulates disinfectants and sterilants used on critical or semi-critical medical devices?

3. The FDA regulates disinfectants and sterilants used on critical or semi-critical medical devices.

4. What must a manufacturer of pesticide and germicide products do to obtain a registration for a substance or mixture of subtances?

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4. A manufacturer must first submit specific, detailed data on the safety and effectiveness of each product to the EPA.

5. What could happen if a manufacturer failed to follow the specified use-dilution, contact time, method of application, or any other condition of use?

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5. Failure to do so is considered to be a misuse of the product and so health care workers (or consumers) are liable to be penalised under the FIFRA.

6. Substance and mixture of substances intended to prevent, destroy, repel or mitigate any pest or microorganisms except those in living organisms must be registered with the FDA. (true of false?)

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6. False. Any substance or mixture of substances intended to prevent, destroy, repel or mitigate any pest or microorganisms INCLUDING those in living humans and animals must be registered.

7. Summarise what role the EPA (Environmental Protection Agency), the FDA (Food & Drug Administration) and CDC (Centers for Disease Control and Prevention) play at Biogen.

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7. (…)

8. The EPA's Antimicrobials Division and OPP (Office of Pesticides Program) regulate which chemical products?

8. the EPA regulates chemical germicides (e.g. sanitisers, disinfectants or sterilants).

9. What determines whether a product can be sold and distributed within the United States?

9. A product may be sold once the EPA has concluded that the product is safe, or that it is without unreasonable adverse effects.

10. Name a product regulated by the FDA under FFDCA that is considered to be an antimicrobial drug:

10. Anticeptics (among other products) are considered to be an antimicrobial drug, and therefore regulated by the FDA.

11. Which type of chemical used on critical and semi-critical medical devices is no longer regulated by the EPA (since 1996)?

11. Liquid chemical sterilants used on critical and semi-critical medical devices are solely regulated by the FDA.

Thank you for your attention!

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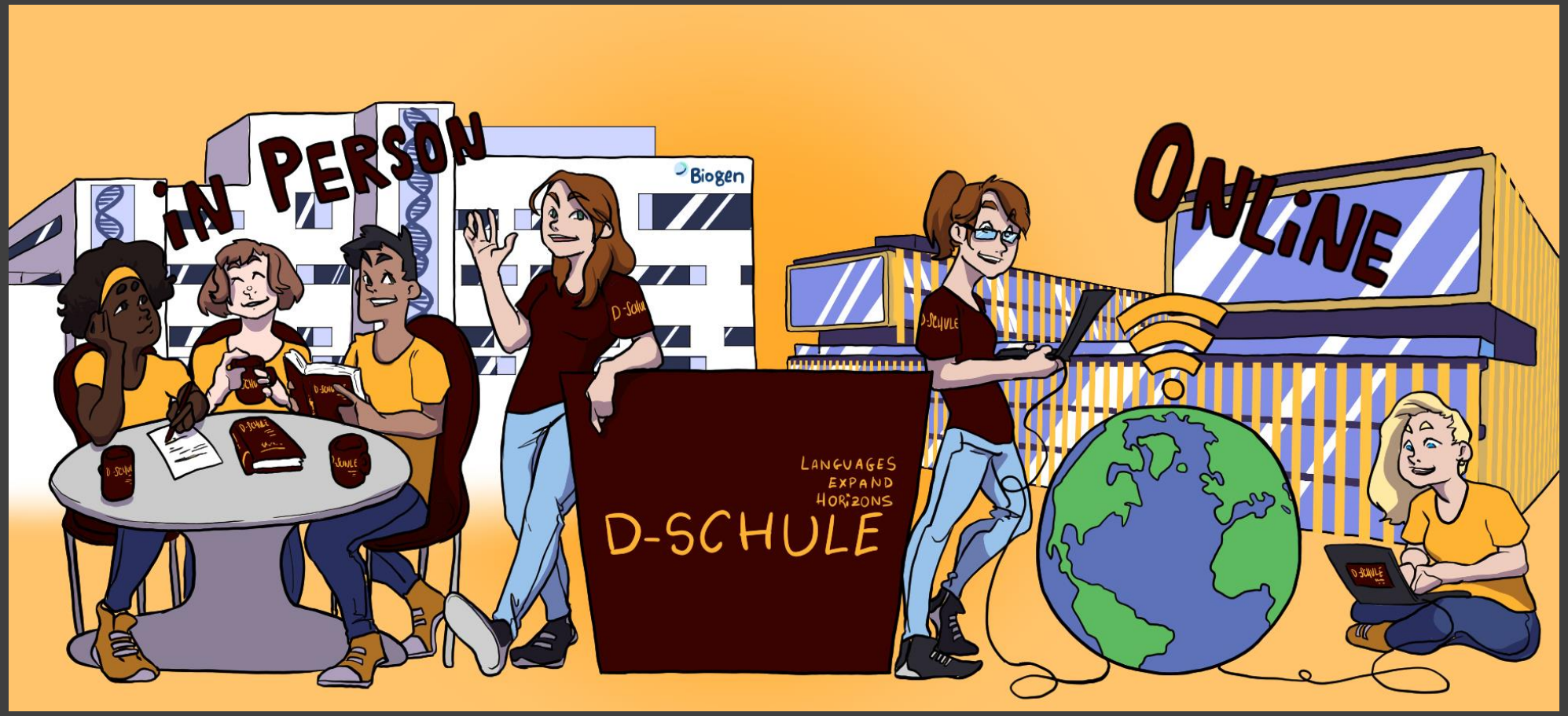

D-SCHULE
Domenika Hüsser
info@d-schule.ch
+41 79 730 52 35