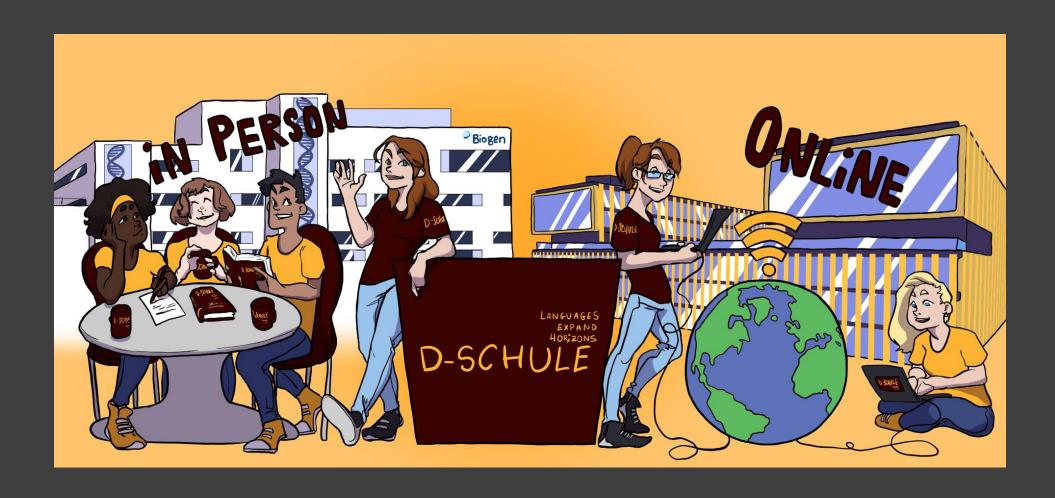
Biogen Specific Teaching Material



Questions & Answers

1. When it comes to the batch record and the release procedure, most pharmaceutical companies have a high first-time-right rate. (true or false?)

1. False. A first-time-right rate is close to zero when it comes to the batch record and the release procedure.

2. The average percentage of deviations due to human error in current manufacturing processes is at _____ percent.





3. If errors go undetected, it can result in performance losses (e.g. fewer batch releases, further deviations, human error)



4. In the end, an effective quality system is predominantly (according to operators) oral. (true or false?)

4. False. An effective quality system is predominantly a written one.



5. Name at least three (3) consequences of deviations of the quality system.

5. Some consequences are increased scrap, more deviations, fewer batch releases, delivery bottlenecks, etc.



6. What does Quality Costs means?

6. Quality Costs relates to preventing, detecting and remediating product issues.

7. Quality costs make up close to _____ of total costs in the pharmaceutical industry.

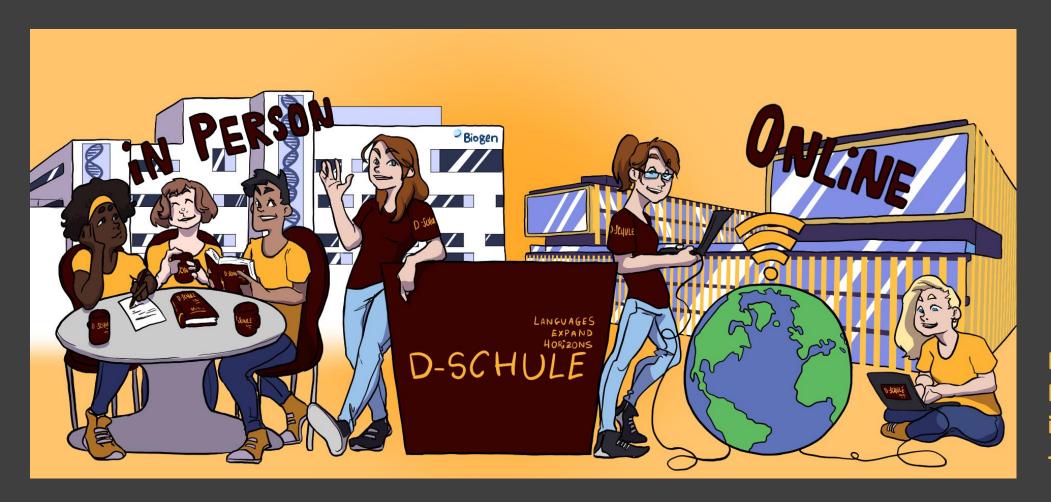
7. Quality costs make up close to 30% of total costs in the pharmaceutical industry.

8. The pharmaceutical industry is one of the biggest spenders in R&D and in quality costs. (true or false?)



Thank you for your attention!

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