



# Biogen Specific Teaching Material

Cleaning and Disinfection –  
Importance of cleaning and disinfection in aseptic processing areas







# Questions & Answers





## Cleaning and Disinfection – Importance of cleaning and disinfection in aseptic processing areas

1. What allows Biogen to determine if cleaning processes and cleaning techniques are effective?
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1. Environmental monitoring allows for effective cleaning processes and techniques.
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## Cleaning and Disinfection – Importance of cleaning and disinfection in aseptic processing areas

2. Cleaning processes help to prevent equipment malfunction or contamination, which can alter what in the drug product?  
(True or false?)







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2. Cleaning processes ensure the safety, identity, strength, quality, or purity of a drug product.







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3. List as many surfaces and items as you can that form part of the weekly cleaning schedule for production rooms at Biogen.







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3. Possible answers: Mopping ceilings, mopping walls, mopping doorframes, mopping floors with the appropriate cleaning solution










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4. Where a COP bath is unavailable, small utensils may be cleaned manually. (True or false?)







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4. True. (Small items, such as utensils, plasticware, may be cleaned by hand, or manually.)







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5. The steam temperature of an autoclave reaches 120° C and 100bar in operation.







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5. False (the autoclave is set to operate at 121° C and 1bar)







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6. A printer, or other recording device, on an autoclave is used for what purposes?







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6. The printer, or recording device, serves to provide process information such as temperature, pressure and cycle progress.







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7. What does Clean In Place (CIP) refer to?






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7. CIP is the system used for cleaning equipment that is too large for manual cleaning.










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8. Which item is NOT used in the CIP for sanitising equipment?  
Chemicals, heat, salinated water, compressed air.






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8. Salinated water is not used for CIP. (hot water is, nevertheless, used)







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9. What is done to ensure the contaminant level of the environment in which manufacturing occurs is within acceptable limits?







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9. Testing is performed.







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10. How often does one pour a 5.0% Sodium Hypochlorite solution into all open drains?







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10. A 5.0% Sodium Hypochlorite solution is poured monthly into all open drains.






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11. Define 'environmental monitoring' as best you can.







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11. It refers to tools and techniques designed to observe an environment, characterize its quality, and establish environmental parameters, for the purpose of accurately quantifying the impact an activity has on an environment.









## Cleaning and Disinfection – Importance of cleaning and disinfection in aseptic processing areas

12. What do cleaning processes help to prevent in the manufacturing of drug products?







## Cleaning and Disinfection – Importance of cleaning and disinfection in aseptic processing areas

12. It helps to prevent both equipment malfunction and contamination.







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13. What does COP stand for in the context of processing areas?







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13. It stands for Clean-Out-Of-Place.







## Cleaning and Disinfection – Importance of cleaning and disinfection in aseptic processing areas

14. What is an autoclave?







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14. It is a machine that uses high pressure and temperatures for sterilization.







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15. What is an COP bath?







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15. It is a piece of equipment that cleans typically small, complex, or 'difficult-to-clean' parts.









## Cleaning and Disinfection – Importance of cleaning and disinfection in aseptic processing areas

16. What is a CIP system?







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16. It is a system for cleaning the interior surfaces of process equipment, such as tanks, pipes, and pumps.







## Cleaning and Disinfection – Importance of cleaning and disinfection in aseptic processing areas

17. CIP is the system used for cleaning equipment that is too small for manual cleaning. (True or false?)





## Cleaning and Disinfection – Importance of cleaning and disinfection in aseptic processing areas

17. False. (CIP is used for large equipment.)



# Thank you for your attention!

## D-SCHULE – Your Language School



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