GOOD MANUFACTURING PRACTICES (GMP)

Study Questions

Study questions are designed to reinforce your understanding of the lesson material. Please submit your answers to the study questions after each completed lecture. Please create a Microsoft Word document and submit your completed study questions to the instructor via email.

Module 1

1. Define GMP in your own words
2. Why is GMP important?
3. List the key principles of GMP
4. List 3 desirable conditions within a factory
5. Briefly discuss important elements for proper facility layout
6. How is GMP being used in the cosmetics industry?

Module 2

1. How does the design assist in easy cleaning and maintenance of equipment?
2. Why is equipment cleaning important?
3. What type of equipment cleaning is typically done?
4. What do inspectors typically look for when conducting an audit?
5. What GMP guidelines must be employed for an industrial centrifuge?

Module 3

1. Why is personnel considered a company's best resource and asset?
2. Briefly discuss the role of QA/QC personnel
3. Briefly discuss the role of the QA/QC manager
4. Who is responsible for monitoring compliance to GMP?
5. Briefly discuss what is maintenance, and who is responsible for planning such
6. Who is notified for nonconforming product?
7. Fill in the blank. As the first step in meeting GMP personnel requirements, _____ should select or hire appropriate employees for the tasks to be performed.
8. True/False. Education alone is a good indicator of whether a recent graduate with a scientific degree can design a product.
9. Briefly discuss some of the employee training methods that are used for GMP

10. Briefly discuss 2 factors that should be considered when teaching employees about working in a controlled environment

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Module 4

1. Define sanitation in your own words
2. Briefly discuss the sanitation requirements for an API manufacturer
3. What should ill staff do?
4. Briefly discuss 3 elements of a hygiene program
5. Briefly discuss 3 hygiene requirements for food staff workers
6. Briefly discuss the importance of SSOP. What are some of the important requirements?
7. Define MPB. Briefly discuss its relevance to the sanitation of food processing industries

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Module 5

1. Define raw materials
2. Briefly discuss 2 regulations for raw material testing
3. Briefly discuss the inspection requirements for raw materials
4. When should non-GMP raw materials be used, if any?
5. What is ASTM? What is their purpose?
6. What is a supplier certification?
7. Why does every producer in the chain carries responsibility for his product as part in the final FCM?

Module 6

1. Briefly discuss the GMP requirement
2. What is the purpose of the self inspection?
3. What is HACCP? What is its purpose?
4. What are the benefits of having HACCP?
5. Which industry has the lowest reported knowledge and use of GHP?

Module 7

1. Define quality control
2. Why is the independence of quality control from production is considered fundamental?
3. Who authorizes all documentation that has an effect on product quality?
4. Define sampling
5. Define reference standards
6. Briefly discuss some of the risk associated with pharmaceutical outsourcing

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Module 8

1. Define packaging
2. Who should have control and responsibility for packaging?
3. Define reference number
4. What is the relevance of a reference number in packaging?
5. Define reference standards
6. List 3 things that is recommended to be tested
7. Briefly discuss the performance difference between LDPE and PVC in a MAP application for broccoli

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Module 9

1. How should one handle rejected product?
2. Define reprocessing
3. Define recalled
4. Briefly discuss the optimal conditions for a production area
5. Briefly discuss some of the product quality issues associated with HMPs

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Module 10

1. Define documentation
2. Why is documentation important?
3. When does one verify the documents against actual instruments, equipment, premises?
4. What is a certificate of manufacture?
5. How long is it valid?
6. What are compliance declarations, and why are they important for each stage of the production?

Module 11

1. Define GMP
2. What is the relevance of GMP within a food operation?
3. What is the relevance of GMP within a pharmaceutical operation?
4. Define HACCP
5. What are the objectives of HACCP?
6. Provide an example of how clinical research can be in strict accordance with GMP

Final Exam

Congratulations! Your company, Food A+, has been awarded a $200 million construction project to build a state of the art food packing facility in Omaha, Nebraska.

1. What construction and building criteria need to be considered to ensure that the facility is GMP compliant?
2. What equipment arrangement criteria need to be considered to ensure that the facility is GMP compliant?
3. Food A+ posted an ad in the Omaha Employment Digest. They received 500 prospects for hire. What criteria will be used to narrow the candidate list down to 100?
4. Food A+ hired 50 employees to start the facility up. What training do the employees need to go through to ensure that they are GMP compliant?
5. What organization structure would you recommend?
6. Briefly describe the sanitation and hygiene plan you would implement?
7. Briefly describe the inspection and audit plan you would implement?
8. Food A+ will be purchasing 100,000 lbs. of packaging film in the first year. This film will be used as cooking bags for the turkeys. Briefly describe the test protocol plan for the incoming raw material (film) that you would recommend, and why?
9. Briefly describe the test protocol plan for the finished product (packaged turkeys) that you would recommend, and why?
10. Briefly discuss the records and documentation program that you would recommend for Food A+