PHARMACEUTICAL VALIDATION PROCESSES

Final Project

The Final Project is designed to reinforce your understanding of the lesson material. Please create a Microsoft Word document and submit your completed study questions to the instructor via email.

Congratulations! You have been promoted to Chief Validation Officer for AB Pharmaceuticals. AB is a start-up company, so you will have to initiate a validation program from conception.

1. The Board of Directors are not from the pharmaceutical industry and needs to be education on what validation means and why it is important. Please define this for the Board.
2. How does validation fit within quality assurance?
3. There are several pieces of equipment and systems that will need to be implemented and validation by AB. Discuss the criteria that must be used to assess qualification
4. AB plans to manufacture the drug YTH within the next 2 years. Discuss how AB should validate that the parameters and conditions used in manufacturing of the products are reproducible and will produce consistent results
5. Discuss the operational qualification of AB's mixing operation during large scale production (hypothetical)
6. Congratulations! The YTH process has been established. Discuss how AB should maintain the validated process.
7. The R&D and QC department will house state of art analytical equipment for the YTH process. Discuss to the Board your plan to validate the analytical equipment.
8. The analytical system is showing to be unstable. What would be your plan to reduce variability?
9. The YTH drug can be produced in capsule and tablet form. The tablet has shown to yield off spec color 10% of the time by analytical method, but not to the naked eye. As Chief Validation Officer, would you reject the product? Why or why not?
10. Discuss to the Board some of the critical parameters for the capsule and tablet

Fill in the blank

1. Validation is required to get consistent _____.
2. _____ mandates that every pharmaceutical product be tested for purity, quality and stability before release.
3. _____ applies to documenting and standardizing the protocols involved in the API and excipient manufacturing
4. _____ phase validates that the parameters and conditions used in manufacturing of the products are reproducible and will produce consistent results
5. _____ procedures are those that test the quality of the pharmaceutical product
6. Once a pharmaceutical company buys any equipment, it has to pass the company's _____.
7. _____ is defined as, 'The process of demonstrating that equipment will function according to its operational specifications in the selected environment'
8. Once a validated process has been established, it has to be _____.
9. To carryout retrospective validation, _____ of the established pharmaceutical production is collected and is assumed to be a validated procedure for that particular drug's production
10. _____ is used for sterilization of ampoules and vials