Active Pharmaceutical Manufacturing – Take Home Exam

KSP – Purdue Fall 2018

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Date: \_\_\_24/11/2018\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

To complete this exam please review the handouts associated with each lecture from week 2. Each answer should be no more than 1 paragraph. Answers should be returned by November 26.

1. Outline the scope of ICHQ7 by providing at least four (4) examples of what ICH Q7 addresses and four (4) examples of what ICH Q7 does not address.

*SCOPE*

*-APIs manufactured for use in Human Drugs (Medicinal) Products*

*-APIs Manufactured by chemical synthesis, extraction, ,cell culture/fermentation, recovery from natural sources ,or any combination of these processes*

*-Sterile APIs, but only up to the point immediately before the API is rendered sterile*

*-APIs used in production of drug products for clinical trials*

*ICH Q7 NOT NOT ADDRESS*

*-APIs intended for use in Veterinary drug Products*

*-Registration and filling requirements for APIs*

*-Pharmacopoeias requirements.*

1. What are two important principles of Quality Management?

*-Quality should be the responsibility of all persons involved in manufacturing.*

*-Each manufacturer should establish, document and implement an effective system for managing quality that involves the active participation of management and appropriate manufacturing personnel*

1. Who are the key participants in the DMF process?

*-The person or company who submits a DMF (HOLDER)*

*-The person or company who references the DMF ( SPONSOR)*

1. What is the Quality Overall Summary (QOS) and what is its role in the dossier/application submission process?

*-QOS is all about putting pieces together.*

*The role is to:*

*-Improve the regulatory assessment process including potential risk to patients.*

*-Supports regulatory decision making.*

*-Supports post-approval commitments for NDAs,ANDAs and BLAs*

*-Enables understanding of key data in CTD Module3*

1. What is FDA’s legal basis and regulatory policy for requiring GMPs for API manufacturing?

*-Section 501(a)(2)(B) of the food ,Drug and cosmetic Act (FDCA), requires all*

*drugs to be manufactured in conformance with CGMPs. No distinction is made between an API and a finished pharmaceutical*.

1. Outline the key factors inspectional planning should include.

*-Risk-Based strategy*

*-API systems inspection*

*-API Profile Classes.*

1. Why is it important for GMP facilities and buildings to be designed with a transition zone between the manufacturing area and the general access area or common corridor?

-*To prevent mix-ups or contamination.*

1. How would you know that an approved product made in any manufacturing facility is safe and would work as it is intended to?

*-Drug quality link to Drug Product*

*-The circle in terms of Attributes*

*-ICH Q11 3.1.1*

1. What is the goal of API process development?

*-Consistently producing drug substance of intended quality designing in Quality.*

1. How would you know when your control strategy is not adequate?

*-If the control Strategy does not assure quality through the product Life circle*

1. Refer to Slide #10 in “Manufacturing by Fermentation”

Propose 2 in-process controls that you might implement to ensure that your process is successful with high quality. Indicate the analytical method you could use.

*INPROCESS CHECKS*

*-Temperature as we are dealing with live organism*

*-PH for stability of the organism and the product*

*-Oxygen for suitability of fermentation*

*ANALYTICAL METHOD*

*-Bio-assay*

*-HPLC*

1. Refer to slide #27 describing CDER’s review of Genentech’s BLA for pertuzumab.

List three 483 items cited in this inspection.

*-Equipment’s cleaning validation studies are inadequate*

*-Quality oversight of documentation is inadequate*

*-Inadequate control of materials*