From: Smith, Michael (CBER)
Sent: Friday, August 13, 2021 3:36 PM
To: Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Rohlfing, Paul <Paul.Rohlfing@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: STN 125742.0: 7 facility questions from the DMPQ team

Neda and Paul,

The DMPQ review team has the below seven facility questions. Please respond as soon as possible and no later than noon on Tuesday, August 17, 2021.

Drug Substance (Pfizer Andover; (b) (4)):

1. Regarding the computer systems, please provide the following:

    a. A list of the critical BNT162b2 drug substance manufacturing steps that are computer-controlled with the computer system identified.
    b. For each computer system identified in Part 1a, provide a narrative description of the validation process, certification that the installation and operational qualification (IQ and OQ) have been completed; explanation of the parameters monitored and tests performed; and a validation data summary.

2. For each cold room, freezer, and (b) (4) freeze/thaw system (b) (4) in (b) (4) (b) (4) in (b) (4)) used in the manufacture of the BNT162b2 drug substance, please identify the equipment with its unique identifier and provide a concise description of the qualification (e.g., IQ, OQ, performance qualification (PQ)).

Drug Product (Pfizer Puurs and Kalamazoo)

3. Regarding the recent Information Request (IR) responses (Response to FDA 26 Jul 2021 and Response to the August 5, 2021 FDA IR) STN 125742/0.24 and STN 125742/0.43, the Agency has additional inquiries for the Kalamazoo facility. You provided Table 8 (appended in the Response to August 5, 2021 FDA IR), which lists the BNT162b2 product contact equipment. Please provide the operational and performance qualification (OQ/PQ) summary documents for all new pieces of equipment. In addition,

please provide representative OQ/PQ summary documents for all families or groupings of tanks, regardless of whether they are existing or new.

4. Regarding the equipment utilities at Pfizer-Kalamazoo please provide the following information:
    a. Please provide the WFI/PW water quality criteria and a description of the monitoring program.
    b. Please provide all uses of the compressed air and nitrogen specific to BNT162b2 manufacture. If the respective utility is used in the process, please provide the monitoring limits.

5. Regarding the cleaning validation summary for the direct product-contact equipment at Pfizer-Kalamazoo, please provide the following information:
    a. Please provide the data to support the validated clean hold times for all direct product-contact equipment.
    b. Please explain why the acceptance criterion for residual cleaning agent is higher for the BNT162b2 (b) (4) (b) (4)) than it is for the other equipment (b) (4) (b) (4)).

6. Regarding visual inspection of the BLA process validation lots of BNT162b2 filled vials at Pfizer-Kalamazoo, please provide the following information:
    a. Please describe which PPQ/process validation lots were 100% visually inspected by automated inspection and which lots were 100% visually inspected manually.
    b. Please provide the acceptance criteria for the allowable limit of rejects during visual inspection.
    c. Please provide the defect/reject categories and the percentage of the rejects in each category for each BLA process validation lot.

7. Please update section 3.2 A.1 with the current cleaning validation status at Pfizer Puurs. Please update the status of your microbiological cleaning validation, outstanding manual cleaning and any cleaning validation deviation information, as applicable.

Regards,

Mike

- Please confirm receipt of this e-mail and let us know if you have any questions.

Mike Smith, Ph.D.
Captain, USPHS

Senior Regulatory Review Officer
Food and Drug Administration
Center for Biologics Evaluation & Research
Office of Vaccines Research & Review
Division of Vaccines and Related Products Applications
Tel: 301-796-2640
michael.smith2@fda.hhs.gov

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