

From: Hoffman, Kelsy
Sent: Wednesday, January 13, 2016 10:55 AM
To: 'ksmyth@paxvax.com'
Cc: Houck, Christina M
Subject: BLA 125597/0 IR

Mr. Smyth,

We have the following comment regarding your BLA 125597/0, "Cholera Vaccine, Live, Oral:"

1. For the equipment used in the upstream manufacturing operations at (b) (4) [REDACTED], please provide a table listing of all major product contact equipment used in the manufacturing of the intermediate bulk drug substance and indicate if the equipment is shared or dedicated and how this equipment is cleaned (i.e. (b) (4) [REDACTED]).
2. Please provide the summaries of the qualifications (OQ and PQ) for the HVAC system, in addition to major equipment (fermenters, freezer dryer, and BSCs) used in the manufacturing of intermediate bulk drug substance at (b) (4) [REDACTED].
3. Please provide the cleaning validations for major product contact equipment (fermenters, freezer dryer etc.) used at (b) (4) [REDACTED] for the manufacturing of intermediate bulk drug substance.

Please respond to this Information Request (IR) no later than **February 12, 2016**. Also, please let me know if you have any questions.

Thank you,

Kelsy

Kelsy F. Hoffman, Ph.D.

LCDR, USPHS

Primary Reviewer/Regulatory Project Manager

FDA/CBER/OVRR/DVRPA

10903 New Hampshire Ave.

WO71-3205

Silver Spring, MD 20993-0002

Office- 301-796-2640

Fax- 301-595-1124

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