

Davidson, Mark

From: Tull, Lori
Sent: Monday, July 24, 2017 3:05 PM
To: 'Rizwana Sproule'
Cc: Davidson, Mark
Subject: BLA 125643 - request for information

Dear Dr. Sproule,

We have the following request for information. Would you please respond to this request by Wednesday, 8/9?

1. Reference equipment used for the manufacture and storage of (b) (4) : Please confirm the accuracy of the Equipment ID numbers, Room numbers, and associated qualification numbers in the following table (in particular, the autoclave and (b) (4) tank) provided in the submission:

Part Number	Equipment	ID Number	Room	Qualification Document
(b) (4)				

2. Reference the revised 3.2.A.1, Facilities and Equipment, sent in an amendment (rec'd 06/26/17): Section 1.1.1 Overview [first paragraph] has not been updated to reflect the current qualification status of the manufacturing suites. Please provide an updated document in an amendment to the application.
3. In reference to the Kite (b) (4) facility, please provide a summary of the alert and action limits for Environmental Monitoring that you have established for all room classifications.
4. In reference to the Aseptic Processing Validation at (b) (4) Facility:
 - a. How did you select the (b) (4) BSCs (in the Suite (b) (4) study) and the (b) (4) BSC (in the Suite (b) (4) study) for use in your Aseptic Processing Validation? Was a risk assessment performed to identify the specific BSCs used in the initial studies? If so, please provide the risk assessment.
 - b. Do you plan to include the use of the other BSCs in subsequent AOQs? If so, please provide your general plan. If not, please provide a justification.

5. Reference your qualification of the Kite Final Product Shipper (for axicabtagene ciloleucel): Was physical testing such as drop and vibration testing performed as part of your qualification study?
6. In reference to (b) (4) Environmental Monitoring (EM) program, please provide the EM action and alert limits for non-viable Particulate and viable Airborne and Surface sampling for Grade [REDACTED] areas (i.e. BSCs)
7. In reference to (b) (4) purified water system program, please provide the action and alert limits that established for the (b) (4) testing for Bioburden, Endotoxin, Conductivity, pH, and Total Organic Carbon.
8. Please provide a list of all product components (i.e. culture flasks, pump tubing, filters, etc.) used the processing of (b) (4).
 - a. Please indicate whether the component is received already sterilized by supplier or sterilized at (b) (4)
 - b. Please state whether Extractable/Leachable studies have been completed for the component.
9. Please provide a summary of the qualification (IQ/OQ/PQ) of the autoclave used to sterilize product contact components used in the processing of (b) (4).
10. Please provide a summary of the Aseptic Processing Simulation Validation Study for aseptic processing of (b) (4) performed at (b) (4)
11. Please provide a summary of the Container Closure Integrity Testing qualification for the (b) (4) cryostorage (b) (4).

Regards,

Lori Tull
Team Lead
Division of Regulatory Project Management
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research
(240) 402-8361



"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone."