

Davidson, Mark

From: Davidson, Mark
Sent: Wednesday, September 13, 2017 4:14 PM
To: Rizwana Sproule (RSproule@KitePharma.com)
Cc: 'Alex Babayan'; 'Nadia Agopyan'
Subject: Kite Pharma BLA 125643 Facilities Information Request 9.13.17

Importance: High

Dear Dr. Sproule,

Please provide the following facility request for information:

1. In reference to (b) (4) EM program, please describe the in-process environmental monitoring that is performed during the (b) (4) (in (b) (4)) in (b) (4) in Room (b) (4) . Please provide the acceptance criteria.
2. Please provide a representative IQ/OQ Summary Report for the (b) (4) Units.
3. Reference manufacturing of axicabtagene ciloleucel at Kite: In table format, please provide a list of the all critical components (i.e. processing bags, final container bag) and raw materials (i.e. excipients and viral vector) and the incoming testing performed by Kite on each material or component for release to manufacturing. If only a Certificate of Analysis evaluation is performed, please provide your justification.
4. In reference to production at Kite: please provide an overview of how you have verified that you will be able to produce at full capacity (i.e. all BSCs in use at the same time in (b) (4) Production suites) without compromising product quality or safety.
 - a. Please confirm that all BSCs in Suites (b) (4) are qualified for use in commercial manufacturing.
5. In reference to (b) (4) WFI system:
 - a. How many drops does the system have?
 - b. How often is the WFI system tested for Bioburden, Endotoxin, Conductivity, pH, and Total Organic Carbon?
 - c. Please provide the acceptance criteria for Bioburden, Endotoxin, Conductivity, pH, and Total Organic Carbon.

Please request that they respond by Wednesday 09/20/17.

Best

Mark L. Davidson, RHIA
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