

Davidson, Mark

From: Davidson, Mark
Sent: Monday, September 25, 2017 4:21 PM
To: Rizwana Sproule (RSproule@KitePharma.com)
Cc: 'Nadia Agopyan'; Alex Babayan
Subject: Kite Pharma 125643/0: Facility IR for (b) (4) (via Kite) 9.25.17

Hi Dr. Sproule,

We have the following-up facility request for conformation that 483 actions have been completed: See below.

Please respond by 4:00pm Thursday 09/28/17.

Mark L. Davidson, RHIA
Regulatory Project Manager
OTAT/CBER/FDA
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 240-402-8277
Fax:301-595-1303
mark.davidson@fda.hhs.gov

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As follow-up from 483 inspection responses, please confirm that the following actions have been completed:

Action	Due Date from Response Letter(s)
Completion of CAPA 288059	18 Aug 2017
Completion of CAPA 288060	18 Aug 2017
Completion of CAPA 288062	18 Aug 2017
Completion of Risk Assessment RA035	31 Aug 2017
Performance of QAL109: "Cleaning validation of biosafety cabinets"	31 Aug 2017
Revision of SOP PROC-CLD-OP-011627, "Operation, Cleaning and Maintenance of the Biological Safety Cabinets"	31 Aug 2017
Performance of Qualification, QAL1087, for (b) (4) specific material transfer from (b) (4)	31 Aug 2017
Completion of revised risk assessment RA017	31 Aug 2017

Finalization of and Training on PROC-CLD-OP-048860, "Transfer and Storage of (b) (4) Product and Production Samples from Manufacturing to Product Storage"	31 Aug 2017
Completion of CAPA 288058	31 Aug 2017
Completion of the Risk Assessment RA038	15 Sep 2017
3rd party comprehensive review of all microbiological contamination prevention programs and aseptic operations	30 Sep 2017*

*The Agency understands that we have not reached this date; please state if target will be met.

If any of the above actions are incomplete (with exception of *), please provide an update on its status and the expected completion date.

Please respond by 4:00pm Thursday 09/28/17.