

## 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](mailto:mark.davidson@fda.hhs.gov)

"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 immediately by e-mail or phone."

**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

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

\*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.**