

## Davidson, Mark

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**From:** Davidson, Mark  
**Sent:** Friday, September 22, 2017 3:39 PM  
**To:** Rizwana Sproule (RSproule@KitePharma.com)  
**Cc:** 'Nadia Agopyan'; 'Alex Babayan'  
**Subject:** Kite Pharm 125643 Facilities IR 9.22.17

Dear Dr. Sproule,

Please see the facilities request for additional information:

In reference to (b) (4) WFI System:

According to (b) (4), water sampling for microbial and bacterial endotoxin testing is expected to occur (b) (4) somewhere in the system, with each outlet being sampled (b) (4), based on a risk assessment, to characterize the quality of the water.

1. Please provide your justification (risk assessment) for only (b) (4) sampling.
2. Do you use WFI in preparation of any products or buffers?

In reference to (b) (4) EM program:

1. Please provide your justification for not performing active air sampling (viable and non-viable) during the (b) (4) (b) (4) in the BSC in Room (b) (4).

**Please respond by Tuesday 09/26/17 or ASAP.**

Thank You

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)

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