

From: Kristine Riley [KRiley@Organo.com]

Sent: Tuesday, February 28, 2012 7:31 PM

To: Bobo, Qiao

Subject: RE: Organogenesis 125400/0 Information Request Feb. 27, 2012

Hi Qiao:

Deviation # 11-8072 relates to the finding in April 2011 that the clean steam procedure (b)(4), *Sampling Procedure for Clean Steam* was not followed as required. Specifically, sampling was not performed on a (b)(4) basis. An impact assessment was performed and concluded there was no product impact. Corrective actions were implemented in July 2011 and included procedural revisions and personnel training. In addition, internal Quality audits now include verification of the clean steam operation and sampling procedures. The clean steam system has since been routinely monitored for TOC, Conductivity, bioburden and endotoxin at a minimum frequency of (b)(4) per revised SOP QCP-043, *Water for Injection, Purified Water, and Clean Steam Sampling Procedure*.

Please let me know if you have any additional questions regarding this matter.

Best regards,
Kristine

From: Bobo, Qiao [Qiao.Bobo@fda.hhs.gov]

Sent: Tuesday, February 28, 2012 1:36 PM

To: Kristine Riley

Subject: RE: Organogenesis 125400/0 Information Request Feb. 27, 2012

Kristine, please let me know what deviation 11-8072 is. Thanks, Qiao

From: Kristine Riley [mailto:KRiley@Organo.com]

Sent: Tuesday, February 28, 2012 1:00 PM

To: Bobo, Qiao

Subject: RE: Organogenesis 125400/0 Information Request Feb. 27, 2012

Hi Qiao:

Please find attached our response to your IR questions dated 27Feb2012. Let me know if you have any additional questions regarding this matter.

Best regards,
Kristine

From: Bobo, Qiao [mailto:Qiao.Bobo@fda.hhs.gov]

Sent: Monday, February 27, 2012 4:19 PM

To: Kristine Riley

Subject: RE: Organogenesis 125400/0 Information Request Feb. 27, 2012

Great. Thanks for your quick turn around. Qiao

From: Kristine Riley [mailto:KRiley@Organo.com]

Sent: Monday, February 27, 2012 4:15 PM

To: Bobo, Qiao

Subject: RE: Organogenesis 125400/0 Information Request Feb. 27, 2012

Hi Qiao:

We're finalizing the response now and will have it to you by tomorrow afternoon or sooner, once it goes through team review.

Have a nice evening!

Kristine

From: Bobo, Qiao [mailto:Qiao.Bobo@fda.hhs.gov]
Sent: Monday, February 27, 2012 9:45 AM
To: Kristine Riley
Subject: Organogenesis 125400/0 Information Request Feb. 27, 2012

Dear Ms. Riley,

Below is additional information needed for reviewing STN125400/0. Please let me know if you have any questions.

(1) During the pre-license approval inspection, Organogenesis indicated to me that the alert limits for Water-For-Injection, Purified Water and Clean Steam systems were being implemented. Please provide the newly established alert limits, and the rationale for limits established.

(2) Please provide Clean Steam monitoring data for May-July, 2011 including bioburden data.

Thanks,

Qiao Bobo, Ph.D., RAC
LCDR, USPHS, Regulatory Officer
Division of Manufacturing and Product Quality (DMPQ)
Office of Compliance and Biologics Quality (OCBQ)
Center for Biological Evaluation and Review (CBER)
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