

Information Request on 483, July 25, 2013 - Novoeight

From: Melhem, Randa
Sent: Thursday, July 25, 2013 1:08 PM
To: -----(b)(6)-----
Cc: Pracht, Leigh
Subject: RE: Novo Nordisk BLA 125466 responses to 483 observations
Hi --(b)(6)--,

As a follow-up to our telecon today regarding the 483 responses, I included my comments regarding SOP 119131 and 129431.

SOP 119131 (v.15).

The SOP describes the expansion of cell culture: Thawing of cells, propagation days (b)(4) and propagation days (b)(4). The format of the SOP for thawing and propagation days (b)(4) includes in a table format the following: What needs to be done, How is it accomplished (step by step instructions), Status to be achieved and Who performs each step (Lab technician at (b)(4) bench or the lab assistant or either one). However the format for section "propagation days (b)(4)" is different in that it does not include the column Who would perform the task; instead that is written in the How column of the table, and it is not very specific: "Propagation in days (b)(4) may be performed by (b)(4) laboratory technicians. If there are (b)(4) laboratory technicians, it may be helpful for the (b)(4) technician to perform all tasks outside of the grade (b)(4) bench, including environmental samples in grade (b)(4)."

In addition the following comments do not give clear instructions, which was a discussion item during the PLI, and Novo Nordisk management agreed that instructions should be more explicit, so that there would be no room for interpretation by the operators.

Section 1.1: "A final review of the propagation log book may be performed in office areas"

Sections 6.1.1, 6.2.1 and 6.3.1:

"----- (b)(4) ----- are assembled in the general lab and this may be performed using method A or B as preferred".

"It may be beneficial to divide the work between (b)(4) laboratory technicians"

"We recommend that the assembled ----- (b)(4) ----- are sent for ----- (b)(4) ----- before cells are prepared for passaging on days (b)(4)".

"We recommend that --- (b)(4) --- take place - (b)(4) - before cells are prepared for passaging on days (b)(4)"

SOP 129431 (v.7)

The acceptance criteria for (b)(4) is set at ? ---(b)(4)--- and not at ? (b)(4) as presented during the PLI.

Please provide clarification/justifications for the comments above. In addition, please provide the effective dates for the SOPs submitted in the 17-Jun-2013 response.

Please provide the responses by Wednesday 07-Aug-2013.

Thank you,

Randa
Tel: 301-827-6999

From: -----(b)(6)----- [mailto:-----(b)(6)-----]
Sent: Wednesday, July 24, 2013 4:04 AM
To: Melhem, Randa
Subject: RE: Novo Nordisk BLA 125466 responses to 483 observations
Thanks Randa, Thursday is fine, I'm available at 9:00 and 11:00. Let's say I call you at 9:00?

Torben

From: Melhem, Randa [mailto:Randa.Melhem@fda.hhs.gov]
Sent: 23. juli 2013 21:34
To: -----(b)(6)-----
Subject: RE: Novo Nordisk BLA 125466 responses to 483 observations

Hi (b)(6),

Hope you had a nice vacation.

Is Thursday 25-July-2013 at 9:00 am or 11:00 am good for you to discuss the 483 responses.

Thanks,

Randa
Tel: 301-827-6999

From: -----(b)(6)----- [mailto:---(b)(6)---]

Sent: Friday, July 05, 2013 5:50 AM

To: Melhem, Randa

Subject: RE: Novo Nordisk BLA 125466 responses to 483 observations

Thanks Randa, that's great, I'll contact you when I'm back 22 July. In the meantime we will go through the SOP and make the necessary corrections in order to avoid room for interpretation.

Also I'll get information about the acceptance limits for the -(b)(4)-.

Regards (b)(6)

From: Melhem, Randa [mailto:Randa.Melhem@fda.hhs.gov]

Sent: 4. juli 2013 21:04

To: ----(b)(6)-----

Subject: RE: Novo Nordisk BLA 125466 responses to 483 observations

Hi (b)(6),

I really do not want to intrude on your vacation. We can discuss the responses to the 483 when you get back.

My comments are about the consistency of the different sections of the SOP as well as the use of "may" which does not provide precise instructions, but allows room for interpretation, and thus a procedure would be performed differently from one operator to the next.

The lack of consistency and precision in the SOPs was a discussion item during the inspection, and Novo Nordisk management agreed that instructions should be more explicit, so that there would be no room for interpretation by the operators.

I have another comment about the (b)(4) acceptance limits: during the inspection, Novo Nordisk committed to set the acceptance limits at ? (b)(4)(attached presentation); however in the recent response to the 483, the -(b)(4)- is set at ? ---(b)(4)--- (Appendix 5, Table 4 of SOP129432, v. 7).

Regards,

Randa

Tel: 301-827-6999

From: ----(b)(6)---- [mailto:---(b)(6)----]
Sent: Thursday, July 04, 2013 2:41 AM
To: Melhem, Randa; -----(b)(6)-----
Subject: Re: Novo Nordisk BLA 125466 responses to 483 observations
Hi Randa

I'm on vacation right now, but I'll find the informations regarding the SOP. Can we discuss any time Friday?
Kind regards (b)(6)

Fra: Melhem, Randa [mailto:Randa.Melhem@fda.hhs.gov]
Sendt: Tuesday, July 02, 2013 02:34 PM Romance Standard Time
Til: ---(b)(6)---
Emne: RE: Novo Nordisk BLA 125466 responses to 483 observations

Dear (b)(6),

I hope all is well. I reviewed the responses to the 483, and I have few comments regarding updated SOP 119131.
When is a good time to discuss this SOP.

Thank you,

Randa

Randa Melhem, Ph.D.
Consumer Safety Officer
FDA/CBER/OCBQ/DMPQ
Phone: 301-827-6999 Fax 301-827-3536

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