

# Answer to Questions Email, September 17, 2012 - Ducord

From: Joanne Kurtzberg, M.D. [joanne.kurtzberg@duke.edu]  
Sent: Monday, September 17, 2012 6:17 PM  
To: Gavin, Denise K; Rebecca Durham  
Cc: Bruce Burnett, Ph.D.  
Subject: Re: answers to some of your questions  
Follow Up Flag: Follow up  
Flag Status: Red  
Sorry. I meant (b)(4). J

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From: Gavin, Denise K [mailto:Denise.Gavin@fda.hhs.gov]  
Sent: Monday, September 17, 2012 06:14 PM  
To: Rebecca Durham  
Cc: Joanne Kurtzberg, M.D.; Bruce Burnett, Ph.D.  
Subject: RE: answers to some of your questions

previously you said STCL-SOP-036 will be used for pt (b)(4), here you say (b)(4)....please clarify.

thanks, Denise

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From: Rebecca Durham [mailto:rebecca.durham@duke.edu]  
Sent: Monday, September 17, 2012 5:10 PM  
To: Gavin, Denise K  
Cc: Joanne Kurtzberg, M.D.; Bruce Burnett, Ph.D.  
Subject: FW: answers to some of your questions

Denise,  
This email bounced for some reason.  
Becky

Rebecca J. Durham  
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From: Joanne Kurtzberg, M.D.  
Sent: Monday, September 17, 2012 4:58 PM  
To: Denise.Gavin@fda.hhs.gov  
Cc: Rebecca Durham; Bruce Burnett, Ph.D.  
Subject: answers to some of your questions

Dear Denise:

We thought it was important to get these answers to you by email. Your questions are in blue, our answers are in black.

When did you start using STCL-PROC-036 as the procedure to wash thawed CBU?

The effective date for STCL-PROC-036 was 24AUG2012. This is ---(b)(4)--- wash protocol and is used to wash units that will be infused into patients who weigh (b)(4) or more. Units for smaller patients are processed by the --(b)(4)-- procedure (028). .

Was this protocol used for any of the units in the stability data analysis submitted in amendment 013?

STCL-036 was not used for any of the units in the stability data analysis submitted in amendment 0123.

Comment: the validation report for comparison of the ---(b)(4)--- wash method and --(b)(4)-- wash method will be forwarded to you tomorrow 18SEPT2012.

Sincerely,

JK and the Duke CCBB Team

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