

Parker, Bryan

From: Sullivan, Glenn <glenn.sullivan@cardinalhealth.com>
Sent: Wednesday, December 14, 2016 10:11 AM
To: Parker, Bryan
Cc: Still, Cami
Subject: [External_Sender] AU amendments

Bryan, sorry for the confusion. I hope that this table will provide an explanation as to why we requested the AU's and how.

As discussed during our pre-licensing inspection, many of the Subject Matter Experts on certain processes, such as Drug Product Batch Manufacturing or Quality Control test methods, were trained by Line 1 in Norway and had no previous training in Radiation Safety, therefore they had to complete our 200 hour training course and receive additional hours handling RAM. This Rad Safety didactic course was completed after their extensive process training in Norway. Therefore, when they returned they started the training course, but at the same time, started to train others on the processes since they were now the Subject Matter Experts. This was laid out as our "Train the Trainer" program. The first amendment request for Elizabeth, Chad and Aaron, was due to the fact that they had the radiation safety training hours needed, and had completed the training from the individuals located in the first table, the Subject Matter Experts. Although the SME's signed off on the *specific process* training, all training and handling was performed under the supervision of a site Authorized User. We added in all of the process training paperwork to supplement their general Handling Hours paperwork (which was signed off by Site Authorized Users.)

The second amendment was to add all the other AU's that had completed the process training as well as all the radiation safety training needed to complete the AU course.

AU's being requested that are Subject Matter Experts. They have been trained by individuals involved with Line 1 in Norway and completed the Cardinal Health's AU course as well as all site specific Radiation Safety training. Additionally, all RAM handling hours were completed under the supervision of a previously named Authorized User.

Name	Authorized Use
John Bain	Quality Control
Nicole Botimer	Quality Control
Aaron Stephens	Production
Stacy Fulk	Production
Jana Nees	All

AU's being requested that were trained by the above SME's and/or previously named AU's as well as completed the didactic AU coursework:

Name	Authorized Use
Elizabeth Tindle	All
James Brading	Quality Control
Kevin Elmer	Quality Control
Chad Warkentien	Production
Luzelva Shaw	Quality Control
Laura K. Sturdevant	Quality Control

Let me know if you have any additional questions. I will be in Indy tomorrow through Saturday and if you would like a conference call with Cami and myself, please do not hesitate to let me know.



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