

Teleconference Regarding Data - Ducord

RE: Teleconference regarding Data from Duke (b)(4) Pilot Study

Time: 4:30pm

Attendees can use the following number for the call:

Number: ----(b)(4)-----

Passcode: ---(b)(4)---

Duke University (Sponsor) Regarding missing data that demonstrate that the Hespan and Centrifugation do not significantly reduce the number of contaminating microorganisms in the post-process (b)(4) and (b)(4) fractions (with respect to the respective HPC-C fraction). FDA is verifying that this study is being done before sponsor move to the repeat validation.

Discussion:

1. The sponsor has clarified that they tested the effect of Hespan and centrifugation on the distribution of microorganisms in the --(b)(4)-- sample. However, they were not able to keep the initial inoculum under -----(b)(4)----- as proposed earlier. The experiment on -----(b)(4)----- is pending and all data will be formally submitted with the Phase II validation data.
2. FDA recommended that they change their "target" inoculum level to ----- --(b)(4)----- for the Phase II repeat studies to safely stay under the required regulatory limit of -----(b)(4)-----.
3. FDA also recommended that they verify their dilution series and the actual inoculum level per bottle (by plate assay) in triplicate.

Attendees:

FDA:

Joydeep Ghosh, CMC Reviewer

Mark Davidson, RPM

Duke University:

Amanda Parrish- Associate Director, Regulatory Affairs; Duke Translational Medicine Institute/Duke University

Tracy Gentry- GMP Lab Director; Robertson Clinical and Translation Cell Therapy Program

Rebecca Durham- Project Leader; Robertson Clinical & Translational Cell Therapy Program-CT2- DTRI

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