

**From:** Simone, Lisa  
**Sent:** Tuesday, December 05, 2017 1:50 PM  
**To:** Simone, Lisa <Lisa.Simone@fda.hhs.gov>  
**Cc:** Duncan, Robert <Robert.Duncan@fda.hhs.gov>; Mahajan, Babita <Babita.Mahajan@fda.hhs.gov>  
**Subject:** BL125589 AFIA Telecon minutes

Telecon Minutes  
BL125589 AFIA  
December 5, 2017  
FDA: Lisa Simone, Babita Mahajan  
Oxford Immunotech, Inc: Katie Pomerantz, Product Specialist, 508.281.8595,  
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I requested clarification on the AFIA risk assessment documentation provided December 4, 2017 (001\_Attachment-1\_LAB-DSGN-5\_AFIA Risk.xlsm), for two issues outlined below. These deficiencies were not sent, but were developed in preparation of the conversation and were the focus of the interaction.

- a. Residual risk no longer appears in the risk table, and we are unable to reconcile how you calculate or record residual risk. Your risk table shows 13 risks that remain Not Acceptable after mitigation. The assessment is significantly longer than the previous risk table because it appears you separated each of the individual risk control measures into a separate row to assess individually. This is acceptable. We believe that you are somehow combining the effect of several risk mitigations together because you periodically include a grey row with "Summary of above countermeasures" in the "Risk Controls" column. However, your new Risk Procedure (LAB-QA-62) states that residual risk is to be added to the Product Risk Analysis record, but it does not clarify how to combine the individual risks from the risk table to produce the residual risk. Even though some rows indicate that the risk controls are a "summary of above countermeasures," the formula for the calculation of those summary row values does not appear to include any risk information from the other rows they are supposed to summarize. Finally, at least one "summary" row has a post-mitigation assessments of "Not acceptable" (e.g., Sequential ID 725). Please clarify how you calculate residual risk, what the "summary" rows indicate, and how final risk levels of "Not acceptable" are to be interpreted. This information should be included in your risk process or risk documentation to aid in interpretation.
- b. It appears that an error exists between your definition of Severity in the "Front page" sheet and the assignment of Severity values in the "Review Hazards" sheet. Several Hazard IDs are associated with a potential harm of death and are assigned a Severity of '4' although "death" is assigned a Severity value of '5'. The Severity values should be corrected and the risk table updated.

For a), Katie explained that yes, the summary lines were meant to convey the summary of previous risk entries. The automatic formulas are not used to calculate residual risk, but a user manually reviews the multiple risk entries and manually enters the lowest probability estimate of all associated risk rows for the summary row. She stated that the summary row for Sequential ID 725 reference above was an error and would be corrected.

For b), Katie stated that Severity 5 wouldn't apply because "death" was not certain. I explained that if death is possible, Severity 5 would be used, but then they would estimate that the probably would be lower. I said it was up to them how they wanted to resolve the discrepancy, but it should be addressed to avoid confusion. Katie agreed to address.

Katie will relay the questions to the appropriate staff, and will contact us for a telecon if additional information is needed. She requested, and I agreed that they could send an updated version for me to check before they formally submit the updated version. I also mentioned that they should align the table with their Risk process document (LAB-QA-62) to ensure residual risk is captured correctly, clarify how it is calculated and ensure that it is captured correctly. She agreed.

**Lisa K. Simone, PhD**

*Software Review and Policy*

**Center for Biologics Evaluation and Research (CBER)**

**Office of Blood Research and Review (OBRR)**

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