Draft minutes

Conference call for the MITA assay validation study

Date ： June 26th, 2019

Validation Management Team: Corsini, E., Roggen, E., Germolec, D., Inoue, T., Aiba, S., Kimura, Y., Omori, T., Kojima, H.

1. Welcome address and approve draft agenda
   Kojima welcomed to join this meeting and the VMT members approved the agenda.
2. Results of phase I
   Omori introduced results of phase I. For within-laboratory reproducibility, the ratio of AIST tukuba was 100%(5/5) and one of Tohoku Univ. was 80% (4/5). Unfortunately, one of AIST, Shikoku was 60% (3/5) as shown in Table and the results of this laboratory had not met the success criteria of within-laboratory reproducibility (80%) in the study plan..
3. Proposal of the revised positive criteria
   To dissolve this concern, Aiba suggested three proposals. They are 1) Change the acceptance criteria, 2)Judgement and 3)The threshold and the positive results at 2000 μg/mL. Based on these proposals and the data re-analyzed by Kimura, all the members discussed and considered the current data may meet the success criteria if the changed acceptance criteria uses. The all agreed to change the acceptance criteria (see the attached new SOP).
4. Re-analysis of phase I
   Omori promised to perform re-analysis of phase I data and provide the results by e-mail after this meeting.
5. Future plan
   Kojima talked about the future plan as a prerequisite the success criteria of within-laboratory reproducibility meet using re-analysis data of phase I. In this case, he declares the completed phase I and coordinate the next F2F meeting on July 15th in Hawaii for chemical selection phase II.

   He mentioned to request the VMT members support the revision of IL-2 Luc validation study and develop the Detailed Review Paper on in vitro immunotoxicity in the next meeting.