MITA F2F meeting draft minutes in Hawaii

Date: July 15, 12:00-14:45

Venue: Syokudo & StarBucks in Ala Moana Hotel

Participants: Emanuela Corsini, Dori Germolec, Setsuya Aiba, Hajime Kojima

1. Development of DRP

   Kojima reported the OECD WNT approved to develop a detailed review paper (DRP) on in vitro immunotoxicity and proposed to support this project to the MITA validation management team (VMT). Based on the previous Corsini & Rogen's papers, he considers to develop the DRP. All the participants agreed and Kojima asked them to select additional experts for the project. Corsini and Germolec recommend him following candidate experts. He will contact them soon and he will coordinate the F2F meeting in January or February, 2020. Before the F2F meeting, he will make a draft ToC with Corsini and Dori and share to all.

   -Laura Gribaldo (JRC)

   -Henk van Loveren (Maastricht Univ.)

   - Barbara Kaplan (Mississippi State Univ.)

2. IL-1βassay validation study

   Kojima welcomed you agreed to complete the experiment of phase I. According to the revised criteria, the within-laboratory reproducibility of this assay is perfect at three laboratories. However, do not forget Corsini's previous comments.

   1. Regarding the maximum concentration, it is always possible write in the SOP that final concentrations higher than 1 or 1.5 mg/ml should not be tested to avoid false positive response.

   2. It is important that in the next phase, classification criteria remains as there are now. It is not correct to continue changing the criteria to fit the results, to me, this indicates the non-optimization of the method.

3. Reply to peer review panel

   To reply to the comments from peer review panel for the IL-2 assay validation report, Aiba's comments as their reply confirmed. Especially, we discussed the positive criteria of test chemicals for predictive capacity.

   As the positive criteria, we fixed the thymus weight reduction plus T cell proliferation, T cell mediated function, cytokine induction or DTH response by in vivo, in vitro and ex vivo data. The data depending on only one paper is not accepted.

   Based on this discussion, Aiba will revise the validation report and share it to all. After checking it, Kojima will share the final one to the peer review panel.

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Chemical selection for phase II

Based on the candidate chemicals recommended by Corsini and Germolec, we discussed 20 test chemicals for phase II. We agreed 17 test chemicals in accordance with their suggestion and discussed more three chemicals. Kojima requested one more negative test chemical including total more than 6 negatives considering balance of test chemicals. The following three chemicals was selected.