**KHIDI-KASBP Regulatory Affair Workshop Draft Agenda**

**Seoul, Korea**

**August 2019 (TBD)**

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| Time | Speaker | Topic | Discussion Description |
| 9 am |  | FDA overview | Overview of overall FDA structure. Review of a review division as an example. Typical FDA team members for assigned programs. |
| 10 am |  | eCTD submission | The format requirements for an actual submission to FDA; specifications and structure. |
| 11 am |  | networking | Attendees should meet each other in a networking session. |
| Noon | All | lunch | Sustenance break. |
| 1 pm |  | preIND/IND success | The components that are required for a successful preIND/IND will be discussed.  For example:  - strategy / goals  - timelines / planning  - team roles and meeting practice  - medical writer input to documents and briefing package  - maintenance of the IND |
| 2 pm |  | preIND “how to” including content | A to Z on what and how to request and complete a preIND meeting. |
| 3 pm |  | IND overview and M1, M2, M5 | Overall review of an IND. |
| 4 pm |  | M3 CMC detailed content review | CMC content |
| 5 pm |  | M4 Pharm/Tox detailed content review | Nonclinical content |
| 6 pm |  |  | M1 = administrative documents such as forms, investigator’s brochure, labeling  M2 = summary documents  M5 = clinical protocol (s) |
| 6-pm |  | Q&A |  |

**Speakers (Preliminary):**

Regulatory Affair: Sandy Suh, Exeltis R&D, Head - Regulatory Affairs

Regulatory Affair: John Kim, Pierre Fabre, Vice President - QA and Regulatory Affairs

M3 CMC: Young Chun Jung, Akebia Therapeutics, Director – Technical Operation

M4 Pharm/Tox: Sean Kim, Blueprint Medicines, Senior Director -Non-clinical Development