Meeting Minutes: Best practices for determining and updating storage temperate and shelf life Workshop
9 of December 2020

Actions:

Action	Responsible	Date
Reach out to sustainable.manufacturing@cepi.net if you are interested in securing vials or DP capacity. (Details below)	All	Ongoing

Decisions:

- N/A

ITEM 1iii: [Notes]

Introductions, meeting overview and rules

- **CEPI Announcement - Vials & DP Capacity available for COVID-19 Vaccines**
  CEPI has secured vials and DP capacity to support >2BN doses of COVID-19 vaccine and has allocated capacity to each partner who has requested it. Unallocated vial capacity as well as DP capacity (non-live product only) remains and CEPI is interested in understanding if this could be helpful to anyone's COVID-19 vaccine production response. If you have any interest in these vials or DP/DS capacity, please contact sustainable.manufacturing@cepi.net.

Principles and practices of vaccine stability and manufacturing modeling

Tim Schofield gave a presentation that included an over of a basic release model, manufacturing modeling, tradeoffs in stability and manufacturing modeling and the benefits of modeling. Additional details can be found in the final presentation materials.

Case study: A vaccine's journey from factory to field

Renske Hesselink's presentation covered the planned and unplanned conditions of drug product from manufacturing to administration. Additional details can be found in the final presentation materials.

- There was discussion of issues with Arrhenius modelling and a recommendation to build in a safety margin to account for the variable temperature of the the vial and shipping containers.
- VVM was noted as the preferred option for monitoring vial temperature so as not to overestimate temperature excursions.

Case study: nOPV lessons learned

Erman Tritama gave an overview of Bio Farma's lessons learned while developing nOPV2 and collecting stability data. Additional details can be found in the final presentation materials.

Industry Position: Best practices for updating stability data

Chrissy Richards and Didier Clénet from Sanofi presented on the relevance of stability consideration for COVID Vx. supply, stability modeling as a tool to ensure fast supply of vaccines with examples, vaccine specificities and commonalities vs. biotherapeutics as well industry reflections on what is needed from WHO and CEPI. Additional details can be found in the presentation.

- The vendor of the smart trackers referenced is AKTS. You can learn more about them and contact the company via the following link: https://www.akts.com/contact-us/

- The modeling approaches shares have not yet been compared with the VVM approaches but there is promise that it could be more accurate.
- The clinical models are accurate for the lots that are used to produce the model. The recommendation is to use at least three lots to build a kinetic model. You can validate by comparing models and confirming the predictive bands overlay one another.
- QR codes have the capability to track both pharmacovigilance data and stability data by lot.

WHO assessment of stability data to ensure programmatic suitability for LMIC – Carmen Rodriguez Hernandez, WHO

Carmen Rodriguez Hernandez presentation explained the added value of PQ to ensure supply chain in LMIC, stability data requirements and addressed challenges as well as proposed a way forward.

- VVM is required for programmatic suitability. VVM is not required for PQ but sufficient data will need to be submitted to make a decision. Implementation of VVM on the vial will depend on the procurement agency.
- WHO is discussing the development of lower VVM's with TempTime. There are also conversations with potential additional vendors.
- Some developers will be printing both the manufacturing date and expiry date on the primary label.
- Carmen emphasized COVID-19 vaccines must be stored at the appropriate temperature even in the absence of a VVM requirement during this stage of the pandemic.
- "Expiry TBC": refers to guidance that will need to come from the country level regarding whether an expiry date needs to be printed on the label or not

Meeting close announcement

- Jim Robinson shared that CEPI has an open EOI "Vaccine Drug Products in alternative primary packaging and delivery devices". The EOI offers the opportunity to explore advancement of a novel multidose Drug Product presentation, the 200-dose bag developed by INTACT Solutions, a subsidiary of MEDInstill. You can view the EOI document here and contact Renske.Hesselink@cepi.net with questions. **The deadline is Friday 15 January 2021, 15:00 CET.**