Table 19: Streamlining Shipping Qualifications/Transportation Validation

Facilitators –

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Scope:

Global harmonization of requirements and efficient shipping processes can help streamline shipping validations. During this roundtable, we hope to look at challenges seen during shipping of COVID-19 vaccines including synchronizing different requirements from regional health authorities as well as how effectively product was shipped to locations across the globe under such expeditious and rigorous timelines.

While strategies for shipping might shift due to pandemic situations, requirements for testing and qualifications has not. Let us delve into requirements from container closure integrity and product testing to qualification criteria for component changes.

Can we utilize some of these pandemic era strategies in creating efficient but still compliant methods for shipping product across the globe?

Questions for Discussion:

1. What were the shipping challenges that new COVID-19 vaccines faced? How did the companies accommodate the extreme shipping conditions, tight turnaround times and different requirements from regional health authorities? Did COVI-19 vaccines have the same product testing, CCIT and qualification criteria as other vaccines? Can lessons learned from the pandemic be used to harmonize/streamline shipping validation across the globe?
2. What type of product testing including CCIT is required as part of shipping validation for ADCs, biologics, and small molecules? Are guidelines available? Can development work on CCIT be utilized to support shipping validation if required?
3. If certain components (different size trays, different size of vial, etc.) are being changed in a shipping system, are any type of qualifications activities required to support this change?
4. Should the last mile shipping be included in overall shipping validation strategy and plan? Should there be consideration of alternative short-term condition in the last mile and use period? What additional stability studies would be needed to support that portion?
5. What type of qualification activities are needed if new modality of product (liquid) is introduced to the shipping program?

Discussion Notes:

February 4 –

1. Shipping validation is needed before BLA filing

2. There are 3 stages of shipping validation

A. Validate the shipper (in USA validated shippers are available from vendors) or select a commercial validated shipper

B. Operation qualification (determine the boundary) : verify that product X in shippers can maintain temperature for Y hours during summer and winter time (Thermo aspect). The product can tolerate vibration and shaking during transport (physical aspect)

C. Performance qualification: send product to normal shipment three times.

3. Active cold chain maintenance: refrigerated unit with power back up from www.Envirotainer.com