EALTH CONTRIBUTION TO PUBLIC CONSULTATION ON REVISION OF ANNEX 15

Topic:

Discussion on the draft "Annex 15: Qualification and Validation; EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use; 6 February 2014".

Contribution is considered in red on the following points

Chapter	Current Version	Proposed Version	
General			
	Proposition of addition : **During the Qualification Design period if a handling or shipping risk is identified, then appropriated tests should be defined and considered during the commercial manufacturing and if a specific information is defined and has to be shared, then its management with the concerned entity should be organised**		
3. QUALIFICATION STAGES FOR EQUIPMENT, FACILITIES AND UTILITIES			
3.3	**Design qualification (DQ)** The next element in the validation of new facilities, systems or equipment is DQ where the compliance of the design with GMP should be demonstrated and documented. The requirements of the user requirements specification should also be verified during the design qualification.	The next element in the validation of new facilities, systems or equipment is DQ where the compliance of the design with GMP should be demonstrated and documented. The requirements of the user requirements specification should also be verified during the design qualification. **Processes and tests concerning packaging and transportation should be included in the design qualification to minimize risks during the whole life cycle of the products.**	
5. VERIFICATION OF TRANSPORTATION			
5.2	It is recognised that validation of transportation may be challenging due to the variable factors involved however transportation routes should be clearly defined. For transport across continents seasonal variations should also be considered.	It is recognized that validation of transportation may be challenging due to the variable factors involved however transportation routes should be clearly defined. For transport across continents seasonal variations **need to be** considered.	
5.3	A risk assessment should be performed to consider the impact of conditions other than temperature during transportation e.g. humidity, vibration, handling, delays during transportation, failure of data-loggers, topping up liquid Nitrogen, product susceptibility	A risk assessment should be performed to consider the impact of conditions other than temperature during transportation e.g. humidity, vibration, handling, delays during transportation, failure of data-loggers, topping up liquid Nitrogen, product susceptibility,	

	and any other relevant factors.	**breach in the supply chain integrity, theft, falsification** and any other relevant factors.	
5.4	Due to the variable conditions expected during transport e.g. delays at airports, continuous monitoring of any critical environmental conditions to which the product may be subjected should be performed.	Due to the variable conditions expected during transport e.g. delays at airports, continuous monitoring **and recording** of any critical environmental conditions to which the product may be subjected should be performed.	