Plenum discussion

The devil is in the detail

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EXAMPLES

1. The drug product storage temperature is -20°C. After freezing the Fill-Finish partner informs you that some vials are not frozen (supercooling / technical batch).
2. The Fill-finish partner informs you that they cannot take the shipped drug substance into the facility because their internal intake procedures are not met. The shipment will be returned asap.
3. The CMO informs you that it is nessesary to include a holding time of three days in between two unit operations and ask for stability data and storage temperature, which you do not have.
4. In a shipment of GMP drug product glass type I vials at -60 to -80°C (dry ice) several vials were cracked upon arival at the distribution partner.
5. The courier thermologger temperature profile were out of specification set by the courier.

EXAMPLES

1. A change in UV-profile was observed and the operaters had to take a quick decision on collection of the product resulting in lower protein concentration in the eluate.
2. A shipment of GMP quality was send to the wrong address not being a part of the GMP loop. The parcel was redirected to the correct address and without any temperature OOS. Has this batch lost its GMP status?
3. In a SE-HPLC method specified to address content of HMW (but not providing an impurity profile) peaks of more than 1% LMW was observed in a phase I material stability study – do you need to take any actions?
4. A drug substance is stored at -20°C (-25 to -15°C) but an OOS was filed due to a temperature increase to -14°C for 30 minutes.

FOR DISCUSSION

1. How to handle OOS in phase I+II clinical batches manufacture