

PDA PV IG - Virtual Meeting Sep 30, 2024

PDA PV IG Leaders;

Robert Dream, HDR COMPANY LLC Mauro Giusti, Eli Lilly & Co.





Q1: Shipping Validation

- **A Temperature Sensitive Products**
- **B** Low Temperature Products (-80°C)

Q1: Shipping Validation

A – Temperature Sensitive Products

Q1: Shipping Validation

B – Low Temperature Products (-80°C)

- Q2: Transfer from CT production to PV How do you establish that you can move from CT material production to PV in the final commercial site? Examine the following cases:
 - **A Gene Therapy Medicinal Products**
 - **B Cell Therapy Medicinal Products**

Q2: Transfer from CT production to PV - How do you establish that you can move from CT material production to PV in the final commercial site? Examine the following cases:

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Team comments:

Q3A:

Q2: Transfer from CT production to PV - How do you establish that you can move from CT material production to PV in the final commercial site? Examine the following cases:

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Team comments:

Q3B:



PDA Process Validation IG

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