

# CCI – Multi Temperature Analysis

## Product

- Biologic
- Oncolytic Virus
- Melanoma
- Commercially available

## Issue

- Concern regarding container closure integrity at T of air shipment
  - 120°C to -80°C
- Requirement of EMA

## Resolution

- Developed/validated container closure integrity method for these T's
- Audited by EMA
- Resultant date accepted

