ChecklistGuro

Pharmaceutical Cold Chain Compliance Checklist

Temperature Monitoring & Recording

Ensures continuous temperature monitoring and accurate record-keeping throughout the cold chain.

Monitoring Start Date

Enter date...

Monitoring Start Time

Temperature (Initial)

Enter a number...

Temperature Reading 1

Enter a number...

Time of Reading 1

Temperature Reading 2

Enter a number...

Time of Reading 2

Notes/Observations

Write something...

Equipment Calibration & Maintenance

Verification and upkeep of refrigeration units, data loggers, and other critical equipment.

Last Calibration Date

Enter date...

Calibration Standard (e.g., NIST traceable)

Enter a number...

Calibration Accuracy (±)

Enter a number...

Calibration Procedure Followed

Write something...

Calibration Certificate

⬆ Upload File

Calibration Status

☐ In Calibration

☐ Calibration Complete

☐ Out of Calibration

Next Calibration Due Date

Enter date...

Maintenance Notes/Observations

Write something...

Transportation Validation

Confirms the temperature control effectiveness during transport (vehicles, shipping containers).

Validation Date

Enter date...

Start Time of Validation

End Time of Validation

Initial Temperature (Cooler/Vehicle)

Enter a number...

Final Temperature (Cooler/Vehicle)

Enter a number...

Transportation Method

☐ Refrigerated Truck

☐ Insulated Container (Dry Ice)

☐ Insulated Container (Gel Packs)

☐ Other (Specify)

Observations During Validation

Write something...

Temperature Logger Data File

⬆ Upload File

Packaging & Insulation

Verification of appropriate packaging materials and insulation to maintain temperature.

Package Temperature (Initial)

Enter a number...

Insulation Thickness (cm)

Enter a number...

Insulation Material

☐ EPS

☐ PUR

☐ Vacuum Insulated Panel (VIP)

☐ Other

Packaging Features

☐ Phase Change Material (PCM)

☐ Temperature Indicators

☐ Shock Indicators

☐ Waterproof Barrier

Packaging Specifications Document

⬆ Upload File

Batch/Lot Number of Packaging Materials

Write something...

Deviation Management & Corrective Actions

Procedures for identifying, documenting, and correcting temperature excursions.

Date of Deviation

Enter date...

Time of Deviation

Detailed Description of Deviation

Write something...

Temperature Excursion (Degrees)

Enter a number...

Duration of Excursion (Hours/Minutes)

Enter a number...

Root Cause Identified?

☐ Yes

☐ No

☐ Under Investigation

Root Cause Analysis

Write something...

Corrective Actions Taken

Write something...

Corrective Action Completion Date

Enter date...

Corrective Action Verification Signature

Documentation & Traceability

Ensuring complete records for each shipment and lot, allowing full traceability.

Shipment Date

Enter date...

Lot Number

Enter a number...

Product Description

Write something...

Shipping Method

☐ Air

☐ Ground

☐ Sea

Packing List Document

⬆ Upload File

Receiving Remarks (any notes upon receipt)

Write something...

Expiration Date

Enter date...

Quantity Shipped

Enter a number...

Training & Personnel

Confirmation of adequate training for personnel involved in cold chain handling.

Number of Personnel Trained

Enter a number...

Date of Last Training Session

Enter date...

Training Program Used (e.g., SOP-ColdChain-001)

- [ ] SOP-ColdChain-001
- [ ] Custom Training Program
- [ ] Other (Specify in Long Text)

Specify 'Other' Training Program (if applicable)

Write something...

Training Topics Covered (Check all that apply)

- [ ] Temperature Monitoring Procedures
- [ ] Emergency Response to Excursions
- [ ] Packaging & Handling Best Practices
- [ ] Documentation & Traceability
- [ ] Equipment Operation & Maintenance
- [ ] Regulatory Requirements

Trainer Signature

Trainer Name

Write something...

Facility Compliance

Verification of facility temperature control systems and environmental conditions.

Ambient Temperature (Facility Entry)

Enter a number...

Refrigerator/Freezer Temperature (Reading 1)

Enter a number...

Refrigerator/Freezer Temperature (Reading 2)

Enter a number...

Last HVAC System Maintenance Date

Enter date...

HVAC System Status

☐ Operational

☐ Maintenance Required

☐ Out of Service

Notes/Observations Regarding Facility Environment

Write something...

Temperature Graph/Log File

⬆ Upload File

Emergency Power Backup Status

☐ Functional

☐ Requires Testing

☐ Out of Service

Supplier Qualification & Monitoring

Assessment and ongoing monitoring of cold chain suppliers.

Supplier Cold Chain Certification Status

☐ Certified

☐ Pending Certification

☐ Not Certified

Supplier Temperature Excursion Frequency (Last 12 Months)

Enter a number...

Last Supplier Audit Date

Enter date...

Summary of Last Supplier Audit Findings

Write something...

Key Cold Chain Risks Identified by Supplier

☐ Packaging Integrity

☐ Transportation Delays

☐ Equipment Malfunction

☐ Data Logger Accuracy

☐ Other (Specify in Long Text)

Supplier's Cold Chain Manual/Documentation

⬆ Upload File

Supplier Performance Rating (Overall Cold Chain)

☐ Excellent

☐ Good

☐ Satisfactory

☐ Needs Improvement

Product Receipt & Storage

Procedures for receiving and storing pharmaceuticals upon arrival at the destination.

Receipt Date

Enter date...

Receipt Time

Temperature on Receipt (ºC)

Enter a number...

Temperature Within Specification?

☐ Yes

☐ No

Observations/Comments (e.g., Packaging Condition)

Write something...

Condition of Packaging

☐ Intact

☐ Damaged

☐ Wet

☐ Compromised

Quarantine Required?

☐ Yes

☐ No

Storage Location

📍 Set My Current Location