



EDUCATIONAL RESOURCES

Navigating Cold Chain Packaging

Best Practices for Specialty Pharmacies

 PHARMACY



ACHCU IS A BRAND OF ACCREDITATION COMMISSION *for* HEALTH CARE



Welcome



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TempAid: Your Cold Chain Solution



ACHC's Temperature Control Requirements

- What accreditors expect to see in your documentation
- ACHC's Core Requirements:
 - Evidence-based temperature control procedures
 - Documented validation for all shipping configurations
 - Performance data supporting your temperature ranges
- Common Gaps
 - Using packaging without proper validation documentation
 - Operational procedures that don't match testing conditions
 - Missing component specifications in procedures
- ACHC's Expectation
 - Evidence that your temperature control system works as documented, consistently, and that staff understand and follow the data.



Understanding Testing Standards – OQ vs PQ

- The foundation of evidence-based validation
- Operational Qualification (OQ), Chamber Testing:
 - Recognizable thermal profiles such as ISTA 7E and 7D
 - Foundation for all validation documentation
 - Required at minimum for both summer and winter seasonal profiles
- Performance Qualification (PQ), Field Testing:
 - Must reflect typical payload that can be supported by your order management system (OMS)
 - Validates that OQ predictions work in your operations
 - Required to be tested in triplicate for statistical validity
- Critical Difference

Payload Strategy and Geographic Considerations

- Building realistic testing around your actual operations
- Understanding Your Baseline
 - Work with vendors to analyze your OMS data for realistic testing
 - Avoid oversized payload testing that artificially inflates performance data
 - More payload = longer duration
- Avoiding Common Validation Errors:
 - Oversized payload testing
 - Undersized payload testing
 - Target approach
- Geographic Pack-Out Strategy
- Shipping Method Considerations
 - Air next day, Lane-specific strategy, Universal vs. Seasonal Specific

Component Consistency – The Accreditation Requirement

- Why changing validated components breaks compliance
- ACHC's Perspective
- Critical Component Rules
 - Mass matters
 - Refrigerant type
 - Buffer materials
 - Viscosity differences
- Documentation Standard



The Flash Freezing Problem

- A hidden compliance risk that arrives “cool” but compromised
- The Real Challenge
- What Happens
- Prevention Through Thermal Buffering
 - Water Blankets
 - PCM Mats
 - Bubble Wrap
 - Never: Frozen gel packs directly against product cartons



Duration Expectations and Realistic Performance

- Performance limits and cost optimization
- Realistic Performance Targets
 - EPS & Recyclable Coolers
 - Extended Duration (72+ hours)
- The Cost Cycle



Accessory Management

- Managing thermal load in cold chain pack-outs
- The Accessory Problem
- Solutions
 - *Best Practice:* Ship separately when possible
 - *If required:* Pre-condition to 2-8°C for 48+ hours before packing
 - *Alternative:* Scale up pack-out size to accommodate thermal load, establish SOPs for accessory handling, and validate with accessories conditioned to product temperature



Refrigerant Conditioning

- Proper preparation of your pack-outs refrigerant, the "battery"
- What is Refrigerant Conditioning?
 - Charging the "battery" of the pack-out:
 - Water-based gel packs: Charged at 0°C (frozen at -13°C)
 - Cold Chain PCMs: Charged at specific temperatures (e.g., 4-5°C for 2-8°C applications)
 - Ambient PCMs: Self-conditioning at warehouse temperature



Phase Change Materials – Types and Applications

- When advanced refrigerants make compliance sense
- Types of Refrigerants:
 - Water-based PCMs
 - Advanced PCMs
- Cold Chain PCMs (2-8°C):
 - PCM 4-5
 - Application
- Ambient PCMs (15-25°C):
 - Lower range (closer to 15°C)
 - Upper range (closer to 25°C)
 - Advantage



Vendor Qualification and Investigation Requirements

- Building ACHC-compliant supplier oversight
- Vendor Reg Flags
 - Custom “in-house” thermal profiles
 - Oversized PQ payload testing that inflates performance data
 - Missing component specifications
 - Inadequate change control processes
- ACHC Investigation



Building Your ACHC-Ready Program

- Implementation roadmap for accreditation success:
 1. Validation Foundation
 2. Operations
 - ACHC Training Focus
 3. Investigation Capability
 4. Vendor Management



Key Takeaways for ACHC Success

1. Evidence-based validation
2. Component consistency
3. Realistic field testing
4. Geographic strategy
5. Investigation capability



- Remember: ACHC accreditors want evidence that your temperature control program is
 - Designed based on data
 - Implemented consistently
 - Continuously improved



Q&A

Got questions? We've got answers.



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Thank you

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