



Original Research Article

Logistics of the CAR-T Medicines in a Hospital Pharmacy Service

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Abstract: Chimeric Antigen Receptor T cell (CAR-T) therapies are transformative, patient-specific cancer treatments requiring advanced logistical management in hospital pharmacy services. The intricate processes of storage, traceability, handling, and administration demand strict coordination between pharmacy, hematology, cell processing, and external manufacturers. This review provides a comprehensive analysis of CAR-T logistics in the hospital pharmacy environment, including workflow integration, regulatory considerations, quality assurance, and continuous support for patient safety.

Keywords: CAR-T Cell Therapy, Hospital Pharmacy, Logistics Management, Quality Assurance, Patient Safety.

INTRODUCTION

CAR-T medicines are patient-specific, genetically engineered cell therapies that have redefined approaches to hematological malignancies. Their autologous nature and biological fragility necessitate a highly controlled, multidisciplinary logistical system that ensures product integrity and patient safety from apheresis to infusion^{[1][2][3]}.

WORKFLOW OVERVIEW IN CAR-T PHARMACY LOGISTICS

1. Patient Eligibility and Apheresis Coordination

- Initial steps involve confirming patient eligibility by the clinical team.
- The pharmacy collaborates in scheduling and logistics for leukapheresis, the collection of patient T cells, which are then dispatched to a manufacturing facility.

2. Ordering, Shipment, and Chain of Custody

- The pharmacy verifies and logs the CAR-T manufacturing order.
- Ensures compliance with regulatory mandates for Good Manufacturing Practice (GMP) and chain-of-custody documentation.
- Integrates digital tracking systems that record every handover and transit event to ensure traceability and safety^{[4][3]}.

3. Reception and Storage

- CAR-T products arrive cryopreserved in vapor phase liquid nitrogen containers, at sustained temperatures often below -150°C .

- Pharmacy personnel perform product checks: visual inspection, verification against orders (patient identity, batch, and manufacturer data).
- Strict timeframes for transfer from shipping container to on-site ultra-low temperature storage, with continuous temperature monitoring, are enforced.
- Backup power, alarm systems, and deviation protocols are core parts of pharmacy infrastructure^{[1][5]}.

4. Preparation and Dispensing

- The pharmacy verifies readiness for infusion by double-checking patient ID, therapy documentation, and ensures all pre-infusion assessments are complete.
- On the day of administration, CAR-T cells are retrieved from storage, thawed in a controlled environment (usually in specialized stem cell labs or cell therapy units), typically by trained staff under pharmacist supervision^{[2][4]}.
- Accessories and adjunct medications (e.g., tocilizumab) for cytokine release syndrome management are prepared in parallel.
- Dispensing and handoff are logged in both paper and electronic medical records.

5. Administration and Post-Infusion Monitoring

- The pharmacy works alongside hematology and nursing units for timely product infusion.
- Residual product or vials are disposed of or stored according to biohazard and institutional protocols.
- Data on product handling, discrepancies, or deviations are archived for audit and safety review^{[1][2][4]}.

QUALITY ASSURANCE AND REGULATORY COMPLIANCE

Robust Temperature Control

- Continuous electronic monitoring of CAR-T storage with alarms for temperature excursions.
- Regular audits and documented compliance with manufacturer and regulator standards.

Documentation and Traceability

- Digital and physical chain-of-custody records are maintained.
- Robust labeling practices: all products labeled with patient information, product ID, and barcode for bedside verification.

Risk Management Procedures

- Pharmacy develops and rehearses standard operating procedures (SOPs) for storage, retrieval, and adverse event management.
- Established deviation and crisis protocols for power outages, freezer alarms, or shipment delays.
- Full traceability logging of every process step, as required by law and quality systems^{[3][5]}.

Supply Chain and Inventory Challenges

Autologous Manufacturing

- Single-patient, batch-specific nature means minimal room for error—each therapy is irreplaceable.
- Delivery schedules are tightly coordinated to ensure product viability and clinical readiness coincide.

Cold-Chain Transport

- Specialized shippers use GPS and real-time temperature sensors to monitor the journey from manufacture to hospital.
- Contingency plans must be in place for customs, transit delays, or temperature excursions^{[1][5]}.

THE ROLE OF HOSPITAL PHARMACISTS

Multidisciplinary Team Integration

- Act as the central hub linking logistics, clinical care, manufacturing, and laboratory partners.
- Oversee product receipt, verification, storage, dispensing, and record-keeping.

Clinical and Operational Support

- Prepare emergency adjunct agents (e.g., tocilizumab) and educate staff on their readiness.
- Actively participate in patient education and informed consent regarding product risks and handling^{[2][4]}.

Pharmacovigilance

- Monitor for and report adverse events (e.g., cytokine release syndrome, infections).
- Participate in long-term surveillance of post-infusion outcomes and therapy effectiveness^{[2][4]}.

Graphs and Tables

Table 1. Key Steps in CAR-T Cell Logistics in Hospital Pharmacy

Step	Pharmacy Responsibilities	Critical Considerations
Apheresis Coordination	Order verification, shipment	Chain of identity, timing scheduling
Reception & Storage	Inspect, log, store below – 150°C	Temperature monitoring, record deviations
Preparation for Infusion	Double-check, thaw, label	Patient identity, SOP adherence, traceability
Dispensing & Administration	Handoff, documentation	Chain of custody, bedside scan
Pharmacovigilance	Outcome tracking, reports	Audit, regulatory compliance

Figure 1. End-to-End CAR-T Medicine Logistics Workflow

- Patient eligibility and apheresis
- Order placement and shipment
- Reception, storage, and inventory control
- Preparation, thaw, and dispensing
- Infusion and post-administration monitoring
- Event capture and record-keeping

Figure 2. Supply Chain and Cold Chain Management for CAR-T Therapies

- Cryopreserved shipment routes
- Temperature logs and alert rates
- Key cold chain milestones: from receipt to thaw

DISCUSSION

CAR-T logistics in hospital pharmacy services are uniquely complex, demanding robust SOPs, state-of-the-art infrastructure, and multidisciplinary teamwork. The role of the pharmacist extends from ensuring safe, regulatory-compliant storage to the management of emergency drugs, pharmacovigilance, and continuous process improvement. Digital innovations and dedicated tracking systems are becoming essential to minimize risk in this high-stakes, patient-specific process.

CONCLUSION

The safe, timely, and compliant handling of CAR-T medicines in the hospital pharmacy is foundational for clinical success and patient safety. A standardized logistics approach—incorporating storage, traceability, team coordination, and real-time monitoring—enables hospitals to deliver this revolutionary therapy with maximal reliability and clinical benefit.

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