ATMP Shipment Documentation Checklist

Purpose: Ensure complete and compliant documentation for Advanced Therapy Medicinal Product (ATMP) shipments, supporting customs clearance, regulatory requirements, cold-chain integrity, and chain-of-identity/custody.

Scope: Applicable to clinical and commercial ATMP consignments shipped under GDP and GMP frameworks with region-specific notes (EU/UK/US).

Shipment Reference:			
Origin:		Destination:	
Date:			
Carrier / AWB:			

1. Commercial Invoice

A document that provides full product, value, classification and party details required for customs clearance and regulatory compliance.

☐ Full product description (therapy type, batch/lot number)

☐ HS/Tariff code

☐ Country of origin

☐ Quantity (net/gross weight)

☐ Unit value and total shipment value (currency stated)

☐ Applicable Incoterms (e.g., DDP, EXW, FCA)

☐ Exporter / Consignee / Importer of Record details

☐ EORI and/or TIN numbers (EU/UK, where applicable)

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☐ Commercial declaration signed by an authorized responsible party

2. Packing List
Outlines a detailed breakdown of the shipment contents, including package counts, container or shipper IDs, and weight distribution.

- ☐ Detailed contents listed for each package
- ☐ Number of packages / containers
- ☐ Container or shipper IDs
- ☐ Weight breakdown per package or container

3. Certificate of Analysis (CoA)
Confirms product quality, GMP release status, and batch/lot identity. Signed by an authorized quality representative to ensure the material meets required specifications.

- ☐ Confirms product quality and GMP release status
- ☐ Batch/lot number corresponds to shipment
- ☐ Signed by authorized quality representative

4. Temperature Control Documentation
Provides evidence that cold-chain conditions were validated, monitored, and maintained during shipment, including data loggers, calibration certificates, packaging system details, and any excursion assessments.

- ☐ Cold chain compliance statement
- ☐ Validated packaging system (e.g., dry ice, LN_2 shipper, thermal container) w/ hold time
- ☐ Temperature monitoring data logger(s) included
- ☐ Calibration certificates for monitoring devices (IDs, due dates)
- ☐ Alarm thresholds and acceptance criteria defined
- ☐ Excursion assessment (e.g., MKT) and disposition recorded if applicable

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5. Chain of Identity (COI) & Chain of Custody (COC)
Ensures patient-specific material integrity and traceability throughout transport, including identifiers, serialization codes, and custody transfer logs documenting each handoff.

☐ Patient/trial identifiers (where applicable)

☐ Serialization/unique tracking codes (distinct identification code)

☐ Custody transfer log with dates, times, and signatures at each handoff

☐ Tracking from donor to consignee and back (where applicable)

6. Regulatory & Customs Documents
Covers required import permits, clinical trial authorizations, EORI/VAT information, and any special licenses needed to comply with regional regulations.

☐ Import permits or regulatory authorizations

☐ Clinical trial authorization (if applicable)

☐ EORI / VAT registration details (EU/UK)

☐ Temporary import/special licenses (if applicable)

7. Safety & Handling Instructions
Details storage, handling, hazardous materials labeling, and dry ice documentation per IATA, GDP, and GMP rules to ensure safe and compliant transport.

☐ Storage and handling requirements (e.g., ≤ –80 °C, dry conditions)

☐ Hazard labels correctly applied (IATA, GDP, GMP Annex 13)

☐ Dry ice (UN1845) documented per IATA PI 954 (marking, net kg, AWB line)

☐ Empty cryogenic shippers to be declared ‘not restricted per IATA special provision A152’

8. Additional Attachments
Optional but commonly required supporting documents such as clinical trial paperwork, insurance proof, freight forwarding information, and emergency contact details.

☐ Clinical trial documentation (if relevant)

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☐ Insurance coverage details

☐ Freight forwarding and carrier details

☐ Emergency / after-hours contact information

☐ Key contacts at origin, destination, and logistics provider

9. Final Pre-Shipment Verification

☐ All documents reviewed and approved

☐ Consistent information across all documents

☐ Originals and copies prepared according to carrier and customs requirements

Reviewed by (Name):	
Role/Function:	
Signature/Date:	

Region-Specific Regulatory Notes (Reference)

- EU: Comply with EU GDP 2013/C 343/01; EudraLex Vol. 4 GMP; ATMP-specific GMP (risk-based)
- UK: MHRA GDP/GMP inspections and guidance; retained EU GDP applies
- US: 21 CFR Part 211 Subpart H (Holding & Distribution); 21 CFR Part 1271 (HCT/P tracking)
- Air transport: IATA DGR PI 954 requirements for dry ice (UN1845)
- USP <1079> guidance on storage, shipping, and excursion assessment (e.g., MKT)

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Glossary of Terms and Abbreviations:

ATMP: Advanced Therapy Medicinal Product; medicines based on genes, cells, or tissue engineering.

GDP: Good Distribution Practice; ensures safe and compliant storage/transport.

GMP: Good Manufacturing Practice; ensures consistent medicinal product quality.

CoA: Certificate of Analysis; confirms batch quality/release.

CFR: Code of Federal Regulations; U.S. federal rules for medicines and biologics.

COI: Chain of Identity; keeps product linked to the correct patient.

COC: Chain of Custody; documents each handoff in the product lifecycle.

EORI: Economic Operators Registration and Identification; required for EU/UK customs clearance.

IATA: International Air Transport Association; sets aviation safety standards.

AWB: Air Waybill; tracking document for air cargo.

MKT: Mean Kinetic Temperature; evaluates temperature excursions.

MHRA: Medicines and Healthcare products Regulatory Agency; UK regulatory authority.

USP: United States Pharmacopeia; standards for drug quality and storage.

HS / Tariff code: Classification code for traded goods used in customs.

Incoterms: International trade terms defining buyer/seller responsibilities.

Importer of Record: Entity responsible for customs compliance during import.

TIN number: Tax Identification Number used for tax/customs.

UN 1845 / IATA PI 954: Classification and packaging instruction for shipping dry ice by air.

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