FlashGL

SERVICE GUIDE — TIME-CRITICAL AIR LOGISTICS

GDP Temperature-Controlled Pharmaceutical Transport: A Compliance Guide

For logistics managers, QA and QP delegates, and clinical supply leads — how temperature integrity, documentation and deviation handling are controlled from manufacturer to point of administration.

- Service Guide
- FlashGL
- 2026

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WHAT'S INSIDE

A temperature excursion is not a logistics failure. It is a patient safety event.

A vaccine that spends 30 minutes below 2°C may lose potency that **no quality control test can detect**. The vial looks identical, the carton is intact, the seal is unbroken — and the immune response of the patient who receives it is not the same. For a commercial batch, that means rejection, regulatory hold and recall. For an investigational medicinal product (IMP), it means a site cannot dose, a patient enrolment window closes, and a study day is burned at **$50,000–$500,000 per day**.

This guide is written for the people who sign the shipping release: logistics managers, QA and QP delegates, clinical supply leads. It sets out the GDP/GMP/GCP framework we operate under, the three validated temperature ranges, what QP release and controlled-substance clearance actually require, how our loggers report every 10 minutes, and — the section most QA teams turn to first — exactly what happens when a deviation occurs.

What the numbers look like on a real shipment

10 min
Temperature logger upload interval

3
Validated ranges: 2–8°C, 15–25°C, frozen

22 h
Basel → São Paulo, zero excursion

$50K–$500K
Cost per day of clinical trial delay

Undocumented is treated the same as out of range

A gap in the temperature record can trigger a batch rejection **even if the product never left its range**. Regulators and sponsor auditors cannot accept what cannot be evidenced. That is why continuous logging, calibrated instruments and an unbroken handover record are treated here as product attributes, not as reporting niceties.

GDP, GMP and GCP: what each framework governs, and what it demands of us

FRAMEWORK	WHAT IT GOVERNS	WHAT IT REQUIRES OF OUR PROCESS
GDP — Good Distribution Practice	Storage, transport and distribution of medicinal products	Written SOPs at every handover point; qualified, pre-conditioned containers; continuous calibrated temperature records; audit-ready documentation trail from manufacturer to point of administration.
GMP — Good Manufacturing Practice	Manufacture, batch records and QP certification	No break between manufacturing and distribution records. The batch record travels intact through to QP release at origin, and the distribution record picks up where it ends.

GCP — Good Clinical Practice	Clinical trials and investigational medicinal products	Chain of identity for IMPs: the batch, lot and formulation received at the site must be demonstrably what was shipped — with temperature integrity and custodial responsibility recorded at every stage.
Named standards we work to	EU GDP, WHO TRS 961, IATA PCR, US FDA 21 CFR Part 211	Container qualification and pre-conditioning records, calibrated loggers, arrival verification reports, and deviation documentation in the format your quality system expects.

GDP compliance is a process, not a certificate. Plenty of forwarders hold a certificate; what matters is whether handling teams follow written SOPs, document every handover, and can produce audit-ready records on demand.

Three validated temperature ranges

RANGE	SET POINT	TYPICAL PAYLOAD	CONTAINER AND MONITORING REQUIREMENT
Controlled cold	2–8°C	Biologics, vaccines, monoclonal antibodies, most IMPs	Active cooling container, pre-conditioned and set-point verified before loading. Continuous calibrated logger with upload every 10 minutes.
Controlled ambient	15–25°C	Finished dosage forms, APIs, clinical trial kits	Qualified container with continuous logging. Seasonal ambient conditions at origin, transit and destination assessed before container selection — summer tarmac heat and winter sub-zero ground conditions are different risks for the same 15–25°C product.
Frozen	As specified on the product label / registration	Frozen biologics, certain vaccines, frozen intermediates	Purpose-qualified container. Battery endurance and refrigerant replenishment are planned against total door-to-door time including ground segments and plausible delay, not against scheduled flight time.

Deep-frozen shipments (−60 to −70°C) are not a standard published range — they are qualified project by project. If your product needs it, tell us the set point and the lane, and we will confirm the container and the qualification route for that lane.

Containers, qualification and monitoring

Active cooling, not passive hope

We default to battery-powered active cooling containers with continuous data logging, not passive insulated boxes with dry ice that degrades unpredictably through flight delays, tarmac holds and customs processing. Active units hold set point regardless of ambient conditions. Endurance is specified against the full door-to-door profile, including ground segments and credible delay — never against scheduled flight time alone.

Pre-conditioning and qualification, recorded

Before any cargo is loaded we verify and record container qualification status, battery charge level and pre-conditioning temperature. GDP requires documented evidence that the container was at set point at the moment the product went in — not approximate, not assumed, recorded. The pre-conditioning record ships with the documentation set.

Calibrated loggers, ten-minute cadence

Calibrated data loggers upload temperature readings every 10 minutes throughout transit. On arrival the log is downloaded, the digital report and printout are produced, and container integrity is visually inspected — as mandatory process steps, not optional extras.

Tamper-evident sealing and seal control

Seals are applied at packing and the seal numbers are recorded in the shipment file. Every subsequent handover verifies seal integrity before acceptance, so a broken seal is detected at the point it happens rather than at the receiving pharmacy.

Four steps from requirement to documented delivery

01

Share your cold chain requirement

Product type, temperature range, volume, destination and deadline. The cold chain desk activates within 2 hours: container qualification, route verification and pre-conditioning all start immediately. Pre-conditioning cannot be skipped regardless of urgency — it is a GDP requirement.

02

Container preparation and pre-conditioning

We select, charge and pre-condition the container to your validated set point, then record qualification status and pre-conditioning temperature before the product is loaded.

03

GDP-compliant packing and flight

Packed under SOP, sealed, documented and flown under continuous temperature monitoring with real-time excursion alerts. For IMPs, chain-of-identity documentation is built at this stage — batch, lot and formulation recorded against the shipment, not reconstructed afterwards.

04

Arrival verification and delivery

Temperature log downloaded, container integrity inspected, time-stamped photographic record taken, and documented handover to your receiving team — site pharmacy, hospital dock, or QA-controlled store.

The documentation set

DOCUMENT	WHEN AND WHO	WHO NEEDS IT, AND WHY

QP release documentation	Qualified Person at origin, before dispatch	Without it the batch cannot be released into the market at destination. We confirm its presence before the shipment leaves origin.
Calibrated temperature log (digital report + printout)	Downloaded by our handling team on arrival	The first thing regulators and sponsor auditors ask for: evidence the product stayed within range for the whole transit.
Chain-of-identity and chain-of-custody record	Maintained across every handover	For IMPs, proves the batch, lot and formulation received at the site are what was shipped, and records who held the shipment at each point in time.
Controlled-substance permits and import licences	Licensed brokers, filed before arrival	Controlled substances and APIs cannot clear without them — for example ANVISA expedited import under the clinical trial authorization.
Commercial invoice, packing list, AWB	At dispatch, carried with the courier	Customs valuation and HS classification at import, and the paperwork needed for any subsequent re-import.
Pre-conditioning and packing qualification records	Generated at packing	Demonstrates the container was qualified and at set point at the moment of loading — the evidence GDP specifically asks for.
Arrival verification report	Produced at destination, before handover	Closes the loop: log download, container inspection, seal check, photographic record and signed receipt in one document.

Every item below is produced as a matter of process, not on request. If your quality system needs a different format or additional fields, we map to your template before the first shipment.

Deviation handling: the procedure

01

Alert in real time

Excursion alerts fire while the shipment is still in transit — not days later when the logger is downloaded. The operations team sees the deviation, the duration and the ambient conditions as they happen.

02

Intervene in transit

On alert, we act: refrigerant replenishment or container swap where physically possible, re-routing, or expediting the ground segment. A minor deviation caught at hour two is a manageable event; the same deviation discovered on arrival is a batch rejection.

03

Quarantine and document on arrival

The shipment is held pending assessment. We record start time, duration, magnitude and ambient conditions, attach the complete logger trace and the seal-verification record, and notify your named QA contact the same hour.

04

Assess against the product's registered limits

Your QA or QP delegate makes the release decision against the product's stability data and registered storage conditions. We supply the complete, calibrated record — we do not make the release call.

05

Report and close

Deviation report, root-cause input, and CAPA documentation where your system requires it, delivered in your format.

No unqualified handoff, at any point

GDP-trained handling teams at origin, transit and destination. Couriers are background-checked and bonded. GPS tracking runs continuously and every handover is confirmed with a time-stamped photograph, so custody is evidenced rather than asserted. For IMPs we additionally track chain of identity: who packed it, who loaded it, who received it, and at what time each handover occurred.

Case: IMP at 2–8°C, Basel → São Paulo, 22 hours, zero excursion

T+0:00 ●

Request received

A Phase III site in São Paulo reports IMP stock depleted; the next patient enrolment window is 48 hours away. The sponsor's Basel depot has the 2–8°C biologic ready for dispatch.

T+0:30 ●

Courier dispatched

A GDP-qualified courier is on the way to the Basel depot carrying a validated 2–8°C container, pre-conditioned to set point with a calibrated logger.

T+1:00 ●

Collection and sealing

The courier verifies logger readings against the set point, loads the product, applies tamper-evident seals and records the seal numbers in the shipment file.

T+3:30 ●

Direct departure, ZRH → GRU

The consignment travels with the courier on the direct flight. The logger uploads temperature readings every 10 minutes for the whole transit — no gap, no blind segment.

In transit ●

Import prepared ahead of arrival

Our licensed broker prepares ANVISA expedited import under the clinical trial authorization, so nothing is lost to paperwork on landing.

T+22:00 ●

Delivered to the site pharmacy

Twenty-two hours after the initial call. QP release documentation, the temperature log printout and signed proof of delivery are uploaded to the sponsor's system. Zero excursion. Patient enrolment proceeds on schedule.

Before you release the shipment

The information QA should have confirmed — and that we will ask you for — before a temperature-controlled consignment moves.

- [ ] Product's registered storage range, plus the documented excursion tolerance (allowed magnitude and duration), if the licence defines one
- [ ] Stability data or the reference your QA will use to assess any excursion
- [ ] Temperature range to be maintained, and whether the shipment is IMP, commercial product, API, or a controlled substance
- [ ] Calibration certificate currency for the logger, and the required logging interval
- [ ] QP release documentation in hand at origin, and the named QP delegate at destination
- [ ] Import licence, permit or clinical trial authorization required at destination
- [ ] Receiving site's qualified storage capability at the expected delivery hour — including weekends and local holidays
- [ ] Named contacts at both ends who are reachable during the entire transit window
- [ ] Seasonal ambient conditions at origin, transit and destination airports
- [ ] Declared value and insurance requirement, and whether the excursion needs to be covered

Frequently asked questions

Q Which temperature ranges do you support?

2–8°C, 15–25°C and frozen, each with purpose-qualified containers and validated procedures. Deep-frozen requirements are handled as a project-by-project qualification.

Q How often is temperature recorded, and who sees it?

Calibrated loggers upload every 10 minutes throughout transit. Excursion alerts fire in real time to our operations team, which can intervene while the shipment is still moving. You receive the digital report and printout at arrival.

Q What happens if there is an excursion?

You get the alert and then the record, not a surprise. The shipment is quarantined on arrival, we document magnitude, duration and ambient conditions with the full logger trace attached, and your QA or QP delegate makes the release decision against the product's stability data. We do not make that call ourselves.

Q Can you clear controlled substances and APIs?

Yes. Our licensed brokers handle controlled-substance clearances, API import permits and clinical-trial-authorization imports, with same-day clearance at most major ports.

Q How fast can an emergency cold chain shipment start?

Quote within 10 minutes; the cold chain desk activates within 2 hours, with container qualification, route verification and pre-conditioning starting immediately. Pre-conditioning is a fixed step — an active container has to be at set point before product goes in, and no amount of urgency removes that requirement.

Send us your SOP. We will map our process to it.

Send your temperature ranges, excursion tolerances and documentation requirements, and we will return a lane-specific plan: container type and qualification, route, monitoring cadence, and the exact document set that ships with your product. Email service@flashgl.com or call the 24/7 cold chain desk +86 400-011-9188.

GET COLD CHAIN QUOTE

EMAIL
service@flashgl.com

24/7 DESK
+86 400-011-9188

WEB
flashgl.com