

Pharmaceuticals – claims and how to prevent them



Christian Gieschen

Ass. jur., LL.M.

Surveyor and Claims Handler

Battermann & Tillery Global Marine GmbH

Agenda

1. Liability risk
2. GMP + GDP
3. Critical deviation and risk-based damage assessment
4. Crucial steps in claims handling
5. Claim examples

Pharmaceuticals – claims and how to prevent them

1. Liability risk

Three factors which may result in big losses:

- High cargo values
- Low requirements for proof of loss
- Recourse claims with little prospect of success



! Liability agreements are crucial !

Pharmaceuticals – claims and how to prevent them

2. GMP + GDP

Good Manufacturing Practices (GMP)

Good Distribution Practices (GDP)



Heavily regulated and protected products

Ready-to-use packaged pharmaceuticals

Active pharmaceutical ingredients (API)

Pharma excipients

Medical devices

Life science products, in-vitro diagnostics, medical reagents

Veterinary products

Less or not regulated/protected products
(often just ISO or industrial standards)

Primary packaging material

Medical protective gear

Certain components for medical devices, like inactive none-sterile parts

Certain types of laboratory equipment

Cosmetics and care products

Dietary supplements (unless registered as a drug)

Pharmaceuticals – claims and how to prevent them

Requirements imposed on pharmaceuticals

- Quality (identity, content, purity, physical properties etc.)
- Efficacy (prevention, healing, alleviation)
- Safety (no harmful side-effects other than those revealed during clinical trials and accepted according to applicable risk-benefit ratio)



Properties that apply at all times.

Pharmaceuticals – claims and how to prevent them

Regulatory examples to ensure pharmaceutical properties

Certified licences

Monitoring by authorities

Quality Management Systems

Qualification of all operating equipment

Process validation

Service provider audits

SOP for each work step



Pharmaceuticals – claims and how to prevent them

3. Critical deviation and risk-based damage assessment

Deviation means quarantine

Qualified Person, Safety Officer

Loss mitigation vs. validation

Note:

Unlike the regular claimant who must prove that their product has been damaged, the pharmaceutical claimant, on the other hand, must prove that a deviation from GMP or GDP guidelines does not affect the product.



Pharmaceuticals – claims and how to prevent them

4. Crucial steps in claims handling

Ideally, the Surveyor and Claims Handler should

- Help to provide all relevant information as any gap in documentation is considered a risk.
- Support the Qualified Person as decision maker with calculations.
Example: The cooling unit of a reefer container stops working
- Contact the MAH or manufacturer for temperature stability limits or temperature-based risk assessments of a product if the wholesaler will not.
- Determine the root cause of damage as soon as possible.
- Review the claim statement carefully.

Pharmaceuticals – claims and how to prevent them

5. Claim examples

Example 1: “Out-of-control” shipments

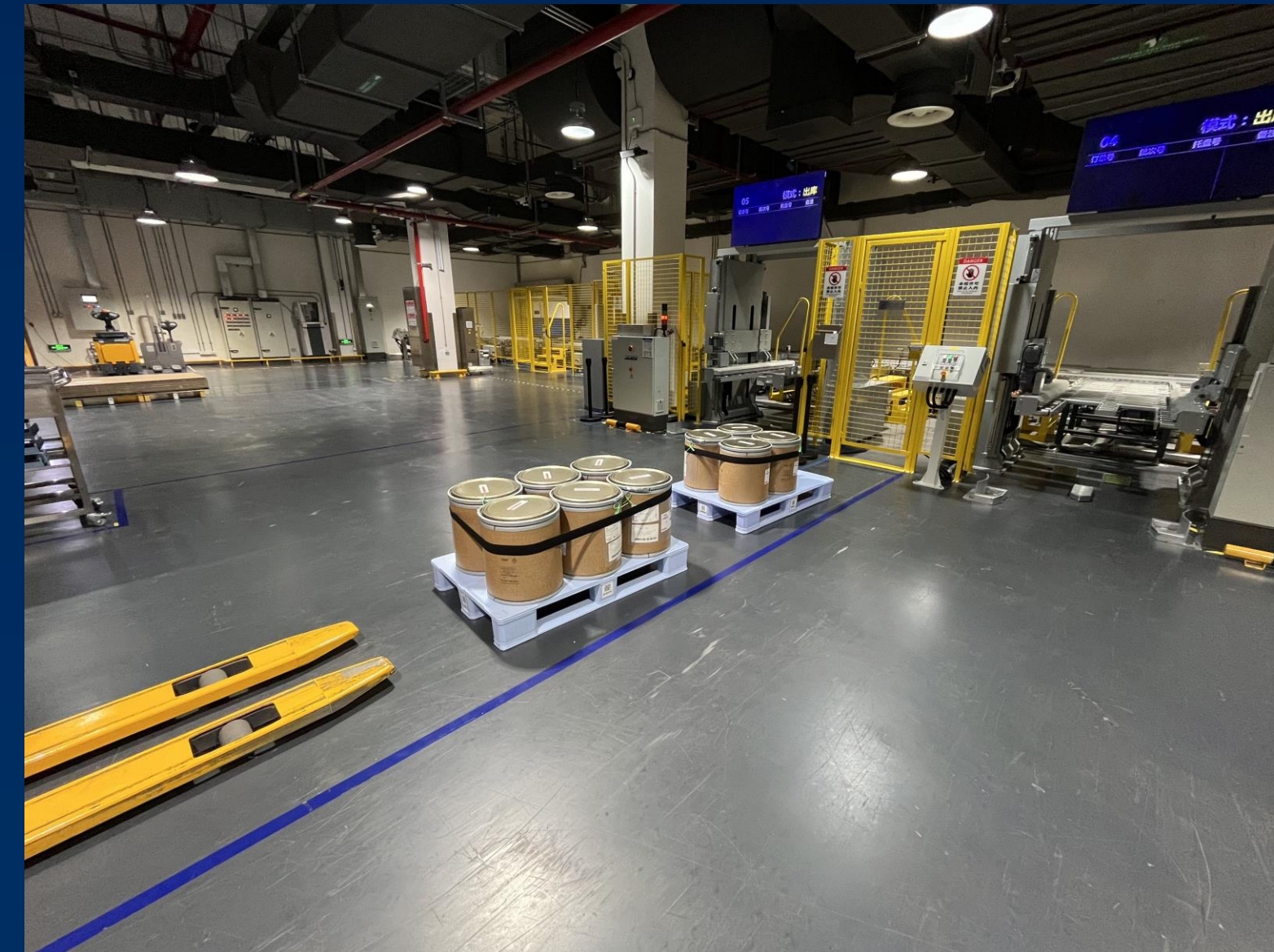
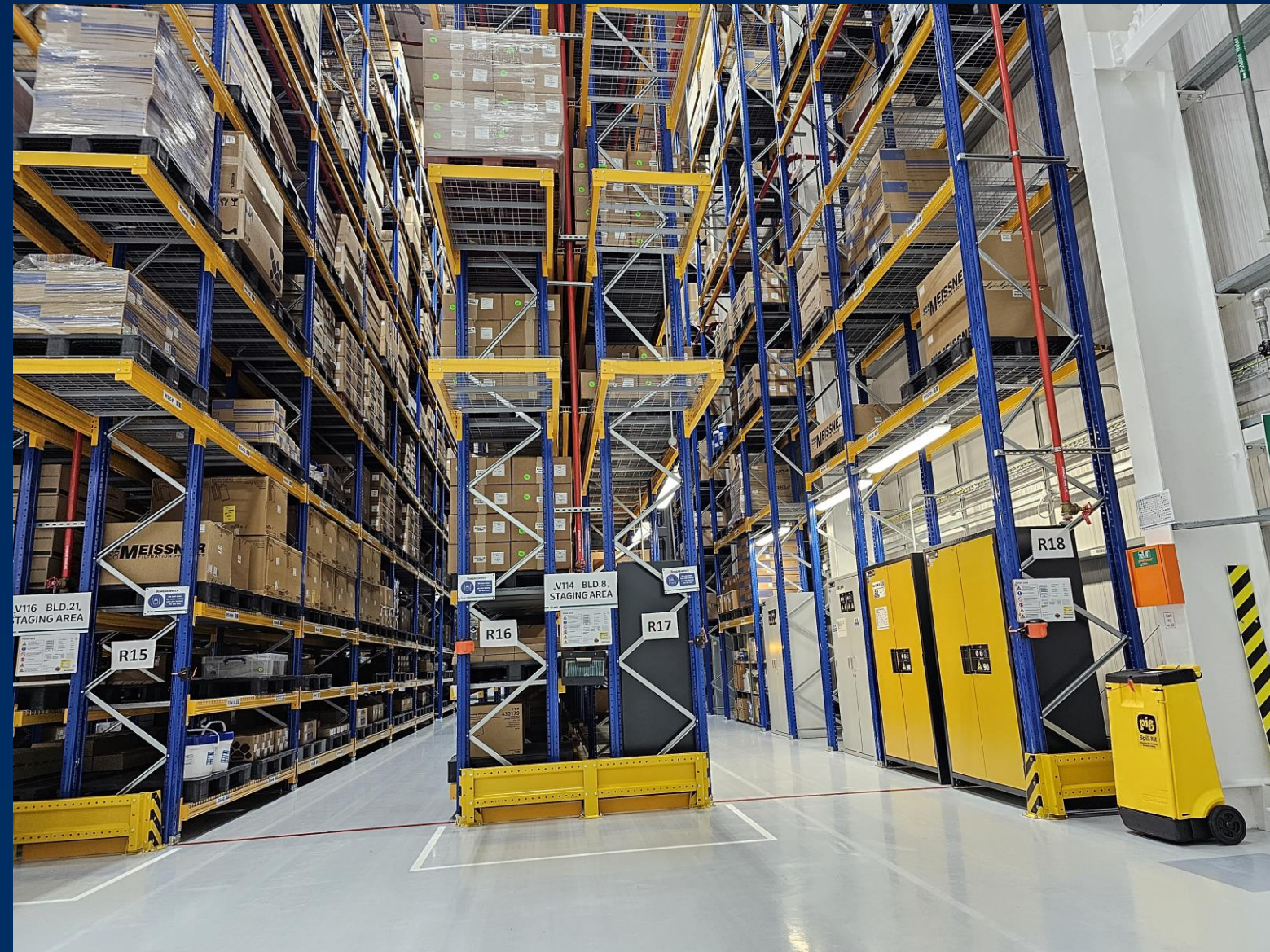
Keep in mind: Pharmaceuticals require storage in a clean, protected and product-compliant manner. Unauthorised people must not have access.

- Missing container seals (FCL)



Pharmaceuticals – claims and how to prevent them

- Non-GDP-compliant storage during transport



Pharmaceuticals – claims and how to prevent them



Outsourced activities
require GDP agreements

Pharmaceuticals – claims and how to prevent them

Example 2: Mechanical damage

Keep in mind: Damage to the product packaging mostly means a total loss of the respective sales unit.
Damage to the outer packaging can mean a total loss for the contents.



ULD consolidation, cargo nets



Bad packaging

- Use sturdy outer packaging, crates or cases
- Secure your product and make sure to avoid free spaces
- Use “Do not-stack” handling instructions as per ISO 7000, No. 2402



Pharmaceuticals – claims and how to prevent them

Example 3: Contamination

- Water damage



Plastic covers help against drizzle during air cargo transshipments, but they do not protect against heavier rain.

Pharmaceuticals – claims and how to prevent them

- Mould (mildew) damage

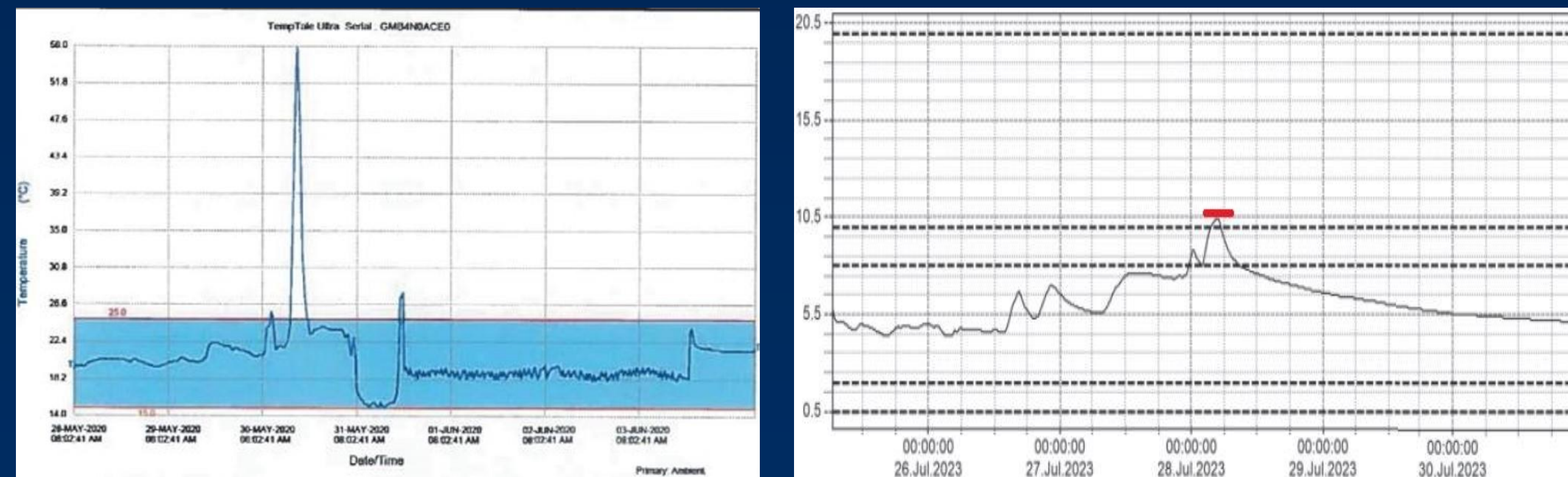


- Do not use wooden pallets!
- Make sure the container is completely dry before loading.
- Close the fresh air ventilation, choose correct dehumidification levels.
- Define permissible limits for mould spores and germ loads on the packaging surfaces if you not only want to reject visibly affected but also apparently inconspicuous packing units.

Pharmaceuticals – claims and how to prevent them

Example 4: Temperature excursions

Temperature peaks and stability data



Temperature deviations can occur regardless of the mode of transport. Even with CY/CY temperature-controlled transports, temperature excursions cannot always be prevented as active temperature control is suspended when the container is disconnected from the power supply in the port for discharge from the motor vessel. Insulated packaging can bridge this critical period.

Pharmaceuticals – claims and how to prevent them

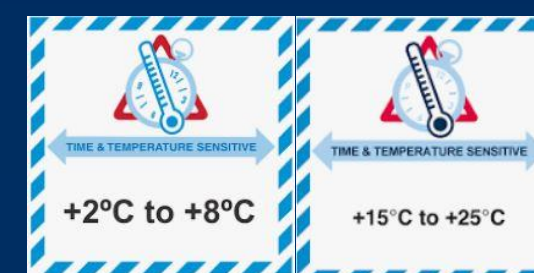
Air cargo: Errors in transport preparation

Transport options	Temperature control	Level of protection
Special air freight container	Active	Very high
Cool box with coolant *	Passive	Fair - but limited durability
Thermal bonnet *	Passive	Low
None of the above	None	None



*] Mandatory:

- IATA temperature labels
- Mobile temperature recorders for each packing unit



Pharmaceuticals – claims and how to prevent them

Loss of marketability: "The damage before the damage"



How can you guarantee the marketability of a pharmaceutical product that has been shipped as consolidated cargo without temperature monitoring?

(You cannot.)

Thank you!



Christian Gieschen

christian.gieschen@ba-ty.com; +49 (0) 421/38 98 633

www.ba-ty.com