

# FRA Station (FRA / Frankfurt) Location Capabilities

GENERATED ON 17 Dec, 2018 BY Dominik Misskampf





# **Summary**

**General Information** 

Name

FRA Station (FRA / Frankfurt)

Address

CargoCity Süd 537, Frankfurt, 60549, Germany

**Contact Details** 

Phone

+49 (0) 69 698 19 154

Email

d-misskampf@lug-fra.de

Website

http://www.lug-fra.de

Contact Person

Dominik Misskampf

Location Map





# **Capabilities**

### Certificates

# ISO 9001

# ISO 22000 # ISAGO

TAPA: FSR - Level B

RA3

\* Wholesaler Licence

**#** ISO 14001

# IATA CEIV Pharma

# GDP

**★** C-TPAT**★** OHSAS 18001

# IFS

**User Roles:** 

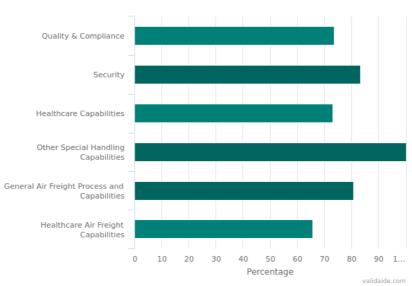
Responsible:

Dominik Misskampf

Approved by:

Dominik Misskampf

on 17 Dec 2018



### Healthcare Capabilities

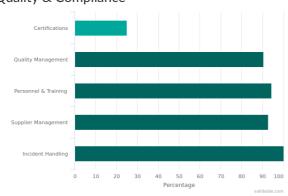
	CRT (+15°C to +25°C)	Cold Rooms (+2°C to +8°C)	Freezer (< -10°C)
Total Area (m <sup>2</sup> )	480	290	45
Dedicated to Pharma (m $^{2}$ )	480	290	45
Proper Separation	×	✓	✓
ULD Build-up / Break-down	×	×	×
ULD Storage	✓	✓	✓
Customs Clearance	✓	✓	✓
Security Checks	×	×	×
Supported Shipment Types	Export Transit Import	Export Transit Import	Export Transit Import
Healthcare Cargo Loading	×	×	n/a
Healthcare Cargo Offloading	×	×	n/a



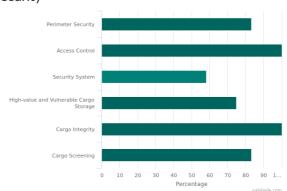


# **Capability Graphs**

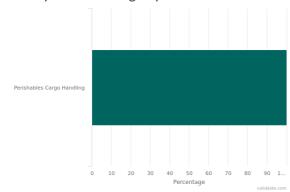
### Quality & Compliance



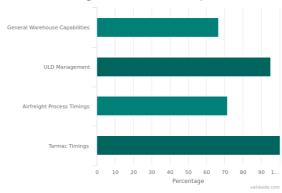
#### Security



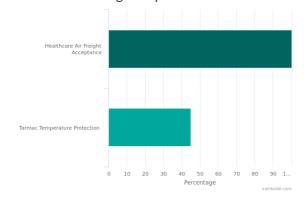
### Other Special Handling Capabilities



## General Air Freight Process and Capabilities



### Healthcare Air Freight Capabilities







# Questionnaire

#	Question		
1.	Certifications		
1.1	Does the location have a valid ISO 9001 certification?	~	
1.2	Does the location have a valid GDP certification?	×	
1.3	Does the location have a valid IATA CEIV in Pharmaceuticals certification?	~	
1.4	Does the location have a valid TAPA certification?	fsr - le	evel b
1.5	Does the location have a valid C-TPAT certification? (United States Customs - Trade Partnership Against Terrorism)?	×	
1.6	For EU-based locations: is the location certified as Regulated Agent (RA)? For Non-EU locations: is the location a validated Regulated Agent under ACC3 security control (RA3)?	~	
1.7	Does the location have a valid ISAGO certification? (IATA's Safety Audit for Ground Operations)?	×	
1.8	Does the location have a valid ISO 14001 certification?	×	
1.9	Does the location have a valid OHSAS 18001 certification? (Occupational Health- and Assessment Series)?	×	
1.10	Does the location have a Wholesaler license of the respective health authority to handle and store healthcare products?	×	
1.11	Does the location have a valid IFS Certification (International Featured Standards)?	×	
1.12	Does the location have a valid ISO 22000 Certification (Food Safety Management)?	×	
2.	Quality Management		
2.1	Is there a documented Quality Management System (QMS) in place?	~	
2.2	Is there a change control procedure in place for the Quality Management System (QMS)?	~	
2.3	Does the management have a formal process for reviewing the Quality Management System (QMS) on a periodic basis?	~	
2.4	Are documented Standard Operating Procedures (SOPs) in place that clearly define operational activities for sensitive cargo?	Healthcare Security Dangerous Goods Perishables	~ ~ X
2.5	Has a risk assessment to assess Critical Control Points in operation processes been performed and documented?	~	
2.6	Are self-inspections conducted in order to monitor implementation and compliance to GDP principles, including the documentation of observations?	~	
2.7	Do you have an archiving procedure to retain documents (if yes, please add a comment to indicate how long documents/files are stored)?	<b>~</b>	
2.8	Is there a Hygiene, Safety and Environment (HSE) policy?	~	
3.	Personnel & Training		
3.1	Is the organizational structure defined in an organization chart?	Healthcare Security Dangerous Goods Perishables	~ ~ X
3.2	Are roles and responsibilities of employees documented in job descriptions, with arrangements for delegation?	<b>~</b>	
3.3	Is there a training program for all relevant staff that covers policies, procedures, and work instructions in accordance with relevant regulations such as GDP, ADR, ISO22000/IFS?	Healthcare Security Dangerous Goods Perishables	~ ~ X





3.4	Does the training program/matrix ensure personnel receives continuing training relevant to their role?	<b>~</b>
3.5	Are security awareness protocols in place?	<b>~</b>
3.6	Are employee training records and qualification records maintained and up-to-date?	✓
3.7	Is there a Responsible Person with the defined authority and resources to fulfill their responsibilities as defined by GDP Guidelines?	<b>~</b>
3.8	Does the location perform background checks on new staff?	<b>~</b>
3.9	Do all employees that handle Dangerous Goods have relevant qualifications and a valid license to perform such operations (e.g. IMDG Code/ ADR/ RID/ IATA DG Regulation)?	<b>~</b>
4.	Supplier Management	
4.1	Have critical suppliers been identified?	✓
4.2	Are all critical suppliers selected according to their competence and compliance with healthcare and security regulations?	<b>~</b>
4.3	Are written contracts in place with all relevant suppliers that reflect the GDP principles and clearly define responsibilities and communication processes?	<b>~</b>
4.4	Is the performance of critical suppliers monitored and reviewed?	<b>~</b>
4.5	Is a supplier risk analysis performed that provides input to the frequency of audits?	<b>~</b>
4.6	Are supplier audits conducted for all relevant suppliers prior to commencement of outsourced activities?	<b>~</b>
4.7	Are deviations linked to suppliers managed through an Incident Handling process?	<b>~</b>
5.	Incident Handling	
5.1	Is there a documented procedure to ensure that appropriate corrective and preventive actions (CAPA) are taken to correct deviations?	<b>~</b>
5.2	Is there a complaint procedure in which complaints are recorded with original details and that triggers a CAPA process when required?	<b>~</b>
5.3	Is there a documented process for the handling and reporting of alarms, security threats and security incidents?	<b>~</b>
5.4	Is there a quarantine procedure for the handling of pharmaceutical products that are damaged, rejected, returned, recalled or suspected of being counterfeit?	<b>~</b>
5.5	Is there a documented process for timely reporting to the contract giver of incidents (e.g. lost or missing cargo, temperature excursions, damages)?	<b>~</b>
6.	Perimeter Security	
6.1	Does the location have adequate perimeter fencing?	<b>~</b>
6.2	Are fencing inspections conducted periodically for integrity and damage?	<b>~</b>
6.3	Does the location have adequate lighting?	<b>~</b>
6.4	Are all doors, windows and any other openings in the warehouse walls and roof secured?	<b>~</b>
6.5	Is there an alarm system that specifically covers windows and other openings to detect entry?	<b>~</b>
6.6	Are fire exits secured by an alarm system?	<b>~</b>
7.	Access Control	
7.1	Has the location implemented security measures for access control to prevent unauthorized access to all areas where cargo is handled?	<b>~</b>
7.2	Is access controlled between office and warehouse or dock?	<b>~</b>
7.3	Are all employees and contractors issued, and display, a company photo-ID badge?	<b>~</b>
7.4	Is there a visitor policy in place that ensures that visitors are always accompanied?	<b>✓</b>





7.5	Are all visitors identified using government-issued photo-ID (e.g. driver's license; passport or national		
7.5	ID card)?	<b>~</b>	
7.6	Are all visitors registered and a visitor log maintained for minimum of 30 days?	~	
8.	Security System		
8.1	Is a CCTV system installed at the Location?	<b>~</b>	
8.2	Is an intruder alarm/detection system installed in the Location?	<b>~</b>	
8.3	Are motion detector alarms installed in the warehouse?	×	
8.4	Is a minimum of 60 day records on system alarms maintained?	~	
8.5	Are there documented maintenance programs in place for all technical (physical) security installations/systems (i.e. CCTV, Access controls, Intruder detection, Lighting, etc.)?	~	
8.6	Is service of all technical security systems guaranteed 24/7 days per week?	<b>~</b>	
9.	High-value and Vulnerable Cargo Storage		
9.1	Is high-value and theft-vulnerable cargo stored in an area with restricted access?	<b>Vault</b> Cage	×
9.2	What is the total floor space (in m2) of warehouse cage for high-value cargo?	0	
9.3	What is the total floor space (in m2) of warehouse vault for high-value cargo?	800	
9.4	Is there a documented process to ensure that access to the cage and/or vault is restricted to personnel that is authorized and trained?	~	
9.5	Is access to the cage or vault controlled electronically?	<b>~</b>	
9.6	Is there complete / 100% CCTV coverage on cage or vault entrance and the internal area?	<b>~</b>	
10.	Cargo Integrity		
10.1	Is the integrity of cargo and packaging (e.g. box, pallet, container, or trailer structure) verified/inspected upon receipt?	~	
10.2	Are truck's seals checked prior to door opening, if applicable?	<b>~</b>	
10.3	Is there a documented process to verify that individuals making the delivery of high-value cargo present an official identification document?	<b>~</b>	
10.4	Is there a documented process to ensure that cargo tendered is properly identified?	<b>~</b>	
10.5	Are ULDs sealed during conveyance?	~	
10.6	Is there a process to protect secured consignments from unauthorized interference and tampering, and to verify compliance therewith?	~	
11.	Cargo Screening		
11.1	Does the location have X-ray equipment?	~	
11.2	Does the location have an explosion detection unit?	~	
11.3	Does the location use sniffer dogs?	×	
11.4	Is there a process to ensure that screening is performed in accordance with ICAO standards and national provisions?	~	
11.5	Is screening equipment tested and maintained in accordance with the applicable standards and regulations?	~	
11.6	Is there a process to ensure that entities tendering screened/secured cargo have an established security program?	~	
12.	Controlled Room Temperature		
12.1	Is there a warehouse storage area at Controlled Room Temperature between +15°C to +25°C?	~	
12.2	What is the total floor space (in m2) for storage at Controlled Room Temperature between +15°C and +25°C?	480	





12.3	How much of this total floor space (in m2) is dedicated for pharmaceuticals only?	480	
12.4	Is there a documented process to ensure that pharmaceutical products in this temperature range are stored in a clearly marked segregated area?	~	
12.5	Can ULD (Unit Load Device) build-up and break-down be performed in Controlled Room Temperature environment between +15°C and +25°C?	×	
12.6	Is it possible to store ULDs in controlled room temperature between +15°C and +25°C before aircraft loading and after unloading?	~	
12.7	Can security checks be performed in Controlled Room Temperature environment between +15°C and +25°C?	×	
12.8	Can customs clearance activities be performed in Controlled Room Temperature environment between +15°C and +25°C?	~	
12.9	Please indicate for what types of shipments the storage area between +15°C and +25°C is available?	Export Transit Import	<b>* * *</b>
12.10	Can healthcare cargo be loaded from the truck in an environment between +15°C and +25°C without exposure to ambient temperature?	×	
12.11	Can healthcare cargo be offloaded from the truck in an environment between +15°C and +25°C without exposure to ambient temperature?	×	
13.	Cold Rooms		
13.1	Is there a warehouse Cold Room for storage between +2°C and +8°C?	~	
13.2	What is the total floor space (in m2) in the location for storage between +2°C and +8°C?	290	
13.3	How much of this total floor space (in m2) is dedicated for pharmaceuticals only?	290	
13.4	Is there a documented process to ensure that pharmaceutical products in this temperature range are stored in a clearly marked segregated area?	~	
13.5	Can ULD (Unit Load Device) build-up and break-down be performed in a Cold Room between +2°C and +8°C?	×	
13.6	Is it possible to store ULDs in a Cold Room between +2°C and +8°C before aircraft loading and after unloading?	~	
13.7	Can security checks be performed in a Cold Room between +2°C and +8°C?	×	
13.8	Can customs clearance activities be performed in a Cold Room between +2°C and +8°C?	<b>~</b>	
13.9	Please indicate for what types of shipments the storage area between +2°C and +8°C is available?	Export Transit Import	<b>* * *</b>
13.10	Can healthcare cargo be loaded from the truck in an environment between +2°C and +8°C without exposure to ambient temperature?	×	
13.11	Can healthcare cargo be offloaded from the truck in an environment between +2°C and +8°C without exposure to ambient temperature?	×	
14.	Freezers		
14.1	Is there a warehouse Freezer for storage at -10°C or colder?	~	
14.2	What is the total floor space (in m2) in the location for storage below -10°C?	45	
14.3	How much of this total floor space (in m2) is dedicated for pharmaceuticals only?	45	
14.4	Is there a documented process to ensure that pharmaceutical products in this temperature range are stored in a clearly marked segregated area?	<b>~</b>	
14.5	Can ULD (Unit Load Device) build-up and break-down be performed in a Freezer below -10°C?	×	
14.6	Is it possible to store ULDs (Unit Load Devices) in a Freezer below -10°C before aircraft loading and after unloading?	~	





14.7	Can security checks be performed in a Freezer below -10°C?	×	
14.8	Can customs clearance activities be performed in a Freezer below -10°C?	<b>~</b>	
14.9	Please indicate for what types of shipments the storage area below -10°C is available?	Export Transit Import	<b>*</b>
15.	Monitoring & Maintenance		
15.1	Do you have a temperature monitoring system in place for all Storage Areas used for pharmaceutical products?	<b>~</b>	
15.2	Is there a procedure for the calibration of equipment used to control or monitor the storage areas of pharmaceutical products?	~	
15.3	Have you conducted a thermal mapping during extreme seasons (e.g. summer and winter) for all storage areas where pharmaceutical products are placed?	<b>~</b>	
15.4	Is the temperature monitoring equipment located according to the results of the temperature mapping exercise?	<b>~</b>	
15.5	Are alarm systems in place to provide alerts when there are excursions from pre-defined storage conditions, including a procedure for 24/7 follow-up on alarms?	<b>~</b>	
15.6	Is there a procedure and a maintenance contract available for the planned maintenance of heating/cooling devices, with adequate records of repair and maintenance?	×	
15.7	Does the location have back-up facilities for temperature-controlled storage available (e. g. by third party provider)?	<b>~</b>	
16.	Healthcare Cargo Acceptance		
16.1	Is there a documented process to ensure that healthcare shipments are in proper condition upon acceptance?	<b>~</b>	
16.2	Are truck temperature condition and logs checked and collected upon acceptance of healthcare shipments?	<b>~</b>	
17.	Container Handling Services		
17.1	Please indicate the type of containers that can be handled in the location?	Envirotainer CSafe DoKaSch va-Q-tec SkyCell	***
17.2	Please indicate the total number of storage locations for active containers?	20	
17.3	Please indicate the number of the plug-ins available to recharge active containers?	10	
17.4	Does the location have capabilities for battery replacements?	<b>~</b>	
17.5	Are active containers stored in the location monitored on temperature, re-icing and battery levels?	~	
17.6	Does the location offer pre-conditioning of containers?	~	
17.7	Is the location a Qualified Envirotainer Provider?	×	
17.8	Can specific passive packaging solutions be handled and arranged on request?	~	
18.	Dry-ice Services		
18.1	Does the location have capabilities for the re-icing of dry-ice shipments?	~	
18.2	Please indicate the type of dry-ice available at the location?	5 kg blocks Wrapped Unwrapped 10 kg blocks 1-2 kg blocks	> > >
18.3	Does the location have dry-ice on stock?	×	





18.4	Can dry-ice be made available within 24 hours at the location?	~	
19.	Location Hygiene		
19.1	Is there a policy concerning food, drinks and smoking inside the location?	✓	
19.2	Is there a written cleaning program in place for all areas where pharmaceutical products are handled?	✓	
19.3	Are the cleaning records available?	<b>~</b>	
19.4	Are cleaning equipment and agents chosen to avoid contamination of products, for example with ammonia-free agents?	~	
19.5	Is there a documented preventive pest control system in place to protect against the entry of insects, rodents or other animals?	~	
20.	Perishable Cargo Handling		
20.1	Is there a documented process to ensure that perishable shipments are in proper condition upon acceptance?	~	
20.2	Are truck temperature condition and logs checked and collected upon acceptance of perishable shipments?	~	
20.3	Can perishable cargo be offloaded from the truck and directly placed in the required temperature-controlled area without exposing to ambient temperature?	~	
20.4	Is there a documented process to check that all perishable shipments are labelled with the IATA Perishable Label?	~	
20.5	Is there a vacuum cooler for the storage of perishable cargo?	<b>~</b>	
21.	General Warehouse Capabilities		
21.1	What is the total floorspace (in m2) of the warehouse?	33000	
21.2	Are you authorized by the local CAA/Airport authority to perform the ramp handling function?	×	
21.3	Do you have direct ramp access from the warehouse?	<b>~</b>	
21.4	If you do not have direct ramp access from the warehouse, what is the average driving time (in minutes) from the warehouse to aircraft ramps?	-	
21.5	Is customs clearance available in the warehouse 24x7?	<b>~</b>	
21.6	Do you have a dedicated express channel to handle shipper built units (BUP) to the airside?	<b>~</b>	
22.	ULD Management		
22.1	Do you have dedicated ULD Storage Areas?	<b>~</b>	
22.2	Please indicate the types of transportation for ULD movements in the Location?	Slave Pallets Dollies Rollerbeds Forklifts Pallet Movers	X
22.3	Is there a documented process to ensure that any ULD is inspected and found to be airworthy before build up and loading to aircraft?	~	
22.4	Is there a documented process to ensure that any ULD being built up is within the required limitations such as Maximum Gross Weight?	~	
23.	Airfreight Process Timings		
23.1	What is the standard freight cut off time of loose cargo with known security status before scheduled time of departure?	420	
23.2	What is the standard freight cut off time (in minutes) of shipper built units (BUP) before scheduled time of departure?	-	
23.3	Is there an optional express service with reduced cut off time before scheduled time of departure?	~	
23.4	What is the typical duration (in minutes) of ULD buildup and breakdown for a single ULD?	120	





23.5	What is the typical duration (in minutes) of ULD storage before transportation to aircraft or truck?	0
23.6	What is the typical duration (in minutes) of customs clearance procedures for import shipments?	240
23.7	What is the typical time (in minutes) of freight availability after time of aircraft arrival?	240
24.	Tarmac Timings	
24.1	What is the typical duration (in minutes) from the warehouse until cargo is loaded on a passenger aircraft?	120
24.2	What is the typical duration (in minutes) from the warehouse until cargo is loaded on a freighter aircraft?	120
24.3	What is the typical duration (in minutes) for outbound shipments from cargo loaded on aircraft until scheduled time of departure?	45
24.4	What is the typical duration (in minutes) from the arrival of a passenger flight until cargo is stored in the warehouse?	120
24.5	What is the typical duration (in minutes) from the arrival of a freighter flight until cargo is stored in the warehouse?	90
25.	Healthcare Air Freight Acceptance	
25.1	Is the IATA Acceptance Checklist for Time and Temperature Sensitive Healthcare Shipments used and documented upon arrival of all pharmaceutical shipments?	<b>~</b>
25.2	Is there a documented process to check that all healthcare shipments are labelled with the IATA Time $\&$ Temp. Sensitive Label?	<b>~</b>
25.3	Is there a documented process to check that the temperature range on the IATA label matches the Air Waybill (AWB)?	<b>~</b>
26.	Tarmac Temperature Protection	
26.1	Please indicate the standard protection for temperature-controlled tarmac transportation of healthcare shipments at the location?	Thermal Blanket Temp. controlled Dolly Temp. controlled Aircraf Temp. controlled Truck
26.2	Please indicate the optional protection for temperature-controlled tarmac transportation of healthcare shipments at the location?	Temp. controlled Truck  Thermal Blanket  Temp. controlled Dolly  Temp. controlled Aircraf
26.3	Who owns and operates the indicated equipment for tarmac temperature protection?	None
26.4	Is there a high-priority process for ramp transportation and cargo loading/unloading of temperature-sensitive products?	<b>~</b>
26.5	Are there defined procedures on the handling of temperature-sensitive shipments in case of flight delays?	<b>~</b>





## Reference