

Holistic Approach to Pharma Supply Chain

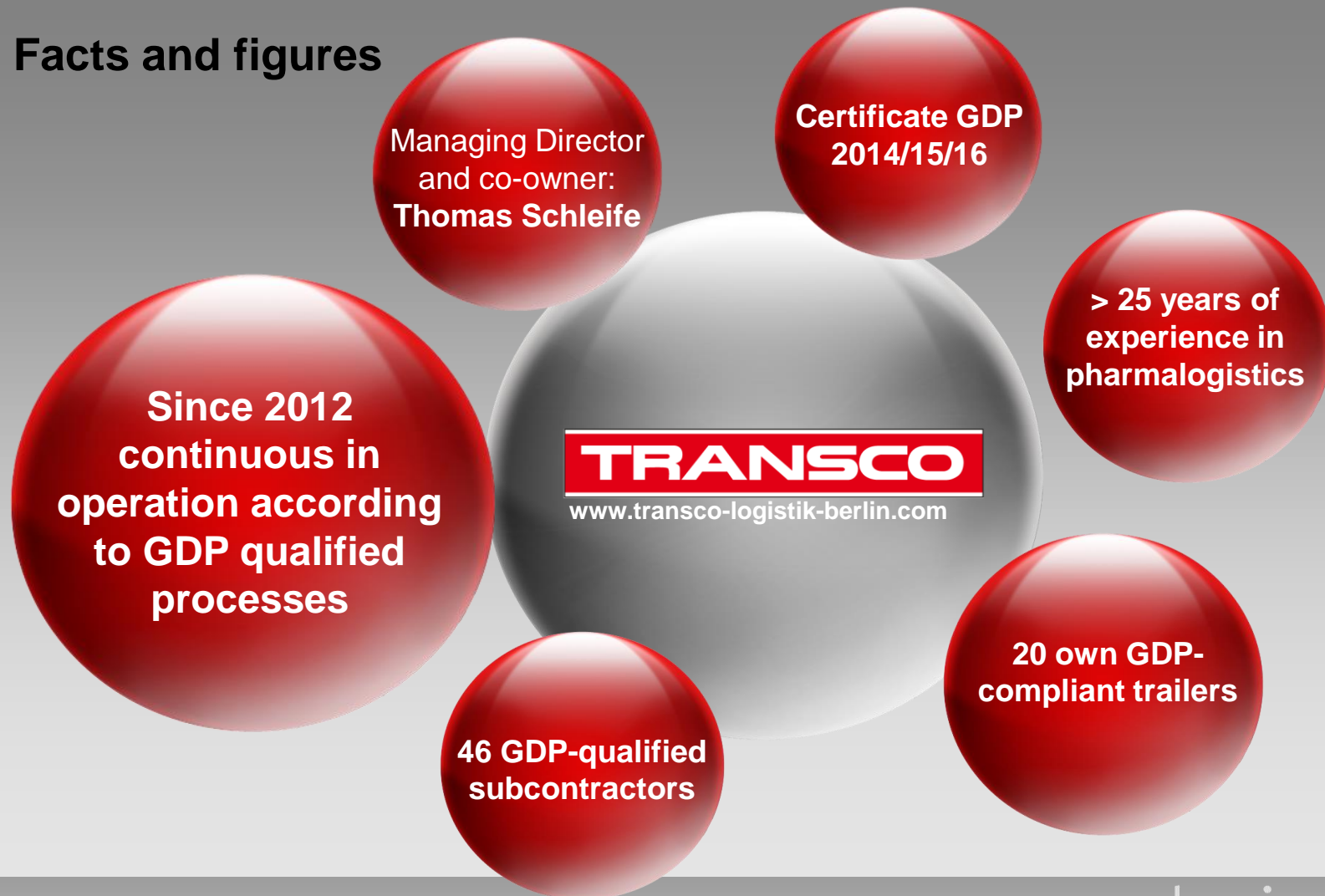


GDP corresponding transportation

Structure

1. TRANSCO Berlin-Brandenburg
2. What is the matter with GDP?
3. What do transportation companies do to work GDP-compliant?
4. What could happen in reality?
5. Conclusion

Facts and figures



Profile

- TRANSCO Berlin Brandenburg (T BB) operates as:
 - a) pharmaceutical carrier
 - b) pharmaceutical freight forwarder
- Transports in Europe, all CIS countries, Mongolia, Turkey and Iran
- GDP guidelines implemented in 2011
- Own QMR and corporation with pharmacist to support GDP-compliant process



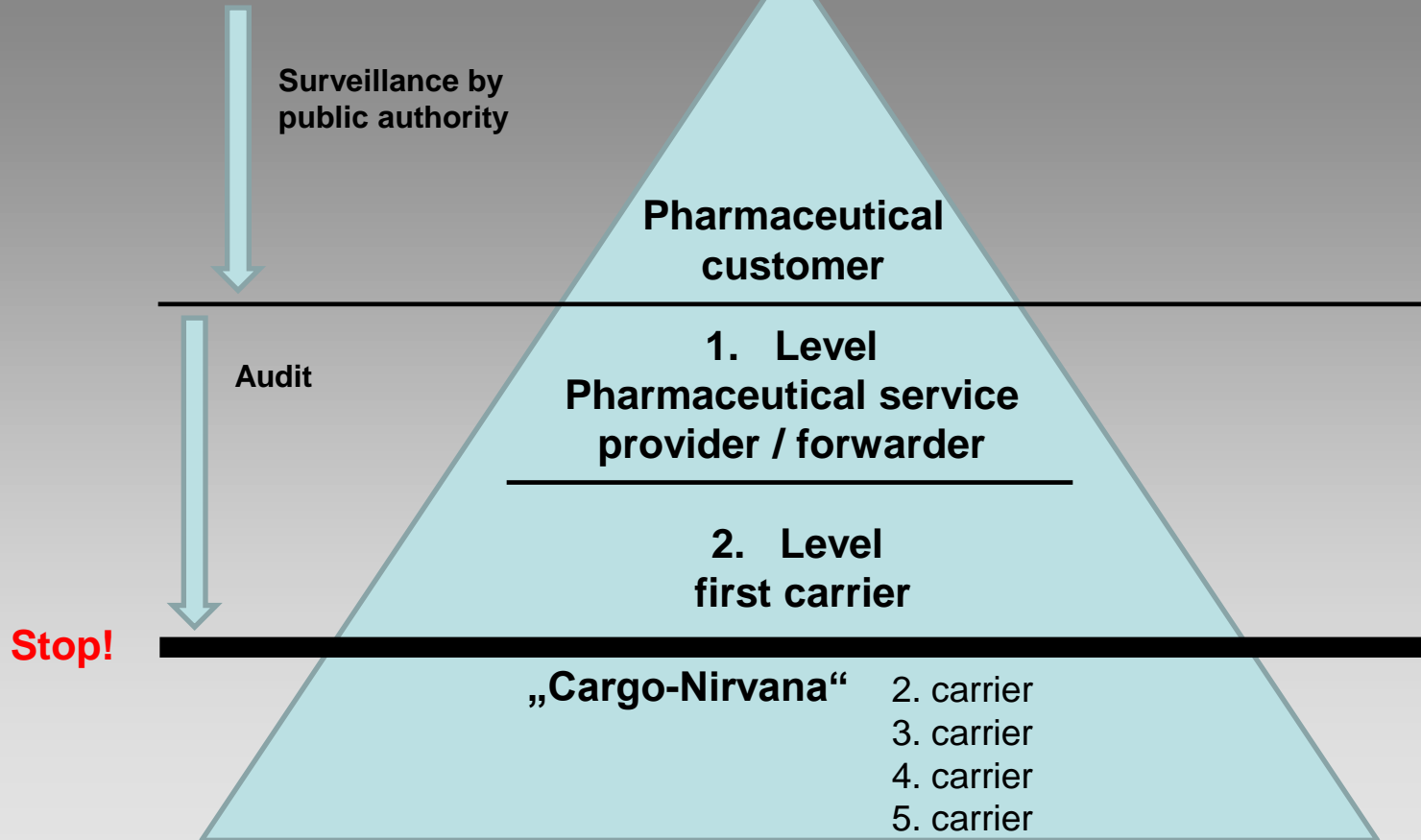
Summary

- Guideline of EU for quality assurance of pharmaceuticals while transporting them
- Purpose:
 - Ensure controlling of the supply chain and accordingly maintain quality and integrity of pharmaceuticals
- Further legal guidelines
 - WHO GMP-Guideline (Good Manufacturing Practice)
 - Medicinal Products Act (German Law)
 - PIC (Pharmaceutical Inspection Convention)
 - AMWHV (Arzneimittel- und Wirkstoffhandelsverordnung / Germany)
 - DIN EN ISO



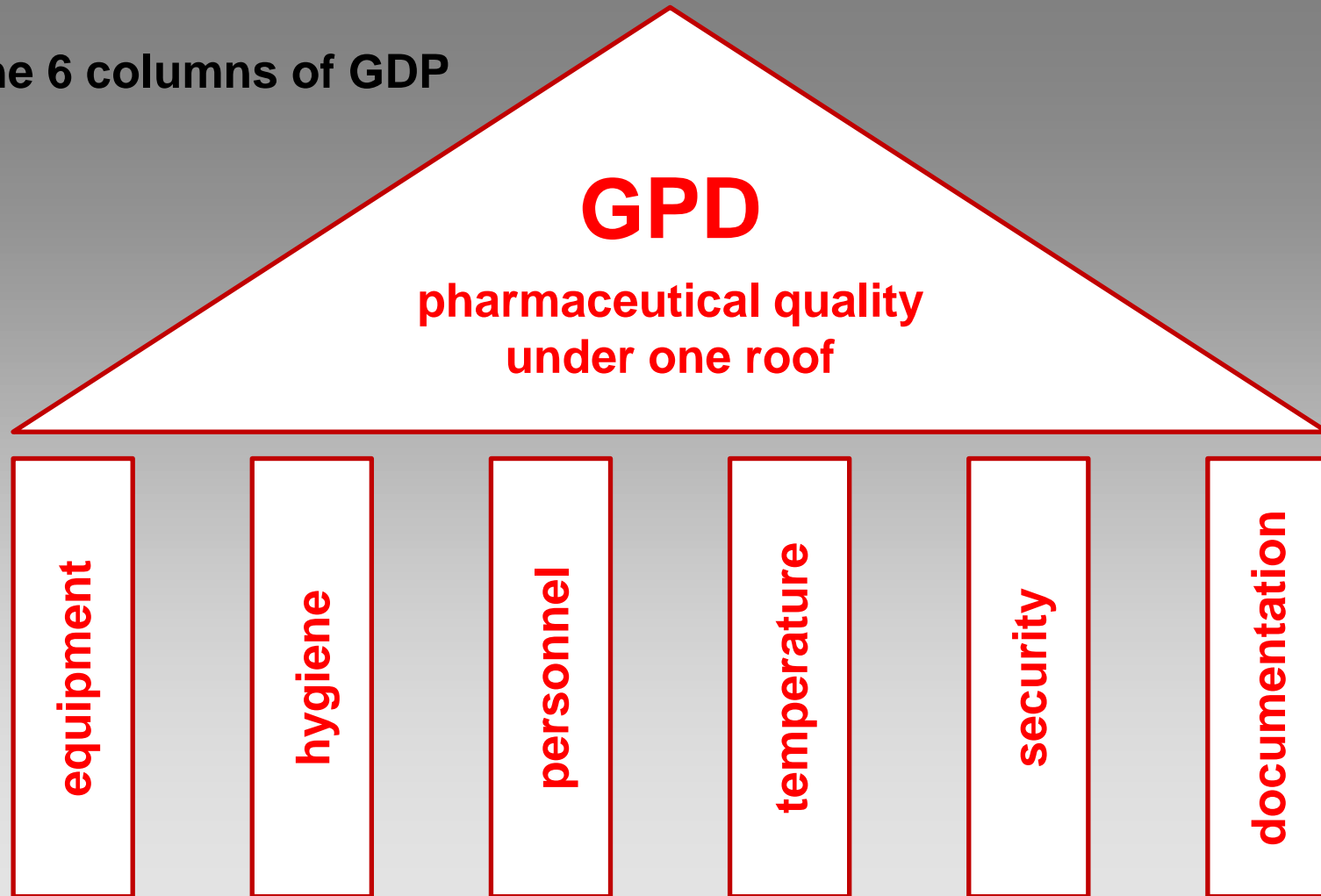
2. What is the matter with GDP?

GDP-pyramid



2. What is the matter with GDP?

The 6 columns of GDP



Equipment

- Modern technique – regular replacement of transportation fleet
- Valid ATP-certificate
- Calibration of sensors by qualified specialist workshop (at least 1x per year)
- Calibration record of reference device
- Sufficient number of safety bars / cargo bars
- Regularly inspection of vehicles



Hygiene

- Vehicle has to be clean (inside and outside)
 - Odor-free (no meat, no fish, i.a.)
- Pest-control per optical control
- Loaded goods have to be in good condition
- Take care at loading place that there is enough space for air circulation



Personnel

- Quality is only as good as the weakest link in the chain



- Training of personnel including success control

3. What do transport companies do to work GDP-compliant?

Temperature

- Sensors in truck measure temperature
- Tendency is to remove temperature printers – modern systems / theft / paper quality of printouts



TF DV 63 (F0641553)
Details - TF DV 63 (F0641553)

TControl

Temperaturen

Temp 1 [°C]	3.00
Temp 2 [°C]	2.00
Temp 3 [°C]	2.50
Temp 4 [°C]	2.50

Kühlmaschine

Tankstatus [l]	160
Tank Reserve	false

Datum	Typ	Status	Temperaturen	Position
03.03.2017 14:15	COOL 30		Temp 1: 20.00°C Temp 2: 19.00°C Temp 3: 19.00°C Temp 4: 19.00°C	M-38/M-38, Carassay, KZ
03.03.2017 14:15			Temp 1: 20.00°C Temp 2: 19.00°C Temp 3: 19.00°C Temp 4: 19.00°C	
03.03.2017 14:10			Temp 1: 19.50°C Temp 2: 19.00°C Temp 3: 18.50°C Temp 4: 19.00°C	
03.03.2017 14:05			Temp 1: 20.00°C Temp 2: 19.00°C Temp 3: 18.50°C Temp 4: 19.00°C	
03.03.2017 14:00	COOL 30		Temp 1: 20.00°C Temp 2: 19.00°C Temp 3: 19.00°C Temp 4: 19.00°C	A-2/A-2, Carassay, KZ

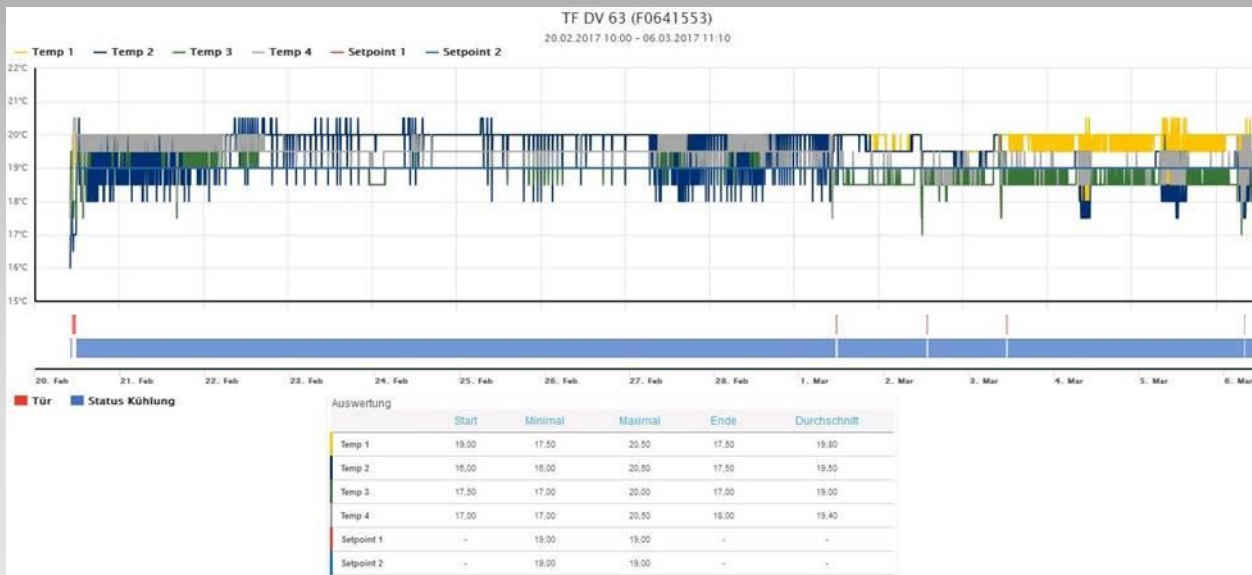
Thermo King WinTrac 5 Device: CargoWatch
Unit SN: 000005001257657
Revision: 76a0
Release: [5.7]
Trailer ID: WM67940
Serial number: 015050613390T3
Temperature: °C Pressure: PSI

Time	Setpoint Temperature	Logger Sensor 1	Op Mode Zone-1
2016-12-01			
21:15	19.0	19.5	Null
21:30	19.0	19.4	Null
21:45	19.0	19.3	Null
22:00	19.0	19.1	Null
22:15	19.0	18.9	Null
22:30	19.0	18.8	Null
22:45	19.0	18.7	Null
23:00	19.0	18.6	Null
23:15	19.0	18.4	Null
23:30	19.0	18.3	Null
2016-12-01			
23:45	19.0	18.2	Null
2016-12-02			
00:00	Start of trip		
00:00	Setpoint Temperature: 19.0		
00:00	19.0	18.1	Null
00:01	Setpoint Temperature: 19.0		
00:01	19.0	17.9	Null
00:15	19.0	17.9	Null
00:30	19.0	17.8	Null
00:45	19.0	17.7	Null
01:00	19.0	17.7	Null
01:15	19.0	17.7	Null
2016-12-02			
01:30	19.0	17.6	Null
01:45	19.0	17.5	Null
02:00	19.0	17.5	Null
02:15	19.0	17.4	Null
02:30	19.0	17.4	Null
02:45	19.0	17.4	Null
03:00	19.0	17.3	Null
03:15	19.0	17.3	Null
03:30	19.0	17.2	Null
03:45	19.0	17.2	Null
2016-12-02			
04:00	19.0	17.2	Null

3. What do transport companies do to work GDP-compliant?

Temperature

- Control during and evaluation after transport with telematics tools



KRONE TELEMATICS Reporting

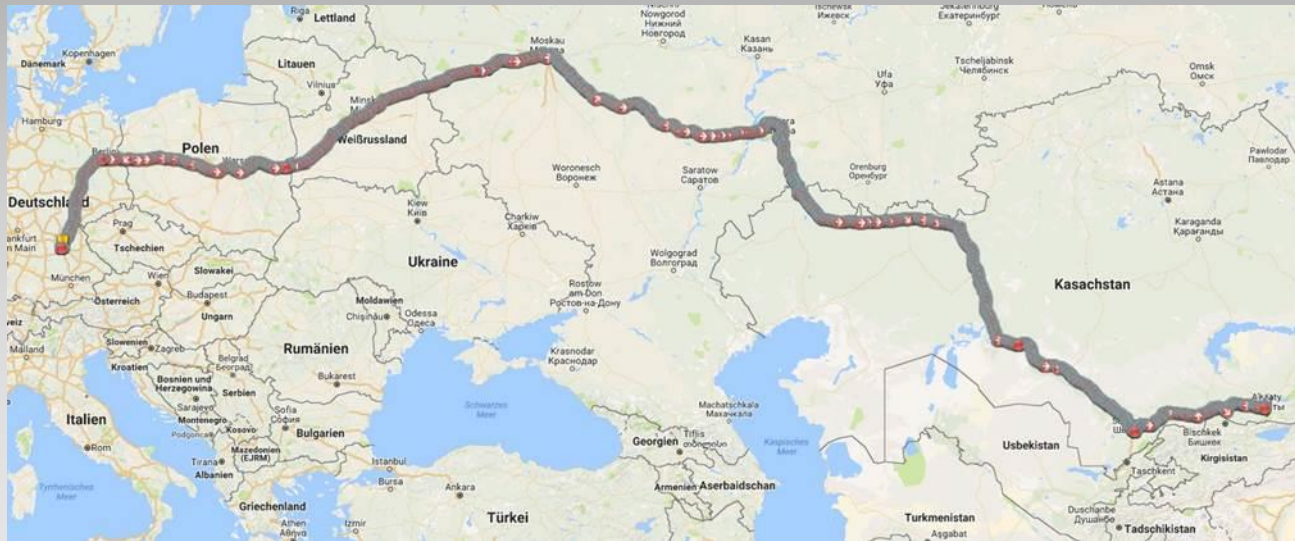
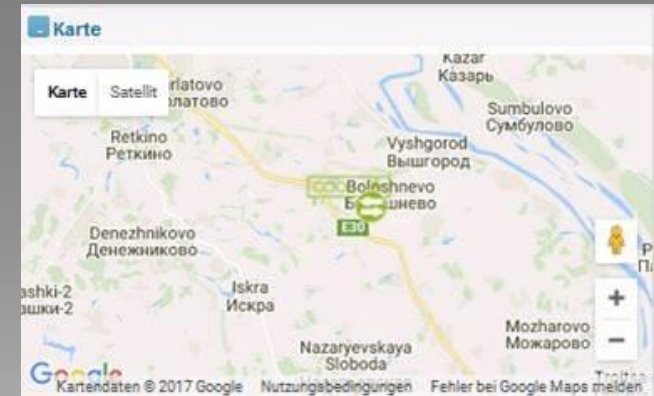
Reportzeitraum: 24.10.2016 10:00 - 26.10.2016 18:10
Fahrzeug TF DV 63 (F0641553)

Ereigniszeitpunkt (Box)	Tür	Status & Kühlzu PG	Temp 1	Temp 2	Temp 3	Temp 4	Setpo int 1	Setpo int 2	Position
24.10.2016 10:00	-	-	7,0	6,5	6,5	6,5	-	-	52° 22,72' N 013° 19,33' E
24.10.2016 10:00	-	-	7,0	6,5	6,5	6,5	-	-	Osdorfer Ring, 14979 Großbeeren, UK
24.10.2016 10:05	-	-	7,0	6,5	6,5	6,5	-	-	52° 21,67' N 013° 17,68' E
24.10.2016 10:10	-	-	7,0	6,5	6,5	6,5	-	-	52° 18,89' N 013° 16,70' E
24.10.2016 10:15	-	-	7,0	6,5	6,5	6,5	-	-	52° 18,94' N 013° 16,03' E
24.10.2016 10:15	-	-	7,0	6,5	6,5	6,5	-	-	Transco Berlin Brandenburg GmbH
24.10.2016 10:20	-	-	7,0	6,5	6,5	6,5	-	-	52° 18,94' N 013° 16,03' E
24.10.2016 10:25	-	-	7,0	7,0	6,5	6,5	-	-	52° 18,94' N 013° 16,03' E
24.10.2016 10:30	-	-	7,0	7,0	6,5	6,5	-	-	52° 18,94' N 013° 16,03' E
24.10.2016 10:30	-	-	7,0	7,0	6,5	6,5	-	-	Transco Berlin Brandenburg GmbH
24.10.2016 10:35	-	-	7,0	7,0	6,5	6,5	-	-	52° 18,94' N 013° 16,03' E
24.10.2016 10:40	-	-	7,5	7,0	6,5	6,5	-	-	52° 18,94' N 013° 16,03' E
24.10.2016 10:41	*	-	7,5	7,0	6,5	6,5	-	-	Transco Berlin Brandenburg GmbH
24.10.2016 10:41	-	-	7,5	7,0	6,5	6,5	-	-	Transco Berlin Brandenburg GmbH
24.10.2016 10:45	-	-	7,5	7,0	7,0	7,0	-	-	52° 18,94' N 013° 16,03' E
24.10.2016 10:47	-	*	7,5	7,0	7,0	7,0	-	-	Transco Berlin Brandenburg GmbH
24.10.2016 10:50	-	*	7,5	7,0	7,0	7,5	-	-	52° 18,95' N 013° 15,97' E
24.10.2016 10:55	-	*	12,5	9,0	10,5	11,5	-	-	52° 20,46' N 013° 16,97' E
24.10.2016 11:00	-	*	17,0	12,0	14,5	15,0	-	-	52° 21,94' N 013° 13,15' E
24.10.2016 11:00	-	*	17,0	12,0	14,5	15,0	19,0	19,0	Stahnsdorfer Weg, 14532 Stahnsdorf, DE

3. What do transport companies do to work GDP-compliant?

Security

- GPS transmitter should be in trailer
- Possibility to delegate a route via telematics / geofencing
- Every door opening is displayed in map



TF DV 63 (F0641553)	
Details - TF DV 63 (F0641553)	
TControl	
Allgemein	
Ereigniszeitpunkt (Box)	09.03.2017 14:15
Eingangszeitpunkt (Server)	09.03.2017 14:15
Position	Okruzhnaya doroga, Ryazan', RU
Geschwindigkeit [km/h]	22
GPS Höhe	172
Laufleistung (gesamt) [km]	103897
Voltage [V]	27.50
Status Kühlung	Aus 44:15
Koppelstatus	An
Tür	Geschlossen 76:19
Fahrt seit [h]	03:00
Anzahl Satelliten	11
Temperaturschreiber	TControl
EBS	
EBS Typ	WABCO_EXT
Chassis Nummer	F0641553
Laufleistung Gesamt [km]	373563
Geschwindigkeit [km/h]	22
Rote Kontrollleuchte	aus
EBS Achslast [t]	8.20
Beladung [t]	8.20
Beladungszustand EBS	beladen

Security

- Possibility to install different alarms in telematics system
 - Enter temperature range
 - Insert accurate GPS data
- Automatically generated information in case of alert (mail, call, SMS)



The screenshot shows a web interface for managing alarms. At the top, there is a search bar and three checkboxes: 'Aktiv', 'Sende E-Mail', and 'Sende SMS'. Below this is a table with the following columns: 'Name des Alarms', 'Aktiv', 'Sende E-Mail', 'Sende SMS', and 'Letzter Zeitstempel'. The table contains six rows of alarm data.

<input type="checkbox"/>	Name des Alarms	Aktiv	Sende E-Mail	Sende SMS	Letzter Zeitstempel
<input type="checkbox"/>	!!! Temperaturabweichung !!!		<input checked="" type="checkbox"/>		26.10.2016 17:00
<input type="checkbox"/>	!!! KÜHLAGREGAT !!!	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		07.03.2017 18:08
<input type="checkbox"/>	!!! Türöffnung !!!	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		09.03.2017 04:44
<input type="checkbox"/>	Bereitet die Dokumente vor, die Fahrer sind gleich bei uns im Büro !!!	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		21.02.2017 09:08
<input type="checkbox"/>	Seitenwandüberwachung	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		22.03.2016 10:28

3. What do transport companies do to work GDP-compliant?

Security at its best



Monitoring / telematics

- 7/24 monitoring of temperature-controlled vehicles
 - **Temperature**
 - Temperature must be in range and has to be monitored over the entire transportation period
 - Recording of temperature data at least every 15 min.
 - Vehicle has to be pre-tempered before loading
 - **Position**
 - Constant monitoring of product → GPS / geofencing
 - Automatic message when truck arrives at loading/unloading place
 - **Security**
 - Doors must be closed during entire period of transport
 - Door locking system has to be activated
 - Fuel level of cooling unit

Monitoring / telematics

- Different systems but same opportunities
- You can choose the relevant parameters but have to pay for it

The screenshot shows a web-based tracking interface. At the top, there's a navigation bar with 'Tracking-Liste' and 'Berichte'. Below that, a search bar and various filters are visible. The main content area displays a table of tracked vehicles. The table has columns for Status, Fahrzeugbetrieb, Letzte bekannte Position, Datum, SP 1, S1, S2, Dieselmotorstunden, Batteriespannung, Tür 1, Kraftstoffstand, and Umgebungstemperatur. One vehicle is highlighted: KN-I 8864, located in Bobr, Minskaja Voblasts', BLR, on 09/03/17 at 14:48:29. Below this, a detailed view of the vehicle's status and temperature data is shown.

Status	Fahrzeugbetrieb	Letzte bekannte Position	Datum	SP 1	S1	S2	Dieselmotorstunden	Batteriespannung	Tür 1	Kraftstoffstand	Umgebungstemperatur
	KN-I 8864	Bobr, Minskaja Voblasts', BLR	09/03/17 14:48:29	19°C	18.9°C	18.4°C	631	14	geschlossen	172 (in Litern)	13.8°C

Datum	Typ	Status	Fahrzeug	Temperaturen	Standort	Aktionen
09.03.2017 14:08			TF DV 63 (F0841553 Vanloox)		E30/M5/M5/E30, Turlatovo, RU	
09.03.2017 14:00			TF DV 63 (F0841553)	Temp 1: 3.00°C Temp 2: 2.00°C Temp 3: 2.50°C Temp 4: 2.00°C	E30/M5/M5/E30, Ryazanskiy, RU	

Documentation

- Tenet: „Documentation must be written“ e.g.
 - Transport order
 - Calibration records
 - Cleaning journal
 - Contingency plan
 - Training schedule
 - Documents have to be archived
- Positive impact:
 - Avoid errors, which could slip in verbal communication
 - Traceability
 - Fault prevention

Qualitäts-/Umweltmanagement
TRANSCO Berlin Brandenburg GmbH
VA-S-02-FO-1_Notfallplan Arzneimitteltransport
Gültig ab: 01.11.2014

TRANSCO

Notfallplan Arzneimitteltransport allgemein

1. Fahrer / Unternehmer meldet sofort nach Bekanntwerden der Abweichung an TRANSCO (via Notfall Handy-Nr.).
2. TRANSCO informiert umgehend den Kunden (siehe Liste Notfallnummern Kunden).
3. Abstimmung über Maßnahmen.
4. Wenn Kunde nicht erreichbar ist (z.B. Wochenende), werden entsprechende Maßnahmen zum Schutz der Ware durch TRANSCO eingeleitet.
Abweichungen sind u.a. (nicht ausschließlich):
 - a. Bei Temperaturabweichungen im Fahrzeug ist umgehend die nächstgelegenen Werkstatt aufzusuchen.

Falls Reparatur nicht innerhalb von 3 Stunden möglich,
→ Suche nach Ersatzfahrzeug

→ Umladung der Ware auf ein geeignetes temperiertes Lager

→ Bei Transporten unter Zollregime muss Abstimmung mit nächstem zuständiger Zollamt erfolgen.
 - b. Bei potentiellen Diebstählen umgehende Information an die nächste Polizeidienststelle.
 - c. Bei Verkehrsunfällen umgehend die zuständige Polizei informieren.
5. Dazu ständige Abstimmung zwischen der Geschäftsführung und der Disposition von TRANSCO und dem entsprechenden Subunternehmer.
6. Maßnahmen, die durch TRANSCO eingeleitet wurden, werden dem Kunden parallel schriftlich mitgeteilt.
7. Nach Transportende wird eine abschließende Auswertung der Abweichung gemeinsam mit dem Kunden durchgeführt.
→ evtl. werden Prozessverbesserungen definiert

Basics of quality management

- Trainings
- Self-inspections
- Complaints processing
- Emergency management
- Quality Agreements with customers
- Self-assessment form for subcontractors
- Audits – certificates

TRANSCO
Self-assessment form for subcontractors

Company data _____ Date of issue _____

COMPANY NAME	_____
Year of registration	_____
ADDRESS	_____
PHONE	_____
FAX	_____
WEBSITE	_____
E-MAIL	_____
TRANSPORT SERVICE	_____
LOCATION	_____

<input type="checkbox"/>	Road transport	<input type="checkbox"/>
<input type="checkbox"/>	Pharmaceutical transport	<input type="checkbox"/>
<input type="checkbox"/>	Transport of dangerous goods	<input type="checkbox"/>
<input type="checkbox"/>	Other _____	<input type="checkbox"/>

Essentials:
You only have to fill in the sections which are applicable for the intended or contractually agreed transport services. You can put further comments in attachment.

Stamp in the form please sign (company) and send back to:
TRANSCO
Transco Berlin Brandenburg GmbH
Brandenburgische Str. 11/12
14241 Lohrdorfstraße

or completely signed and scanned via fax to:
transco.berlin@transco.de

For any further question your contact person at Transco Berlin Brandenburg GmbH is:
Mrs. Heidemarie
phone: +49 30 3074 9100 10
e-mail: transco.berlin@transco.de

Seite 1 von 7

QUESTIONNAIRE FOR THE PRE-ASSESSMENT TRANSPORT COMPANIES

LOGO

Introduction

The purpose of this questionnaire is to evaluate the compliance level of your company with regards to the implementation of GDP, which can be applied as basis to future quality audits on site. Please fill the form completely and enclose the requested technical information. Additional information or comments are welcome and can be enclosed at the end of the questionnaire.

Please return all documents to the attention of:

Company	_____
Global Quality Management	_____
Name	_____
Place	_____
Country	_____

Details, Information

Company Name:	Transco Berlin Brandenburg GmbH
Address (Administrative office):	Brandenburgische Str. 11/12 Lohrdorfstraße
Phone:	+49 30 3074 9100 0
Fax:	+49 30 3074 9100 10

What could happen in reality?



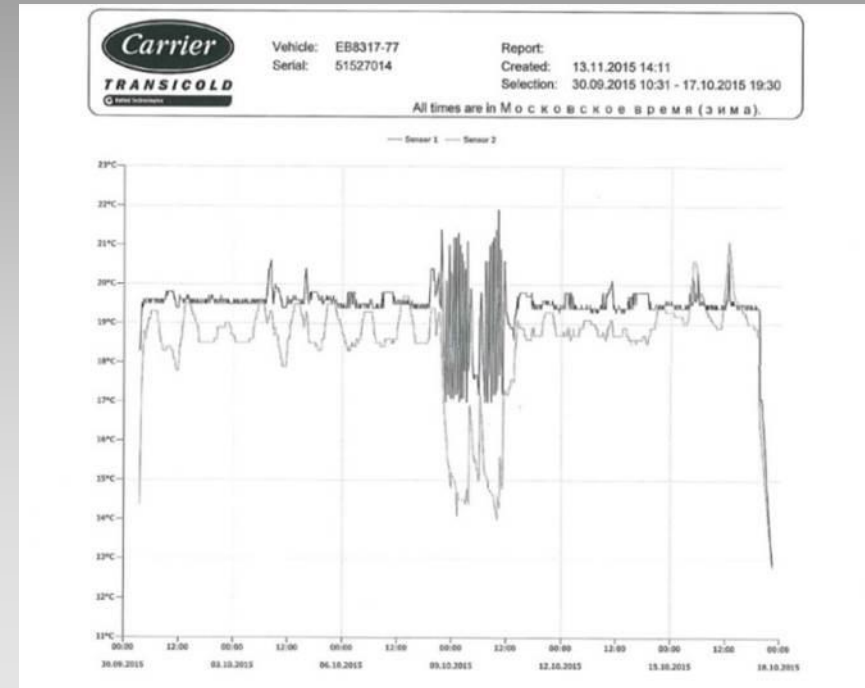
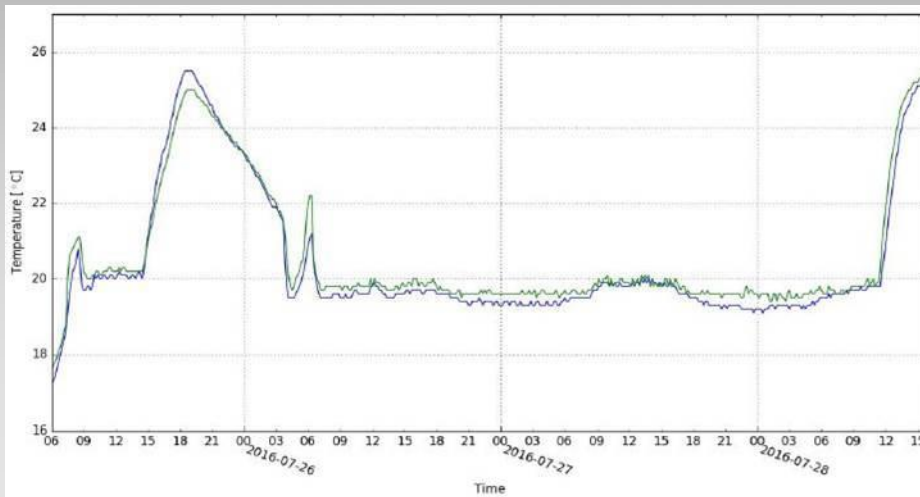
4. What could happen in reality?

Temperature

- Damaged sensor
- Problems with cooling unit
- Second loading place (non-GDP-compliant)

Wednesday 03/02/2016

	T1	T2
	°C	°C
03/02 10:28	18,9	-40,0
03/02 10:00	18,6	-40,0
03/02 09:48	17,7	-40,0
03/02 09:28	14,1	-40,0
03/02 09:08	10,2	-40,0
03/02 08:48	7,5	-40,0
03/02 08:28	6,9	-40,0
29/01 10:55	6,3	-40,0
29/01 10:35	6,6	-40,0
29/01 10:15	6,6	-40,0
29/01 09:55	6,6	-40,0
29/01 09:35	6,6	-40,0
29/01 09:15	6,6	-40,0
29/01 08:55	6,6	-40,0
29/01 08:35	6,6	-40,0
29/01 08:15	6,6	-40,0
29/01 07:55	6,6	-40,0



4. What could happen in reality?

Position

- There are regions (e.g. Turkmenistan) where you do not have a GPS signal
- Highway in Turkmenistan
- parking place in Turkmenistan



4. What could happen in reality?

Position

- TRANSCO Berlin-Brandenburg performs adventure-tours (e.g. Kazakhstan)
- Camels
- Sand-track
- First aid
- ...



4. What could happen in reality?

Security

- This is what we are laughing about...



- ...but sometimes it is the truth – security?



4. What could happen in reality?

Security

- Wrong securing of cargo is also possible in Europe
- Bad road conditions or customs inspection – this is the result



4. What could happen in reality?

Hygiene

- Things could happen you never thought about
 - Breakfast on trailer
 - Dirty trailer / unsuitable equipment
 - “Declaration of love”



4. What could happen in reality?

Hygiene

- transport companies are using modern technique but there are non-GDP-compliant situations



4. What could happen in reality?

Hygiene

- Crazy loading situations



4. What could happen in reality?

Hygiene

- Result of these loading conditions: cartons are wet



GDP corresponding transportation is only one part – for a holistic approach to pharma supply chain the following is crucial:

- Clear agreement between customer and service provider (e.g. QAA)
- Build partnership between pharmaceutical customer and service provider
 - find solutions - optimize processes together
 - not only delegate responsibility and insurance risk
 - price dumping and minor priority of quality of pharmaceutical customers are not the best way to act in a good cooperation
- Relations: customer to service provider and service provider to subcontractor – sending paper is not enough; you have to check regular on site and provide open communication

GDP corresponding transportation is only one part – for a holistic approach to pharma supply chain the following is crucial:

- Most important aspects for service providers:
 - Implementation of comprehensive quality management system
 - Qualification of transport process, equipment and personnel
 - Keeping temperature in range all the time
 - Keep goods secure over the entire transport
 - Documentation should be written in clear, unambiguous language

Thank you for your attention !

Managing Director
& Co-owner:

Thomas Schleife
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mobile: +49 172 3819100
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Quality Manager

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