

IATA AirPharma Conference

29 – 31 October 2019, Amsterdam, Netherlands





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29 – 31 October 2019, Amsterdam, Netherlands



Opening Day 3

Andrea Gruber
Head Special Cargo
IATA





#IATA_Cargo



coffee break



IATA Competition Law Compliance

Do not discuss:

- Pricing, including fares, service charges, commissions, etc.
- Bids on contracts or allocation of customers
- Geographic/Product market allocations and marketing plans, including
 - Expanding or withdrawing from markets
 - Group boycotts
 - Your commercial relations with agents, airlines or other third parties

Any discussion aimed at influencing the independent business decisions of your competitors

You will be asked to leave the meeting, and the meeting may be terminated, if the above-mentioned discussions occur.

Remember: All discussions count, even informal ones outside the meeting room!



Thank you to all our sponsors!



Shaping Europe's smartest cargo hub at Amsterdam Airport



Welcome Back Day 3

Chairman Opening Remarks

Maarten van As

Managing Director

Air Cargo Netherlands (ACN)



Keynote Speech

Showcasing how Customs and Industry can work better together

Henriette Bongers

Director

Customs District Schiphol Cargo



Deviation Management

challenges and problems within airfreight

Sven Sachsse & Christopher Stein

Transport Experts

Bayer AG





Deviation Management

*challenges and
problems within
airfreight*



**IATA Air
Pharma Conference**

2019-10-30 /
Sven Sachsse and Christopher Stein /
Version 1.0





Why?



What?



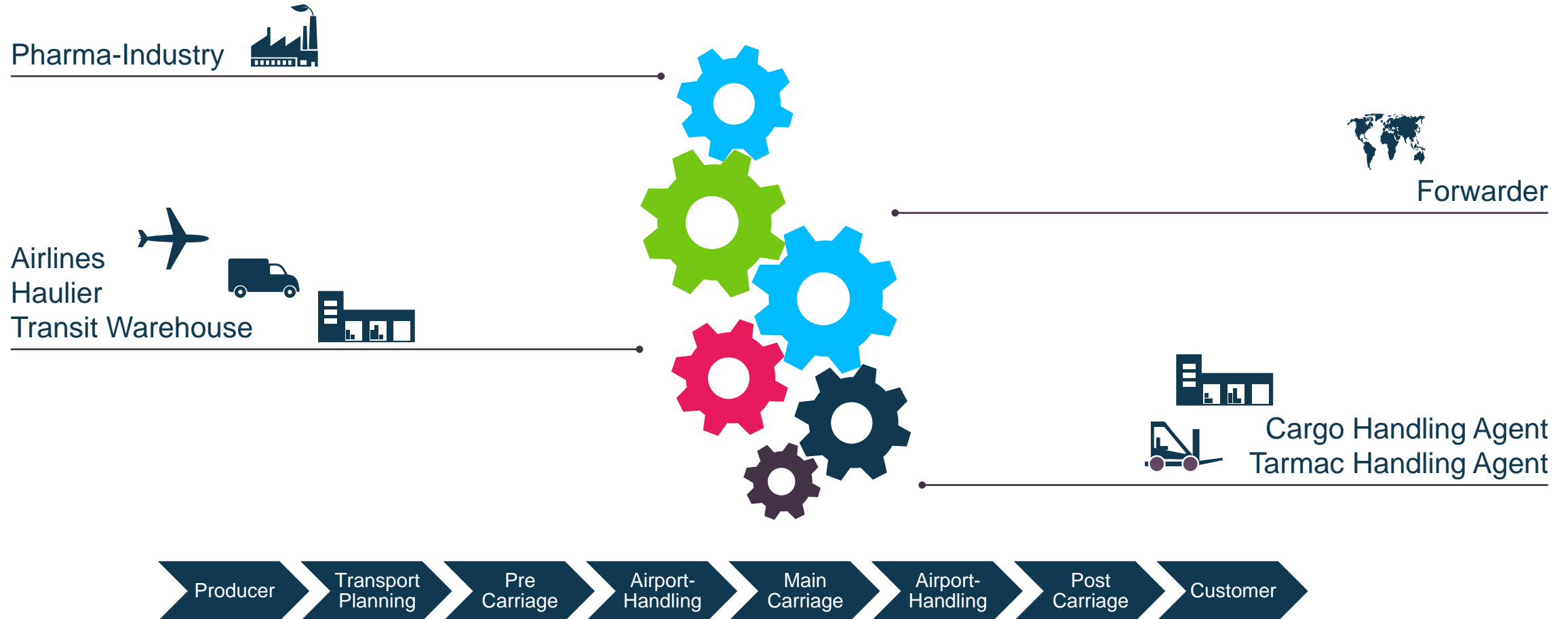
How?





01 Why?

Air Freight Transport Process – Parties Involved





01 Why?

Air Freight Transport Process – Regulatory Requirements

Good Distribution Practices:

WHO TRS 957 Annex 5; EU GDP Guidelines (2013/C 343/01)

// Scope:

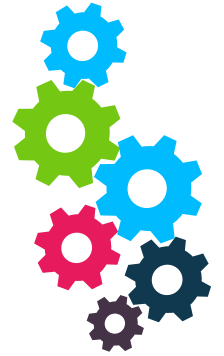
- // All parties involved in the distribution of pharmaceutical products have a responsibility to ensure
 - // that the quality of pharmaceutical products and
 - // the integrity of the distribution chain is maintained throughout the distribution. (WHO 4.1, EU GDP)

// Risk Management:

- // Distributors should from time to time conduct risk assessments to assess potential risks to the quality and integrity of pharmaceutical products. (WHO 8.8, EU 1.3)

// Deviation Management:

- // Deviations from established procedures are documented and investigated. (WHO 13.5-13.7, EU 1.2)
- // Appropriate corrective and preventive actions (commonly known as 'CAPA') are taken to correct deviations and prevent them in line with the principles of quality risk management. (EU 1.2)



02 What?

Air Freight Transport Process – Risks / Deviations



- // Damage of goods
- // Sabotage / manipulation of goods
- // Loss of goods
- // Intermixing at the pallet level
- // Insufficient quality management or processes



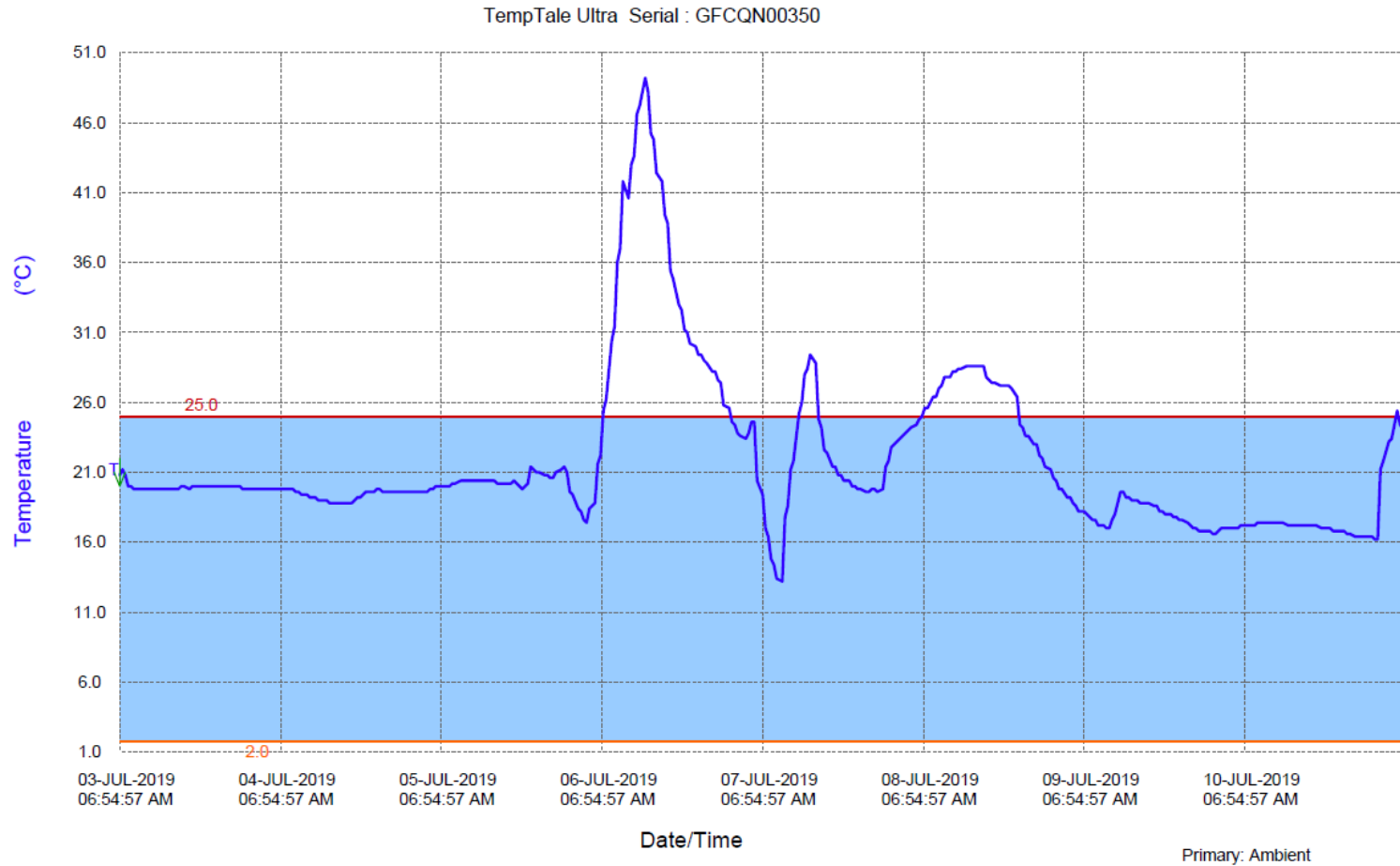
- // Temperature deviation
- // Crushed / destroyed pallets or packaging
- // Moldy, moist, smelly pallets or packaging
- // Crosslabelling
- // Theft
- // Counterfeight





02 What?

Air Freight Transport Process – Deviations





02 What?

Air Freight Transport Process – Deviations





02 What?

Air Freight Transport Process – Deviations





02 What?

Air Freight Transport Process – Reasons for Deviations



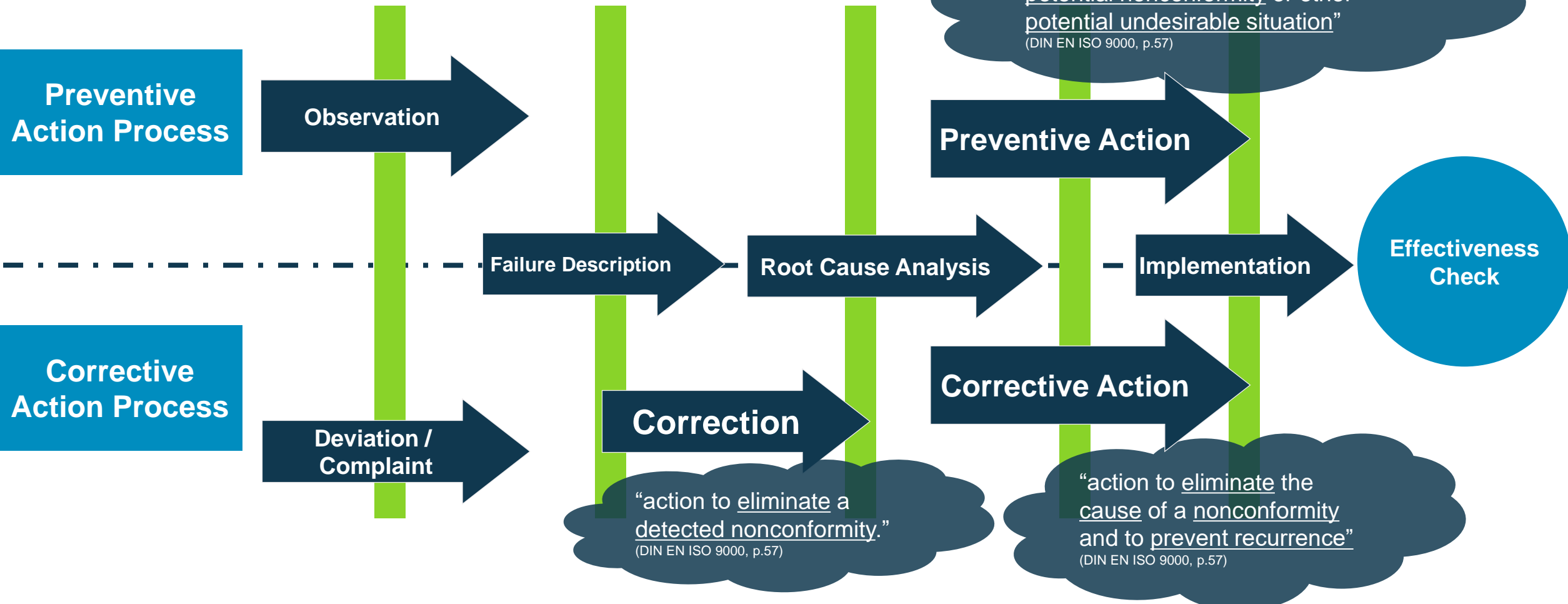
- // Nonattention of personnel
- // Missed / delayed flights
- // Strikes
- // Weather impact (e.g. rain, sun)
- // Security / customs check
- // Wrong freight hold temperature
- // Incompliance of services to used mitigations





03 How?

Investigation / CAPA Process Flow





03 How?

Examples of CAPA reports for temperature deviations:

Standard actions from different airlines (ambiguities are marked in red)

// **Preventive Action:** Temperature-sensitive goods have to be moved from the temperature-controlled warehouse **as late as possible** for loading.

// **Preventive Action:** **Immediately after the arrival** at the transit or destination airport, the goods have to be taken out of the aircraft and brought to the temperature-controlled warehouse.

// **Preventive Action:** The people involved in the ramp and ground handling agent are **trained again**.

// **Preventive Action:** It is recommended to use an **appropriate packaging** to endure **varying conditions** (hot during summer and cold during winter time).

// **Preventive Action:** We will keep handling times during freight is exposed to ambient temperatures to an **absolute minimum**.

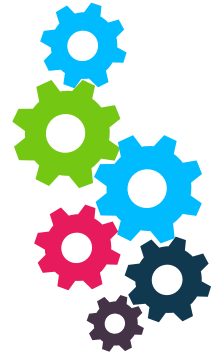
// **Preventive Action:** An **active packaging solution** is usually more sufficient than a **passive packaging solution**.



03 How?

Challenges and Problems - Perspective of a pharmaceutical producer and wholesaler

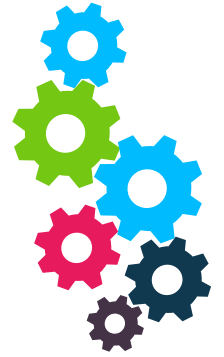
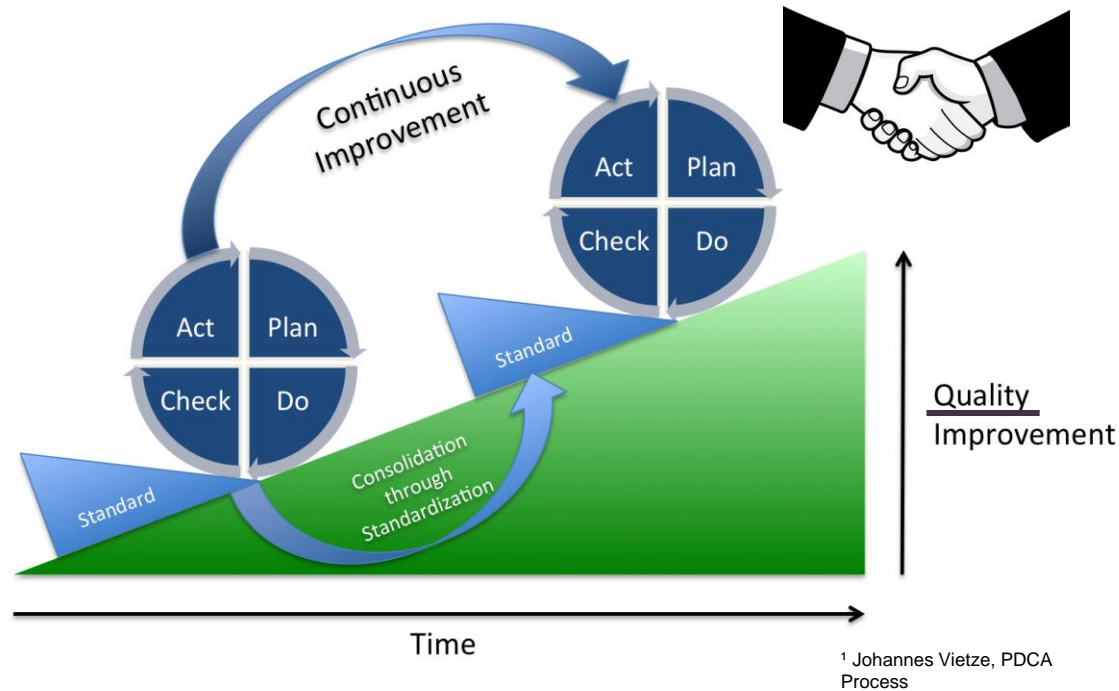
- // Missing transparency of capabilities
- // Missing knowledge pharma wholesaler about the booked service from forwarder by airlines
 - // What is in- and outside of the used logistic service?
 - // Are there service differences by airport?
- // Missing support for investigations by forwarder, airlines and ground handlers
 - // lack of awareness regarding distribution of pharmaceutical goods





03 How?

Challenges and Problems - Perspective of a pharmaceutical producer and wholesaler



- Not all problems can be solved, but it is our commun responsibility to
- // ensure quality of pharmaceutical products and
- // define right mitigation to reduce the accordant risk related to quality and economic aspects.



Deviation Management -
challenges and problems within airfreight

Thank you!



Bye-Bye



Networking break 10:30 – 11:00

Kindly sponsored by;



The changing DNA of an airline Sales Partner to improve transparency and service all stakeholders in the healthcare & humanitarian relief goods logistics chain

Esther Romar

Business Development Director

Inter Aviation Services




Temperature Excursions: Industry Standard of the Past A case study

Marrie Groeneveld

CCO

SkyCell AG



SKYY  CELL

Safest Pharma Containers.
Worldwide.

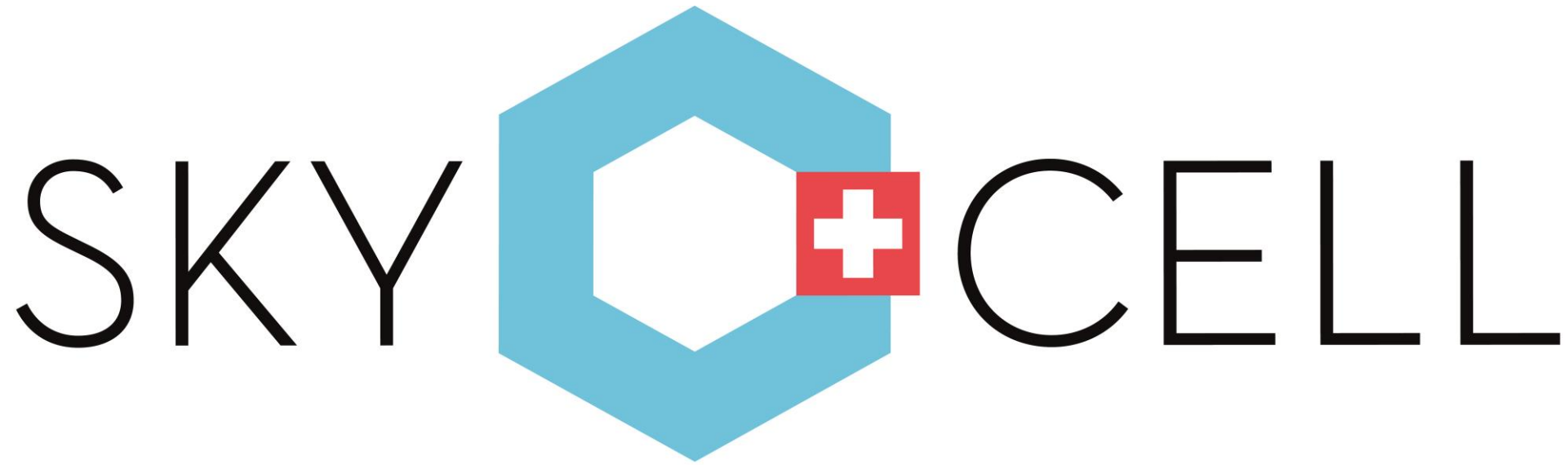


Safest Pharma Containers.
Worldwide.

IATA AirPharma
Conference 2019



Marrie Groeneveld
Chief Commercial Officer



**Temperature Excursions:
Industry standard of the past**

**Case Study:
Hybrid pharma container:
The new standard**



About

SkyCell is the 3th largest pharma airfreight container provider with the mission to supply the safest pharma containers worldwide. This is achieved through the unique combination of hardware, software and service, enabling our clients to master logistical challenges, eliminate temperature excursions and most of all let more patients **have access to medicine.**



ISO 9001: 2015



GDP certified

The Global Industry Challenge



Between 2 and 8 % of shipments experiencing excursion during transportation in pharma containers

The Global Industry Challenge

December 2018: Market study

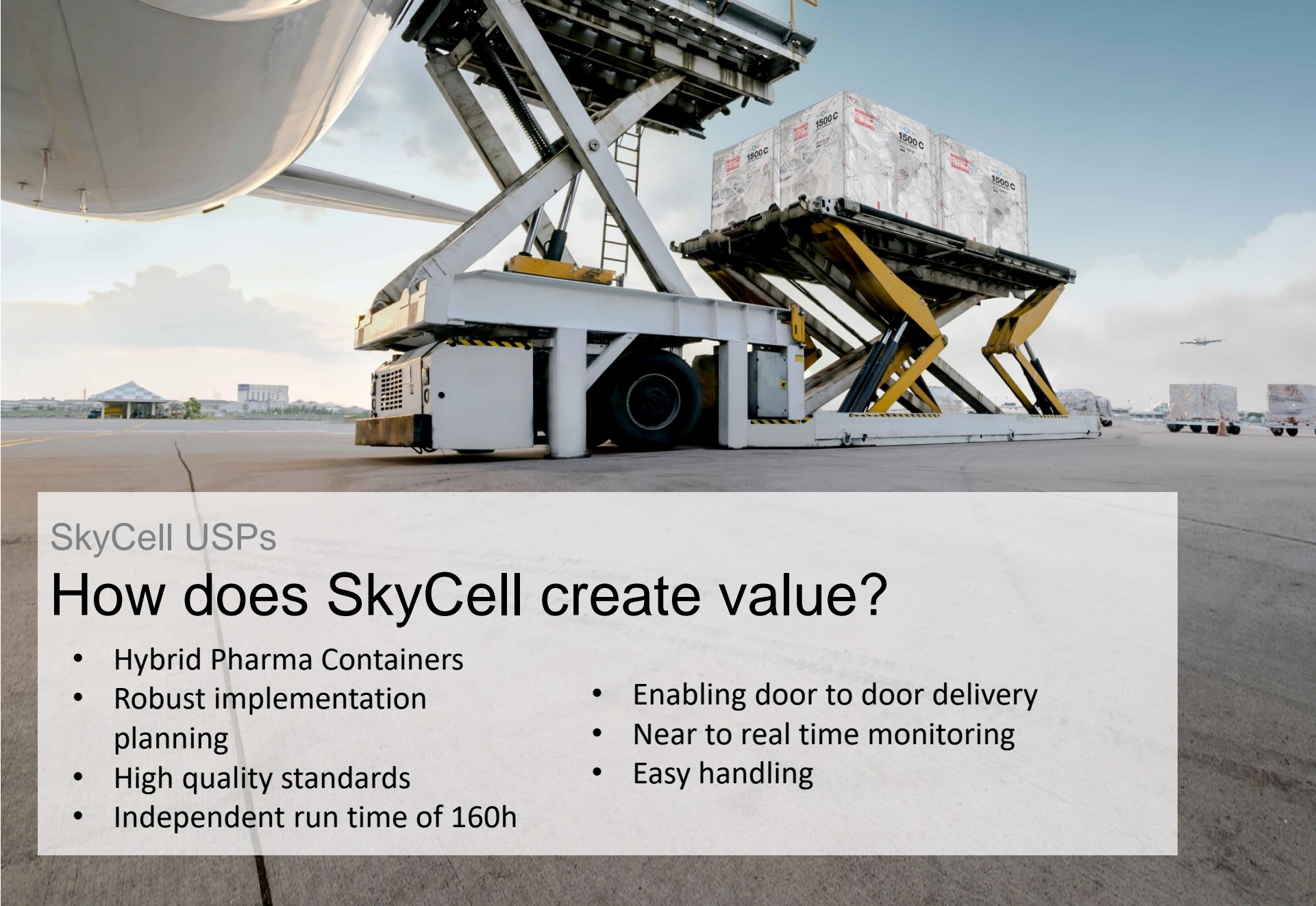


- 7 out of 11 largest pharma companies
- Findings: 5 to 6 % excursions
- Globally: at least 4% excursions
- Leaning towards PCM solutions

SKYY CELL

Challenge:

- Eliminate temperature excursions,
- Reduce total cost,
and
- Reduce CO2 emissions



SkyCell USPs

How does SkyCell create value?

- Hybrid Pharma Containers
- Robust implementation planning
- High quality standards
- Independent run time of 160h
- Enabling door to door delivery
- Near to real time monitoring
- Easy handling



SkyCell approach

- Dedicated SkyCell team
- Involve all the relevant client teams
- Easy handling, limited training need
- Improve processes
- Seamless implementation
- Superior hardware & software
- Show results

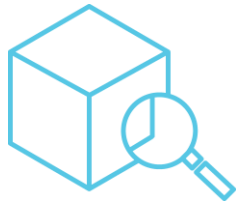


Implementation

Hardware & Software

Results

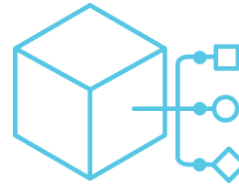
SkyCell Implementation Milestones



Validation



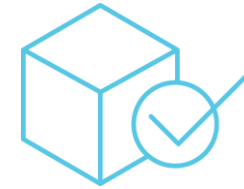
- Business award
- Solution design:
Process flow mapping
- Responsibilities identification:
Who does what and when?



Integration



- Loading tests:
Maximize the loading capacity
- Lane SOP:
Volume, origine, destination, airline
- Lane simulation with risk assessment
- Test shipment:
Analyse result



Go Live / Launch



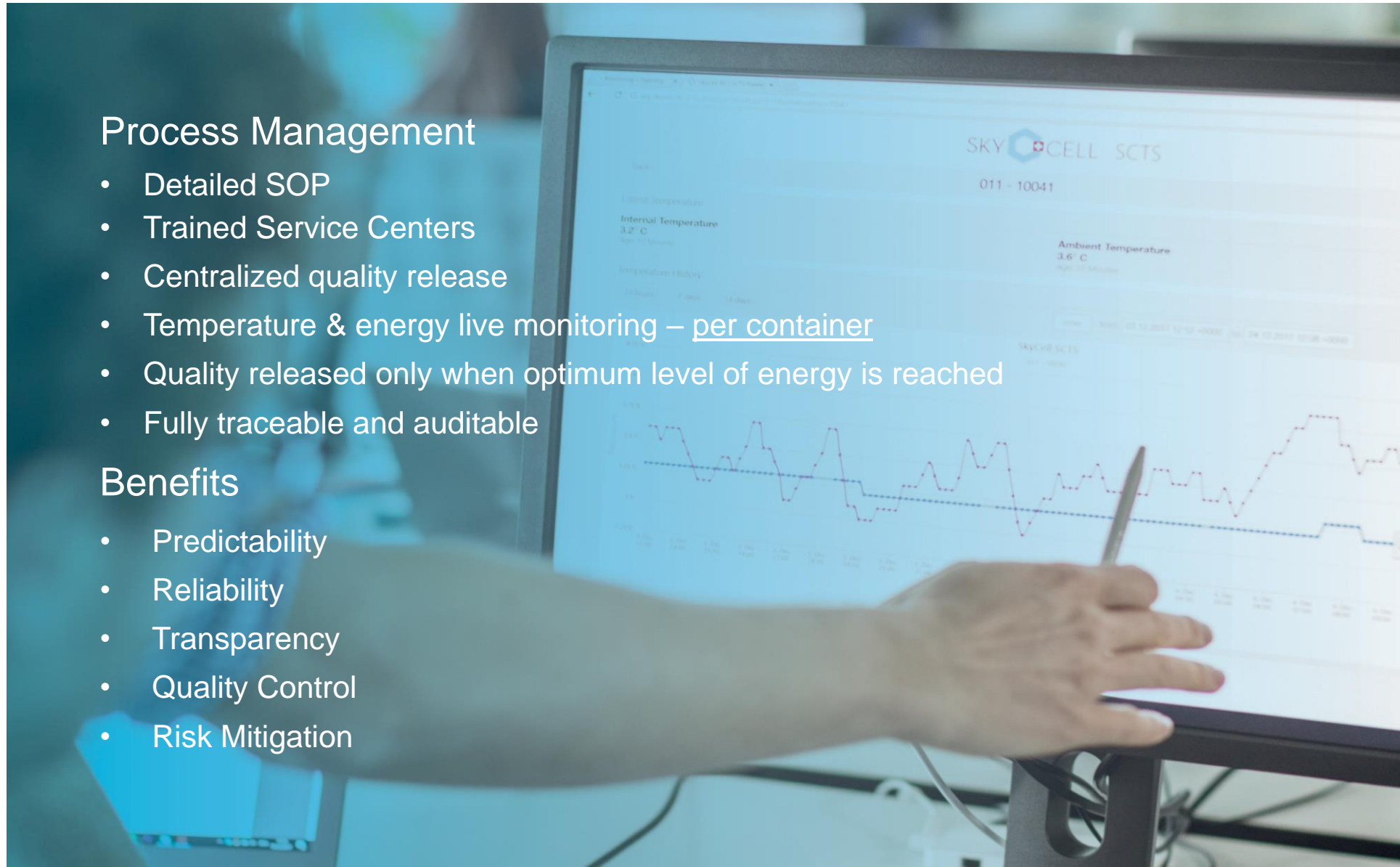
Implementation

Process Management

- Detailed SOP
- Trained Service Centers
- Centralized quality release
- Temperature & energy live monitoring – per container
- Quality released only when optimum level of energy is reached
- Fully traceable and auditable

Benefits

- Predictability
- Reliability
- Transparency
- Quality Control
- Risk Mitigation



Implementation SkyCell Transport Planner

SKYCELL Safest Pharma Containers. Worldwide.

Product options:

- SkyCell 1500C: +2°C to +8°C
- SkyCell 1500CRT: +15°C to +25°C
- SkyCell 770C: +2°C to +8°C
- SkyCell 770CRT: +15°C to +25°C

Map showing flight route: New York (JFK) to Dubai (DXB).

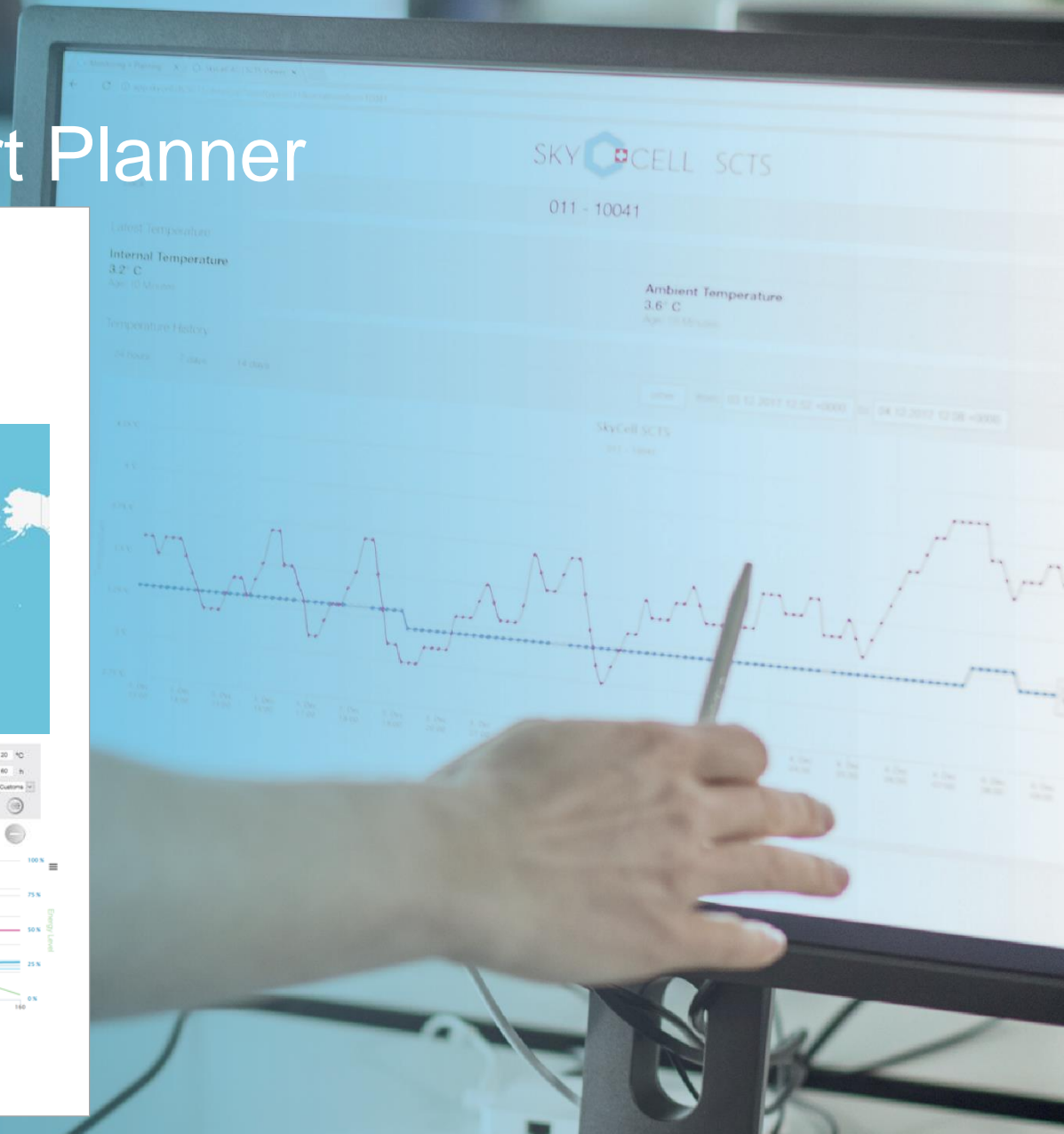
Simulation parameters:

Ambient Temperature	Time	Mode
-5 °C	2 h	Truck
20 °C	12 h	Airport
-10 °C	4 h	Plane
15 °C	18 h	Plane
88 °C	12 h	Plane
15 °C	24 h	Warehouse
88 °C	4 h	Plane
15 °C	10 h	Plane
20 °C	80 h	Customs

Simulation graph showing Internal Temperature (°C) and Ambient Temperature (°C) over Time (h). The graph shows a fluctuating internal temperature that remains within the target range despite varying ambient temperatures.

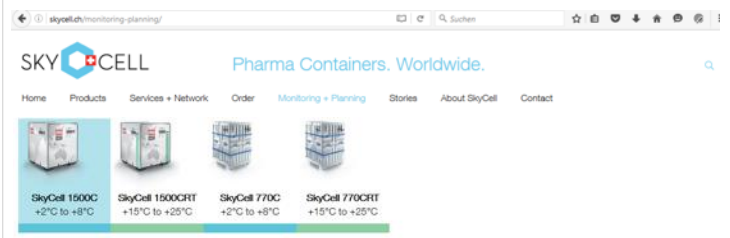
Legend: Energy Level (green), Internal Temperature (blue), Ambient Temperature (red).

Email: Send




The Software (Transport Planner – Lane Simulation)


1



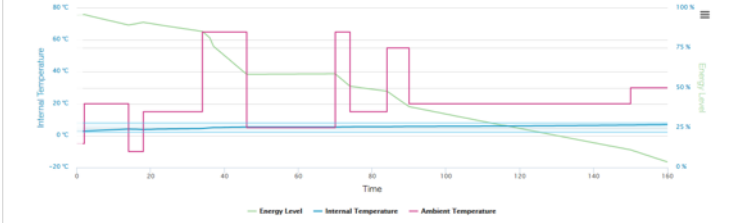
2




3




4



5



Steps

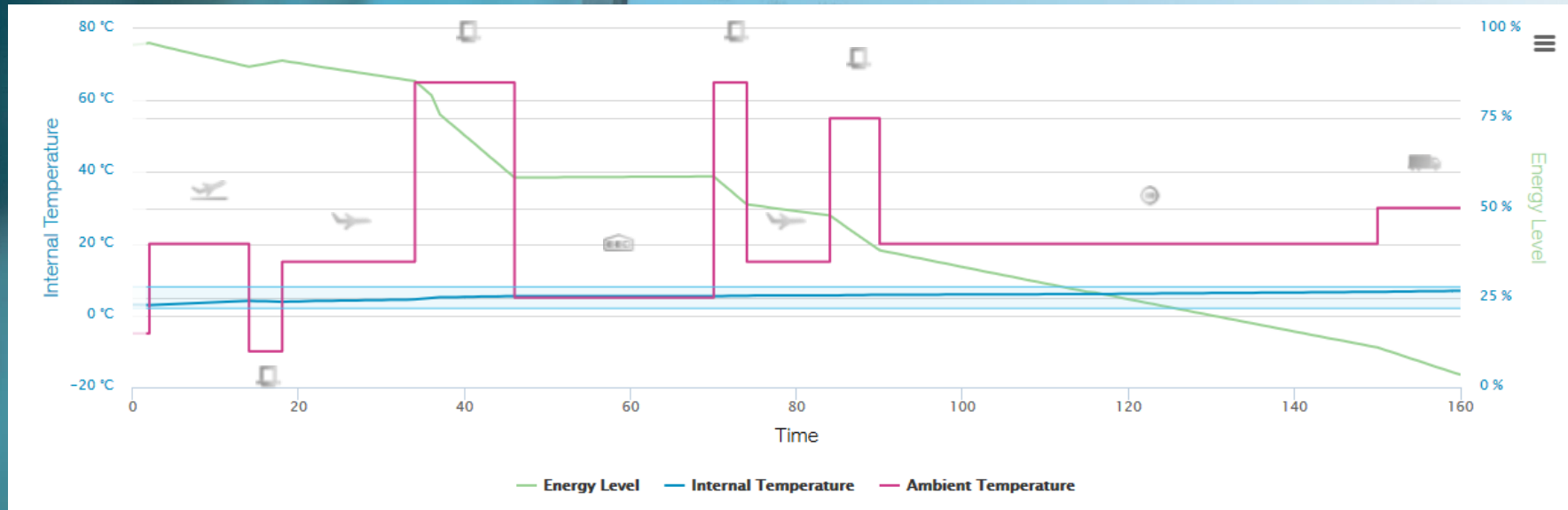
- 1 Choose Hardware
- 2 Define route
- 3 Define Logistics Milestones

- 4 Analysis (Energy Level)
- 5 Send link

Benefits

- Simulates the individual pharma supply chain
- Shows expected performance through real-life data
- Compare routing options
- Make decisions on risk-based approach and define risk mitigation strategy with 3PL
- Safe and share link

Software SkyCell Transport Planner

Analysis



Ambient Temperature	-5 °C	20 °C	+10 °C	15 °C	65 °C	5 °C	65 °C	15 °C	55 °C	20 °C
Time	2 h	12 h	4 h	18 h	12 h	24 h	4 h	10 h	6 h	80 h
Milestones	Truck	Airport	Ramp	Flight	Ramp	Warehouse	Ramp	Flight	Ramp	Customs
Simulate										

SkyCell - Implementation

SKY  CELL



Implementation

Hardware & Software

Results

Hybrid Pharma Containers

2 x EU-Pal
Tareweight: 650 kg



SkyCell 2500C
+2°C to +8°C



SkyCell 2500CRT
+15°C to +25°C

1 x EU/US-Pal
Tareweight: 497 kg



SkyCell 1500C
+2°C to +8°C



SkyCell 1500CRT
+15°C to +25°C

- 3th largest pharma container fleet with more than 20.000 pallets capacity.
- Largest IoT container fleet in the airfreight industry
- Swiss Made containers





SkyCell Container

Easy Handling

Open. Load. Close. Ready to ship.

SkyCell Container

Easy Handling

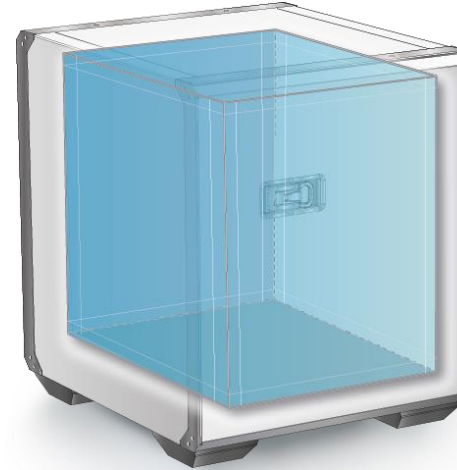
Load optimization through maximal load capacity



- Ready to use delivery
- Easy to implement
- No training required
- Easy to audit

The Hardware

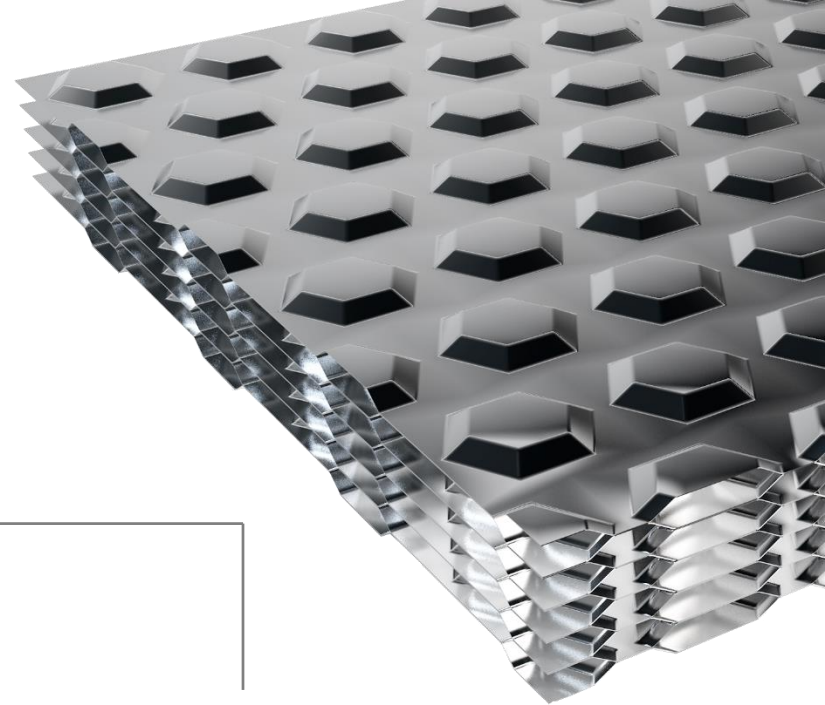
Temperature barrier



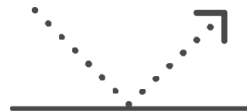
- 5x more energy than traditional methods
Automatically recharged in cooling chamber (without any manual input)
- All parts are integrated and fixed
Completely surrounding the inner chamber for a steady temperature
- No dry ice, no plugs, no manual intervention, no cold-shock

The Hardware

Cutting-edge Technology



Temperature barrier



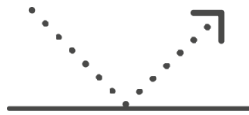
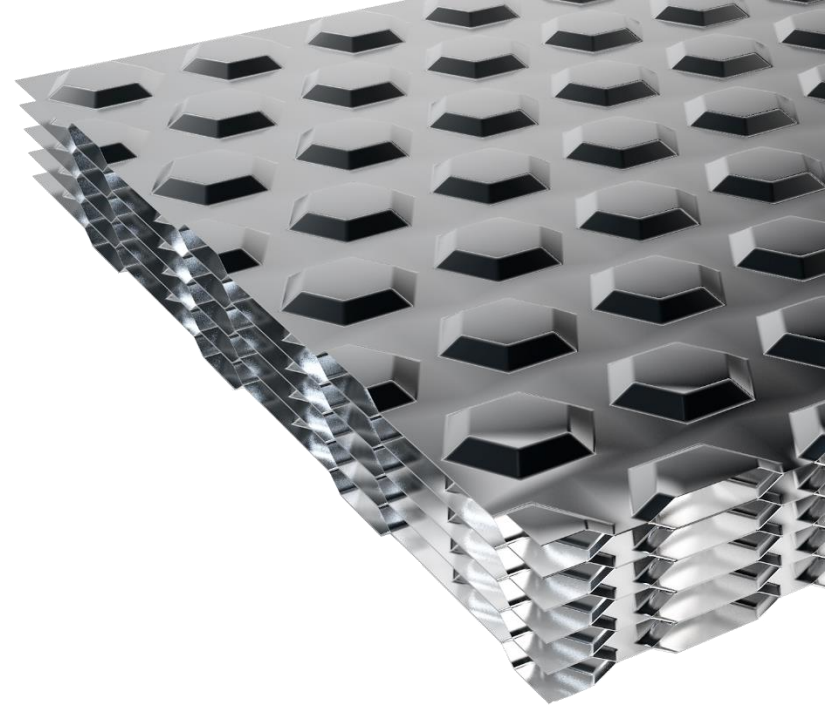
Insulation



Global monitoring

= Failsafe cooling technology
>up to 160h energy storage

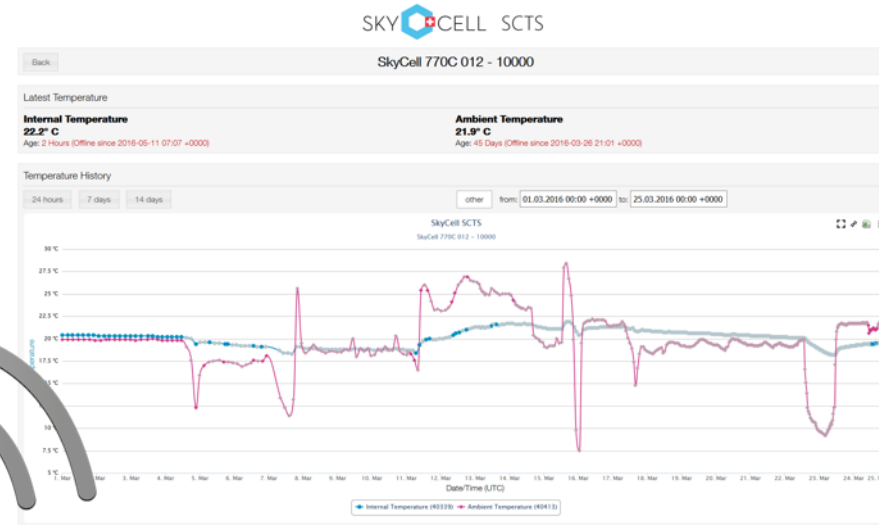
The Hardware Insulation



- All Containers are equipped with high performance insulation technology.
- More than 50 man-years of research and development.
>Over 100 patents
- Nano coating reflects maximum radiation while minimizing heat conduction.
>Recyclable

The Software (Monitoring)

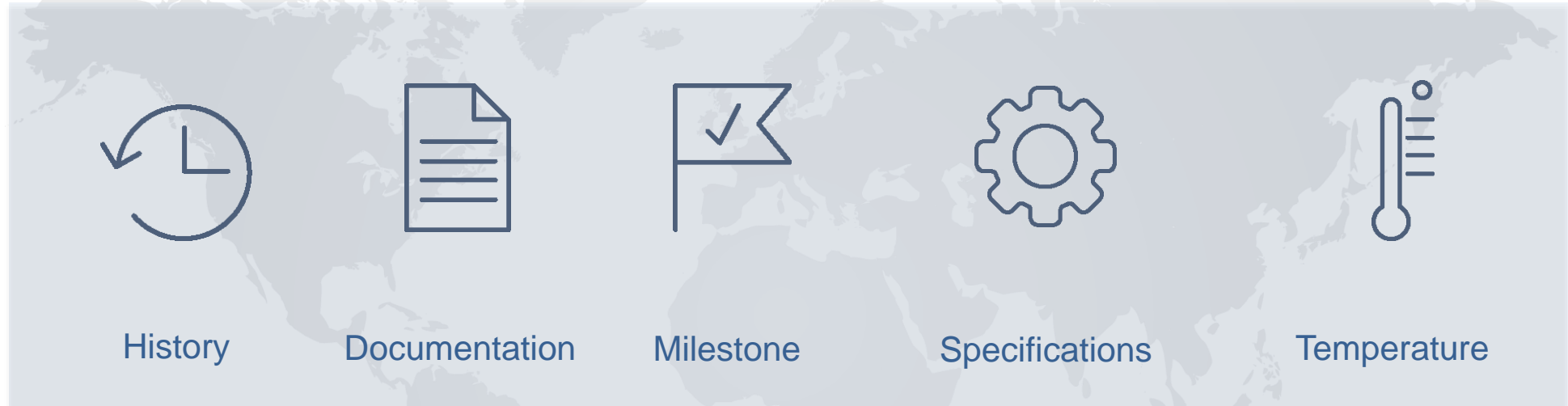
Largest IoT pharma container fleet in airfreight industry.
Near real time monitoring with SkyCell Sensors



2 data loggers track the temperature **inside** and **outside** the container.
As soon as the loggers connect with a gateway, it is possible to read the temperature data in real time.

The Software

All SkyCell containers are tracked on:



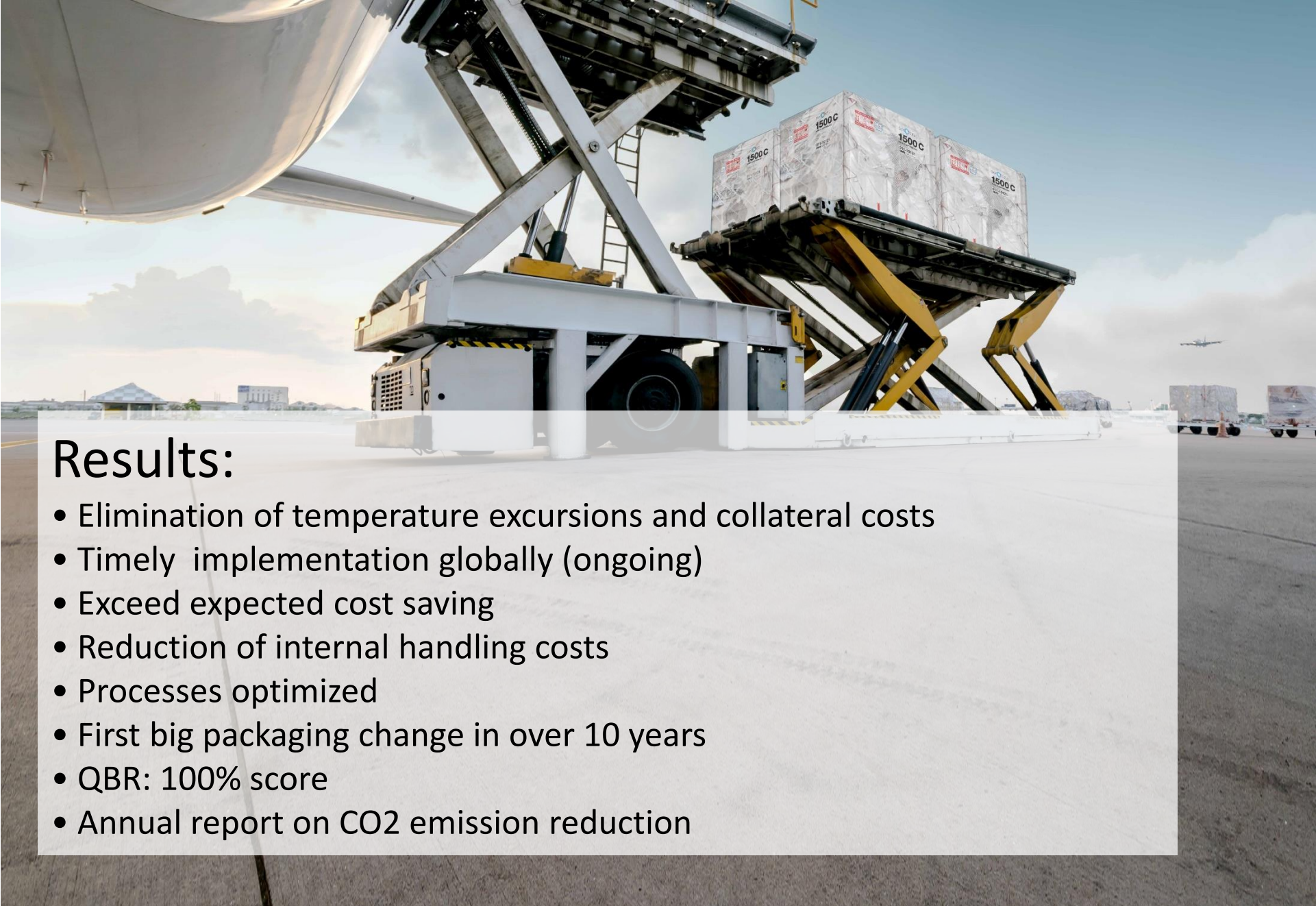
SkyCell - Implementation



Implementation

Hardware & Software

Results



Results:

- Elimination of temperature excursions and collateral costs
- Timely implementation globally (ongoing)
- Exceed expected cost saving
- Reduction of internal handling costs
- Processes optimized
- First big packaging change in over 10 years
- QBR: 100% score
- Annual report on CO2 emission reduction



SkyCell Sustainability

Reducing CO₂ emissions
up to 50%



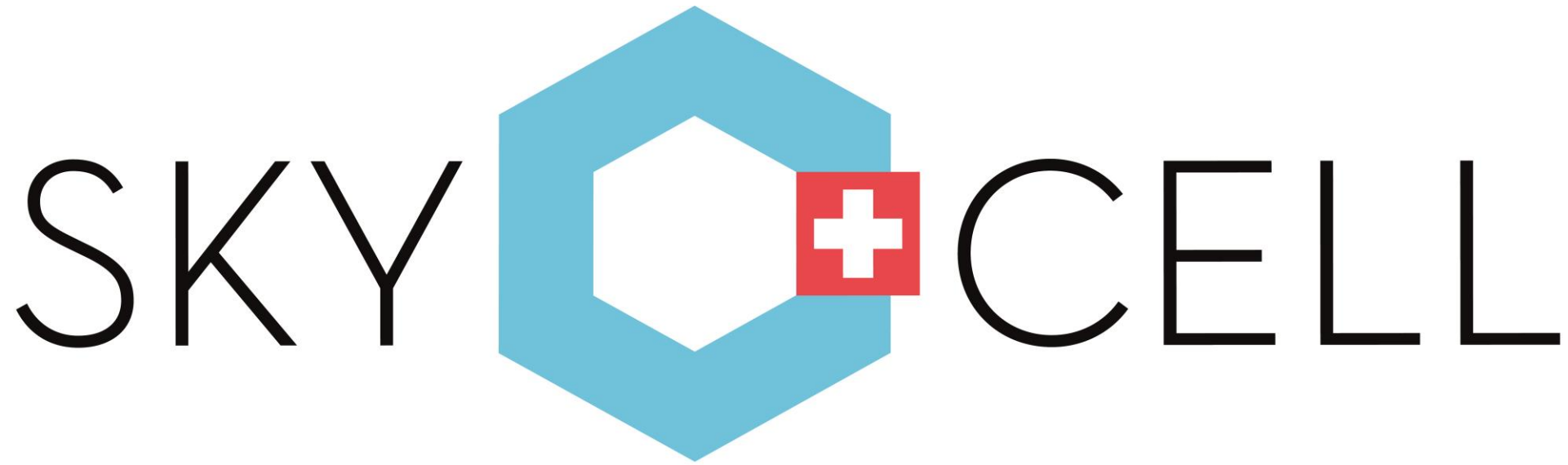
SkyCell Sustainability

How do we achieve that?

Reliability of choice of packaging against temperature excursion
- if you have to ship more product due to temperature loss, then this has the largest impact

Reusability of container –produces significantly less CO₂ and waste than one-way solutions (majority are non recyclable and are incinerated or put in a land fill)

Low volume weight to ship 1 US / 1 EU PAL



**No Temperature excursions
The new industry standard**

SkyCell Hybrid Pharma Containers

SKY  CELL



Q&A

SKY  CELL



Thank you

Conference Wrap up & Chairman Closing Remarks

Maarten van As

Managing Director

Air Cargo Netherlands (ACN)



Networking Lunch 12:30 – 14:00



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Shaping Europe's smartest cargo hub at Amsterdam Airport

