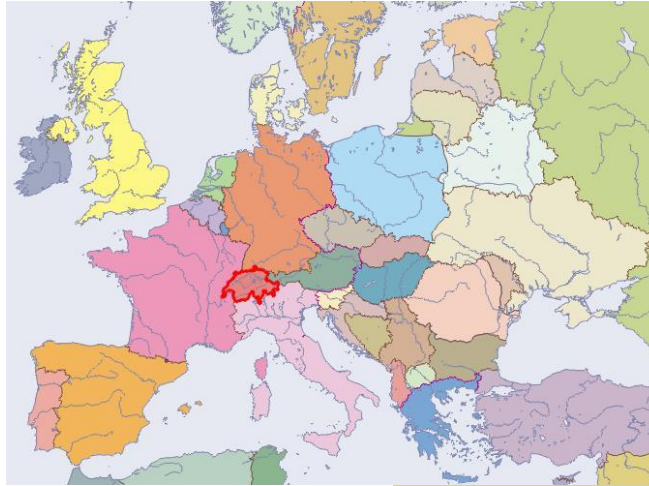


Stability Data the Superhero – Using a Budget In Practice

Leading Minds Seminar, Nov 7th 2017, Princeton

Emanuel Schäpper

ELPRO in Buchs SG Switzerland





ELPRO in Buchs SG Switzerland





ELPRO in Buchs SG Switzerland





ELPRO in Buchs SG Switzerland



Stability Data the Superhero – Using a Budget In Practice



SUPERHERO

STABILITY BUDGET



**STABILITY
BUDGET**

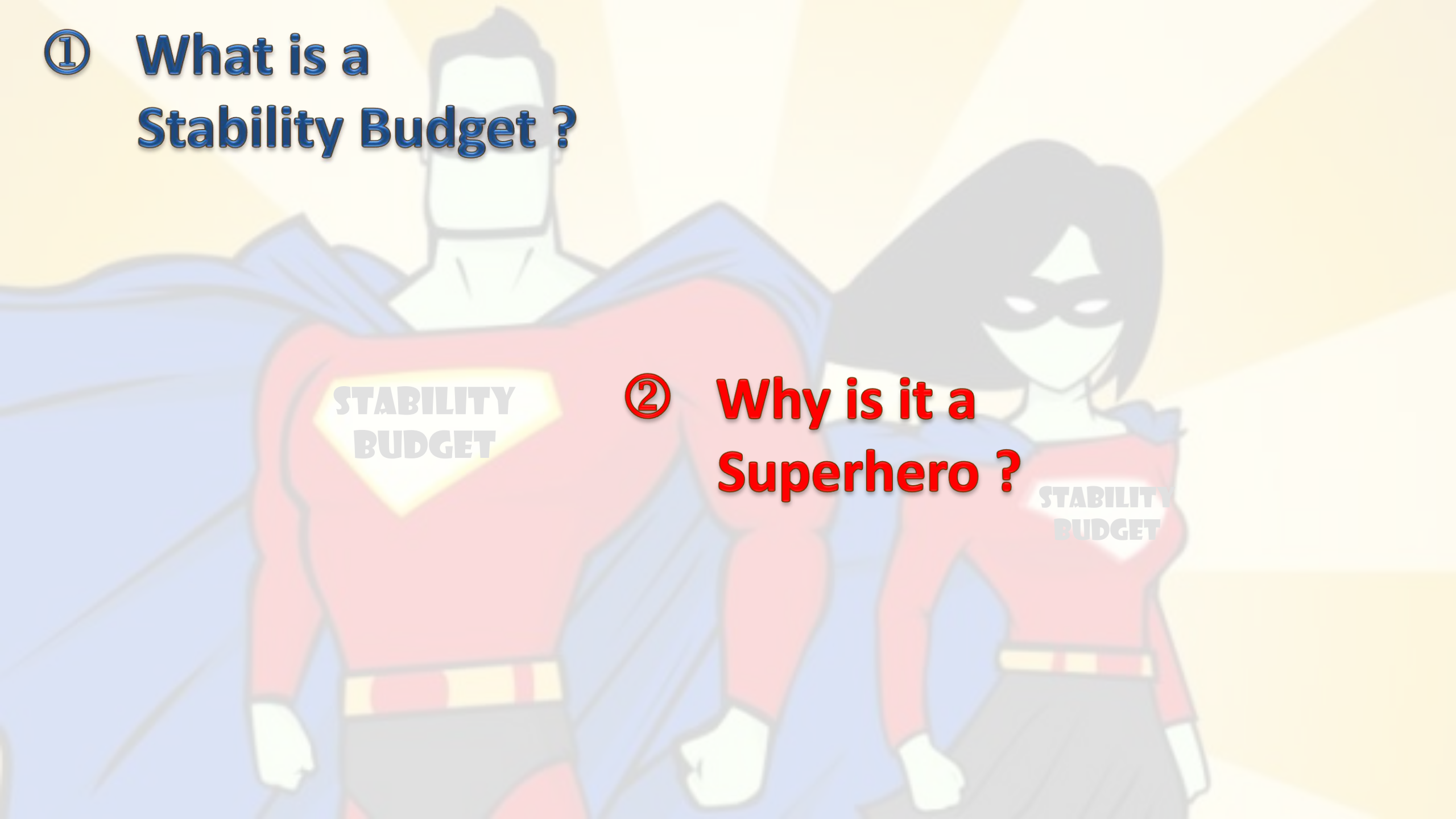
**STABILITY
BUDGET**

① What is a Stability Budget ?

② Why is it a Superhero ?

STABILITY
BUDGET

STABILITY
BUDGET



① What is a Stability Budget ?

Every product has a certain stability



① What is a Stability Budget ?

Every product has a certain stability



①

What is a Stability Budget ?

**In the pharmaceutical
world?**



① What is a Stability Budget ?

In the pharmaceutical world?

- Stability budget is the validated/approved amount of time a drug substance or product can spend out of the normal/labeled storage conditions during its entire supply chain without risk to its quality
- It is defined by two or more temperature limits (defining zones) and an allowed time per zone (budget)

	Allowed Time	Event
H3 25.0°C	0	0
H2 15.0°C	30 minutes	single
H1 8.0°C	3 hours	cumulative
G 2.0°C	Unlimited	Unlimited
L1 0.0°C	1 hour	cumulative
L2 -5.0°C	30 minutes	single
L3	0	0

① What is a Stability Budget ?

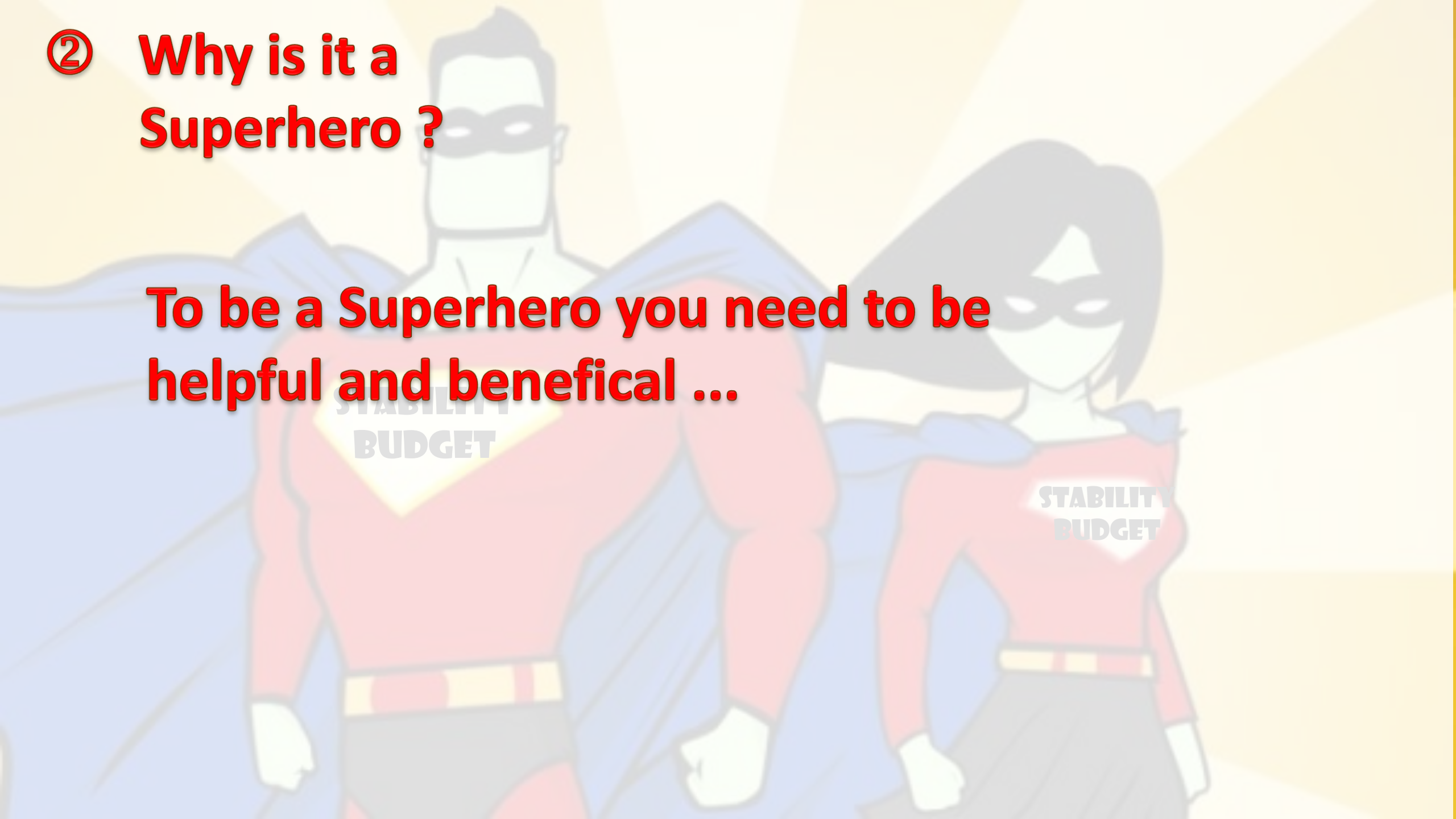
② Why is it a Superhero ?

STABILITY
BUDGET

STABILITY
BUDGET

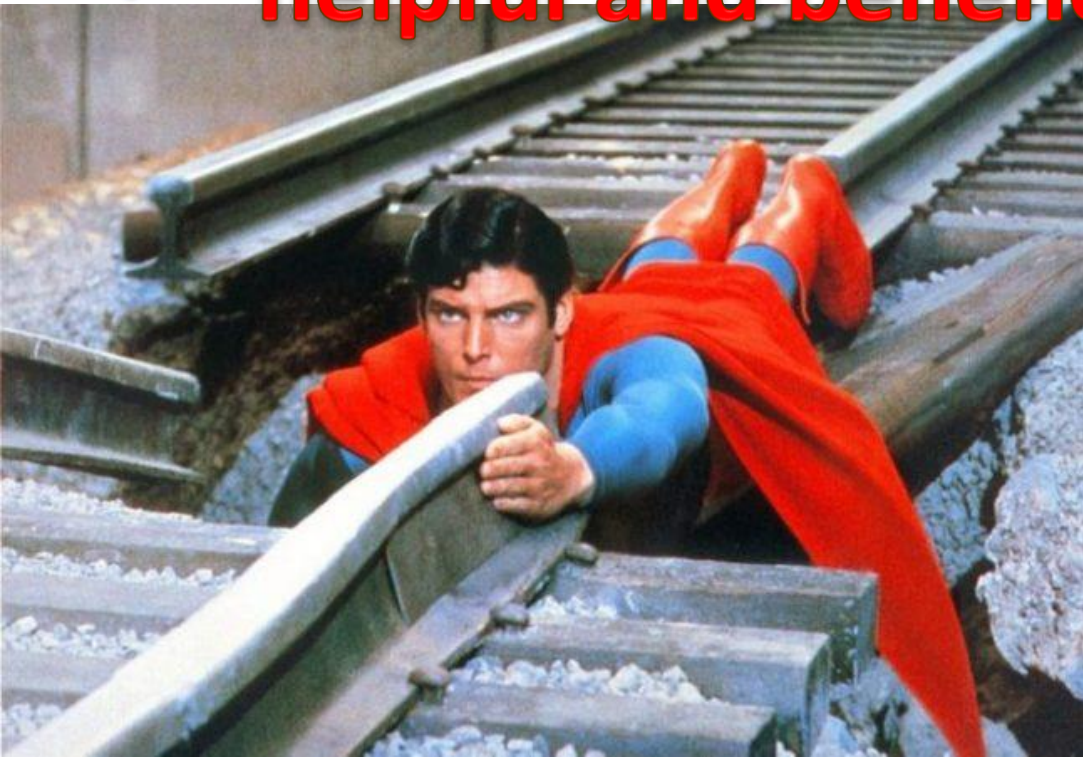
② Why is it a Superhero ?

To be a Superhero you need to be helpful and beneficial ...



② Why is it a Superhero ?

To be a Superhero you need to be
To prevent damages
helpful and benefical ...



To save lives

To help making
things easier

② Why is it a Superhero ?

To prevent damages



Can
Stability Budget
do this ?



To save lives



To help making
things easier

Motivation for using Stability Data in temperature controlled logistics

The keyword is

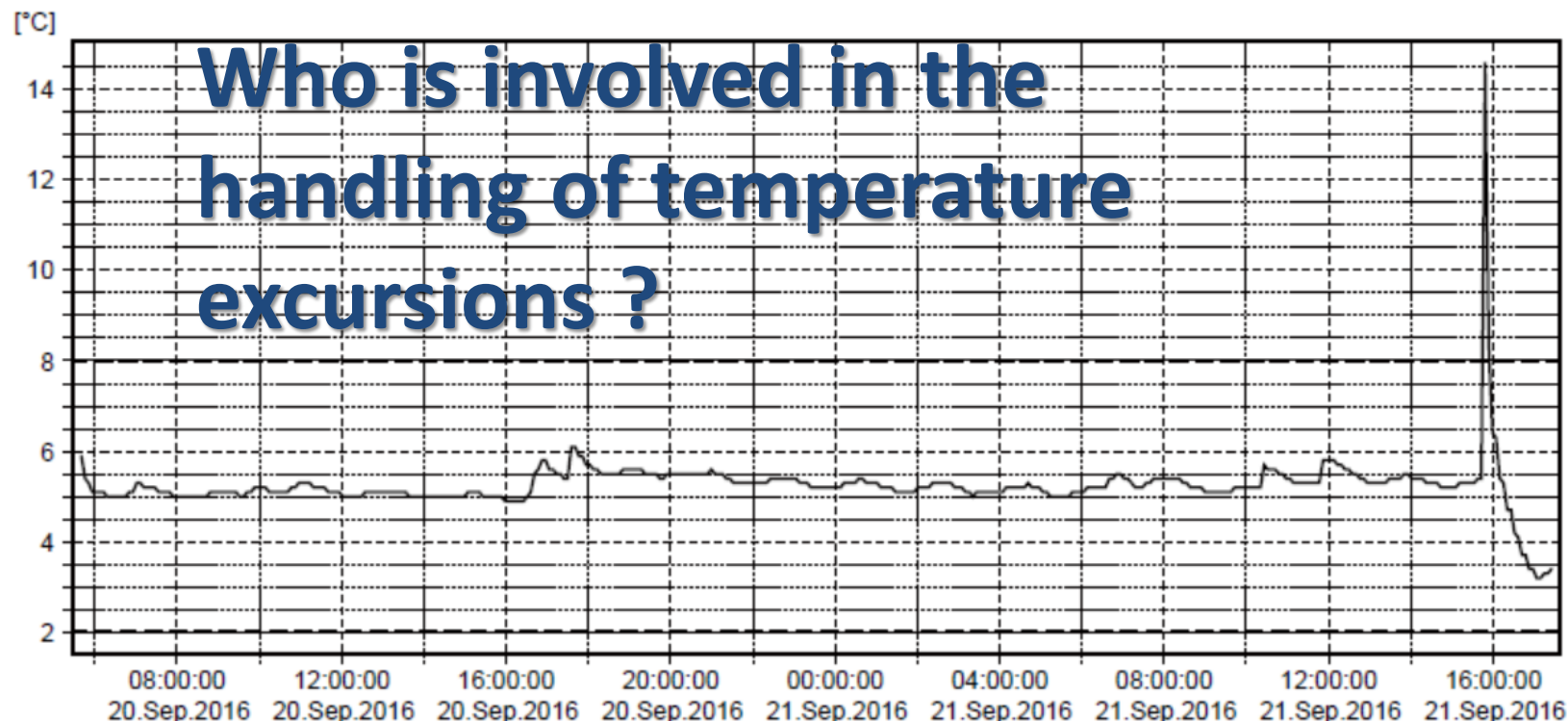
Handling of Temperature Excursions



ALARM

Logging Results

Highest Temperature:	14.6 °C; 21.Sep.2016 15:42:39	Stop at:	21.Sep.2016 17:27:07
Lowest Temperature:	3.2 °C; 21.Sep.2016 17:04:39	Alarm at:	21.Sep.2016 15:41:39
Average Temperature:	5.2 °C	File created:	21.Sep.2016 17:28:10



Handling of temperature excursions

Discussion - share your experience

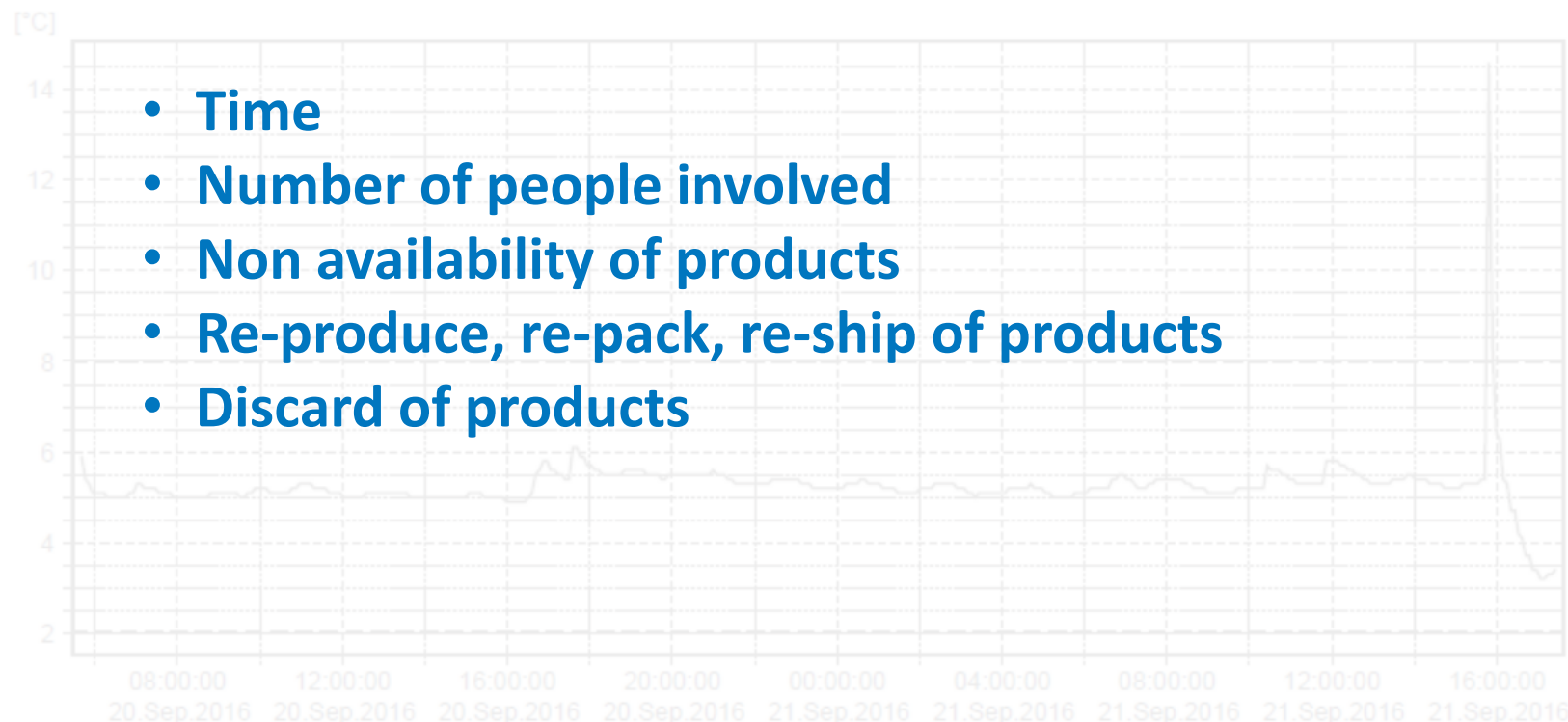
How much effort do you have to invest in handling of temperature excursion?



ALARM

Logistics
Highest Temperature: 14.6 °C; 21.Sep.2016 15:42:39
Lowest Temperature: 3.2 °C; 21.Sep.2016 17:28:10
Average Temperature: 5.2 °C; 21.Sep.2016 17:28:10
File created: 21.Sep.2016 17:28:10

Stop at: 21.Sep.2016 17:27:07
21.Sep.2016 15:41:39
21.Sep.2016 17:28:10



Handling of temperature excursions

Discussion - share your experience

**Would the number of
excursions reduce by
implementing alarm criteria
based on stability data ?**



ALARM

Log File
Highest Temperature: 14.6 °C; 21.Sep.2016 15:42:39 Stop at: 21.Sep.2016 17:27:07
Lowest Temperature: 3.2 °C; 21.Sep.2016 17:28:10
Average Temperature: 5.2 °C File created: 21.Sep.2016 15:41:39



**Handling of
temperature
excursions**

Case Studies

**Impact of using stability data
for temperature controlled shipments**

User experiences

Handling of temperature excursions

Case Study #1

Big German Pharmaceutical Company

Monitoring of Products in Transit

(Jan/2014 - Aug/2017)



Overview all dataloggers



	#	%
ALARM despite Stability Budget	3'903	2.03%
ALARM may be avoided with St..	4'838	2.51%
OK with Stability Budget	27'344	14.20%
OK w/o Stability Budget	156'443	81.26%
Grand Total	192'528	100.00%

Financial impact Stability Budget*



Handling of temperature excursions

Case Study #2

Temperature control management system - large animal health company

- **Project Facts:**
 - Implemented 35+ sending sites
 - 120 destination sites.
 - 300 users
 - >25,000 temperature data files received in first year
- The project created temperature management awareness throughout the company; consequently improving global distribution policy and qualification guidelines for packaging, storage, ocean containers and vehicles.
- With refined temperature management globally, they were able to create an 'excursion allowance model', separating major from minor excursions and reducing QA processing time, by using multiple alarm zone data loggers.
- Overall this reduced total excursions of +15 °C..+25 °C products by 62% and by 77% for +2 °C..+8 °C shipments!
Equating to 11,000 hours/year of reduced workload
Reduction of lost sales equal to \$USD 61 M/year

Using Stability Budget ...

... can really be a Superhero action



STABILITY
BUDGET

STABILITY
BUDGET

Handling of temperature excursions by using Stability Budgets

How to implement the use of Stability Budgets in your processes for temperature controlled shipments ?

	Allowed Time	Event
H3 25.0°C	0	0
H2 15.0°C	30 minutes	single
H1 8.0°C	3 hours	cumulative
G 2.0°C	Unlimited	Unlimited
L1 0.0°C	1 hour	cumulative
L2 -5.0°C	30 minutes	single
L3	0	0

Different ways of implementing the use of Stability Budgets

1. **Logger configured**
2. **Post shipment assessments with analysis software or cloud database**
3. **Stability Budget Management System**
4. **Long-term continuous monitoring**

	Allowed Time	Event
H3 25.0°C	0	0
H2 15.0°C	30 minutes	single
H1 8.0°C	3 hours	cumulative
G 2.0°C	Unlimited	Unlimited
L1 0.0°C	1 hour	cumulative
L2 -5.0°C	30 minutes	single
L3	0	0

1. Logger configured

Configure your temperature data logger with Stability Intelligence



Configuration LIBERO CS (ID 71010001904)

Description
Logging
Temperature Alarm
MKT and Duration Alarm
Time Settings
PDF Options
Handling Options

Temperature Alarm
An alarm is activated when temperature is out of limits for longer than the time allowed or if the number of excursions exceeds the allowed limit. Depending on the LIBERO model configured there is either one high and one low zone available or up to 4 high and 3 low zones. Enter the temperature limits and the allowed time between the limits as well as the number of allowed excursions. Event mode Cumulative will sum up the time when out of limit. When this number is reached the alarm is activated.

Alarm Mode
☒ Enable Temperature Alarm

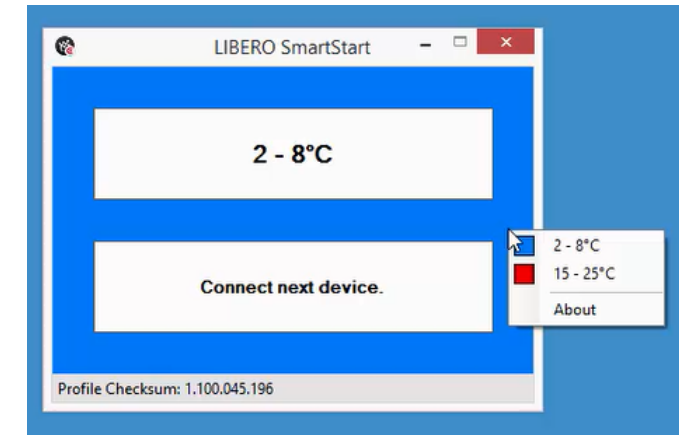
Alarm Zones

Used	T [°C]	Alarm after	Event	Excursions
H4: ☒	40	0 Minutes	Single	unlim.
H3: ☒	25	12 Hours	Cumulative	unlim.
H2: ☒	15	5 Days	Cumulative	unlim.
H1: ☒	8.0	10 Days	Cumulative	unlim.
G: ☒	2.0	No Alarm		
L1: ☒	0.0	10 Days	Cumulative	unlim.
L2: ☒	30	30 Minutes	Cumulative	unlim.
L3: ☒	-10.0	0 Minutes	Single	unlim.

☐ Zone H1 and L1 coupled

Profile Checksum
4.014.568.413

Load Profile Save Profile Apply Cancel Help



- PDF Logger, single use
- Multi-level-alarm (8 ranges)
- Automatic PDF report with embedded data
- Configuration setting software to specify multi-level-alarm zones based on stability data
- A smart, easy configuration tool

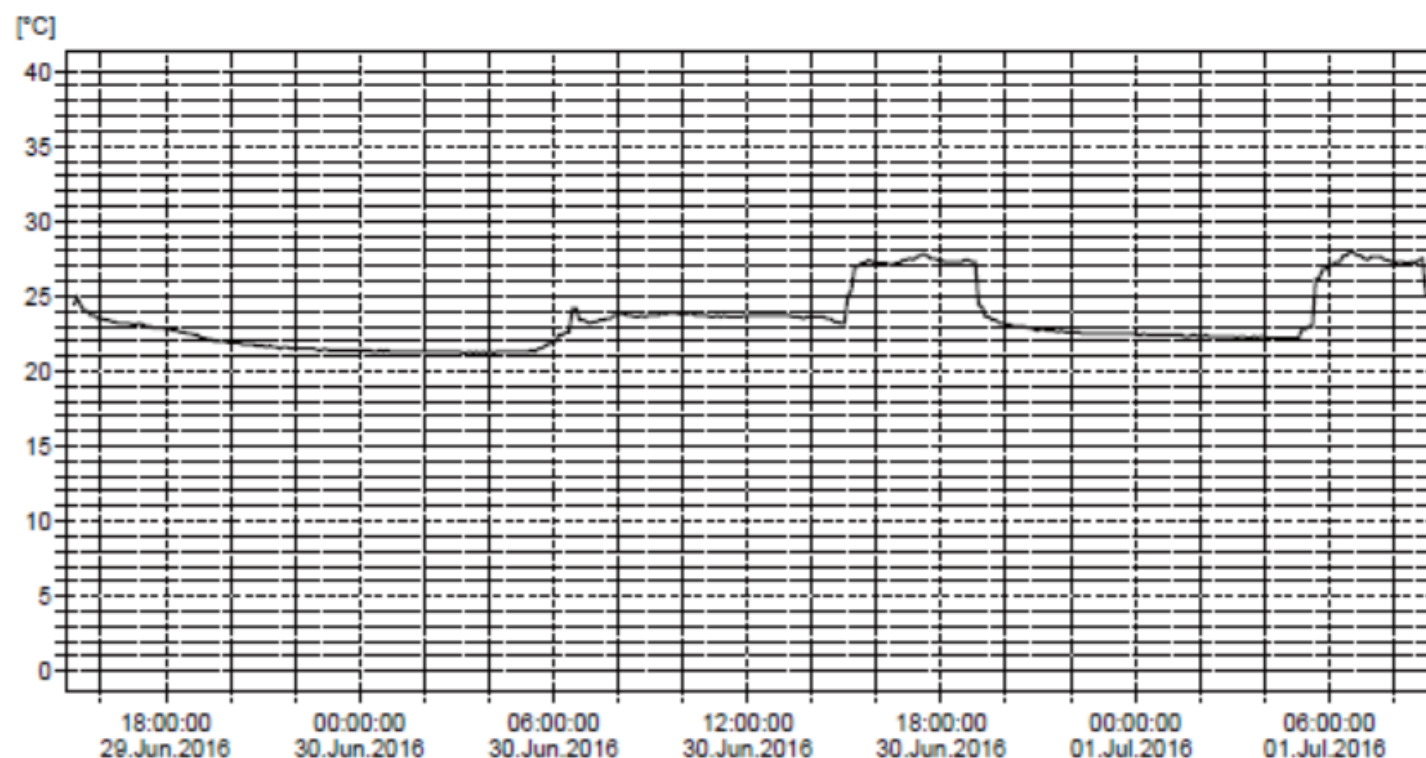


OK

Alarm Zones	Allowed Time	Total Time	No. of violations	Status
Z1: over 40.0 °C	0 s (sin)	0 s	0 / unlim.	OK
Z2: over 30.0 °C	24.0 h (cum)	0 s	0 / unlim.	OK
Z3: over 25.0 °C	5.0 d (cum)	7.5 h	2 / unlim.	OK
Z4: 15.0 to 25.0 °C	unlimited	35.1 h		
Z5: below 15.0 °C	5.0 d (cum)	0 s	0 / unlim.	OK
Z6: below 0.0 °C	0 s (sin)	0 s	0 / unlim.	OK

Logging Results

Highest Temperature:	28.0 °C; 01.Jul.2016 06:39:23	Transit Start at:	29.Jun.2016 15:06:15
Lowest Temperature:	21.2 °C; 30.Jun.2016 03:07:15	Arrived at:	not available
Average Temperature:	23.4 °C	Alarm at:	none
MKT	23.6 °C	File created:	01.Jul.2016 09:40:53



Reminder !



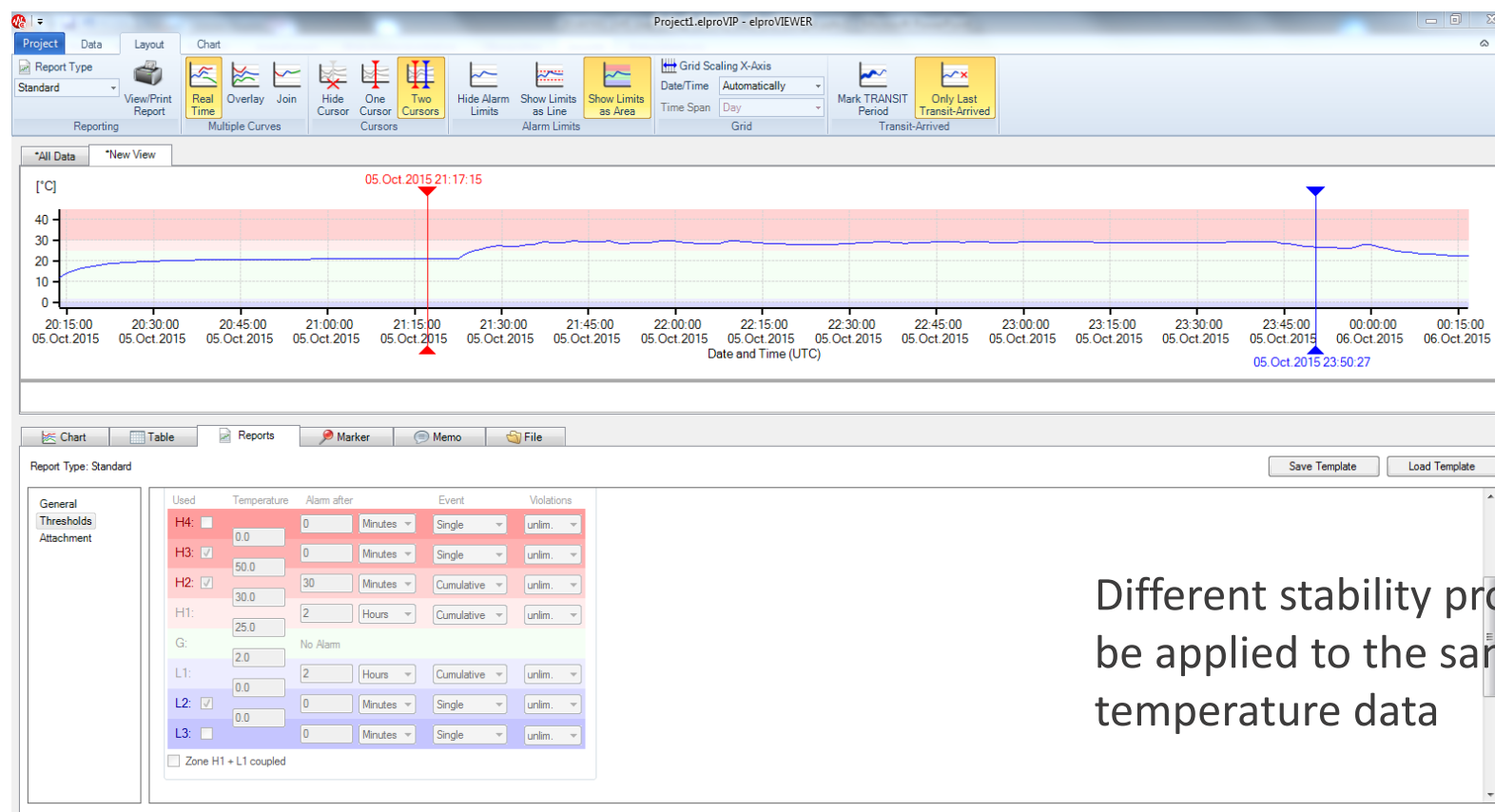
Configure your
temperature
data logger with
Stability
Intelligence

PDF Report

2a. Post shipment assessments with analysis Software

Software supported assessments using stability data

Instead of manually calculating how much stability was used in each step, software tools can be used to apply stability to a shipment.



Different stability profiles can be applied to the same temperature data

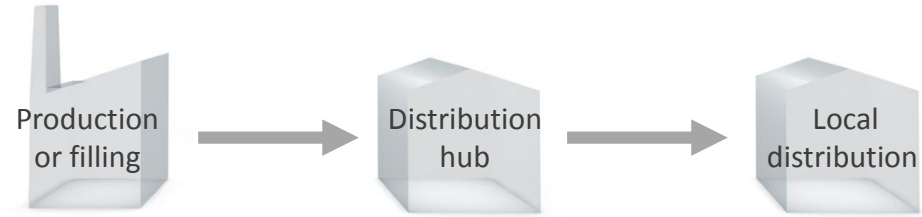
elproVIEWER

Analysis
Software to
assign Stability
Profiles and
assess
temperature
excursions

2a. Post shipment assessments with analysis Software

Joining multi-steps shipments,
re-asses and create assessment reports

Step:

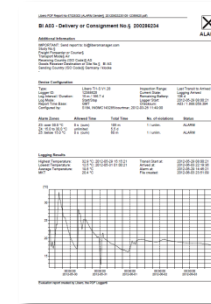
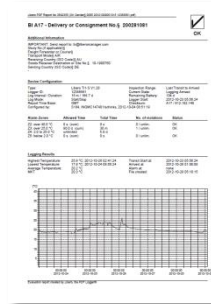


Example:

+15 °C ..+25 °C
(+25 °C..+40 °C < 90 days)

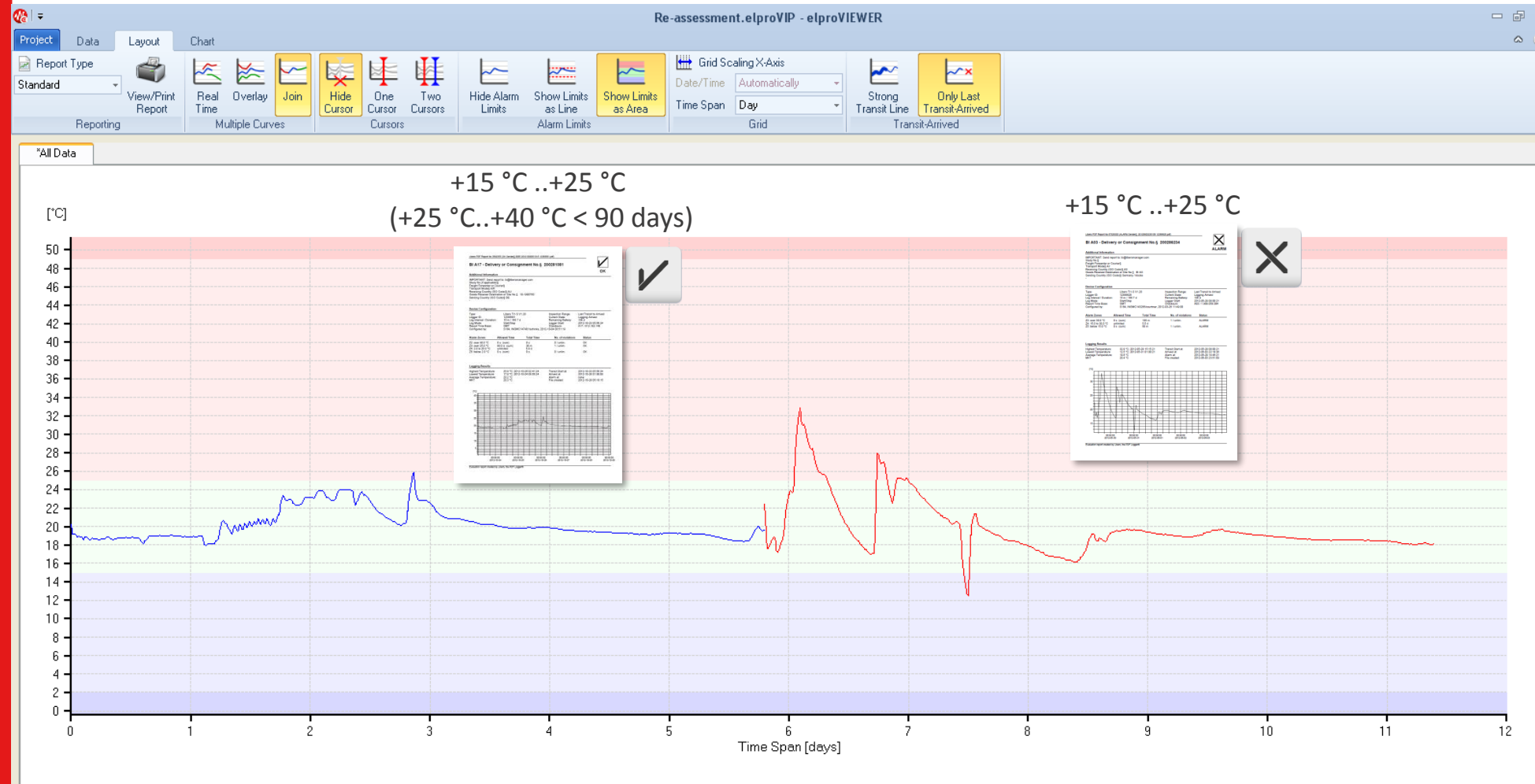
+15 °C ..+25 °C

Result:
(Example)



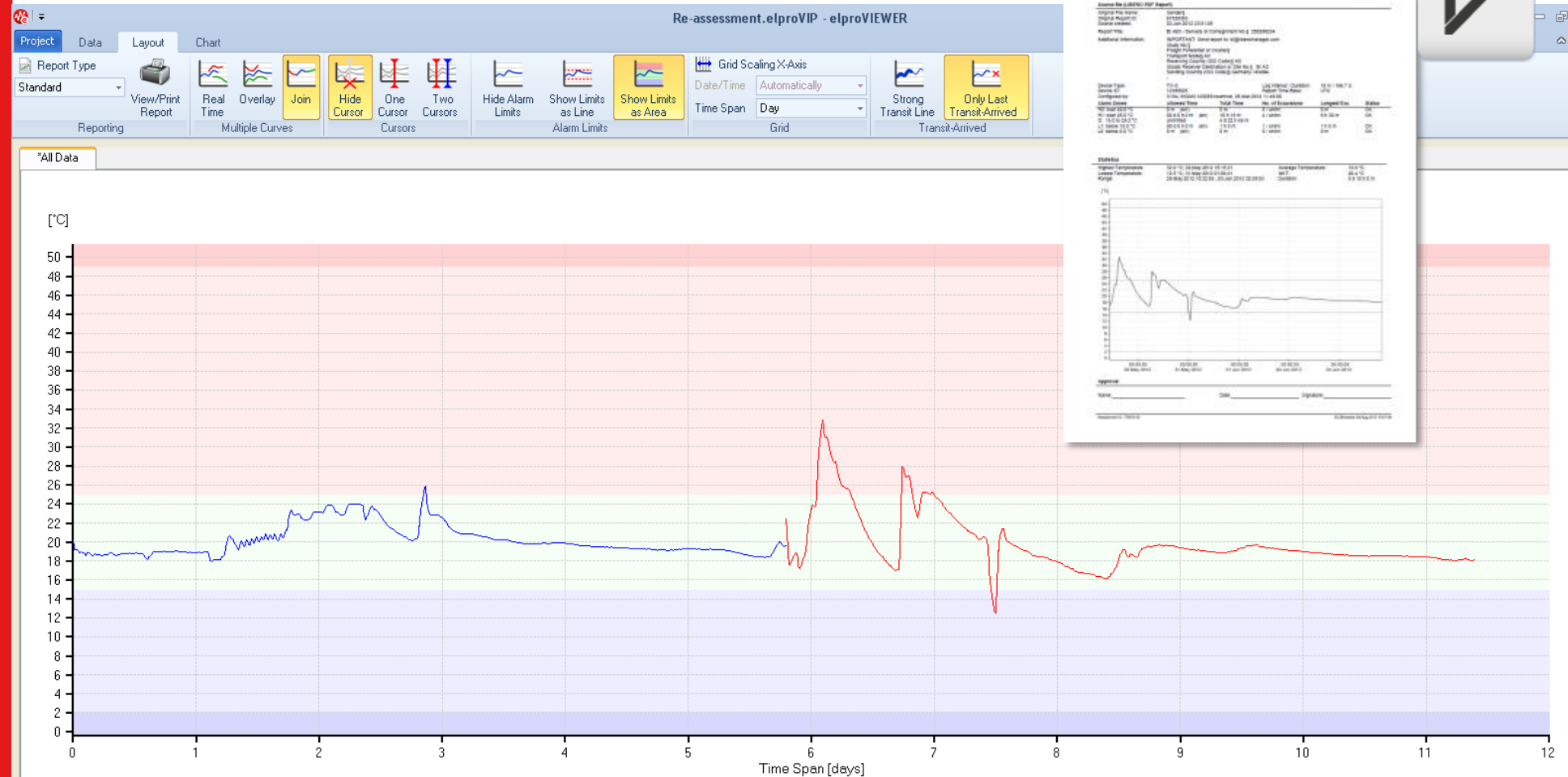


Leading Minds Seminars





Leading Minds Seminars



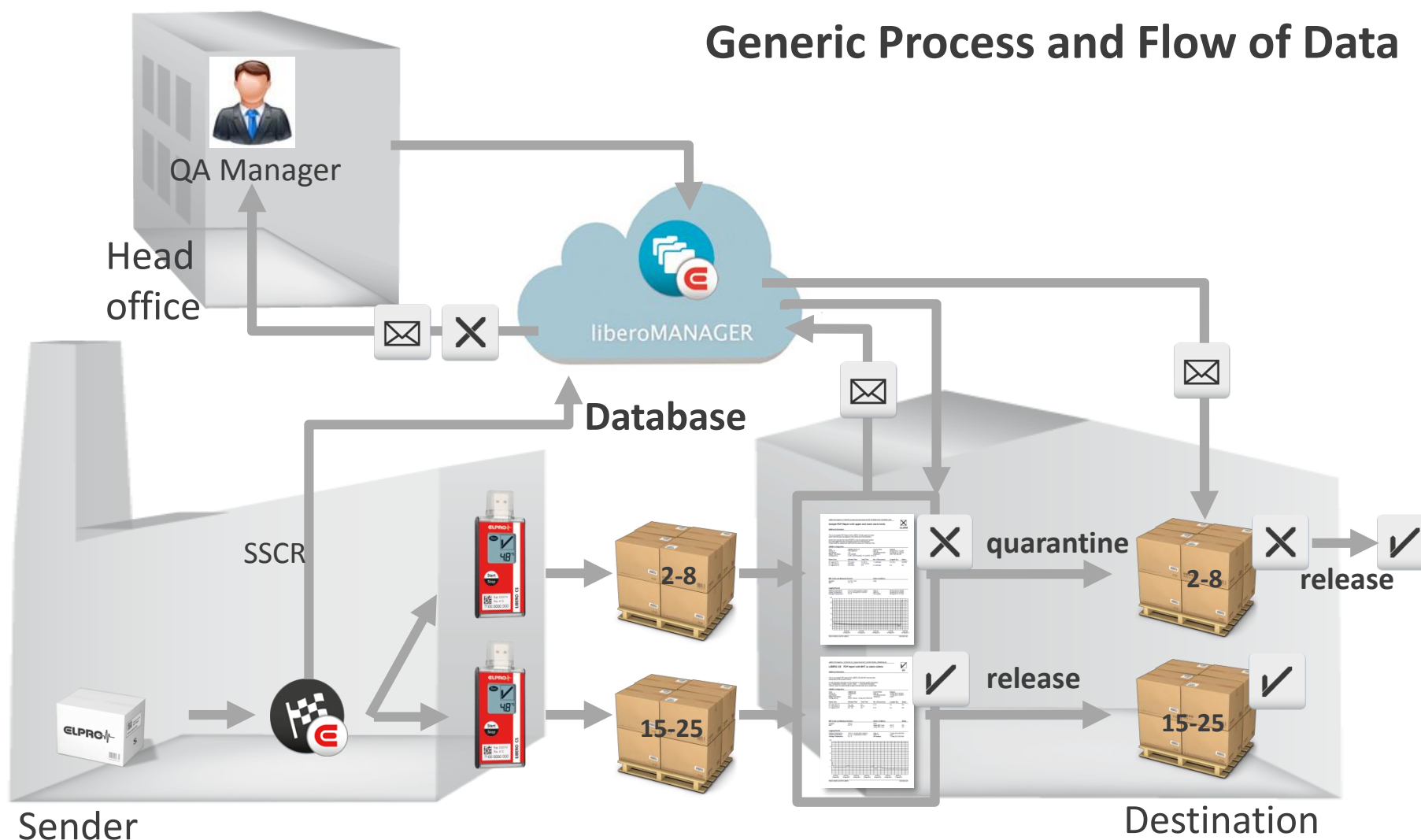
2a. Post shipment assessments with a cloud database

liberoMANAGER

Cloud database
for temperature
monitoring data
of products in
transit


elpro.com

Generic Process and Flow of Data

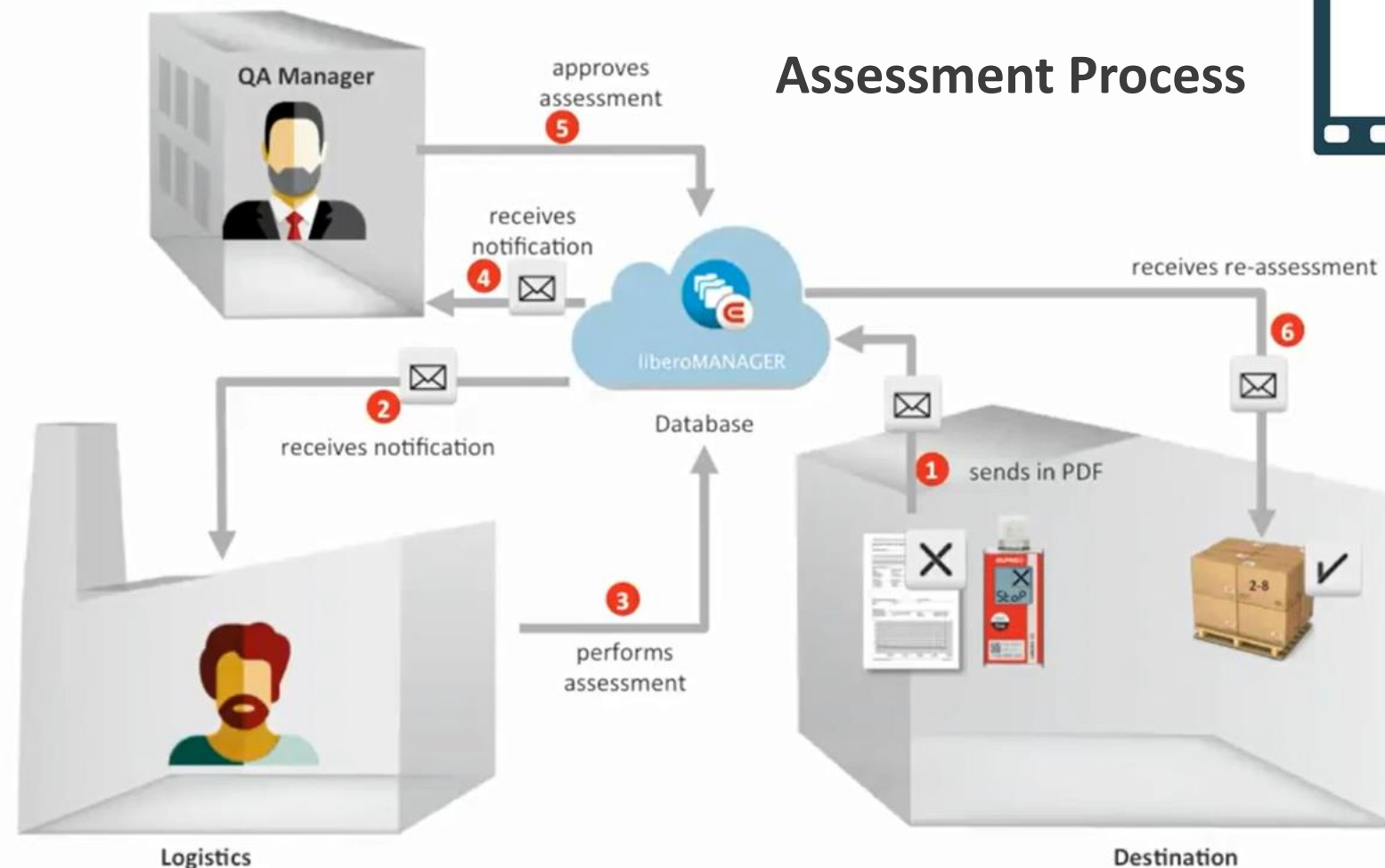


2a. Post shipment assessments with a cloud database

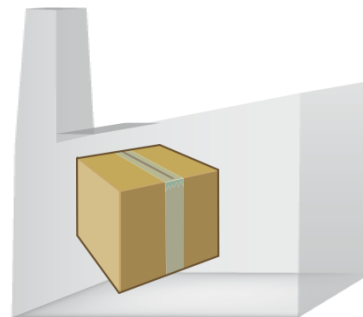
liberoMANAGER

Cloud database for temperature monitoring data of products in transit

Assessment Process



3. Stability Budget Management System



Production / Warehouse



Clinical Site



Fridge A

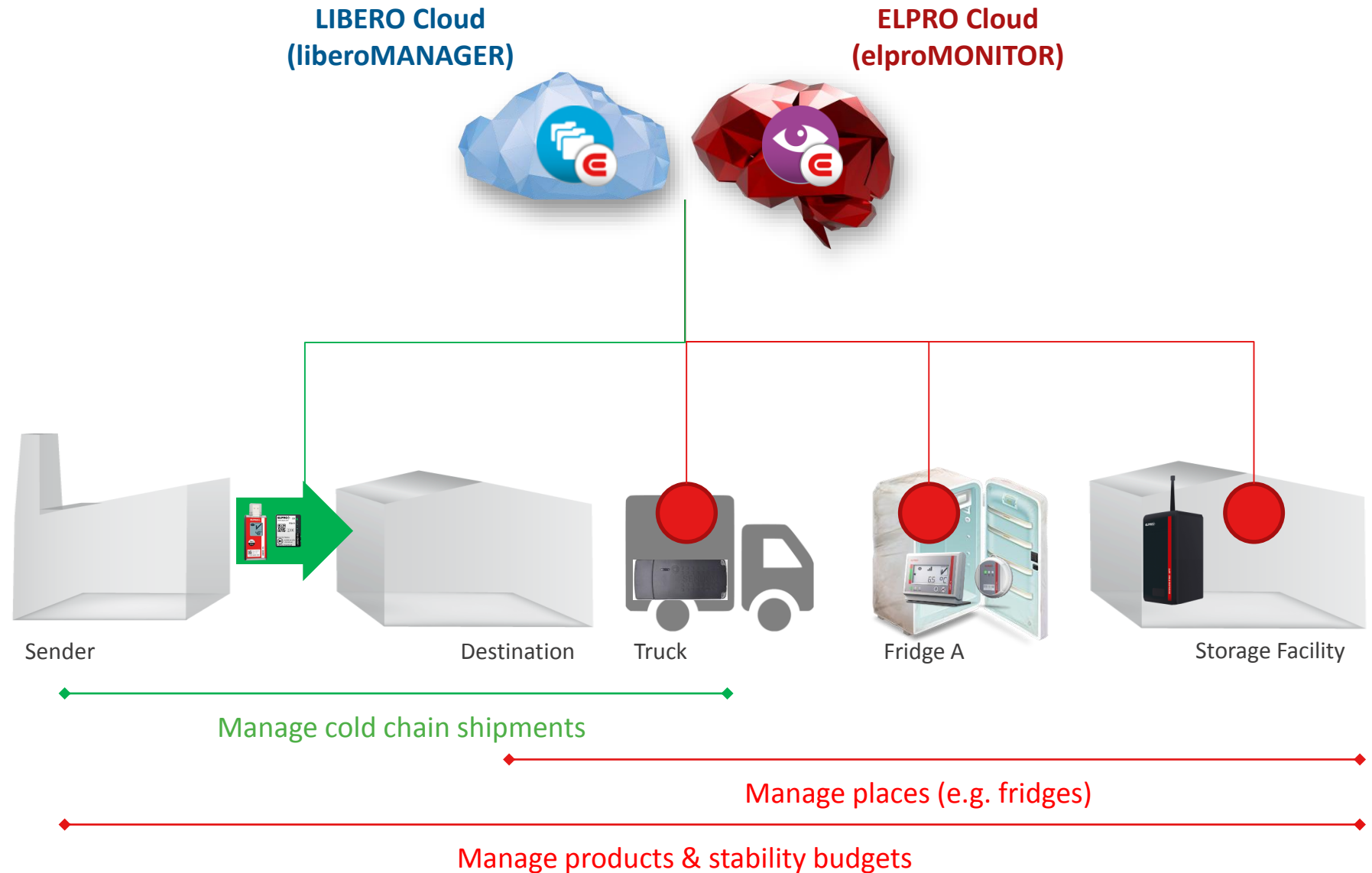


Fridge B

BIG Data

Managing
Stability Budget
of Products
throughout the
entire
distribution
chain

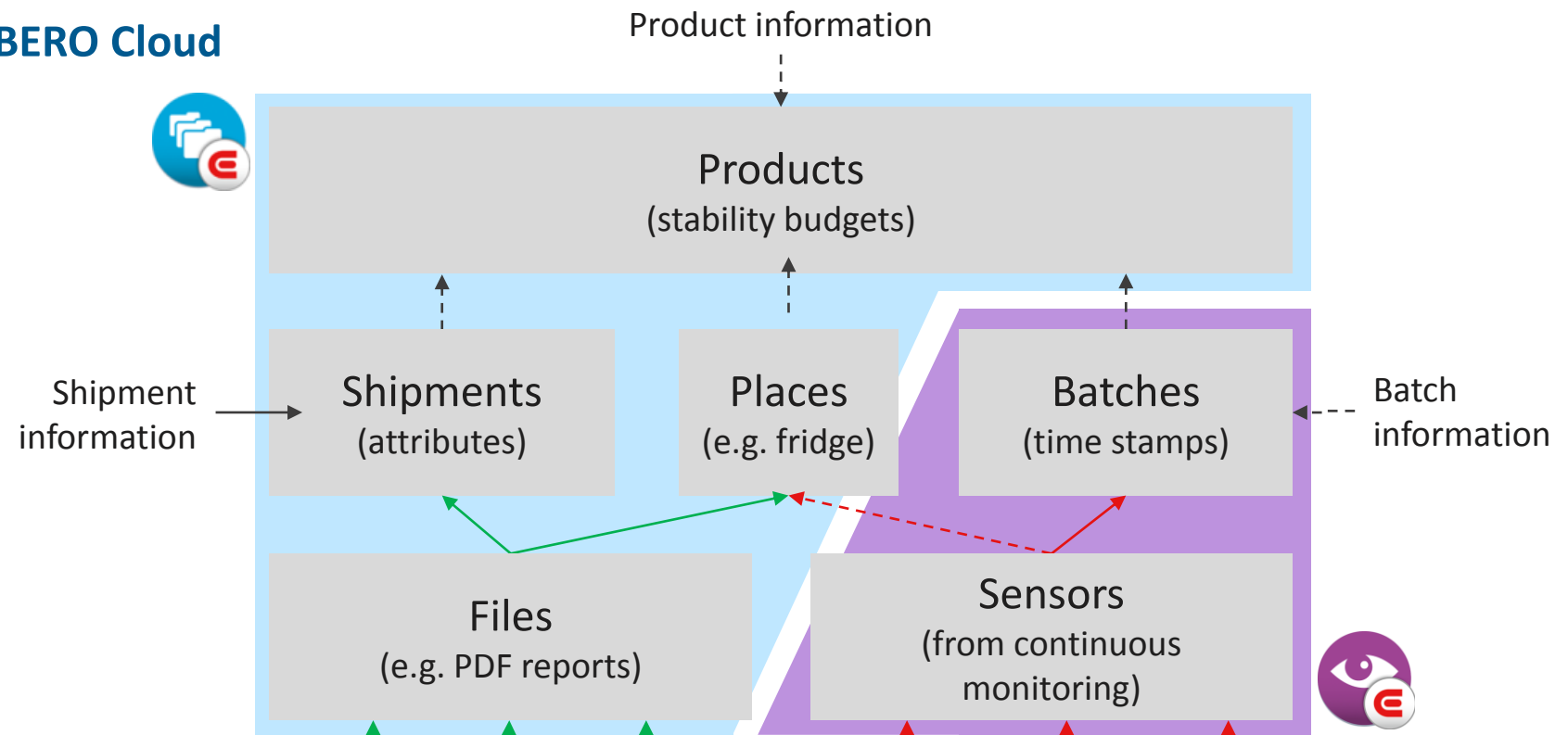
3. Stability Budget Management System



Managing
Stability Budget
of Products
throughout the
entire
distribution chain

3. Stability Budget Management System

LIBERO Cloud

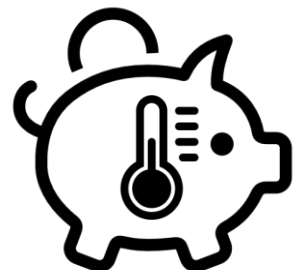


ELPRO Cloud

Managing Stability Budget of Products throughout the entire distribution chain

Solution Elements

4. Long-term continuous monitoring



Product specific stability
budget configuration



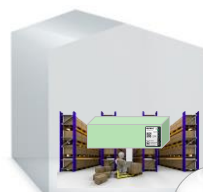
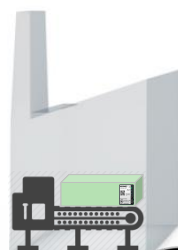
Apply to box
(self adhesive)



Constantly calculates
remaining stability



Any time show or
download the status

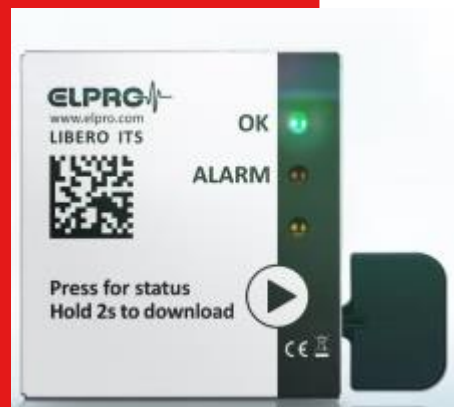


Break tab to start delay
& statistics

Records deviations with
calibrated sensor

Operates and shows
status during 3+ years

Archive Reports on
Cloud Database



Using one
temperature
indicator to
monitor the
entire supply
chain

4. Long-term continuous monitoring

ELPRO 



LIBERO ITS
End-to-end quality assurance
like you've never seen before –
down to unit level.

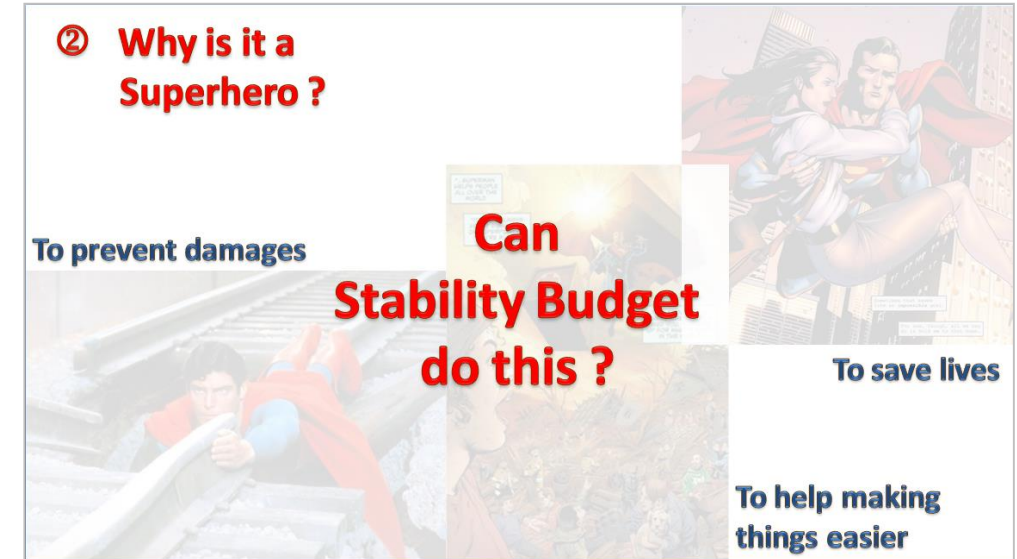
www.elpro.com/liberoits

Using one
temperature
indicator to
monitor the
entire supply
chain



Stability Data - the Superhero?

Using Stability Data for the handling of temperature excursions offers a lot of benefits:



- Increase availability of your products
- Reduction of loss of products
- Avoid re-production, re-packaging, re-shipment
- May allow to reduce requirements and costs for packaging and transport
- Faster release of goods and therefore faster delivery to patients
- Reduction of process time for temperature excursions
- Less people to be involved in the release process

Stability Data - the Superhero?



ELPROlino


elpro.com

② **Why is it a
Superhero ?**

To prevent damages

**Can
Stability Budget
do this ?**

To save lives

To help making
things easier

- Start with analysing your data
- Calculate how many deviations could have been avoided
- Create a business case for all or part of your shipments
- First choose an easy way of implementation
- Gradually expand later

**Comments or
Questions ?**

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Leading Minds Seminar, Nov 7th 2017, Princeton

Thank you very much