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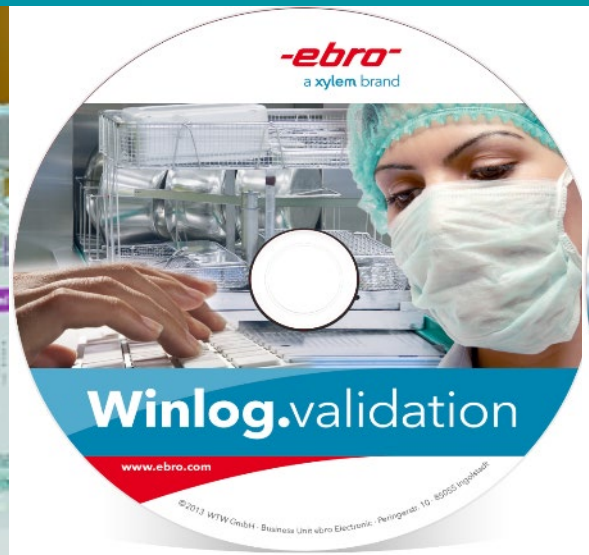
We will begin shortly…

14 July 2021

Welcome!

Ebro Webinar on Pharma Validation and Monitoring Solutions



House Keeping

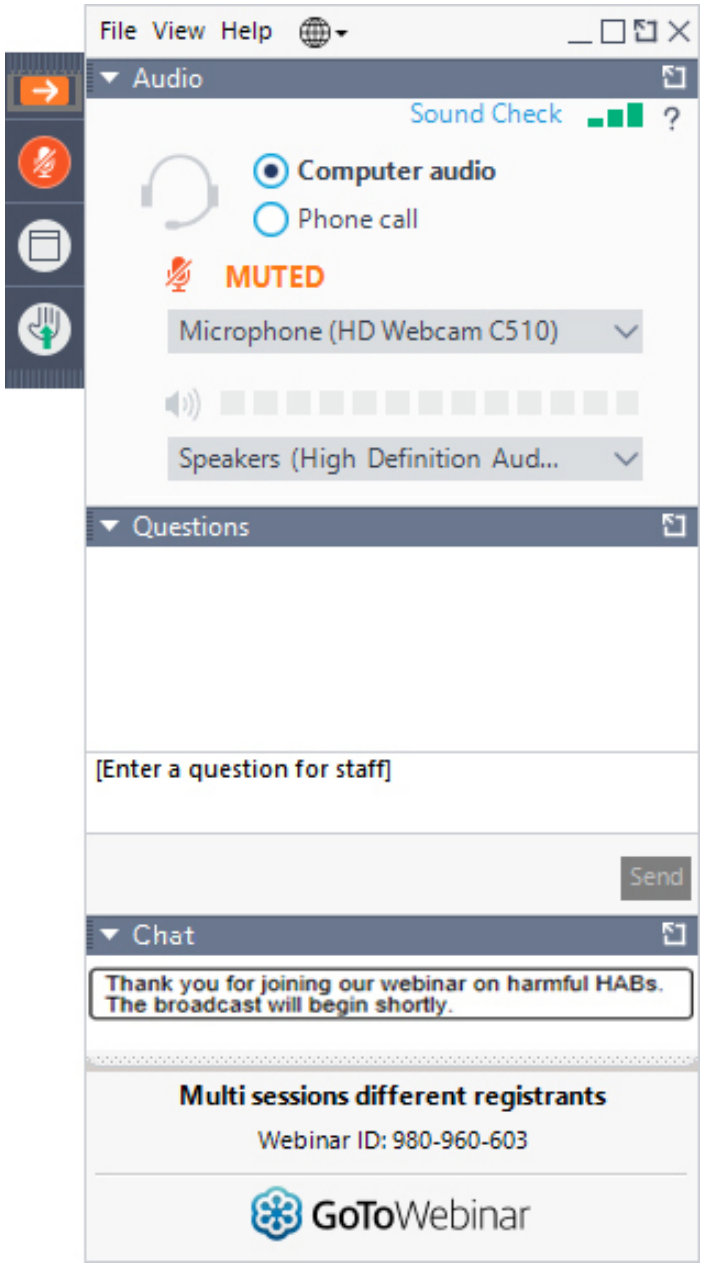
Audio Settings
Make sure you can hear us loud and clear

Ask Questions
We'll try to answer as many as we can during the presentation

Chat
You can also use the Chat panel to ask questions or contact us if you're having technical difficulties

Yes! We are recording
A link to the recording will be available in our follow up email & in our webinar library.

Yes! You can download this presentation
A link to a PDF version of this presentation will be available in our follow up email.



Modify Audio Settings

Please Ask Questions!

Chat for help

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Our Presenters

Allan Javier

Ebro Product Manager (SEA)

- Biochemist by profession
- Process authority for food and pharmaceutical processes
- 20+ years of experience in planning, writing and executing validation and qualification procedures.

Milliya Tsai

Ebro Product Manager (North Asia)

- Specialist in quality management instruments and temperature data loggers
- 4+ years of industry experience
- 7+ years with Xylem (Japan, Taiwan, Germany)
- Xylem Analytics Taiwan area manager

Sebastian Schwarz

Ebro Market Manager Pharma (Europe)

- Chemical and biological engineer
- 7+ years of work experience as consultant in the GMP controlled area.
- Extensive experience as qualification and validation engineer for Pharmaceutical and Biotech companies in Europe

Webinar Topics / Outlines

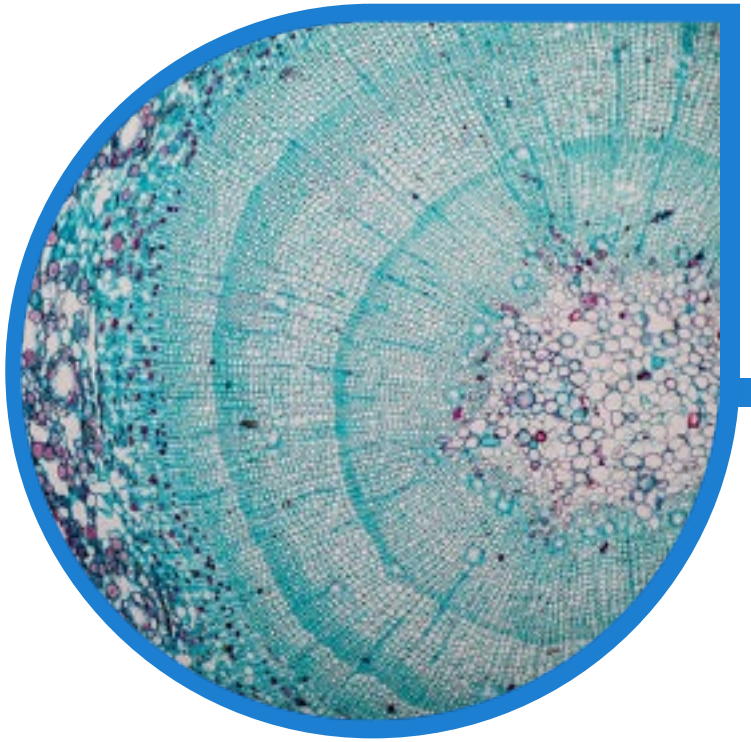
1. Ebro Solutions to the most relevant Pharma Processes that are appropriate to our current global situation

2. Review on Healthcare/Pharma Process Development and Process Flow and how they are implemented

3. What we can provide to your control and implementation of your entire Process from Upstream to Downstream

   * From Material / Raw Material Receipt and Management “USP”
   * To Production and Distribution / Logistics “DSP”

We are Xylem



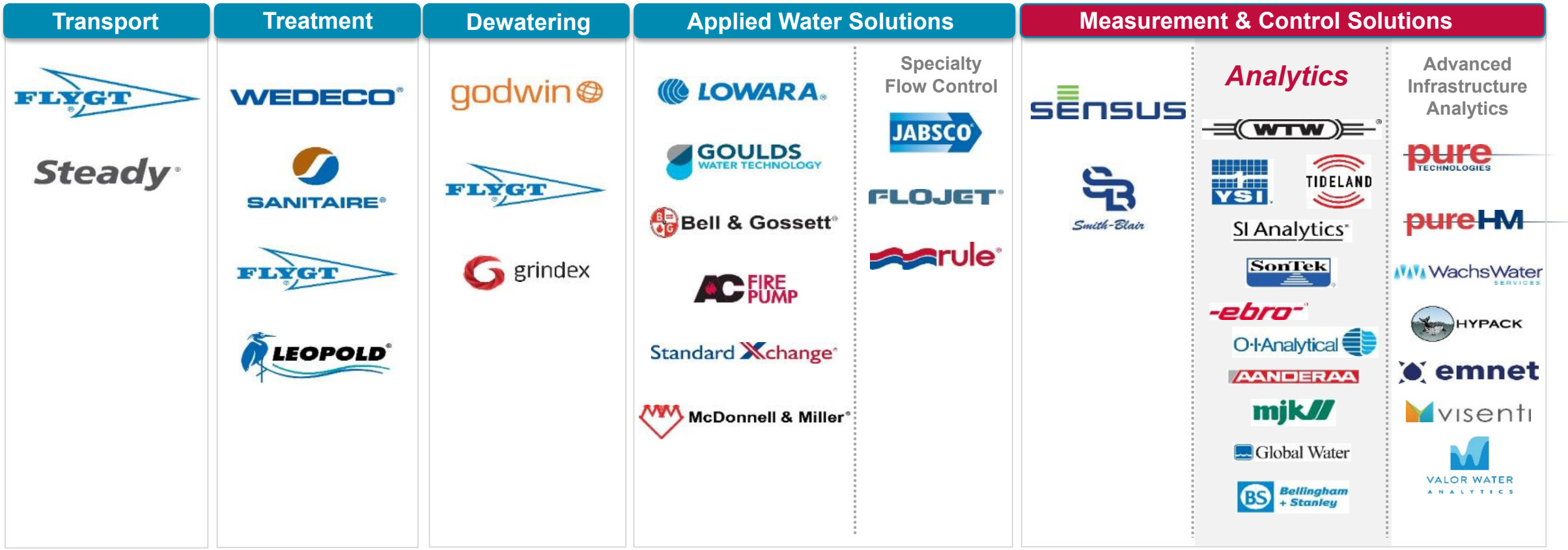
"Xylem" A tissue in vascular plants that helps provide support and conducts water and nutrients upward from the roots.

Xylem (XYL) is a leading

global water technology company committed to developing innovative technology solutions to the world's water challenges.

$5.2bn	**18,000**	**150**	**7**
Revenue	Employees	Countries	Continents

Xylem brings together the most progressive brands



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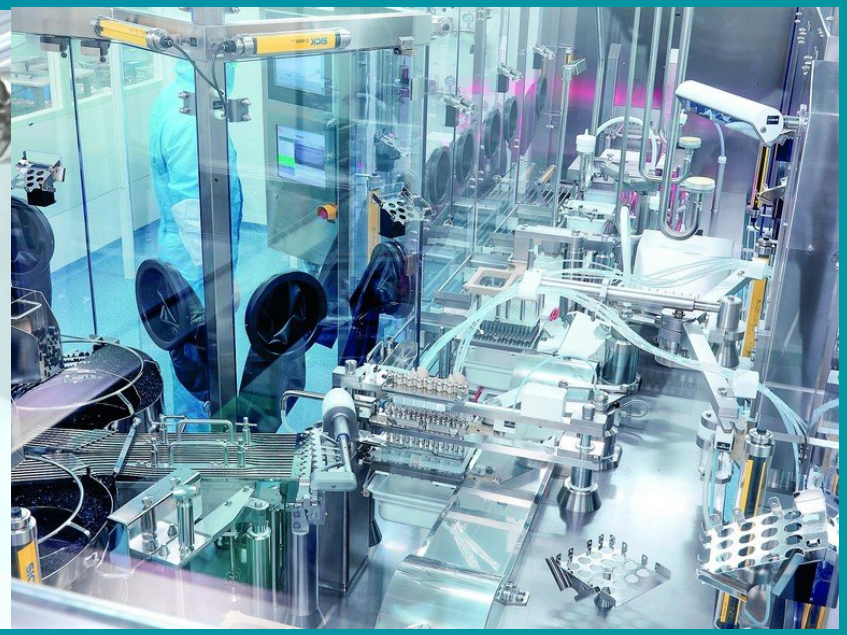

Vaccine Production

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Overview

- Highlighting on Vaccines but may be applicable to other healthcare products
- An outline of Biopharma Processes from handling of biological materials and other raw materials to harvests and tests that included packaging and distribution
- Information Sharing by our Guest Resource person and Colleague from Ebro Germany

Poll Question #1

Which part of the biopharmaceutical process are you most interested in?

A. Bioprocessing and Process Monitoring and Controls

B. Process Validations

C. Logistics: Storage, Transport and Distribution

D. All of the above

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2 Raw Material Management

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Vaccine Production Raw Material Management

Receipt

Vaccine Production Raw Material Management

From receipt to storage - Procedure

1) Acceptance of goods
-> Protection from weather and against confusion. Separation of incoming and outgoing goods. Fast removal from the goods reception to the zones.

2) Control/ cleaning
-> Removal of dust and weather-related contaminants.

3) Appropriation
-> Deposit of quantities and the expiration date; possibly repalletizing wood to plastic. Sampling to ensure identity

4) Status marking
-> Goods with broken seals, damaged packaging, or suspected of possible contamination should be separated (Quarantine).

5) Storage
-> Goods need to be stored under the conditions specified by the manufacturer. First in First out should be ensured. Regulations must be met!

Vaccine Production Raw Material Management

Receipt and storage - Regulations

6.4. Active substances subject to specific storage measures, e.g. narcotics and products requiring a specific storage temperature or humidity, should be immediately identified and stored in accordance with written instructions and with relevant legislative provisions.

6.7. Active substances should be stored under the conditions specified by the manufacturer, e.g. controlled temperature and humidity when necessary, and in such a manner to prevent contamination and/or mix up. The storage conditions should be monitored and records maintained. The records should be reviewed regularly by the person responsible for the quality system.

6.8. When specific storage conditions are required, the storage area should be qualified and operated within the specified limits.

Vaccine Production Raw Material Management

Receipt and storage - Regulations

World Health Organization

„The required storage conditions as specified for the product should be maintained within acceptable limits. The storage areas should be kept clean and dry."

"Where special storage conditions are required (e.g. particular requirements for temperature or humidity) these should be provided, monitored and recorded."

"The supplier of the materials should ensure that the contract acceptor for transportation of the materials is aware of and provides the appropriate storage and transport conditions."

Vaccine Production Raw Material Management

Receipt and storage - Regulations

World Health Organization

“Storage areas should be designed or adapted to ensure good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits.”

“Recorded temperature monitoring data should be available for review. The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained. […] Temperature mapping should show uniformity of the temperature across the storage facility. It is recommended that temperature monitors be located in areas that are most likely to show fluctuations.”

“Equipment used for monitoring of storage conditions should also be calibrated at defined intervals. “

Vaccine Production Raw Material Management

How to ensure proper storage conditions:

1) Temperature mapping should show uniformity of the temperature across the storage facility.

2) Equipment used for monitoring of storage conditions should also be calibrated at defined intervals.

3) The required storage conditions as specified for the product should be maintained within acceptable limits. Alarms should be installed.

4) Data integrity should be ensured

Poll Question #2

Do you have experience with Temperature Data Loggers?

A. Yes

B. No

C. Not yet but I am evaluating now

Solutions ► Cold Chain Monitoring Loggers

EBI 20

- Temperature / temperature & humidity logger
- Needs an interface and a software
- One interface and as many loggers as you want
- Can be programmed with our free software Winlog.basic

Free Software

- -30ºC...+100ºC
- at least ±0.5ºC
- 40.000 values memory

EBI 3x0

- Temperature/humidity USB logger
- Different external sensors are available
- Doesn‘t need an interface or software
- Can be programmed on the website www.ebi300.com
- Automatically creates a PDF report, when connected to PC or printer

Free Software

- -200ºC...+400ºC
- ±0.2ºC and ±0.5ºC
- At least 40.000 values memory

EBI 25

- Automatic wireless temperature and humidity monitoring and alarming system
- Measurement values are displayed on the PC/server nearly in real time
- Software sends alarm emails and creates PDF reports automatically

Pay only Once!

- -200ºC...+200ºC
- ±0.2ºC and ±0.5ºC
- 288 values memory per channel

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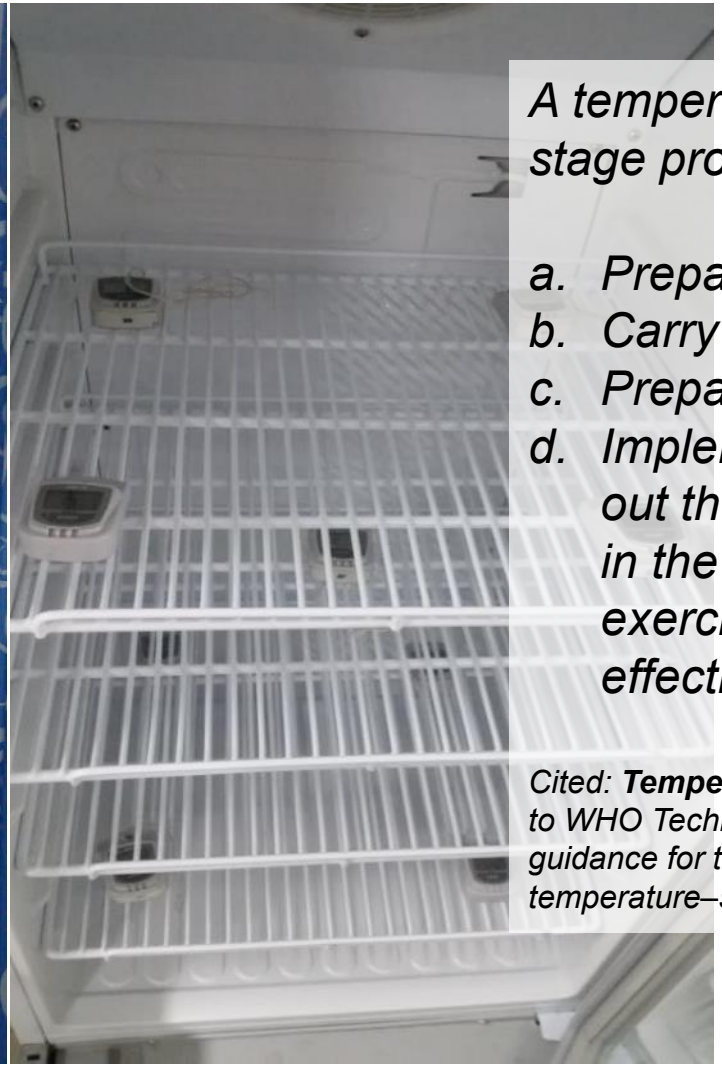
Solutions ▸Thermal Mapping Services



A temperature mapping exercise involves a four stage process, as follows:

a. *Prepare a mapping protocol.*
b. *Carry out the mapping exercise.*
c. *Prepare a mapping report.*
d. *Implement the recommendations by carrying out the remedial and other actions identified in the mapping report. A follow-up mapping exercise may then be needed to verify the effectiveness of the remedial actions.*

*Cited: **Temperature mapping of storage areas** Technical supplement to WHO Technical Report Series, No. 961, 2011 Annex 9: Model guidance for the storage and transport of time and temperature–sensitive pharmaceutical products, 2014*

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3

Upstream Process

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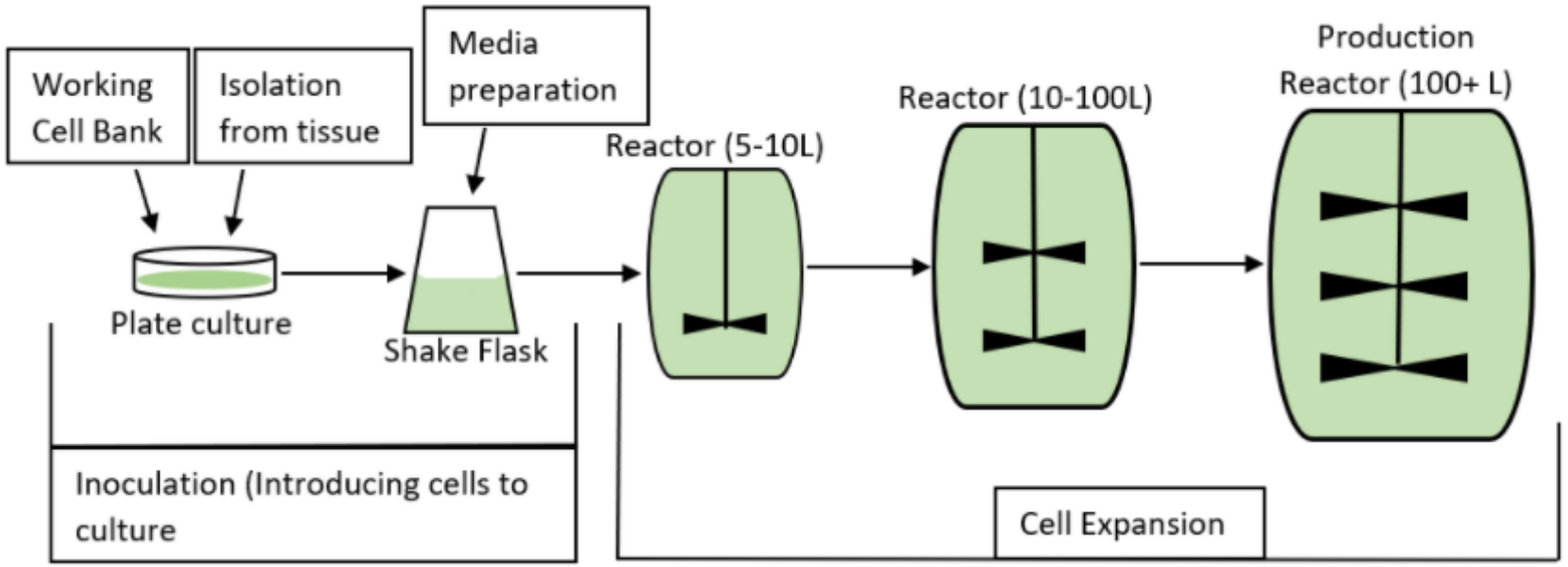
Upstream Process



Textbook definition:
Upstream processing refers to the stage of bioprocessing where cells are grown to the desired quantity in bioreactors, and all stages related to this such as cell isolation, cell cultivation, media preparation, cell banking & storage to culture expansion until harvest.

Upstream Process

Media preparation

- Using specific recipes required for each bioreactor stage of scale up from inoculum to harvest.

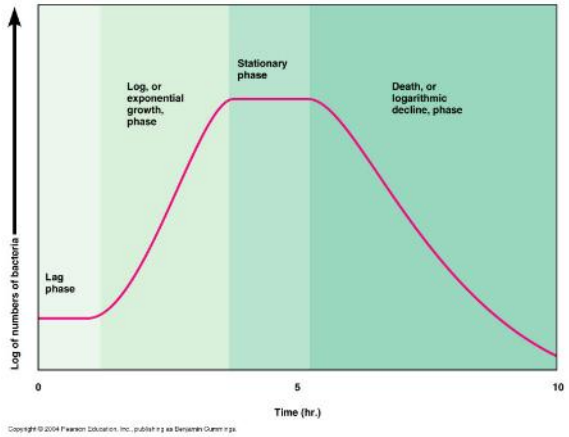
- Media is predominantly made up of carbohydrate (glucose), nitrogen (amino acids), fats (lipids) and trace amounts of salt.

- Prior to introducing the cells to culture it is very important the media is homogeneous and thoroughly mixed.

Upstream Process

Cell Cultivation

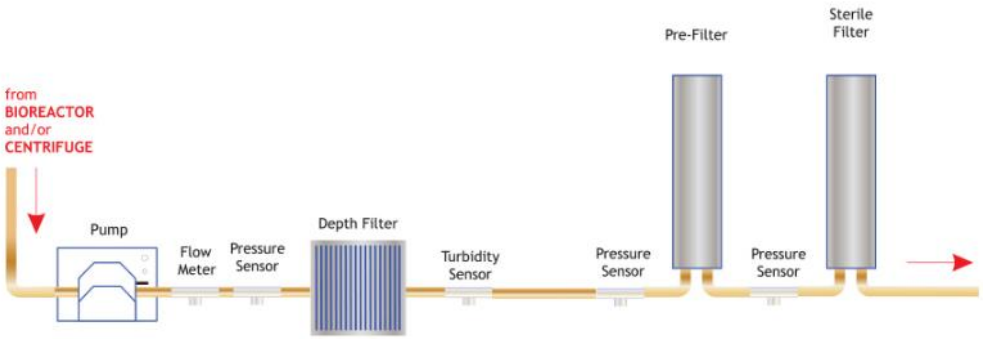
- Cell culture is the growth of cells outside the body (in vitro). The cells divide and continue to multiply once in a suitable environment.
- The correct environment consists of a growth medium as a food source and cell culture vessels for controlling gases and temperature.
- The growth rate is monitored accurately to determine how well cells are growing over particular cycles; this is carried out by taking samples and precisely counting the cells.



Upstream Process

Cell Separation

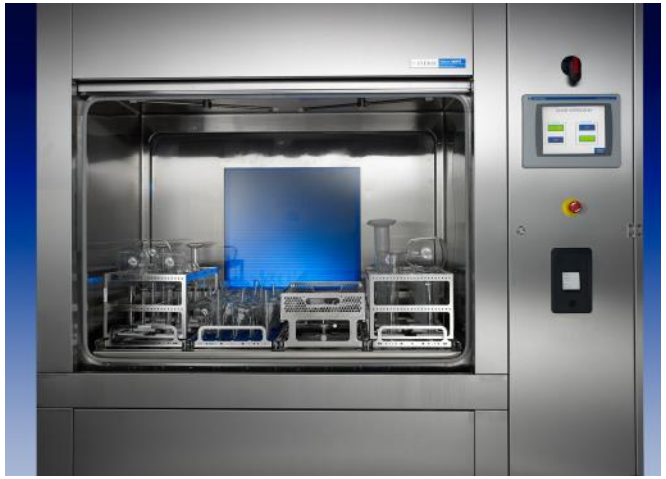
- The first step is usually centrifugation. The technique of centrifugation is based on the principle of density difference between particles to be separated and the medium. Centrifugation is mostly used for separating solid particles from liquid phase (fluid/particle separation).
- The next step is a filtration one to remove the large debris through depth filtration. These depth filter pods are held in a vice-like holder because the plastic housings themselves do not have the required pressure capacity.
- Sterile grade membrane filtration is often the next step during harvest to remove smaller particles and microbial contamination.



Upstream Process

Important topics:

- Conditions within media have to stay stable (pH, T, flow, p)
- Transfer from vessels to bioreactors has to be sterile. Fixed tubing with steam sterilization or transfer via autoclaved bags and container
- Cleaning of all vessels and bottles has to be validated to avoid cross contamination



Depyrogenation

Batch Hot Air Ovens

- The glass containers are loaded into batch ovens and then sterilized generally 2-6 hours depending on the temperature.
- Batch ovens typically require 3 to 8 measuring points depending on size.
- EBI 40 with high temperature probes can be used, but some users prefer not to make any holes in the ovens.

Continuous Hot Air Tunnels

- The glass containers are run via conveyors through the tunnel, typically at 300° C or higher, from 15 to 30 minutes.
- Tunnels usually require 3 rows of 5 monitoring points about 3 feet apart, totally 15 measuring points
- EBI 12 with Double Sensors and Thermal Isolation Box is preferred as the most convenient system to use.

Solutions ► High Quality pH and Conductivity Meters

PHT 810

ProLab 2500

IDS Sensor

Digital sensor recognition

Handheld and Benchtop both available

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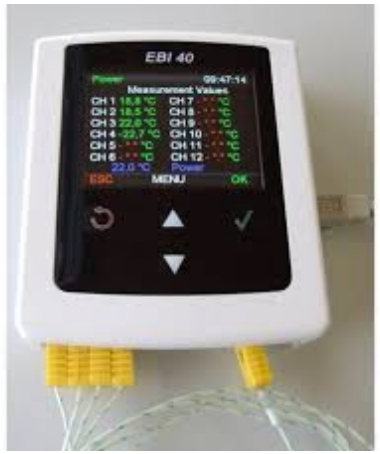
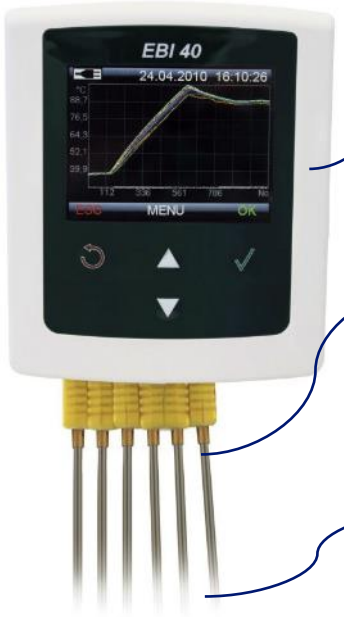
Solutions ► Depyrogenation Validation



EBI 40



TFT Display
12 x 20,000 data

SMP connection
Up to 12 Channels

–200 to 1,200 ° C
Type T or Type K

Thermal Insulation Box : TIB

at 200 °C = 90 min.
at 250 °C = 65 min.
at 300 °C = 55 min.
at 400 °C = 40 min.

Example	Batch Hot Air Ovens	Hot Air Tunnels
Exposure time and Temp	160℃, 2 hours	250℃, 30 mins
Solution	EBI 40	EBI 12 + TIB EBI 40

- ✓ Pt 1000 high accuracy
- ✓ Length: 500mm
- ✓ Diameter: 1.5mm

- ✓ 2 x 50,000 data
- ✓ FIVE calibration points
  250° C+ optional

EBI 12-T421

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Downstream Process

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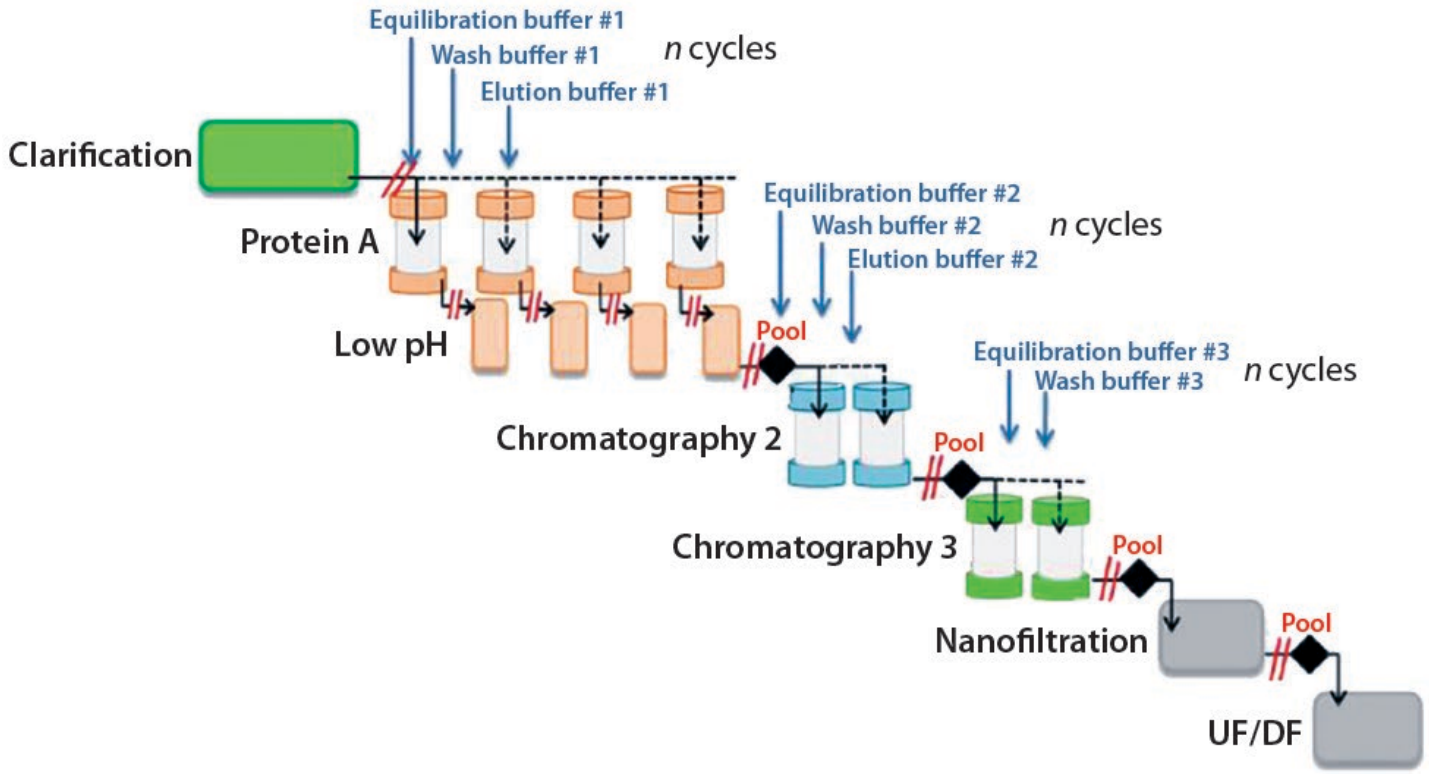
Downstream Process



Textbook definition:
Downstream processing refers to the recovery and the purification of biosynthetic products, particularly pharmaceuticals, from natural sources such as animal or plant tissue or fermentation broth, including the recycling of salvageable components and the proper treatment and disposal of waste.

Sterilization and Processing Methods / “Units” in a Pharma Setting

Moist Heat / Dry Heat Sterilization
Lyophilization / Freeze Drying
EtO Sterilizers
H_2O_2 Sterilization
Depyrogenation
Fermentors
Stability Studies /
Stability Rooms / Chambers, Incubators
Warehouses
Cold Stores

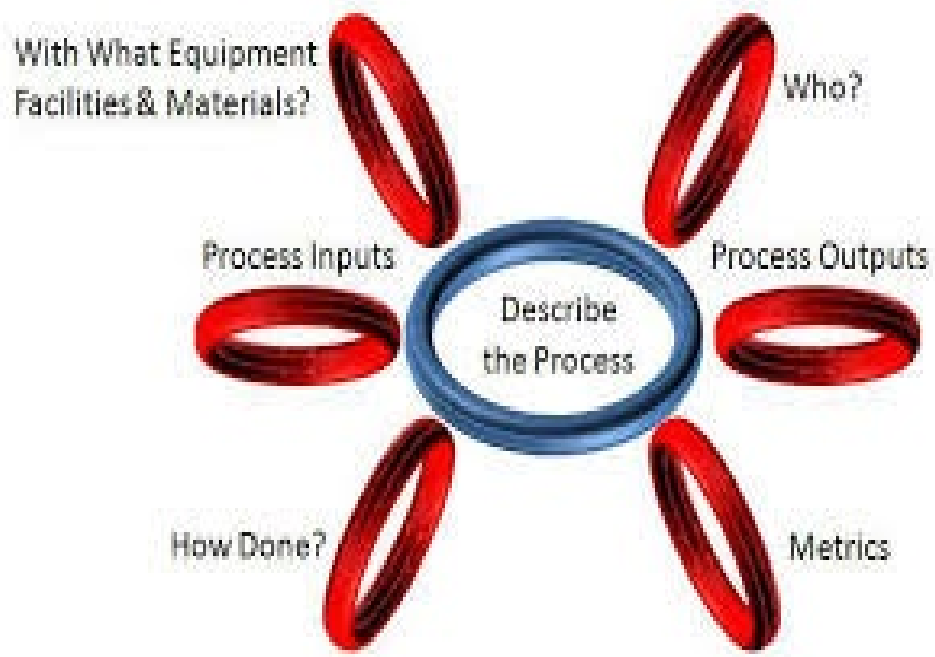







Typical Methods Utilized for Vaccine Production

- Moist Heat / Dry Heat Sterilization
- ***Lyophilization / Freeze Drying***
- ***H_2O_2 Sterilization***
- ***Depyrogenation***
- ***EtO Sterilization (indirectly)***
- Fermentors



Poll Question #3

What is preventing you from investing in new validation systems? (ie. Wireless)

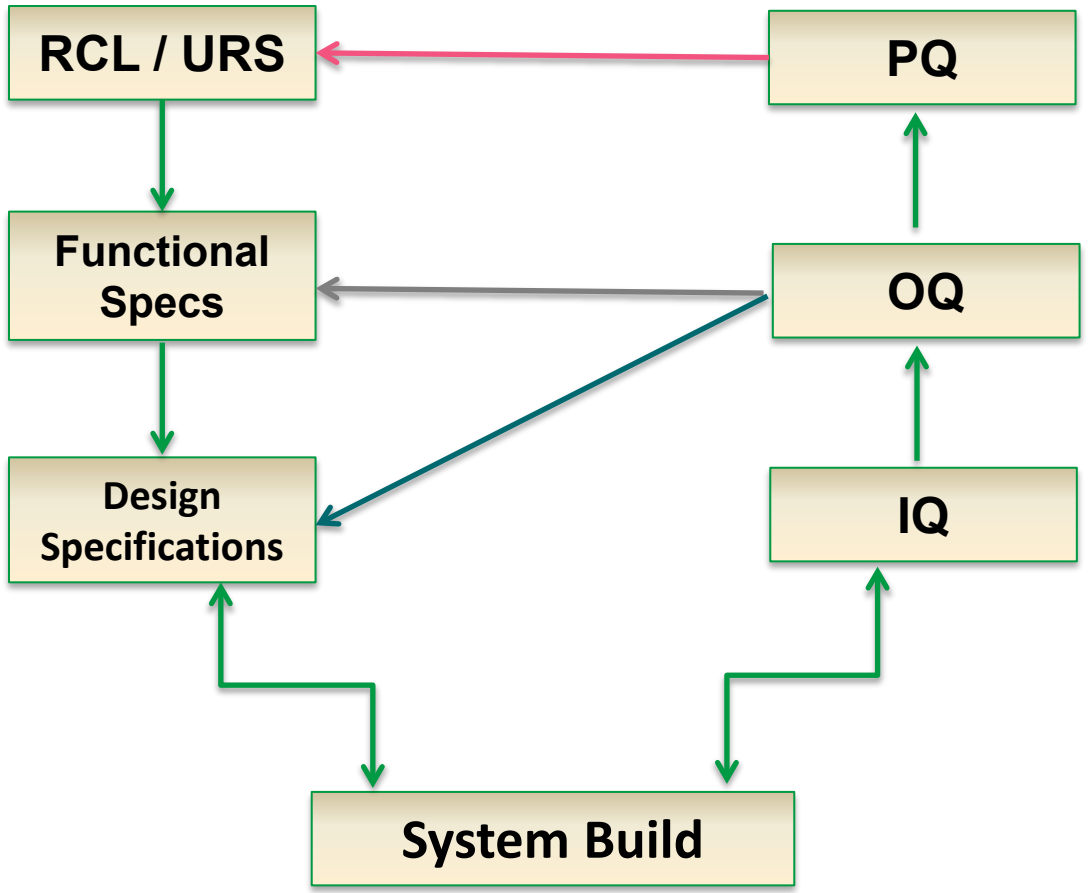
A. Requires additional qualifications, executions and approvals
B. Too much documentation to prepare
C. Unfamiliar wireless tech and validation software

What is **Qualification** and **Validation**?

Validation (Europe and the USA)

Establishing documented evidence which provide a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes.

Action of providing, in accordance with the principles of Good Manufacturing Practice, that any procedure, process, equipment, activity or system actually leads to the expected results.



Lyophilization

Freeze Driers

- The temperature measuring range in typically from -50° C up to + 50° C, but in some cases it can be down to -80° C with an accuracy better than ±0.5 ° C.
- **Freeze Drying is essentially a 3 step process**:

  During the Pre-freeze step the sample is frozen so that all the solvent (normally water) turns to solid (ice). In Primary Drying, the ice sublimates or turns directly to vapour under low pressure (vacuum). In secondary Drying the remaining water, not frozen but bound by molecular bonding to the solute, is removed from the sample.
- **The critical parameters are**:
  Product Temperature (cake), Shelf Temperature, Pressure

Applications of Ebro Solutions

- EBI 12 Data Loggers
- Temperature (Temperature with Low Temperature Sensors)

H_2O_2 Sterilization

- **Hydrogen Peroxide Gas Plasma Sterilisation**
- **The normal process length is approx. 45-60 minutes and the temperature 45-55° C:**
- The Vaccum Phase where the chamber is evacuated reducing internal pressure in preparation for the subsequent reaction.
- The Injection Phase where a measured amount of liquid peroxide is injected into the chamber, evaporating the aqueous hydrogen peroxide solution and dispersing it into the chamber, where it kills bacteria on any surface it can reach.
- The Diffusion Phase. The hydrogen peroxide vapor permeades the chamber exposing all load surfaces to the sterilant and rapidly sterilizes devices and materials without leaving any toxic residues. Chamber pressure is reduced and the plasma discharge is initiated.

H_2O_2 Sterilization

Hydrogen Peroxide Gas Plasma Sterilisation

- The Plasma Phase. An electromagnetic field is created in which the hydrogen peroxide vapor breaks apart, producing a low temperature plasma cloud that contains ultrviolet light and free radicals.
- The Vent Phase. The chamber is vented to equalize the pressure enabling the door to be opened. There is no need for aeration or cool-down. Devices are ready for immediate use.

Applications of Ebro Solutions

- EBI 12 Data logger
- Temperature + Pressure

EtO Sterilization

EtO Sterilisation – DS EN ISO 11135-1

- Pre conditioning – expose product to tropical environment for at least 12 hours - 55° C/70% RH.
- Exposure – pull vacuum and expose to gas usually for 4 to 8 hours (varies per product and must be validated).
- Post conditioning – air out all the EtO gas. 8-12 hours
- Temperature and RH% are critical in pre-conditioning to induce microbial activity EtO will not kill many microbes in their dormant or (spore) stage.
- Moisture is critical as a transfer agent for EtO – it helps to permeate through plastic, paper, cardboard, packaging etc.
- Pulling a vacuum dramatically dries out the product. Therefore steam (RH) is increased to replace lost moisture in the product.
- The influence of pressure is also a factor in helping EtO permeate a product. Pulling a vacuum pulls EtO into product.

<u>8 – 15</u> EBI12 Data Loggers

Temperature and %RH (EX-Certified)

Poll Question #4

Which sterilization process are you interested in?

A. Moist heat / Dry heat
B. Lyophilization / Freeze drying
C. H_2O_2
D. EtO

Solutions ► Validation and Routine Control Loggers

EBI 12

- Temperature range between -200ºC and +400ºC
- Pressure measurement up to 4bar
- Interface and software needed
- Logger can send data in real time via radio
- Calibration certificate
- least ±0.1ºC (0ºC…+120ºC) and ±0.05 (120ºC…+140ºC)
- At least ±10mbar
- Memory: 100.000 values

EBI 11

- Temperature range between -30ºC and +150ºC
- Pressure measurement up to 10bar
- Interface and software needed
- Whole logger inside bottle or can (1.65x2.4cm)
- Calibration certificate
- ±0.1ºC
- Memory: 15.000 values

Solutions ► EBI 12 Series for Sterilization Validation

	Moist heat	Lyophilization	H_2O_2	EtO
Temperature	0~150°C 121°C or 134°C	-80~50°C -50°C	0~55°C 45°C	0~80°C 45°C
Pressure	0~4000mbar 2-3000mbar	0~1050mbar <10mbar	0~1050mbar	0~2000mbar (optional)
Humidity	X	X	0~70rH% (optional)	0~100rH% 40-60%
Ebro's specialty	• 4 channel logger • Auto F0 value calculation • Double sealing design	• Low temperature logger	• High precision pressure logger • Built-in Template	• Explosion Proof (ATEX) • Pressure sensor also available

Example of Used Logger

EBI 12-T671 EBI 12-TP453

EBI 12-T441

EBI 12-TP290

EBI 12-TP290

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Solutions ► Electronic Bowie & Dick Test for Autoclaves

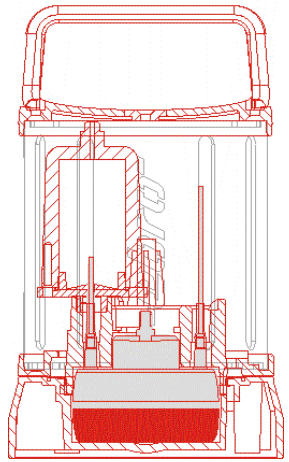
EBI 16

- **Evacuation Test**

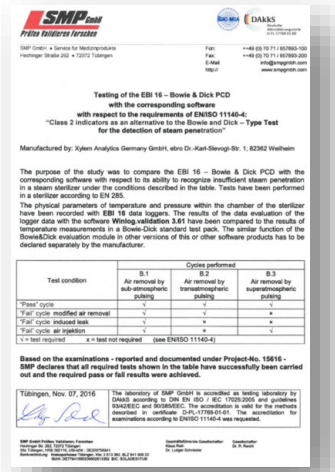
Check if the pump can adequately remove air from the chamber

- **Steam Penetration Test**

Check if there is air leakage inside the chamber so that steam can sterilize devices



Certificate from SMP



Testing of the EBI 16 – Bowie & Dick PCD
with the corresponding software
with respect to the requirements of EN ISO 11140-4:
"Class 2 indicators as an alternative to the Bowie and Dick – Type Test
for the detection of steam penetration"

Manufactured by: Xylem Analytics Germany GmbH, ebro Dr.-Karl-Slevogt-Str. 1, 82362 Weilheim

The purpose of the study was to compare the EBI 16 – Bowie & Dick PCD with the corresponding software with respect to its ability to recognize insufficient steam penetration in a steam sterilizer under the conditions described in the table. Tests have been performed in a sterilizer according to EN 285.

The physical parameters of temperature and pressure within the chamber of the sterilizer have been recorded with EBI 16 data loggers. The results of the data evaluation of the logger data with the software Winlog.validation 3.01 have been compared to the results of temperature measurements in a Bowie-Dick standard test pack. The similar function of the Bowie&Dick evaluation module in other versions of this or other software products has to be declared separately by the manufacturer.

Test condition	Cycles performed B.1 Air removal by sub-atmospheric pulsing	B.2 Air removal by transatmospheric pulsing	B.3 Air removal by superatmospheric pulsing
"Pass" cycle	√	√	√
"Fail" cycle modified air removal	√	√	x
"Fail" cycle induced leak	√	x	x
"Fail" cycle air injection	√	x	√

√ = test required x = test not required (see EN ISO 11140-4)

Based on the examinations - reported and documented under Project-No. 15616 - SMP declares that all required tests shown in the table have successfully been carried out and the required pass or fail results were achieved.

Tübingen, Nov. 07, 2016

The laboratory of SMP GmbH is accredited as testing laboratory by DAkkS according to DIN EN ISO / IEC 17025:2005 and guidelines 93/42/EEC and 90/385/EEC. The accreditation is valid for the methods described in certificate D-PL-17789-01-01. The accreditation for examinations according to EN ISO 11140-4 was requested.

According to ISO EN 11140-4

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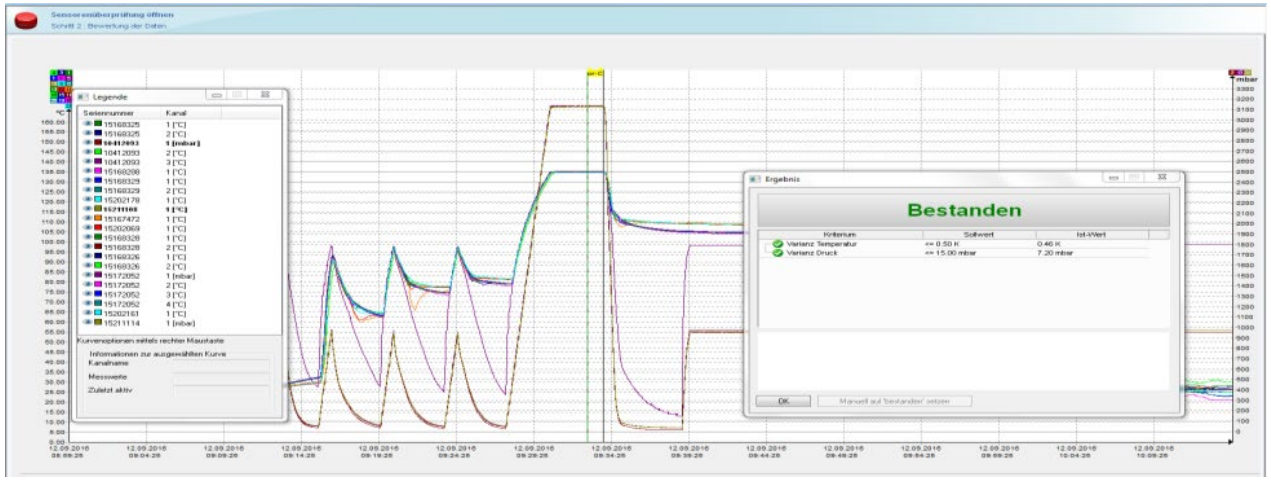
Accessories can help

Eyelet

Battery replace set

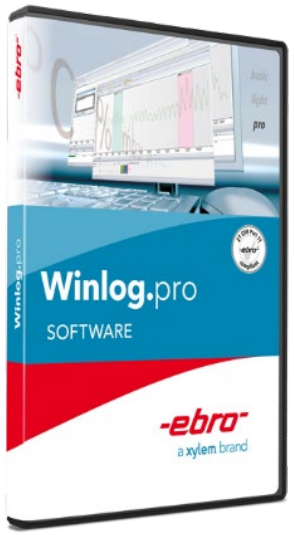
Sensor Check AL 285



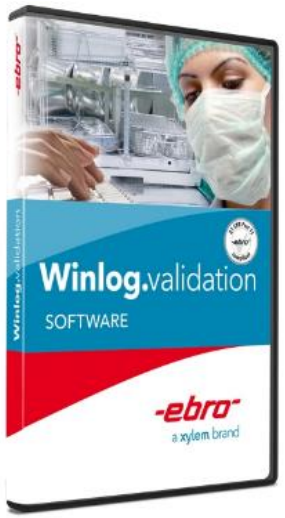
ISO 17665-1, paragraph 9.1.4
Verification of the calibration value of the measuring instrument that is used for the validation of the sterilization process at process condition.

Easy-to-use Software

Winlog.pro
Professional software



Winlog.Validation
Validation software



TÜV Certificate

✓ **FDA 21 CFR Part 11**

✓ **IQ/OQ Documentation**

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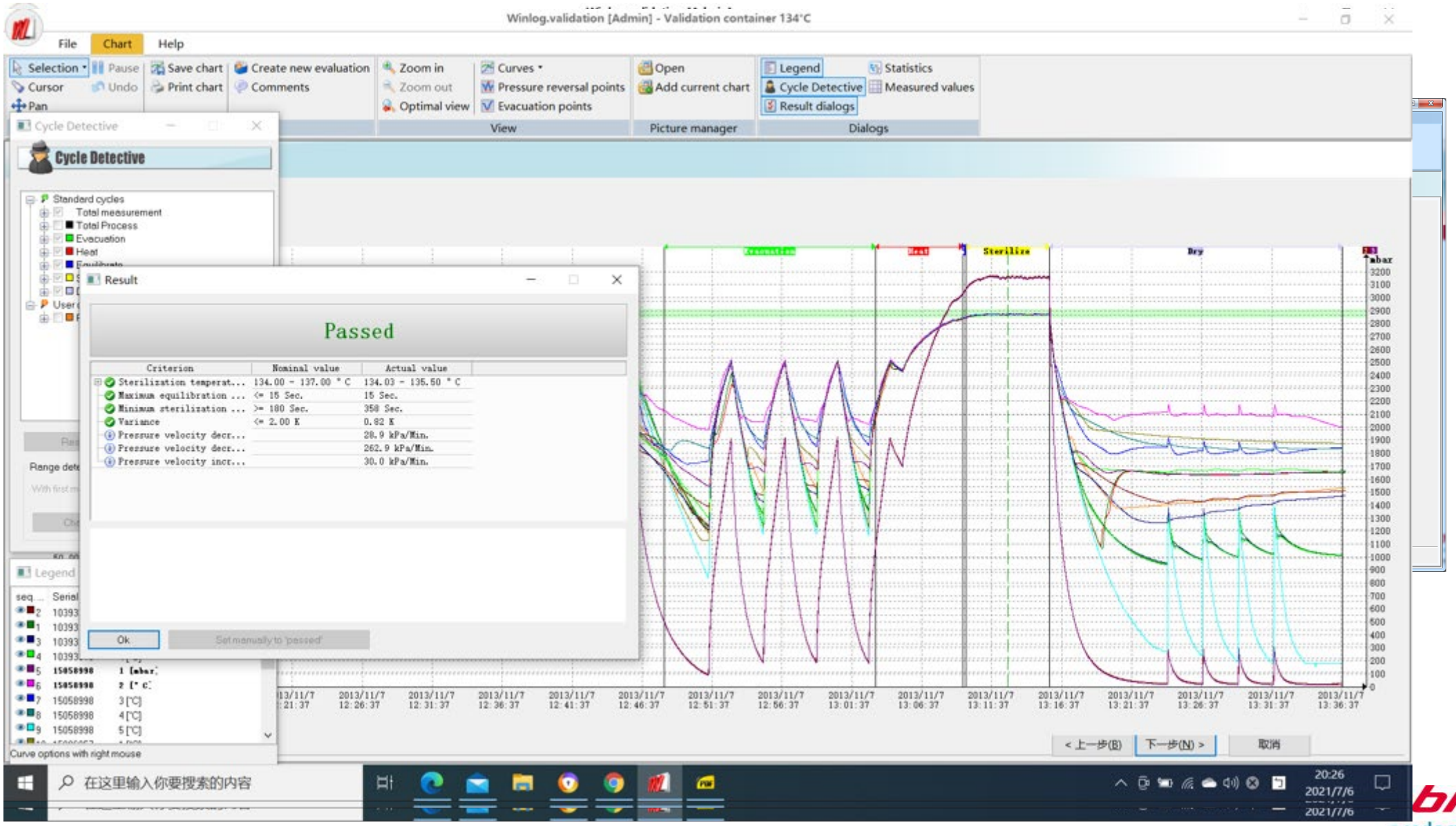
Winlog.Validation – Built-in Template



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5

Cold Chain Process

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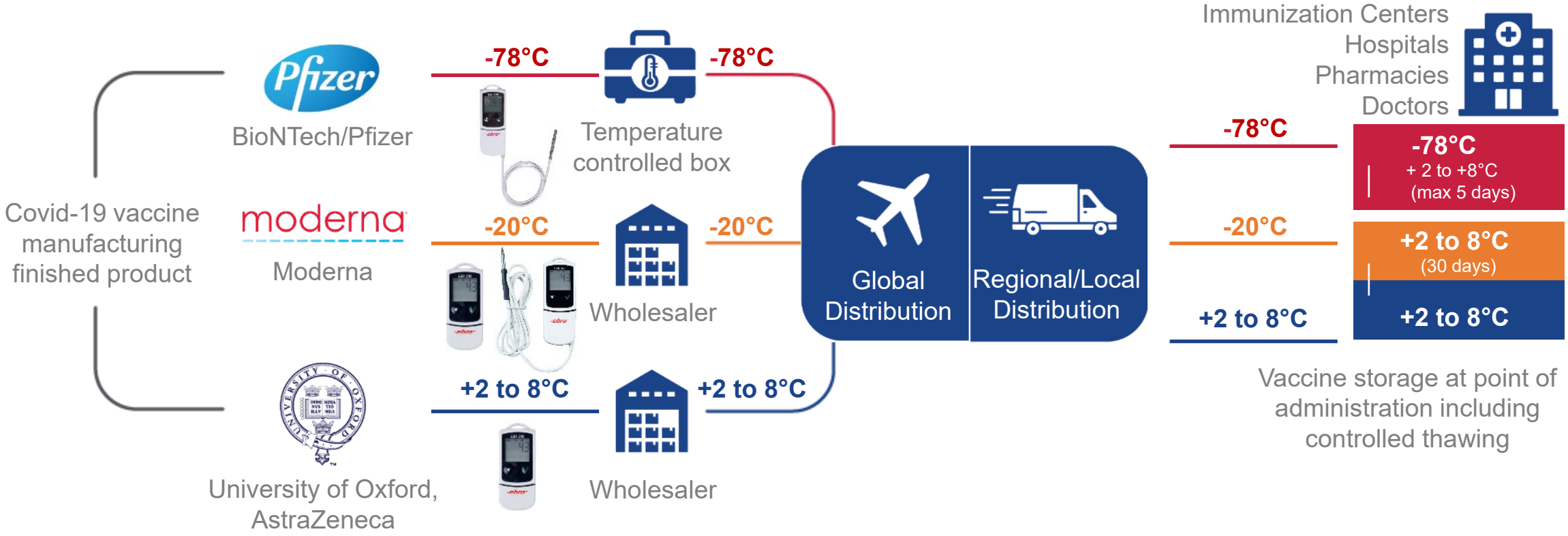
Everything you need for your transportation



For Storage Facilities and Storage Areas, Temperature and Humidity measurements are very necessary.

Temperature and Humidity, when outside the required limits, have
Great and adverse effects to the following:

- Raw Materials
- Intermediate Products
- Final Products
- Retained Samples

Storage conditions must correctly determine and exclude negative impacts on the goods and therefore needs to be monitored.

- *USP, GMP, cGMP, GDP and the Norms/Standards*

http://www.who.int/medicines/areas/quality_safety/quality_assurance/GuideGoodStoragePracticesTRS908Annex9.pdf

World Health Organization; WHO Technical Report Series, # 908, 2003:

Guide to Good Storage Practices for Pharmaceuticals

Storage in dry, well-ventilated premises at temperatures of 15–25°C or, depending on climatic conditions, up to 30°C. Extraneous odours, other indications of contamination, intense light must be excluded. Drug products that must be stored under defined conditions require appropriate storage instructions.

IFP – *International Pharmaceutical Federation*

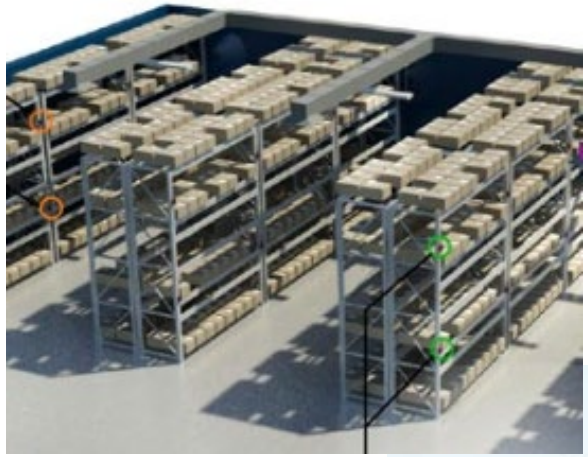
...“The Guidelines are applicable not only to Manufacturers of Medicinal Products but also to Pharmaceutical Importers, contractors and wholesalers and hospital & community Pharmacies...“

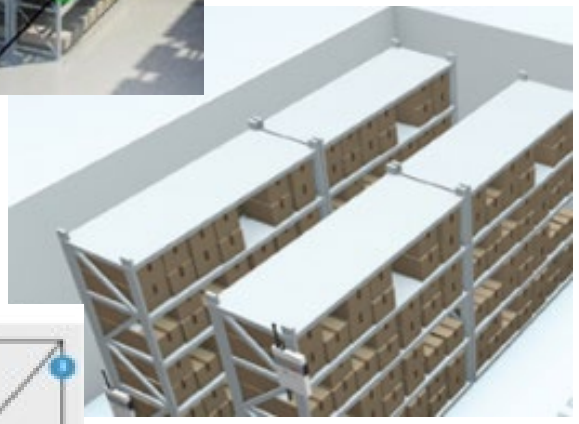
- Pharmaceutical Warehouses

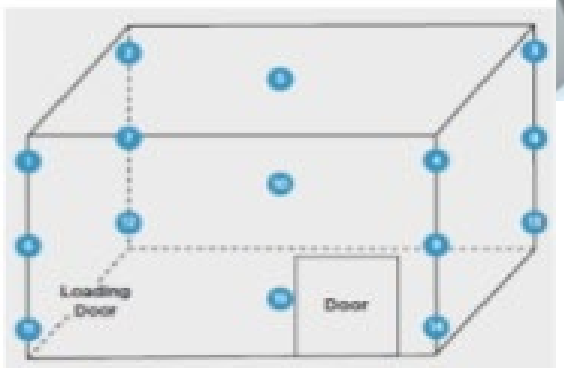
- *Thermal Mapping Protocols*
- *Determine the RCL and URS for the Warehouse/Storage*
- *Approval of the Mapping Protocols as covering both the above documentations*
- *MKT Calculations are required in the Evaluation of the Thermal Mapping Results*

In the Protocols, the most important issues are the following:

- *Determine the grids / distance from one sensor to another*
- *Thermal Mapping Duration*
- *ACCEPTANCE CRITERIA*
- *The right quantity of measuring points that are to be used in the data acquisition and mapping implementations*







Supplement 7

Qualification of temperature-controlled storage areas

Technical supplement to WHO Technical Report Series, No. 961, 2011

Annex 9: Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products

USP 36

⟨1079⟩ GOOD STORAGE AND DISTRIBUTION PRACTICES FOR DRUG PRODUCTS

VALIDATION AND THERMAL PERFORMANCE QUALIFICATION FOR TRANSPORT SYSTEMS

Drug product transport systems should be continuously monitored by calibrated monitoring systems, (continuous verification), or shipping systems should be qualified and based on historical data relative to the process. However, it may be acceptable to use product stability data and supply chain risk assessment to justify shipping without either continuous monitoring or qualification of the shipping system.

Operational and performance shipping studies should on a generic level be part of a formal qualification protocol that may use controlled environments or actual field testing, depending on the projected transport channel. These studies should reflect actual load configurations, conditions, and expected environmental extremes. Testing should be performed on both active and passive thermal packaging systems.

applicable areas, as well as a plan of action in the event of an unacceptable excursion.

TEMPERATURE MAPPING

The basis of any temperature mapping in a temperature controlled space (e.g., facility, vehicle, shipping containers, refrigerator, freezer) is the identification and documentation of a sound rationale used for a given mapping procedure. The temperature variability associated with mapped locations and the level of thermal risk to the product should be defined, unless another process has been put in place to ensure environmental control.

A temperature mapping study should be designed to assess temperature uniformity and stability over time and across a three-dimensional space. Completing a three-dimensional temperature profile should be achieved by measuring points at not less than three dimensional planes in each direction/axis—top-to-bottom, left-to-right, front-to-back, where product will be present.

When temperature mapping is necessary, it should begin

- *PHARMA – **THE DIFFERENT GUIDELINES***

THERMAL MAPPING PROTOCOLS

International Council For Harmonisation

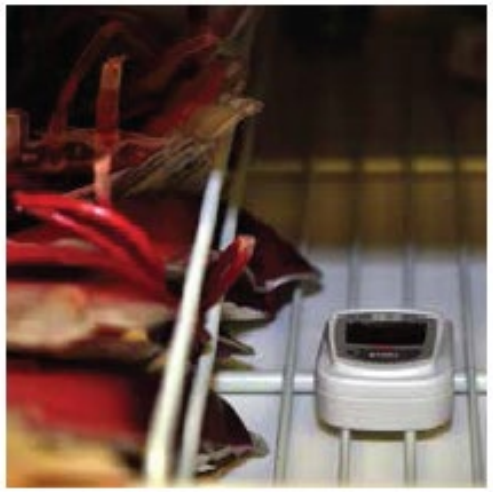
ICH Guidelines are adopted as law in several countries, but are only used as Guidance for the U.S. FDA

Poll Question #5

Does your company conduct thermal mapping internally or by a third party?

A. Internally
B. Third party
C. Depends on the process/instrument
D. Not sure

Solutions ► EBI 20 Series for Temperature Mapping and etc.



Durable ABS housing, Waterproof, Cost effective

Small but tough, -30 ° C to +70 ° C with an integrated NTC-sensor and an easy-to-read LCD display

EBI 20 - Temperature Mapping and Monitoring

Solutions ▸ EBI 25 Series for Continuous Monitoring

Continuous monitoring

EBI 25 wireless temperature and humidity logger

What you need for the EBI 25 system

Wireless Data Points

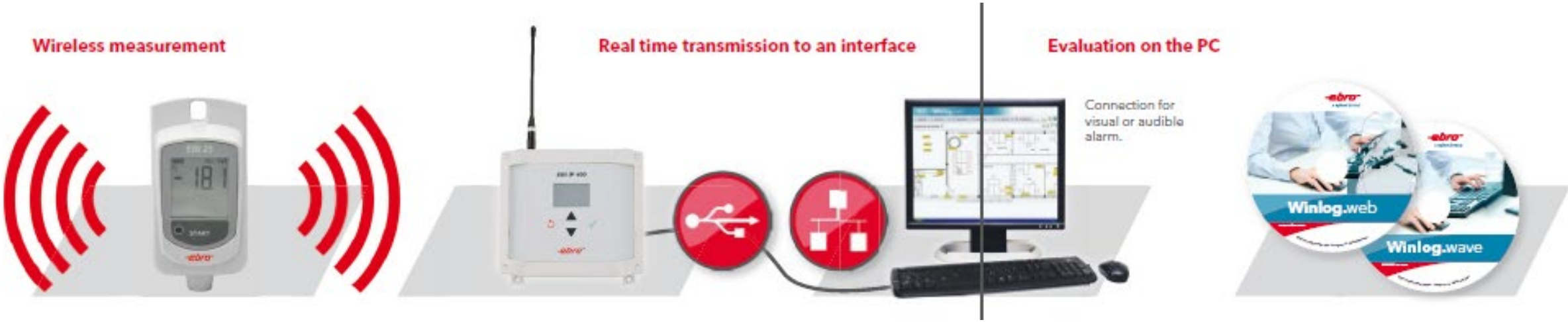
- EBI 25 Temperature sensors
- EBI 25 Humidity Sensors

Data Sources

- IF 400 interface (TCP/IP or USB)
- Other sensors integrated via modbus

Data Display and Storage

- Winlog.Web - network based software
- Winlog.Wave – Single PC based software



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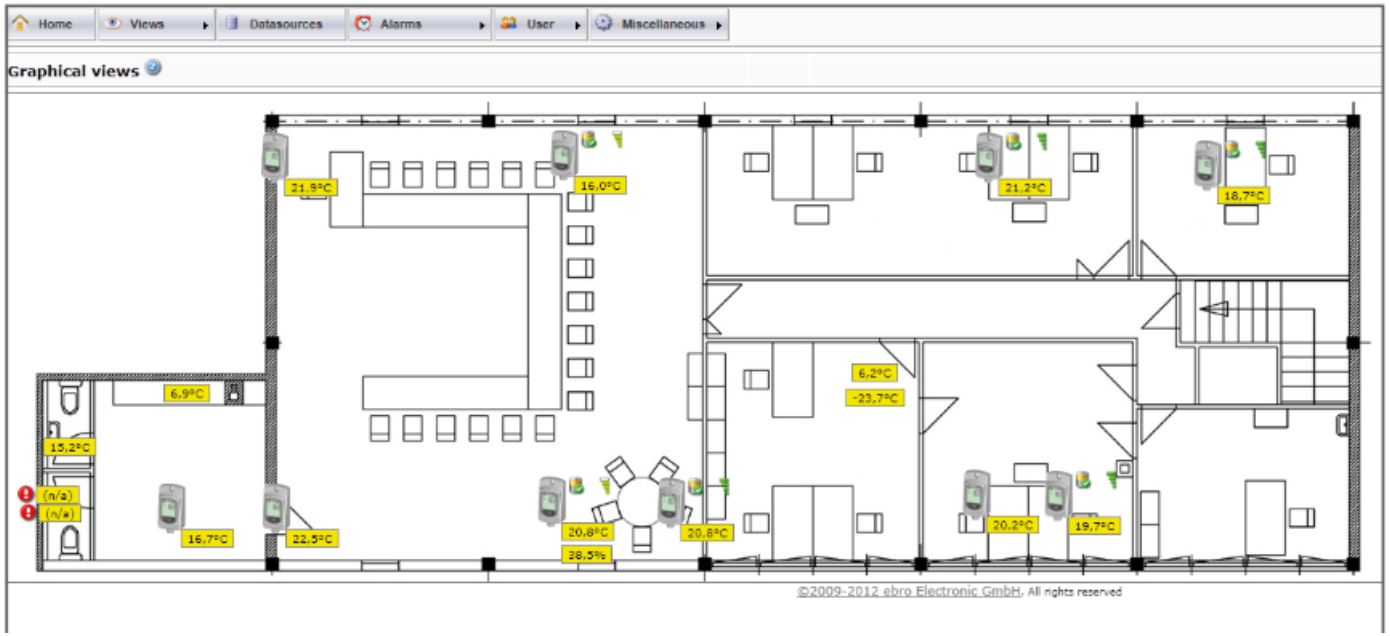
A Pharma Warehouse



800m² wide Pharma warehouse with cold (-2~8°C) and frozen (-20°C) storage zone, 2 x interface with 25 loggers. Integrated alarm system. IQ, OQ required.

Automatic recording, Time-Saving, IQ/OQ Support

Wireless continuous monitoring, -200 ° C to +200 ° C possible, email alarm, Third party alarm support, 3-point factory calibration certificate, Easy installation

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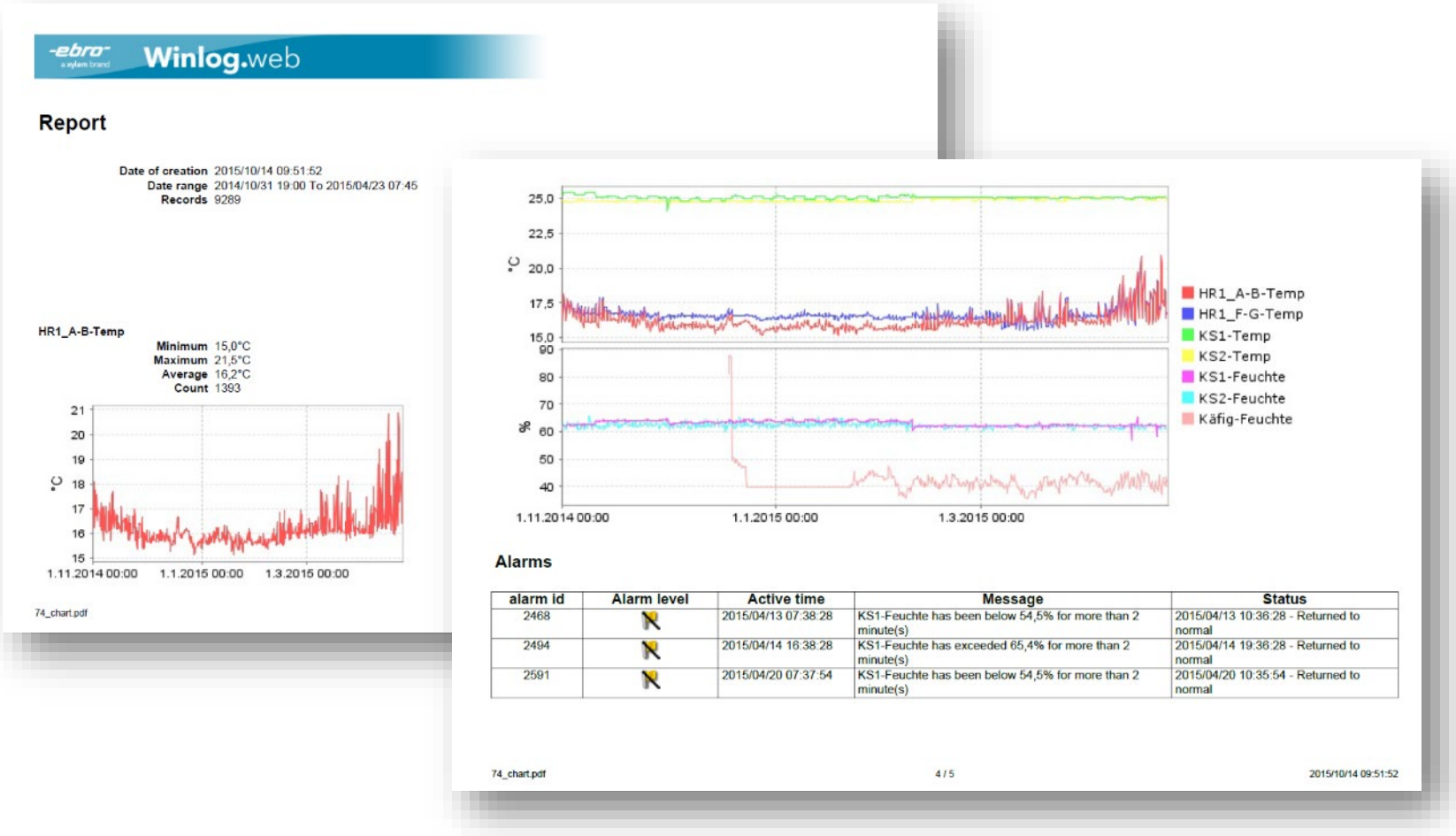
Automatic Report Generation and Mobile APP

Reports can be created and sent as an email automatically



Winlog.Mobile

Recently released in 2021

For Android and IOS

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Flexible Alarm System and Third-party Sensors

- With a Modbus and network
- External sensor with analog output of 4…20mA, eg: **O_2, CO_2, pressure, PM 2.5, dust, particle**
- NO/NC
  - ✓ smoke detection
  - ✓ flood detection
  - ✓ power failure

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Solutions ► EBI 3x0 Series for Transportation and etc.

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Cold Chain Monitoring - EBI 310 multi-use loggers

EBI 310 TH

- Measurement range:
  -30 ºC … +75ºC
  0% rH … 100% rH

- Accuracy:
  ± 2% between 10% and 90% rH, at 25 ºC
  ± 4% for the remaining range
  ± 0.2 ºC (-30 ºC … + 30 ºC) internal sensor
  ± 0.5 ºC (for the remaining) internal sensor
  ±0.5 ºC (0 ºC … + 60 ºC) External sensor
  ±0.8 ºC for the remaining range

Applications
- Room monitoring
- Storages
- Humidity chamber

EBI 310 TX

- Measurement range:
  -200 … +400 ºC
- Accuracy: ± 0,2 ºC…2,0 ºC
- Different sensors available (1m…10m length)

Applications
- Industrial oven
- Ultra low freezer
- Liquid Nitrogen
- Dry ice
- Cryo vessel

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Vaccine Storage in Germany

For a certain type of vaccine, the storage temperature is very low. **EBI 310-TE** was sold to the vaccine manufacturer for storage monitoring.

Wide range, Higher accuracy, User friendly

-200 °C to +250 °C with an external PTFE
cable & PT1000 sensor, 3 point factory calibration certificate

Image source:
https://www.bloomberg.com/news/articles/2020-08-03/ups-readies-freezer-farms-to-ship-virus-vaccine-if-we-get-one
https://www.straitstimes.com/world/united-states/pfizer-biontech-ask-fda-to-approve-easier-vaccine-storage

How is it used in Vaccine Transportation to Clinic

1 Frozen cold packs

Place a layer of cold packs to completely cover the bottom of the cooler.
NEVER USE DRY ICE.

2 Vaccines

Layer vaccine boxes directly on top of the frozen cold packs.

3 Buffered probe

Place the buffered probe with the top layer of vaccines.

4 Frozen cold packs

Spread another layer of frozen cold packs to completely cover the vaccines.

5 Bubble wrap

Layer bubble wrap to fill the remaining empty space and close the cooler.

6 Transport log and display

Record the "Time" and "Temperature of vaccine in cooler before departure" on the bottom of transport log. Attach the digital display and transport log carefully to the outside of the cooler. Drive the vaccines to your alternate storage location.

MSA: giving an In Vivo and In Vitro “Thank you” to Everyone ☺

Please Remember us
when you come across these Key Words:

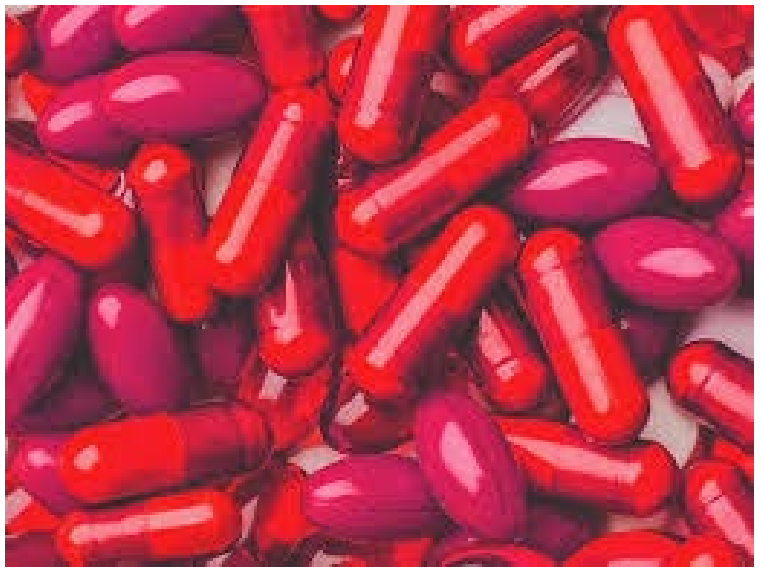
COMPLIANCE
FDA 21 CFR Part 11; GAMP5-Approved from Hardware, firmware to Software

QUALIFICATION and DOCUMENTION
IQ, OQ and PQ

VALIDATION
Thermal Processes, Methods and Instrumentation
According to approved Guidelines and Validation Protocols

ALL MEASUREMENTS: MONITORING and RECORDING
Continuous and Remote Monitoring with Alarm Notifications

CALIBRATION
According to approved procedures



Poll Question #6

Would you like an Ebro product specialist to contact you with more information?

July 29th

Thermal Validation & Thermal Mapping for Retorts in Food Industries

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Let's Solve Water

Questions?

CONSULT YOUR EBRO SPECIALIST

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Milliya Tsai
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Sebastian Schwarz
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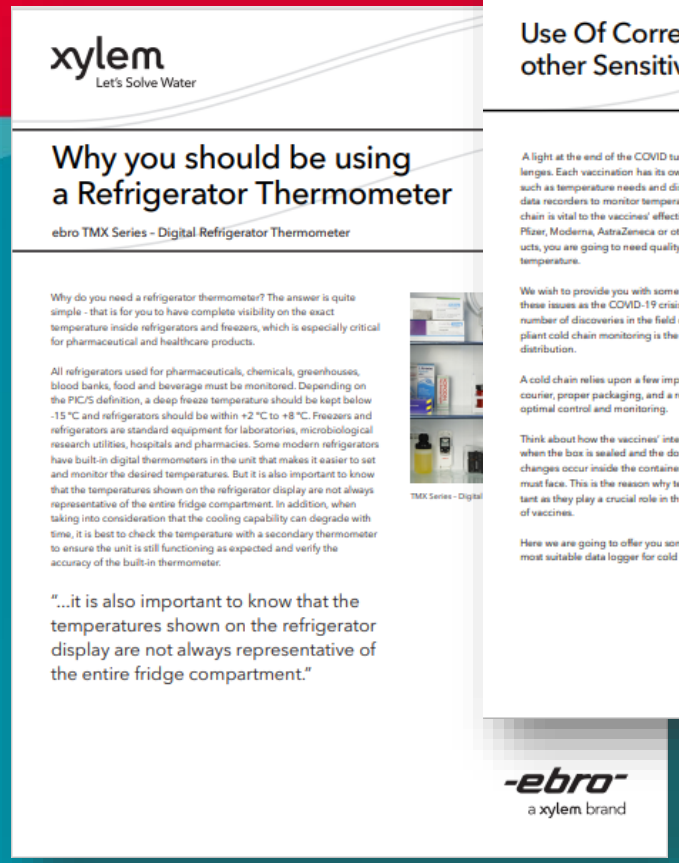
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Let's Solve Water

Why you should be using a Refrigerator Thermometer

ebro TMX Series – Digital Refrigerator Thermometer

Why do you need a refrigerator thermometer? The answer is quite simple - that is for you to have complete visibility on the exact temperature inside refrigerators and freezers, which is especially critical for pharmaceutical and healthcare products.

All refrigerators used for pharmaceuticals, chemicals, greenhouses, blood banks, food and beverage must be monitored. Depending on the PIC/S definition, a deep freeze temperature should be kept below -15 °C and refrigerators should be within +2 °C to +8 °C. Freezers and refrigerators are standard equipment for laboratories, microbiological research utilities, hospitals and pharmacies. Some modern refrigerators have built-in digital thermometers in the unit that makes it easier to set and monitor the desired temperatures. But it is also important to know that the temperatures shown on the refrigerator display are not always representative of the entire fridge compartment. In addition, when taking into consideration that the cooling capability can degrade with time, it is best to check the temperature with a secondary thermometer to ensure the unit is still functioning as expected and verify the accuracy of the built-in thermometer.

"...it is also important to know that the temperatures shown on the refrigerator display are not always representative of the entire fridge compartment."

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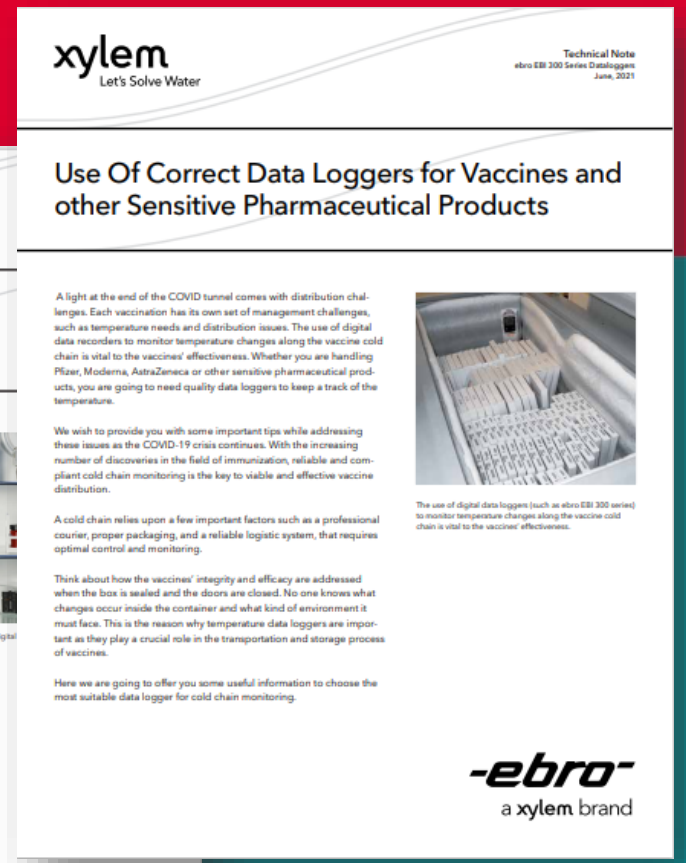
PDF: Why you should be using a Refrigerator Thermometer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Let's Solve Water

Technical Note
ebro EBI 300 Series Dataloggers
June, 2021

Use Of Correct Data Loggers for Vaccines and other Sensitive Pharmaceutical Products

A light at the end of the COVID tunnel comes with distribution challenges. Each vaccination has its own set of management challenges, such as temperature needs and distribution issues. The use of digital data recorders to monitor temperature changes along the vaccine cold chain is vital to the vaccines' effectiveness. Whether you are handling Pfizer, Moderna, AstraZeneca or other sensitive pharmaceutical products, you are going to need quality data loggers to keep a track of the temperature.

We wish to provide you with some important tips while addressing these issues as the COVID-19 crisis continues. With the increasing number of discoveries in the field of immunization, reliable and compliant cold chain monitoring is the key to viable and effective vaccine distribution.

A cold chain relies upon a few important factors such as a professional courier, proper packaging, and a reliable logistic system, that requires optimal control and monitoring.

Think about how the vaccines' integrity and efficacy are addressed when the box is sealed and the doors are closed. No one knows what changes occur inside the container and what kind of environment it must face. This is the reason why temperature data loggers are important as they play a crucial role in the transportation and storage process of vaccines.

Here we are going to offer you some useful information to choose the most suitable data logger for cold chain monitoring.

The use of digital data loggers (such as ebro EBI 300 series) to monitor temperature changes along the vaccine cold chain is vital to the vaccines' effectiveness.

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PDF: Use of Correct Data Loggers for Vaccines and other Sensitive Pharma Products