



# GDP Webinar

## Temperature Qualification in Storage

Date:

Monday, 30 November 2020, 14.00 – 15.30 h CET

Speaker:

Kane Edgeworth, Biomap



ECA has entrusted  
CONCEPT HEIDELBERG with the  
organisation of this webinar.

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## Background

Temperature qualification has long been a requirement for areas used for the storage of pharmaceutical products and the maturing regulatory requirements have increasingly higher expectations for compliance in this area. The EU-GDP Guidelines (Chapter 3 – Premises and Equipment) provide some broad requirements but with little guidance on the 'how to' element, and the WHO guidelines (Supplement 8 –Temperature mapping of storage areas) goes a step further in regards to technical elements.

This webinar is aimed at taking out the guess work of such an exercise and clearly outlining the main components of a successful and compliant qualification.

## Educational Objectives

The aim of this webinar is to provide attendees an overview of the qualification process and its implementation. The following topics will be covered:

- The regulatory landscape in regards to temperature qualification
- The approach to facility qualification using the IQ/OQ/PQ cycle
- How to prepare for the thermal qualification of cold storage and warehousing facilities
- How the process differs with new or existing facilities
- Corrective actions and recommendations for permanent monitoring

## Target Group

This webinar is designed for all managers, supervisors, technical staff, Responsible Persons (RP's) and other employees who are involved in the compliant storage of temperature sensitive pharmaceutical products within a GxP environment. It will be of interest in particular for personnel from the following departments:

- Quality Assurance
- Validation
- Engineering
- Logistics
- Warehousing
- Cold Chain
- Regulatory Compliance

## Speaker



### Kane Edgeworth, Biomap Ltd, UK

Kane Edgeworth is Director at Biomap Ltd, providing temperature validation solutions for the Life Sciences industry.

## Fees (plus VAT)

Single participation: € 249,- for ECA Members

Single participation: € 299,- for non-ECA Members

(This fee does not include the ECA Membership. You will find more about the ECA Membership at <https://www.gmp-compliance.org/about-the-academy>).

## Participation of a Group

You have colleagues who also want to participate in the webinar? Then register yourself and your colleagues as a GROUP! You can view the webinar either together (e.g. in a conference room, etc.) or also each individually on your own PC.

## Group Participation (fee per person):

3-10 Persons € 254,15

11-20 Persons € 224,25

more than 20 Persons € 194,35

## Registration

By mail, fax, e-mail or online on the Internet at <https://www.gmp-compliance.org>. In order to avoid misunderstandings, please indicate the exact address and the full name of the participant. You will receive your access data by e-mail in due time prior to the event.

## Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At <http://www.webex.com/test-meeting.html> you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

## Presentation/Certificate

The presentation will be made available to you prior to the Webinar as a PDF file. After the Webinar, we will automatically send you a certificate of participation.

## Organisation/Contact

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info@concept-heidelberg.de, [www.gmp-navigator.com](http://www.gmp-navigator.com)

## Do you have any questions?

For questions regarding content please contact:

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Email: [funk@concept-heidelberg.de](mailto:funk@concept-heidelberg.de)

For questions regarding organisational aspects please contact:

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## Registration for the GDP Webinar: Temperature Qualification in Storage

on Monday, 30 November 2020, 14.00 – 15.30 h CET

Speaker: Kane Edgeworth

Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

Please tick:

**Single Participation**

**Group Participation**

3-10 Persons

11-20 Persons

more than 20 Persons

**Important:**  
Deadline is 09.00 h on  
30 November 2020

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Title, First Name, Last Name

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Company

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E-Mail (mandatory for your registration)

## General Terms and Conditions

If you cannot attend the conference you have two options:

1. We are happy to welcome a substitute colleague at any time.

2. If you have to cancel entirely we must charge the following processing fees:

Cancellation until 2 weeks prior to the conference 10 %, until 1 week prior to the conference 50 %, within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will

receive a full refund of fees paid.

Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed!)