European Conference on

# SHARING BEST PRACTICES: QUALITY RISK MANAGEMENT, CHANGE CONTROL, VALIDATION AND QUALIFICATION

in Blood Establishments

**17-19 October 2017**

**European Directorate for the Quality of Medicines and HealthCare (EDQM)**

Strasbourg, France

**B-QM Programme**

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# European Conference on SHARING BEST PRACTICES: QUALITY RISK MANAGEMENT, CHANGE CONTROL, VALIDATION AND QUALIFICATION in Blood Establishments

**17-19 October 2017**
Venue: EDQM premises, 7 Allée Kastner, 67081 Strasbourg, France
Working language: English

## BACKGROUND INFORMATION AND OBJECTIVES

Blood transfusion carries intrinsic risks. The implementation of a Quality Management system (QMS) is thus of the utmost importance to manage these risks – ensuring the efficacy, safety and quality of blood components.

The complexity of current quality requirements has led to difficulties for European BEs trying to implement integrated QMSs, especially in the introduction of quality elements such as quality risk management, change management and validation/qualification (three concepts which are intrinsically linked) and their sustainability.

It has been recognised during auditing and inspection schemes that requirements for these elements are subject to interpretation, leading to differing expectations between blood establishments, regulating bodies and inspectors as regards their practical implementation.

While these elements are clearly required by the *EU Blood Directives*, the *Council of Europe Guide to the Preparation, Use and Quality Assurance of blood components* and the recently developed *Good Practice Guidelines (GPG)*, there is currently very little data – and especially little guidance – on "how" these elements have to be followed and "to what extent".

It is worth mentioning that, as from 15 February 2018, the implementation of these elements will become mandatory with the transposition of Commission Directive (EU) 2016/1214 into the national legislation of the European Economic Area (EEA) Member States.

Last but not least, suppliers' and users' duties and responsibilities relating to qualification and/or validation, and especially to acceptance testing, remain currently a grey area. Prompting discussion between blood establishments and suppliers would therefore help to clarify roles and respective expectations.

During this conference, speakers from authorities, inspection bodies, blood establishments and suppliers will provide you with information about the current regulatory requirements and present their knowledge and practical experience in the field of qualification, validation, change management and risk management.

In addition, discussions will aim at clarifying these concepts, delineating their practical implementation and clarifying responsibilities of the different stakeholders.

This event ultimately aims at drafting recommendations to provide the basis for an update of current regulatory standards.

## TARGET AUDIENCE

This conference is designed for:

- Blood Establishments personnel experienced in Change Control, Quality Risk Management, Validation and Qualification
- National, international authorities and inspectors
- Blood establishment suppliers
- Manufacturers of PDMPs

## SPEAKERS

- European Authorities
- National authorities
- Blood Establishments
- Blood establishment suppliers

## HIGHLIGHTS

- Risk Management
- Change Control
- Validation and Qualification
- Good Practice Guidelines (GPG) for Blood Establishments
- Best Practices in Quality Management for Blood establishments

## POSTER SESSION

A poster session on the topics covered by the conference will be organised during the conference.

Call for submission of abstracts to be selected for a poster will be open and reserved for regulatory authorities and blood establishments. Abstracts shall not carry any commercial intent.

Authors should only submit an abstract if they intend to attend the conference.

Instructions for abstract submission and submission deadlines is published on the EDQM conference web-page. Upon the submission deadline, the Organising Scientific Committee will review the abstracts.
The first author will receive a confirmation of acceptance or a notice of rejection by email.

### Abstract topics

- Quality Risk Management
- Change Management
- Validation and Qualification
- Implementation of Good Practice Guidelines (GPG) for Blood Establishments

## DRAFT PROGRAMME

Final Programme – Subject to change

## 17 October 2017 – Plenary Session

### Qualification and Validation

- Key requirements in qualification and validation
- Risk-based qualification and validation
- Users Requirements Specifications (URS) and procurement process
- Critical components of a Validation Master Plan (VMP)
- Documentation for qualification and validation

### Change Control

- Key requirements in change management
- Risk based approach in change management
- Inspecting criteria in change management

### Risk Management

- Key requirements in risk management
- Risk management tools
- Inspecting criteria in risk management

## 18 October 2017 – Parallel workshops

### Risk Management (Workshop 1a)

- Contingency planning in blood establishments
- Managing risks via back-up testing
- Risk-based approach to supplier management

### Serological and NAT assay (Workshop 1b)

- CE marking process
- Example of a national assays pre-validation programme
- Manufacturers' view on the validation extent, FAT and SAT

### Change control (Workshop 2a)

- Implementing a new static collection site
- Change to an automatic testing line
- Change management, inspector's perspective

### Cold chain validation (Workshop 2b)

- Key requirements in cold chain validation
- Blood establishments' experience in cold chain validation
- An example of transport container validation, supplier and blood establishments duties and responsibilities

### Maintenance of a validated state (Workshop 3a)

- Using Statistical Process Control (SPC) to demonstrate that the validated state is maintained – Requirements
- Example of SPC tools in use in a production process
- Inspector's viewpoint on ongoing process verification

### Validation of bacterial testing (Workshop 3b)

- Introduction to bacterial testing systems
- Validation and maintenance of the validated state of a bacterial testing system for labile blood components
- Bacterial testing validation, inspector's perspective

The workshops results will be presented and shared in a plenary session at the end of the afternoon. Time will also be allocated for you to discuss with the authors of the selected posters exhibited throughout the event.

## 19 October 2017 – Post Conference Workshop on the Good Practice Guidelines (GPG)

- GPG, background information, regulatory aspects and revision process
- Introduction to the GPG
- Frequent Asked Questions (FAQs) Session

## REGISTRATION

- The conference is open to up to 100 participants. The link for registration is available on the EDQM website.
- Deadline for registration: 31 May 2017

## REGISTRATION FEES

- Option 1: 70 Euro, Conference and post-conference Worskhop
- Option 2: 120 Euro, Conference and post-conference Worskhop and official dinner (17 October 2017)
- Both fees include all course material, lunch and refreshments. It does not include accommodation and travel expenses.

## ACCOMMODATION

- The EDQM will provide a list of hotel on the Event webpage of www.edqm.eu.
- Lunch & refreshments will be provided throughout the event.

## SOCIAL EVENT - DINNER

- On 17 October 2017, you are cordially invited to a social event. This will be an excellent opportunity to share your experiences with participants in a relaxed atmosphere.

## MORE INFORMATION

- If you have any queries about registering or require further information, please use the HELPDESK via our internet site: www.edqm.eu or email us at drpd@edqm.eu

We look forward to your participation and to welcoming you in Strasbourg

## MEMBERS OF THE ORGANISING COMMITTEE

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