European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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

17-19 October 2017, EDQM Premises, Strasbourg, France

Working language:
English

DETAILED FINAL PROGRAMME

17 OCTOBER 2017 – PLENARY SESSION

8:20-9:00 **REGISTRATION**

9:00-9:10 **Opening and Welcome Address** *S. Keitel, EDQM, Director*

9:10-9:30 **Setting-up the scene** *M-L. Hecquet, EDQM*

QUALIFICATION AND VALIDATION

Moderator: J. Ceulemans
Rapporteur: L. Mitevska

9:30-10:00 **Key issues in qualification and validation – Blood Establishment perspective**
A. Aquilina, B-QM Group Member, EDQM

10:00-10:30 **Risk based approach in qualification and validation**
M. Burgener, SRC, Switzerland

10:30-10:45 ***Coffee Break***

10:45-11:10 **Users Requirement Specifications (URS) and procurement: avoid litigation case**
A. Packham, NHSBT, UK

11:10-11:30 **EuroBloodPack Project, an example of collaborative approach**
H. Evans, NHSBT, UK

11:30-12:00 **Critical components of a Validation Master Plan and Documentation for qualification/validation**
A. Hopkins, MHRA, UK

12:00-12:20 **Questions and Panel Discussion**

12:20-13:40 ***Lunch Break***

17 October 2017 – Plenary Session

CHANGE CONTROL

Moderator: S. Vardy
Rapporteur: M. Van Roosmalen

13:40-14:00 **Key requirements in Change Management**
M. Van Roosmalen, B-QM Group Member, EDQM

14:00-14:20 **Risk based approach in Change Management, BE experience**
S. Vardy, NHSBT, UK

14:20-14:40 **Inspecting Criteria in Change Management/Finding the evidence**
R. Forde, HPRA, Ireland

14:40-15:00 **Questions and Panel Discussion**

15:00-15:15 ☕ ***Coffee Break*** ☕

RISK MANAGEMENT

Moderator: M.L Hecquet
Rapporteur: J. Ceulemans

15:15-15:35 **Risk Management in Quality Management**
A. Aquilina, B-QM Group Member, EDQM

15:35- 15:55 **Risks management tools: Pros and Cons**
M. Amil, Portugal

15:55 -16:15 **Inspecting Criteria in Risk management**
D. Schmidkunz-Eggler, SwissMedic, Switzerland

16:15-16:35 **Questions and Panel Discussion**

16:35-17:30 **POSTER SESSION**

18 OCTOBER 2017 – PARALLEL WORKSHOPS (morning sessions)

	RISK MANAGEMENT Workshop 1a.	SEROLOGICAL/NAT ASSAYS VALIDATION Workshop 1b.
	Moderator: J. Ceulemans/S. Begue **Rapporteur: B. Rothe**	**Moderator: R. Ten Hove** **Rapporteur: M. Pisacka**
9:00-9-20	**Contingency Planning in BEs** *A. Kelly, IBTS, Ireland*	**CE Marking Process** *H. Scheiblauer, PEI, Germany*
9:20-9:40	**Managing risks via back-up testing** *J. Ceulemans, HBRC-Flanders, Belgium & S. Agoston,* Sanquin, *NL*	**Example of a national assays pre-validation programme** *V. Barlet & C. Defer, EFS, France*
9:40-10:00	**Risk based approach to supplier management** *B. Wickens, NHSBT, UK*	**Manufacturers' view on the validation extent, FAT and SAT (30 min)** *N. Dyer, Roche, US*
10:00-10:30	**Risks assessment, a practical example with a PTS non-satisfactory performance with in a TPHA anti-Treponema kit** *M-L. Hecquet, EDQM*	**Validation of NAT system, BE experience (20 min)** *B. Hogema, Sanquin, NL*
10:30-10:50	**Questions and Panel Discussion**	**Questions and Panel Discussion**
10:50-11:05	***Coffee Break***	
	CHANGE CONTROL **Workshop 2a.**	**COLD CHAIN VALIDATION** **Workshop 2b.**
	Moderator:S. Vardy/M. Van Roosmalen **Rapporteur: V. Kiuru**	**Moderator: J. Ceulemans** **Rapporteur: M-L. Hecquet**
11:05-11:25	**Implementing a new static collection site** *M.Van Roosmalen, Sanquin, NL & S. Vardy, NHBST, UK*	**Key requirements in cold chain validation** *B. Rothe/ M-L. Hecquet, B-QM Group, EDQM*
11:25-11:45	**Change to an automation testing line shared by two organisations** *J. Mättö*, *Finnish Red Cross Blood Service, Finland*	**Blood establishments' experience in cold chain validation, example of a transport container** *J. Ceulemans, HBRC-Flanders, Belgium*
11:45-12:05	**Experience of being inspected** *M. Van Roosmalen, Sanquin & S. Vardy, NHBST, UK*	**Cold Chain validation, Inspector's perspective** *A. Hopkins, MHRA, UK*
12:05-12:25	**Questions and Panel Discussion**	**Questions and Panel Discussion**
12:25-13:40	***Lunch Break***	

18 OCTOBER 2017 – PARALLEL WORKSHOPS (afternoon sessions)

	MAINTENANCE OF A VALIDATED STATE Workshop 3a.	VALIDATION OF BACTERIAL TESTING Workshop 3b.
	Moderator: A. Aquilina **Rapporteur: V. Kiuru**	**Moderator: B. Rothe** **Rapporteur: A. Dobrota**
13:40-14:00	**Introduction to SPC and SPC tools in use to maintain the validate state of a process** *D. Le Tallec, EDQM*	**Introduction to bacterial testing systems** *A. Paris, Biomerieux, France*
14:00-14:20	**Using Statistical Process Control (SPC) to demonstrate that the validated state is maintained – Requirements** *G. Sheridan, HPRA, Ireland*	**Validation and maintenance of the validated state of a bacterial testing for labile blood products** *T. Vollmer, HDZ-NRW, Germany*
14:20-14:40	**Sampling plan (title to be confirmed)** *S. Bégué, EFS, France*	**Bacterial testing, inspector's perspective** *M. Prax, PEI, Germany*
14:40-15:40	***Coffee Break*** **POSTER SESSION**	
15:40-16:40	**CLOSING SESSION** : Presentations by Moderators & Discussions on the Workshop conclusions	
16:40-16:50	**CLOSING REMARKS & END OF THE CONFERENCE**	

19 OCTOBER 2017 (morning session)
POST CONFERENCE WORKSHOP ON THE GOOD PRACTICE GUIDELINES (GPG)

Moderator: M-L. Hecquet/G. Rautmann
Rapporteur: M. Van Roosmalen

9:00-9:30	**GPG, background information, regulatory aspects and revision process** *R. MacGeehan, European Commission, DG SANTE (Health & Food Safety) & G. Rautmann, EDQM*
9:30-10:30	**Introduction to the GPG** *D. Schmidkunz-Eggler, SwissMedic - A. Hopkins, MHRA - M-L. Hecquet, EDQM*
10:30-10:45	***Coffee Break***
10:45-11:45	**Frequently Asked Questions (FAQs) Session** *D. Schmidkunz-Eggler, SwissMedic - A. Hopkins, MHRA - M-L. Hecquet, EDQM*
11:45-12:15	**WRAP-UP SESSION**