Maintaining the Quality of Vaccines through the Use of Standards: Current Challenges and Future Opportunities
Library and Archives Canada, Ottawa, Canada
June 21-22, 2023

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Standards are used to ensure the continuous quality of human and veterinary vaccine products. Reference standards can be used in the assignment of vaccine potency, while performance standards are used for instrument calibration.

While the goals for the uses of standards may be clear, the principles and practices associated with these vary. The objective of this meeting is to discuss both technical and regulatory considerations specific to the use of standards in the quality control of human and veterinary vaccines in GMP environment.

This meeting will provide opportunity to clarify a range of issues including terminology such as reference standards versus performance standards; the definition of 'fitness for use' and how to design an effective reference standard program throughout the product life-cycle, including stability, qualification and characterization studies.

A particular emphasis will be placed on the appropriate regulatory oversight and how national regulatory authorities and international standard-setting bodies should coordinate their activities to evaluate the use of standards in the context of Marketing Authorization procedures and ensure the quality of vaccine products against the specifications approved in their Marketing Authorization.

This meeting will bring together regulators, scientists, and industry experts to help resolve existing challenges and to reach consensus that will be valuable in adopting a common approach.

Scientific / Organizing Committee

Maria **BACA-ESTRADA**	Co-Chair ; Health Canada
Carmen **JUNGBÄCK**	Co-Chair; International Alliance for Biological Standardization (IABS), Germany
Ryan **BRADY**	Merck Animal Health, U.S.A.
Tara **DACOSTA**	Canadian Food Inspection Agency
Rick **HILL**	President, International Alliance for Biological Standardization (IABS), U.S.A.
Richard **ISBRUCKER**	World Health Organization (WHO), Switzerland
Laurent **MALLET**	European Directorate for the Quality of Medicines & HealthCare (EDQM), France
Catherine **MILNE**	European Directorate for the Quality of Medicines & HealthCare (EDQM), France
Pieter **NEELS**	International Alliance for Biological Standardization (IABS), Belgium
Tim **SCHOFIELD**	CMC Sciences, LLC, U.S.A.
Dean **SMITH**	Health Canada
Paul **STICKINGS**	National Institute for Biological Standards and Control (NIBSC), United Kingdom
Catrina **STIRLING**	Zoetis, United Kingdom
Sylvie **UHLRICH**	Sanofi, France
Ester **WERNER**	Paul-Ehrlich-Institut (PEI), Germany

DAY 1 – WEDNESDAY, JUNE 21, 2023

8:00 AM Registration & Welcome Coffee

8:40 AM Welcome and introduction to the meeting

Session 1
Use of Reference Standards and Regulatory Expectations

The focus of this session is to introduce the different uses of reference standards, performance standards and controls with the aim of proposing the use of the same terminology throughout this meeting. In addition, the presentations will provide different perspectives and will highlight some of the challenges in the implementation and use of Standards.

Chairpersons:

Sylvie UHLRICH, Sanofi, France
Tim SCHOFIELD, CMC Sciences, LLC, U.S.A.

9:00 AM Introductory presentation (historical perspective including brief overview of terminology)
Catherine MILNE, European Directorate for the Quality of Medicines & HealthCare (EDQM), France

9:30 AM	Development and Implementation of WHO measurement standards for vaccines **TBD**
10:00 AM	Regulatory expectations - veterinary vaccines **Angela WALKER/Geetha B. SRINIVAS**, U.S. Department of agriculture (USDA)
10:30 AM	Break
11:00 AM	Regulatory expectations on the use of vaccine international reference standard for maintaining product quality **Wim VAN MOLLE**; Scienano
11:30 AM	Challenges when assessing multi component vaccine formulations **Paul STICKINGS,** National Institute for Biological Standards and Control (NIBSC), United Kingdom
12:00 PM	World Organisation for Animal Health **TBD**
12:30 PM	Lunch Break
1:30 PM	Manufacturers experience – Human vaccines: Case studies **Geoffrey DUBY**; **Marie-Claire BECKERS**, GSK Vaccines, Belgium
2:00 PM	Panel Discussion

Session 2
Principles and Practices: Technical and Regulatory Expectations

In this session, presenters will describe principles and practices as viewed from a "fitness for use" point of view. They will also highlight the regulatory expectations regarding the design and management of standards programs including the approaches to qualify/calibrate and monitor the stability of standards.

Chairpersons:

Carmen JUNGBÄCK, IABS, Germany
Paul STICKINGS, National Institute for Biological Standards and Control (NIBSC), United Kingdom

2:30 PM	Principles and practices for reference standards **Tim SCHOFIELD,** CMC Sciences, LLC, U.S.A.
3:00 PM	Current approaches in the establishment of International Reference Standards for vaccines **Peter RIGSBY**, National Institute for Biological Standards and Control (NIBSC), United Kingdom
3:30 PM	Break
4:00 PM	Scientific considerations for implementing and maintaining reference standards for the lifecycle management of vaccines

	Tong WU, Health Canada
4:30 PM	Qualification/calibration studies and reference standard stability programs: regulatory expectations: human vaccines **Gayle PULLE**, Health Canada
5:00 PM	US FDA perspective on the use of reference standards to monitor product quality TBD
5:30 PM	End Day 1

DAY 2 – THURSDAY, JUNE 22, 2023

Session 3
Principles and Practices: Industry Practices and Experience

This session will cover manufacturers' approaches to the implementation and standards programs highlighting the challenges and the opportunities to monitor the quality of vaccines throughout the life-cycle. Case studies will be presented to provide insights into some of the current issues and opportunities for improvement.

Chairpersons:

Laurent MALLET, European Directorate for the Quality of Medicines & HealthCare (EDQM), France
Dean SMITH, Health Canada

8:30 AM	Management of reference standards – an overview of the qualification process, stability monitoring practices/requirements, and challenges in the veterinary field **Ryan BRADY**, Merck Animal Health, U.S.A.
9:00 AM	Approach to the design of qualification/calibration studies and reference standard stability programs: manufacturer experience – human vaccines **Manish GAUTAM, Serum Institute of India**
9:30 AM	Manufacturers experience – human vaccines: Case studies **Sylvie UHLRICH, Emmanuelle COPPENS**, Sanofi, France
10:00 AM	Manufacturers experience – veterinary vaccines: Case studies **Catrina STIRLING,** Zoetis, United Kingdom
10:30 AM	Break
11:00 AM	Panel Discussion **Speakers from Session 2 and 3**.
12:00 PM	Lunch Break

Session 4

Breakout sessions:

The purpose of these sessions is to have small groups address the most "burning" issues discussed during the meeting. Groups will be divided into 3 topics: (1) standards programs and regulatory expectations, (2) qualification programs and (3) stability programs.

- 1-hour discussions based on prepared questions
- Facilitators organize discussion and take notes
- Facilitators will report to the whole group during the Workshop Summary and Conclusions.

Chairpersons:

Laurent MALLET, European Directorate for the Quality of Medicines & HealthCare (EDQM), France
Dean SMITH, Health Canada

1:00 PM Breakout groups convene

2:00 PM Break

Session 5
Perspectives from other fields in the use of reference materials

Chairpersons: TBD

2:30 PM The role of International Standards for Monoclonal Antibodies in supporting bioassay data harmonisation: perspectives from the human biotherapeutics field
Sandra PRIOR, National Institute for Biological Standards and Control (NIBSC), United Kingdom

3:00 PM The use of reference materials in the standardization of immunological assays
Valentina BERNASCONI, Coalition for Epidemic Preparedness Innovations (CEPI), United Kingdom

3:30 PM The Future of Reference Standards for Vaccines
Diane McCARTHY, United States Pharmacopeia (USP)

4:00 PM **Summary and Conclusions**

Report back from breakout sessions
Summary and Key items Session 1, 2, 3

Conclusions and Recommendations:

- *Have we achieved the objectives of the meeting?*
- *Do we have consensus on a set of principles and best practices in the development and implementation of standards?*
- *What are the gaps and next steps?*

5:00 PM End of meeting