Companion to the COVID-19 vaccine developers package

EDQM training materials on the European Pharmacopoeia & texts related to vaccines for human use

This document compiles selected EDQM training materials on the European Pharmacopoeia (Ph. Eur.) and on Ph. Eur. texts related to vaccines. It is intended for COVID-19 vaccine developers - many of which are universities and small and medium-sized enterprises - as a companion to the package of pharmacopoeial texts published on Freepub (see "COVID-19 Vaccines Package"). The aim is to fast track their understanding of the Ph. Eur. and show how to apply the relevant texts.

The table provides hyperlinks to presentations and, for each presentation, highlights the content of specific interest for vaccine developers. The list of presentations is not exhaustive and will be reviewed and updated as required.

The presentations were originally given at the February 2020 *EDQM Training Session on Biologicals*, the full content of which is available on the EDQM Training resource webpage.

Presentation	Content includes:
EQDM and the European Pharmacopoeia	
Place and role of EQDM and the Ph. Eur. in the European regulatory framework for medicines	• The EU regulatory framework for pharmaceuticals • EDQM and the European Pharmacopoeia (Ph. Eur.) • Legal status of Ph. Eur. texts
Structure of the Ph. Eur. **General notices, General monographs**	
General concepts in the Ph. Eur.	• Where to start when using the Ph. Eur. • Structure of the Ph. Eur. • General Notices: including flexibility allowed in the Ph. Eur. (alternative methods, waiving of tests, PAT), what does compliance with Ph. Eur. mean, implementation of Ph. Eur. methods by users • General monographs *Substances for pharmaceutical use* (2034) & *Pharmaceutical preparations* (2619) • General texts and chapters vs monographs
Vaccines	
Vaccines for human use in the Ph. Eur.	• Overview of Ph. Eur. standards for vaccines • General chapters supporting vaccine monographs: *Cell substrates for the production of vaccines for human use* (5.2.3), *Tests for extraneous agents in viral vaccines for human use* (2.6.16)

	• General monograph *Vaccines for human use* (0153) • Individual vaccine monographs • Monographs on adjuvants • Technical guide on vaccine monographs* • Reference standards supporting vaccine monographs • Alternatives to Animal Testing: 3Rs in pharmacopoeial testing, recent 3Rs achievement in the Ph. Eur. for vaccines
*** Important note:** the "*Guide for the elaboration and use of monographs on vaccines and immunosera for human use*" is accessible here. This document provides guidance to authors, contributors and users of the Ph. Eur. on the elaboration of monographs for vaccines. It contains information that may help Ph. Eur. users better understand the requirements and structure of these monographs.	
Microbiology	
Microbiology chapters (1/2)	• Sterility test (2.6.1) • Efficacy of antimicrobial preservation (5.1.3) • Viral safety (5.1.7) • TSE safety (5.2.8)
Microbiology chapters (2/2)	• Endotoxin testing: Test for bacterial endotoxins (2.6.14 & 5.1.10), recombinant Factor C • Pyrogen testing
How to interact with the EDQM	
Ph. Eur. online, Knowledge database & Pharmeuropa	• Online version of the Ph. Eur. • Knowledge database (database providing additional information on monographs) • Pharmeuropa (forum for texts under public enquiry)
How to participate in the elaboration and revision of Ph. Eur. texts	• Basis for monographs • Elaboration and revision of Ph. Eur. texts • Proposing a new text, requesting the revision of an existing text • Procedures for elaboration and revision of Ph. Eur. texts (groups of experts and working parties, how to comment, adoption)