Is a certificate of suitability equivalent to a GMP certificate?

Answer:

A certificate of suitability (CEP) is intended to demonstrate that the quality of a given substance can be suitably controlled by the relevant Ph. Eur. monograph(s), with additional tests if necessary (stated on the CEP), and is based on the assessment of a dossier submitted by the applicant.

The manufacturer has to confirm that the substance in question is produced according to GMP requirements; this is an integral part of the CEP application. However, the evaluation of the dossier does not evaluate GMP compliance. A certificate of suitability therefore cannot indicate GMP compliance: it is neither equivalent to a GMP certificate nor does it replace it.

As a complementary part to dossier evaluation, the CEP procedure includes the possibility of GMP inspections of sites involved in the manufacture of the respective substance. In line with EU legislation, the selection of sites to be inspected is based on a risk assessment, which means that there is no routine inspection of all sites. Consequently, a CEP may be granted with or without an inspection of the manufacturing site being performed.

A GMP certificate is granted by EU/EEA national competent authorities after an inspection (with or without the participation of the EDQM). The EDQM itself does not issue a GMP certificate after an inspection, but issues an inspection attestation.