Which GMPs should apply to the sterilisation step of a substance?

Answer:

The introduction to Volume 4, Part II of the rules governing medicinal products in the EU (‘Basic Requirements for Active Substances used as Starting Materials’), which replicate the ICH Q7 guideline, states that the guidelines ‘apply to the manufacture of active substances for medicinal products for both human and veterinary use. They apply to the manufacture of sterile active substances only up to the point immediately prior to the active substances being rendered sterile. The sterilisation and aseptic processing of sterile active substances are not covered, but should be performed in accordance with the principles and guidelines of GMP as laid down in Directive 2003/94/EC and interpreted in the GMP Guide including its Annex 1.’