PHARMACOPOEIAL DISCUSSION GROUP

Q11

STERILITY REV. 1

It is understood that sign-off covers the technical content of the draft and each party will adapt it as necessary to conform to the usual presentation of the pharmacopoeia in question; such adaptation includes stipulation of the particular pharmacopoeia’s reference materials and general chapters.

European Pharmacopoeia
Signature       Name       Date

[Signature]       [Name]       [Date]

Japanese Pharmacopoeia
Signature       Name       Date

[Signature]       [Name]       [Date]

United States Pharmacopeia
Signature       Name       Date

[Signature]       [Name]       [Date]

Local requirements

Local requirements
• In the section on « Test for sterility of the product to be examined », USP will add a paragraph on « Number of articles to be tested ».
• USP will add a requirements for testing of for pharmacy bulk packages (this includes description of media for penicillins and cephalosporins; use of alternative micro-organisms to the those indicated in Table 1; description of additional diluting and rinsing fluids for membrane filtration)
• USP will add requirements for medical devices in Table 2