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
		30/10/2007

Japanese Pharmacopoeia

Signature	Name	Date
for	Toshiro Nakagaki	Oct 30, 2007

United States Pharmacopeia

Signature	Name	Date
		30 Oct, 2007

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