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
	LEI TEL	30.10.2007

Japanese Pharmacopoeia

Signature	Name	Date
Kiyoshi Ono for	Toshiro Nakagaki	Oct 30.2007

United States Pharmacopeia

Signature	Name	Date
	DARRELL R. HERRONEY	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