

# 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

 LEITEL 30.10.2007

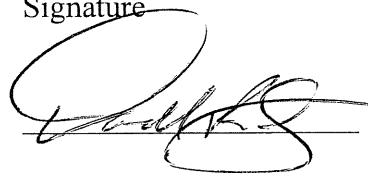
#### Japanese Pharmacopoeia

Signature Name Date

Hiyoshi for Toshiko Nakagaki Oct 30.2007

#### United States Pharmacopoeia

Signature Name Date

 DARRELL 30 Oct 2007  
ASERNEY

#### 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