

Draft Guideline
Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria (RAAPAC)

[Docket No. 2006D-0297]

ICH Topic Q4B

June 2006

Pfizer Comments – September 28, 2006

<u>Key Philosophical or Strategy Issues</u>
<p>Pfizer understands the RAAPAC guideline creates an umbrella document for EP, USP, and JP to achieve harmonization in a more organized manner, which is an excellent concept. It will lead to more harmonized monographs and general chapters. Pfizer believes that mutual recognition by the regulators of the three pharmacopoeias is in line with the philosophy of risk management.</p>

<u>Reference</u>	<u>Relative Importance</u> C=critical M= minor	<u>Key Concerns with Explanation of Position</u>	<u>Proposed change</u>
Title	C	Do not use RAAPAC as abbreviation as it has shown to create interpretation issues in some areas of the world.	Change title to “Regulatory Acceptance of APAC.”
Scope	M	It is stated that regulatory agencies can choose to accept non-PDG text. This could affect labeling if a product is currently labeled EP, USP, or JP.	No change. Comment is to raise awareness.
Figure I	M	Reference is made to regional implementation and inter-regional acceptance, but not reference is made to national interpretation and implementation.	It is our understanding that national interpretation and implementation will be identical and at the same time as the regional implementation.