

Quality Standards for Medicines, Supplements, and Food Ingredients throughout the World

# Track on Reference Standards

## IPC-USP Annual Science Meeting

 U.S. PHARMACOPEIA  
*The Standard of Quality<sup>SM</sup>*

# Speakers and Topics

Speaker	Presentation Title
William Koch, USP	Measurement Science and Certified Reference Materials
S.K. Gupta, ICRI	Reference Standards and Clinical Research
Raman Singh, IPC	IPC Monograph Development Update



# What We Said

- All measurements are comparisons.
- Quality of comparators (ie, reference standards) define or limit the quality of measurements.
- Uncertainty is associated with all measurements and reference standards used therein.
- Choice of reference standards for clinical trials, including reference drug products, is critical.
- IPC is developing capabilities to provide reference standards.



# What We Heard

- USP aims to develop a monograph and reference standard for every medicine, food, and dietary supplement in global commerce.
- India is rapidly growing into a global leader in conduction of clinical trials, requiring availability of good reference standards//products.
- IPC added 73 new monographs in 2008 (currently 1623 monographs).



# What We Do

- Understand, don't underestimate, potential for bias and variability in measurement.
- Develop best possible standards for clinical trials, diagnostic measurements, compendial tests.
- Collaborate between IPC/USP/industry.





QUALITY STANDARDS FOR MEDICINES, SUPPLEMENTS, AND FOOD INGREDIENTS THROUGHOUT THE WORLD

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Thank you!

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