



# Pan American Network for Drug Regulatory Harmonization

## Pharmacopeias Working Group

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II Steering Committee Meeting

March 23, 2001

Orlando, Florida



# Pharmacopeias Working Group

USP  
FEUM  
Brazil Ph.  
Argentine Ph.

Coordinator  
USP

Workplan

Information

Monographs

Training

Ref. Standards

Meetings



# What do Pharmacopeias do?

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Pharmacopeias establish officially recognized standards of quality, strength, purity, packaging and labeling for medications and other health care products.



## PHARMACOPEIAS ACTIVE IN THE AMERICAS

Title	ARGENTINA Farmacopea Nacional Argentina	BRAZIL Famacopea Brasileira		MEXICO Farmacopea de los Estados Unidos Mexicanos	USA The United States Pharmacopeia; The National Formulary
		3 <sup>rd</sup> Edition	4 <sup>th</sup> Edition		
# of Monographs	804	481	364	1210	3873
# of General Chapters	79	50	256	129	170
Mechanism for Public Comments	Internet	Diario Oficial	Internet	“Consult to the Industry”, document for final users; forms and letters from other interested parties.	Pharmacopeial Forum
Reference Standards	43	0	0	134	1675



# Why a PWG

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- Free Trade Area of the Americas
  - reduced trade barriers
  - regulatory harmonization
- Global harmonization
- Resource limitations



# Pharmacopeial Harmonization

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- A pharmacopeial general chapter or other pharmacopeial document is harmonized when a pharmaceutical substance or product tested by the procedure yields the same results, and the same accept/reject decision is reached
- Goal: Pharmacopeia of the Americas



# Meetings

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- Washington, April 14, 2000
- Sao Paulo, May 1, 2000
- Porto Alegre, August 1, 2000
- Orlando, March 26, 2001



# PWG Workplan

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- Information sharing
  - meetings
  - publications
  - other activities
- Training
- Monograph development
- Botanicals
- Reference standards



# PWG Workplan

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- Industry/pharmacopeia meetings
- Expert committees
  - exchange expertise
- PDG/ICH
  - PWG participation



# Bilateral Cooperation

“Adopt and adapt” agreements

Argentina and Brazil

India (pending)

Memorandum of Understanding  
Mexico



# FEUM/USP Collaboration

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- Exchange of staff
- Exchange of monographs
- Workshop: Role of Pharmacopeias and Drug Quality
- Annual policy-level meeting



# PAHO/USP Cooperation in Drug Quality

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- Diagnostic Studies of Official Drug control Laboratories
- External Quality Control Program
- Dissolution Testing Courses
- Good Laboratory Practices Seminar
- Drug Procurement and Quality Workshop



# Pharmacopeial Discussion Group

## PDG

European Pharmacopoeia

Japanese Pharmacopoeia

United States Pharmacopeia



**Thank you**  
**Muchas gracias**  
**Muito obrigado**