“PRIVATE” VS. “PUBLIC” QUALITY OVERSIGHT

Quality Systems approach

- Regulatory oversight
- Voluntary Actions (recalls, etc.)
- Supply chain & complaints system
- Quality Systems
- cGMPs including QC
- Registered details

Traditional Quality Oversight Framework Including Private and Public Laboratory Testing

- Quality Assurance
- Import Testing
- Sampling on the market
- Actions as needed
- Lot Release
- Local Quality Assurance
- Quality Testing
- Release to market
- Local Responsible Person
- Quality Surveillance

Governmental / Public Laboratories

Agreed Specifications (incl. Pharmacopeia chapters and monographs)
PUBLIC QUALITY CONTROL TESTING OF PHARMACEUTICALS
SESSION AGENDA

• **Import Testing - Opportunities for Improved Access to Safe and Efficient Medicines**
  Maria Guazzaroni Jacobs, Pfizer Inc., on behalf of IFPMA

• **Local Re-Testing - The Regulator’s Perspective**
  Q.F.B Iván Valentín Cruz Barrera, COFEPRIS

• **The Mexican Pharmacopeia (FEUM) as a Standard for Pharmaceutical Products**
  Q.F.B Rafael Hernández Medina, COFEPRIS

• **Panel Discussion**
  – Dra. Sonia Mayra Pérez Tapia, UDIMEB, México
  – Teresa Olivo Rosales, Eli Lilly y Compañía de México S.A. de C.V., México
  – Maria Guazzaroni Jacobs, Pfizer Inc.
  – Q.F.B. Iván Valentín Cruz Barrera, COFEPRIS
  – Q.F.B. Rafael Hernández Medina, COFEPRIS