LATIN AMERICAN FEDERATION OF THE PHARMACEUTICAL INDUSTRY

FIFARMA

FEDERACIÓN LATINOAMERICANA DE LA INDUSTRIA FARMACÉUTICA

Recommendations for Regional and Global Harmonization for Biotherapeutic Products

Dr. Thomas Schreitmueller
VII PANDRH Conference, 7-9. Sep., Ottawa, Canada



One World

One Regulatory Standard


Important steps have been
made but many more to go

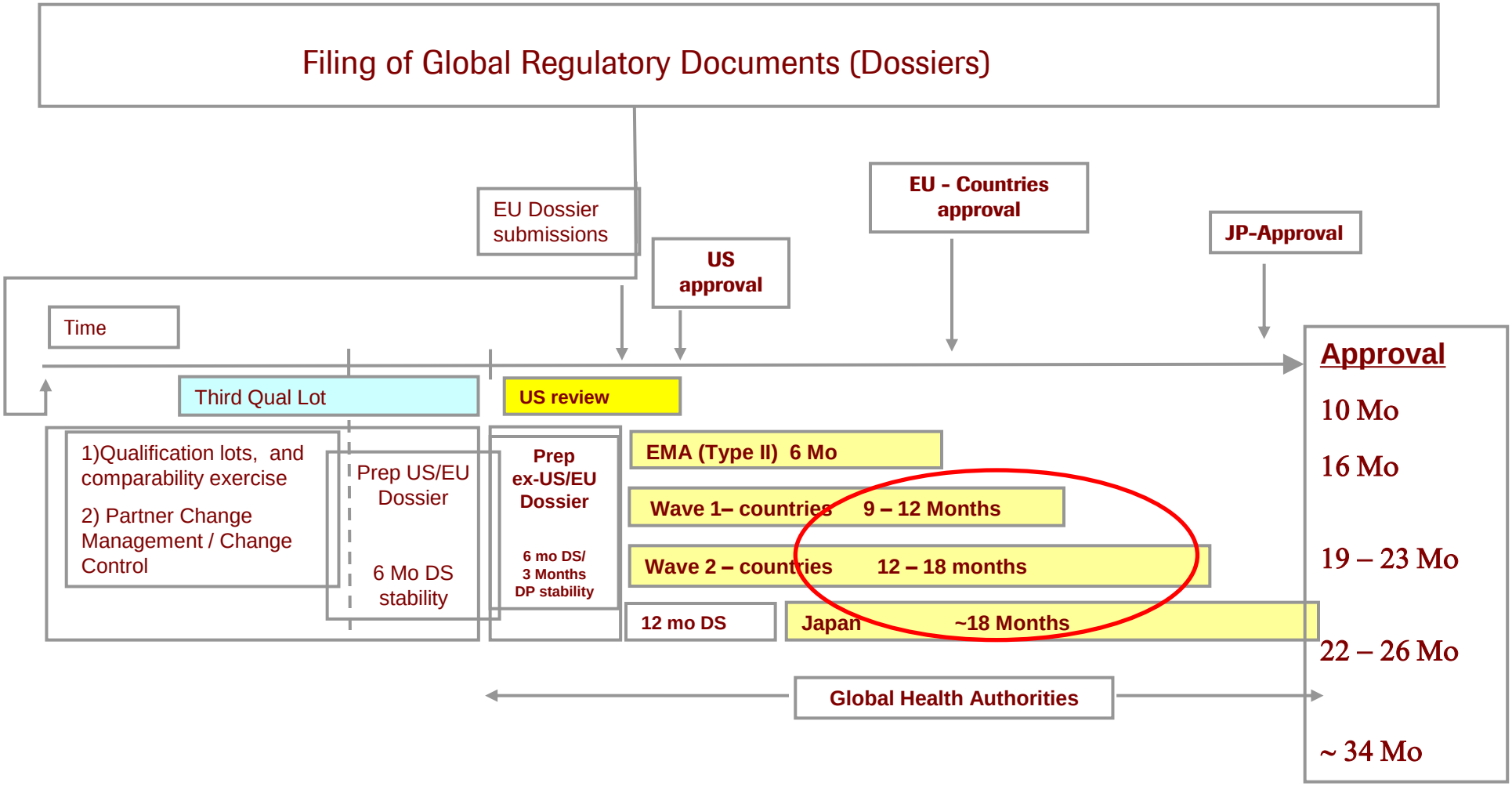
Recent landmarks/efforts for global/regional regulatory convergence (focus biothearpeutics)

- ICH guidelines
- The WHO guidelines for SBPs and rDNA products
- PANDRH technical reports
- ASEAN guidelines

What are topics WHO/PAHO should engage to foster/encourage regional and global harmonization

- Encourage the adoption ICH prinicples/guidelines relevant for biotech products and (pre-)clinical studies
- Establish guidelines for post -approval changes including change classification, data requirements and timelines (focus biotherapeutic products)
- Re-discuss purpose/use of CPPs for new registrations and certain technical changes

Making changes globally is complex and lengthy *(Biologics Example)*



Will take 3 years and more for global approval of a process process change!

What are topics WHO/PAHO should engage to foster/encourage regional and global harmonization

- Develop recommendations/agreements on
  - Removal of redundant in-country testing requirements
  - Mutual recognition of GMP inspections
  - Transparency of regulatory desicions

- Engange in NRA capacity/training issues recognized
  - Encourage trainings and leaverage more industry experience
  - Encourage common reviews of regulatory dossiers
  - Prepare «living» Q&A documents accompanying global/regional guidelines/recommendations
  - Participate and engage more in regional conferences

Thank You !