財團法人醫藥品查驗中心
Center for Drug Evaluation

Regulatory Science,
Service for Life

Transparency and Interaction with Regulatory Authorities

Herng-Der Chern, M.D., Ph.D.
Distinguished Research Fellow
Center for Drug Evaluation, Chinese Taipei

Benefits of "Sharing Assessment Report" in Drug and Device from CIRS APEC Survey

- Better understanding of review process,
- Promote collaboration,
- Could save/reduce resources
- Channels to information exchange
- Enhanced robustness of review due to additional perspectives,
- Greater efficiency in instances where issues of concern have already been addressed.
- Building familiarity, confidence and trust in another agency's reports, a prerequisite to work sharing.
- Facilitate correct understanding about opinions/considerations of other regulatory agencies
- To know more about the same process in other places
- Transparency

Hurdles of "Sharing Assessment Report" in Drug and Device from CIRS APEC Survey

- Lack of Confidentiality arrangements
- Slowdown of assessors experience
- Difference in review system, standards and depth of review
- Timing of review based on submission of application
- Language differences
- Need for translation
- Political issues
- Process may require to much time
- Co worker resistance

Some Highlights from TFDA

- "Clinical Trial Notification" (CTN) Scheme for IND since Aug., 2010
- Stratified regulatory pathways for NDA since Mar, 2011
- Join Pharmaceutical Inspection Co-operation Scheme (PIC/S) since Oct., 2012
- Cross Strait Cooperation Agreement on Medicine and Public Health Affairs signed in Dec., 2010

Jan.~Sep., 2012 Expedited IND Approval – Clinical Trial Notification (CTN) Scheme

- Trials conducted in medical centers of Taiwan as part of Multi-Regional Clinical Trials with same approved protocols by one of 10 referencing regulatory agencies.
- 22% (39/176) of IND, ↑ efficiency and predictability with average 13.2 calendar days (vs. non-CTN 39.9 days review time plus 2-4 weeks of sponsor time)
- ↑ phase II trials (from 26% to 36%)
- ↑ total number of IND (184 for 2011 vs. 176 up to Q3, 2012)

Abbreviated Review for NDA with EMA/FDA Approval

- Sponsor needs to provide full dossiers and the assessment reports by EMA and FDA
- Review focusing on CMC, PK-PD (ethnic sensitivity related issue, proper posology), and Clinical studies
- Reducing target review time by 1/3 with less sponsor time expected too.

PIC/S

- Cooperation in GMP related inspection, information sharing, training, standard/procedure harmonization, member qualification
- Not a trade agreement but can facilitate other agreements (MOU/MRA) in reducing duplication of inspections
- Members in APEC: Australia, Canada, Chinese Taipei (Effective on Jan. 1, 2013), Indonesia, Malaysia, New Zealand (Effective on Jan. 1, 2013), Singapore, US

Cross Strait Cooperation Agreement on Medicine and Public Health Affairs

- Being effective on June 26, 2011, by the Strait Exchange Foundation (Taiwan) and Association for Relation Across the Taiwan Strait (Mainland China)

http://www.cde.org.tw/SubLink/CSCA/cross_strait_Cooperation_Agreement.pdf

Chapter 3: Safety Administration and Research and Development of Medicinal Products

Article 10. Scope of Cooperation

The term “medicinal product(s)” in this Agreement refers to pharmaceutical products, medical devices, health food, and cosmetics, but not including traditional Chinese medicinal materials. Both Parties agree to engage in cross-strait exchanges and cooperation in regulations, technical standards, testing techniques and other relevant matters for non-clinical safety evaluation, clinical trials, pre-marketing approval, manufacturing administration, and post-marketing administration, among others.

Cross Strait Cooperation Agreement on Medicine and Public Health Affairs

Chapter 3: Safety Administration and Research and Development of Medicinal Products

Article 13. Coordination on Standards and Regulations

Both Parties agree to strengthen the cooperation and to actively promote the harmonization or coordination of mutual technical standards and regulations under the universally recognized standards for the safety administration of medicinal products (such as ICH and GHTF, among others), so as to enhance the safety and efficacy of medicinal products.

There will be cooperation in testing, registration, inspection, and regulated manufacturing administration, so as to explore the progressive adoption of implementation results of the other Party on the basis of the above provision.

Cross Strait Cooperation Agreement on Medicine and Public Health Affairs

Chapter 3: Safety Administration and Research and Development of Medicinal Products

Article 14. Cooperation in Clinical Trials

Concerning clinical trials, both Parties agree to engage in exchange and cooperation in the relevant regulations, the management of institute(s) for implementation and executing teams, the protection of human subjects' rights, and the review and approval of the protocols and trial results, among others in matters. For the purpose of reducing repetition of clinical trials, specifically approved institutes and trial projects conforming to the guidelines for Good Clinical Practice (GCP) will be put into operation first so as to positively promote cross-strait cooperation in clinical trials and research and development for medicinal products. Based on this, there will be review of the progressive recognition and acceptance of the trial results of both Parties.

Pilot Study for APEC Pharmaceutical Evaluation Report (PER) Scheme

- Show some interest from different stakeholders
- Premature to promote it unless there are some leadership from major RAs or associations

Future Recommendation

- APEC GRevP survey of CIRS is a good reference for RAs interaction
- APEC PER Scheme is a long term goal taking the experience from previous PER Scheme (1975-2000) and current PIC/S
- Regulatory convergence through APEC GRevP Roadmap

Regulatory Science, Service for Life