ICH and Singapore

Dr Christina Lim
Deputy Group Director, Health Product Regulation Group
Senior Advisor, International Collaboration
Health Sciences Authority
Singapore

November 2008
Overview

• Health Science Authority

• Implementation of ICH guideline in Singapore

• Singapore’s experience
Health Products Regulation

Applied Sciences

Blood Services
Our Mission

➢ To safeguard public health
➢ To wisely regulate health products
Key Functional Areas of Health Products Regulation

HPR Group

Strategy & Policy Devt

HSA

Pre-market

Clinical Trials

Product Evaluation & Registration

Manufacturing & Quality Audit

Pharmacovigilance, Research & Communications

Enforcement & Prosecution

Post-market

Medicinal Product

Medical Devices

Chinese Proprietary Medicines
Why Singapore follows ICH guidelines?

• To leverage on expertise of the developed regulatory agencies

• To keep abreast with international best practice in regulatory science

• To enable Singapore to be an international player in multi-centers pharmaceutical research and development

• To facilitate timely available of medicine
ICH and Drug Evaluation & Registration

- ICH guidelines have been used by Singapore in drug evaluation and registration since their launch

- Use of the guidelines increase as the drug registration system matures
Drug Registration System and Standards: Development Over the Years

- **1987**: Implementation Phase
  - Implementation of DR system

- **1991**: Strengthening Phase
  - Strengthening of DR requirements
  - Strengthening of drug evaluation capabilities
  - Enhancing flexibility, clarity and robustness of DR process
  - Increasing communication between MOH/HSA and stakeholders
  - Enhancing strategic alliances and leveraging on work done by mature and developed agencies

- **2004**: Harmonisation Phase
  - Implementation of Quality Medicines Harmonisation Programme
  - Ongoing efforts to strengthen capabilities, communication with stakeholders and strategic alliances

HSA formed in April 2001
Pre-Market Assessment

• Risk-based and Confidence-based Approach
  ➤ To ensure Safety, Efficacy and Quality
  ➤ Application of international scientific standards and guidelines including ICH guidelines
  ➤ Inherent risk of product (ingredient, route of administration, etc)
  ➤ Confidence based on prior approval by reference agencies

• Enhanced efficiency by
  ➤ Leveraging on evaluations conducted by reference agencies
Drug Evaluation

• Since the late 1990s, relevant ICH guidelines have been used in drug evaluation
  ► Quality
  ► Safety
  ► Efficacy
Dossier Submission

• ICH CTD format was first rolled out at end 2003

• Dossier submission in both ICH CTD or ASEAN CTD format are acceptable

• Presently
  ➤ 53% of dossiers are submitted in ICH format
  ➤ Multinational companies are the major users of ICH format
CTD

Applicable to all new or generic drug applications

ICH CTD
Module 1: Administrative
Module 2: Overview & overall summaries
Module 3: Quality
Module 4: Non-clinical
Module 5: Clinical

ASEAN CTD
Part I: Administrative
Part II: Quality
Part III: Non-clinical
Part IV: Clinical

Acceptable format: ACTD or ICH CTD (innovative products)
Dossier must conform with chosen format and documentary requirements
Experiences till date…

- Some generic drug companies have some problems fulfilling the requirement of ICH
  - Inability to obtain complete information on API
  - Financial issues leading to
    - Inability to provide all the milestones in accordance with ICH recommendation for stability study
    - Limited resources and knowledge in performing the full range of test requirements to ensure reproducibility and reliability
    - Minimal checking for identity and impurities
    - Fewer specification conducted test procedure
ICH and Clinical Trial

- Singapore’s guideline for Good Clinical Practice was adopted from ICH E6: Good Clinical Practice: Consolidated Guideline in 1998
- Singapore’s guideline for GCP include Singapore’s specific administrative requirement
  - Submission to Medical Clinical Research Committee
Experiences till date…

• Need to work with local investigators to fulfill the Singapore GCP guidelines
Future Challenges

• Maintain effective communication with industry and investigator
  ► Appropriate education on the requirements
  ► Consultation meeting

• Assist company and investigator to meet the minimum requirement