

ICH and Singapore

Dr Christina Lim

Deputy Group Director, Health Product Regulation Group

Senior Advisor, International Collaboration

Health Sciences Authority • To be the leading authority in Singapore, advancing national health and safety

*Health Sciences Authority
Singapore*

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Overview



- Health Science Authority
- Implementation of ICH guideline in Singapore
- Singapore's experience



Health Products Regulation

Applied Sciences



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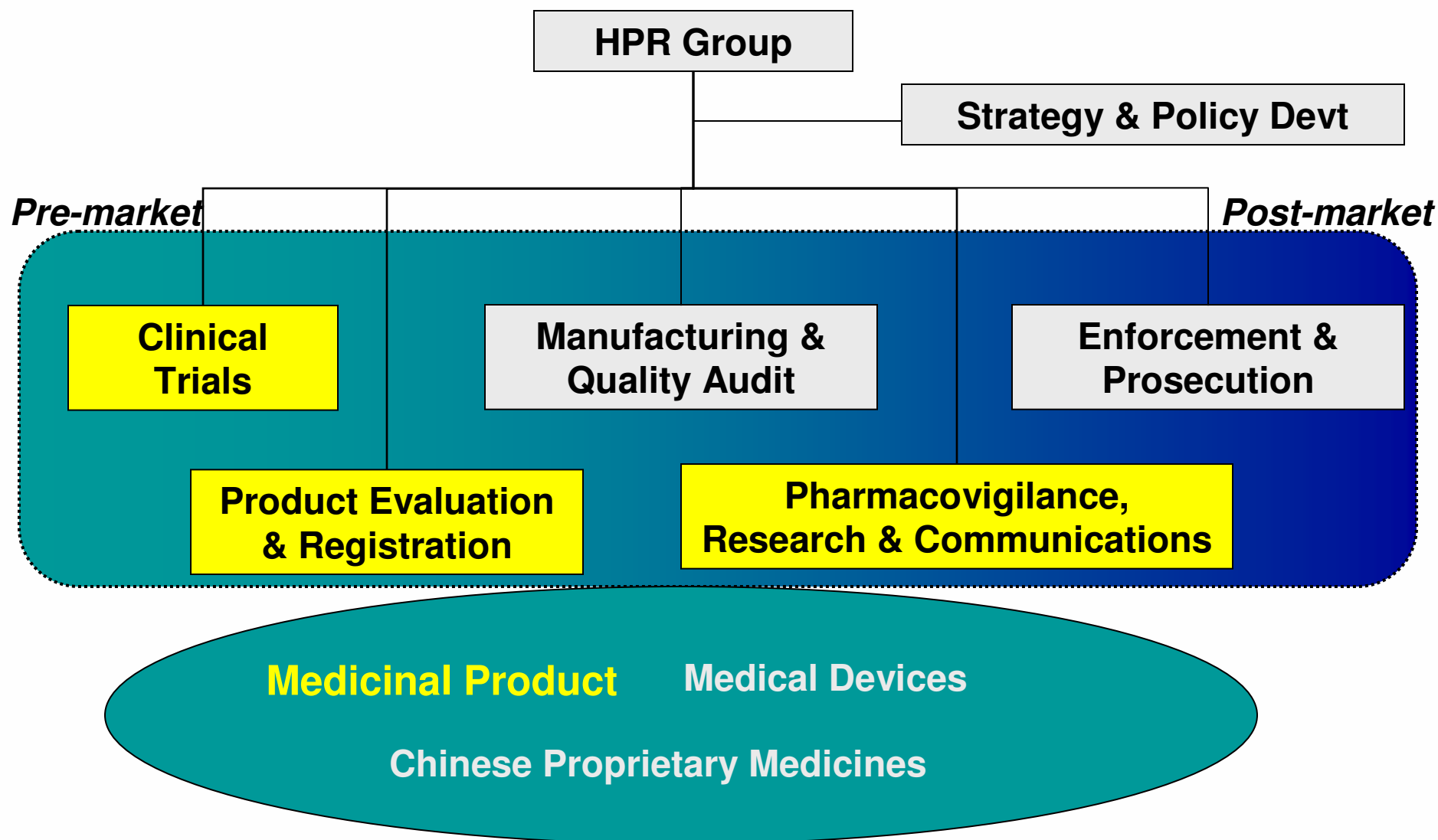
Blood Services

Our Mission



- **To safeguard public health**
- **To wisely regulate health products**

Key Functional Areas of Health Products Regulation



Why Singapore follows ICH guidelines?



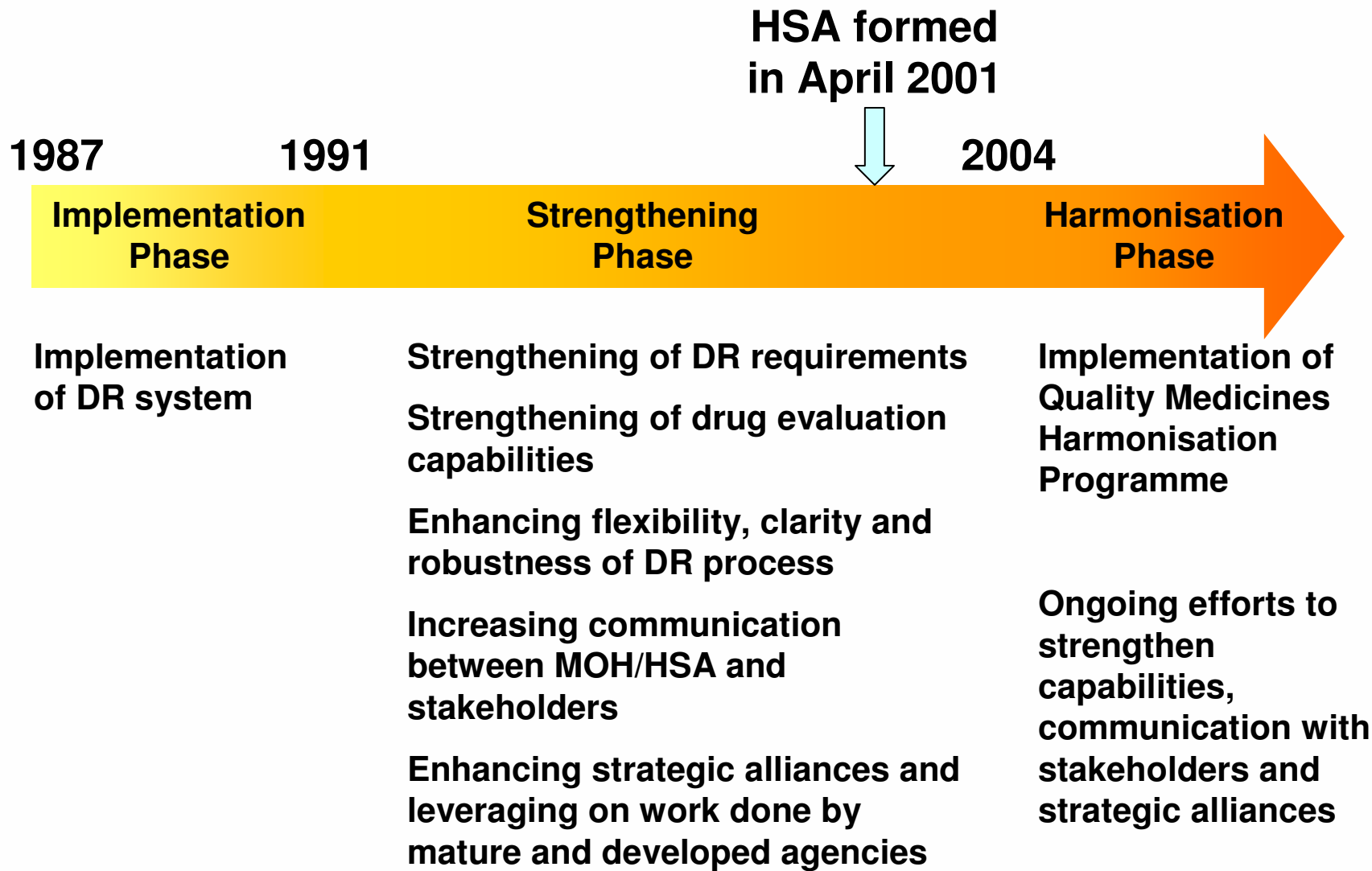
- To leverage on expertise of the developed regulatory agencies
- To keep abreast with international best practice in regulatory science
- To enable Singapore to be an international player in multi-centers pharmaceutical research and development
- To facilitate timely available of medicine

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



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