Good Manufacturing Practice (GMP) Inspection Reliance in Singapore

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The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of HSA/Singapore

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01 Singapore At a Glance

Overview of Singapore's Pharmaceutical Manufacturing Landscape

Diverse Range of Products

Singapore's deep base of skilled talents and strong manufacturing capabilities have drawn several top pharmaceutical companies such as GlaxoSmithKline, Novartis, Pfizer, Lonza, Merck Sharp & Dohme, Amgen, AbbVie, Roche, Wuxi Biologics and Takeda to set up manufacturing facilities in Singapore.

Manufacture a range of products, including:

- Therapeutic Products (TP) *(Chemical and biological)*
- Active Pharmaceutical Ingredients (API)
- Cell, Tissue and Gene Therapy Products (CTGTP)

01 Singapore at a Glance

Safeguarding Public Health Through GMP Inspections

- HSA conducts regular inspections of all local pharmaceutical manufacturers to ensure that licensed manufacturers comply with international GMP standards.
- As a Pharmaceutical Inspection Co-operation Scheme (PIC/S) Participating Authority, HSA enforces GMP standards that align with PIC/S GMP Guides, signifying our commitment to uphold internationally recognized standards for the quality and safety of pharmaceutical products

Dispensing →

Processing →

Filling →

Packaging

01 Singapore at a Glance

Pharmaceutical Inspection Co-operation (PIC/S) Participating Authority

PIC/S is an international organization that facilitates non-binding and informal co-operation and networking between regulatory authorities and regional/international organizations in the field of GMP of medicinal products for human or veterinary use.

Membership in PIC/S facilitates the export of pharmaceuticals as regulatory authorities have a greater confidence in medicines manufactured in countries that are PIC/S participating authorities.

HSA acceded to PIC/S in Jan 2000. Participates actively in technical working groups and sub-committees, including being elected as PIC/S Chair from 2018-2019

Being a PIC/S participating authority sets the basis for Singapore to work with other overseas Regulatory Authorities on GMP inspection recognition and reliance.

02 Mutual Recognition Agreement (MRA)

Introduction

MRA is negotiated as part of Free Trade Agreement (FTA) between respective governments

- Internationally binding agreements between countries to reduce technical barriers and to facilitate trade & market access
- Facilitate the acceptance of conformity assessment results, such as inspection or certification, conducted by the regulatory authority

02 Benefits of GMP Inspection Reliance

Benefits of GMP Inspection Reliance

Formal GMP MRAs and collaborations on GMP inspection reliance reduce duplication of GMP inspections of pharmaceutical manufacturing sites and allows more efficient use of each party's resources where most needed.

- Regulators can focus limited resources on higher risk areas
- Manufacturers will not be subjected to duplicate inspections, focusing resources in critical processes
- Streamline and facilitate process for export of pharmaceutical products
- Benefits patients through faster access to medicines

02 Mutual Recognition Agreement (MRA)

Singapore's MRA Partners for GMP Inspection Recognition

Singapore and Australia formalized the Singapore-Australia Sectoral MRA for medicinal products

Feb 2001
Australia

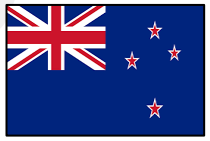
ASEAN Sectoral on MRA for GMP inspection of manufacturers of medicinal products was adopted by all member states

Apr 2009
Association of Southeast Asian Nations (ASEAN)

ASSOCIATION OF SOUTHEAST ASIAN NATIONS

Singapore and New Zealand signed a MRA on GMP inspection of medicinal products under ANZSCEP

May 2019
New Zealand



Singapore and South Korea signed a MRA on the establishment of requirements for GMP for Medicinal Products

Feb 2024
Republic of South Korea

02 Mutual Recognition Agreement (MRA)

APAC
Asia Partnership Conference of Pharmaceutical Associations

Singapore-Republic of South Korea

2010

Singapore's Health Sciences Authority and the then Korea Food & Drug Administration signing Memorandum of Understanding.

2010 Jun

2019

Singapore and the South Korea signed another Memorandum of Understanding for GMP Collaboration

2019 Nov

2020

1-year pilot project initiated to establish mutual confidence in each party's GMP inspection regulatory framework

2020 Aug

2022

HSA and MFDA together with the respective Trade Ministries held discussions to commence the MRA Sectoral Annex drafting process

2022 Jun

2024

MRA Sectoral Annex was officially signed.

2024 Feb

02 Mutual Recognition Agreement (MRA)

Singapore-Republic of South Korea

Pilot Project

- Duration: 01 August 2020 to 31 July 2021 (1 year pilot project)
- Worked towards an MRA on GMP inspection based on MOU signed in 2019
- Establishing confidence on the GMP inspection process and affirmed the equivalency of the GMP regulatory framework as PIC/S Participating Authorities.
- Mutual exchange and review of GMP certificates and inspection reports of selected manufacturing sites located in both countries, with additional information and clarification on these documents, where needed
- This enabled both parties to better understand each other's GMP inspection framework and capabilities

02 Mutual Recognition Agreement (MRA)

Singapore-Republic of South Korea

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02 Mutual Recognition Agreement (MRA)

Singapore-Republic of South Korea

The Sectoral Annex was officially signed by Dr Mimi CHOONG, then-CEO, HSA and Dr Yu-Kyoung OH, Minister of MFDS, on 26 February 24

02 Mutual Recognition Agreement (MRA)

Singapore-Republic of South Korea

- The MRA enables the mutual recognition of GMP inspection and outcomes for the manufacture of investigational medicinal products, active pharmaceutical ingredients, chemical pharmaceuticals, biopharmaceuticals (including biologicals) and herbal medicinal products
- It also facilitates the exchange of information between Singapore and Korea on GMP compliance (e.g., GMP inspection reports)
- Since the signing of the Mutual Recognition Agreement (MRA) in February 2024, five manufacturers in Korea were approved in Singapore via GMP documentary evidence without the need for on-site inspection.

03 Access Consortium

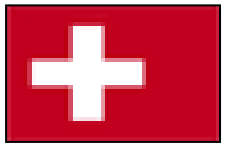
How Access Consortium was formed

Coalition of like-minded medium-sized regulatory authorities

Therapeutic Goods Administration, Australia

Health Canada, Canada

Health Sciences Authority, Singapore



Swissmedic, Swiss Agency for Therapeutic Products, Switzerland

Medicines and Healthcare products Regulatory Agency, United Kingdom

03 Access Consortium

Strategic Plan 2025-2028

Vision

To provide **faster access** to safe, effective and high-quality medicines for all our populations.

Strategic Objectives

- Strengthening Access Work-sharing Initiatives
- Expanding Lifecycle Approach
- Supporting Regulatory Innovation
- Enhancing Engagement

03 Access Consortium

GMP Collaboration

- As Participating Authorities of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), the members commit to accept GMP inspection reports/documentary evidence issued by Access members for GMP inspections conducted within their territory, in lieu of conducting another GMP inspection.

- Access Heads of Agencies issued a collective Statement on GMP Inspections Reliance & Recognition in November 2022 to solidify the Consortium's commitment to demonstrate greater inspection reliance and accept each other's GMP inspection outcomes

03 Access Consortium

GMP Collaboration

- This reliance on GMP inspection outcomes will be based on the review of inspection reports or other documentary evidence for GMP inspections conducted by Access members within their territory, in lieu of conducting another GMP inspection.

- This reduces the regulatory burden on stakeholders and could facilitate timely access to high quality, safe and effective pharmaceutical products

- Framework for reliance is non-binding, building on the work of PIC/S

APAC
Asia Partnership Conference of Pharmaceutical Associations

ACCESS CONSORTIUM
AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND
UNITED KINGDOM

04 Conclusion

GMP Inspection Reliance in Singapore

Inspectorates

- Avoid duplication of GMP inspections
- Optimise limited resources

Pharmaceutical industry

- Reduction in regulatory inspections
- Cost savings
- Facilitate export of pharmaceutical products

Patients

- Potentially faster access to medicines

APAC
Asia Partnership Conference of Pharmaceutical Associations

Thank you!