Challenges of Regulatory Cooperation

October 4th, 2016

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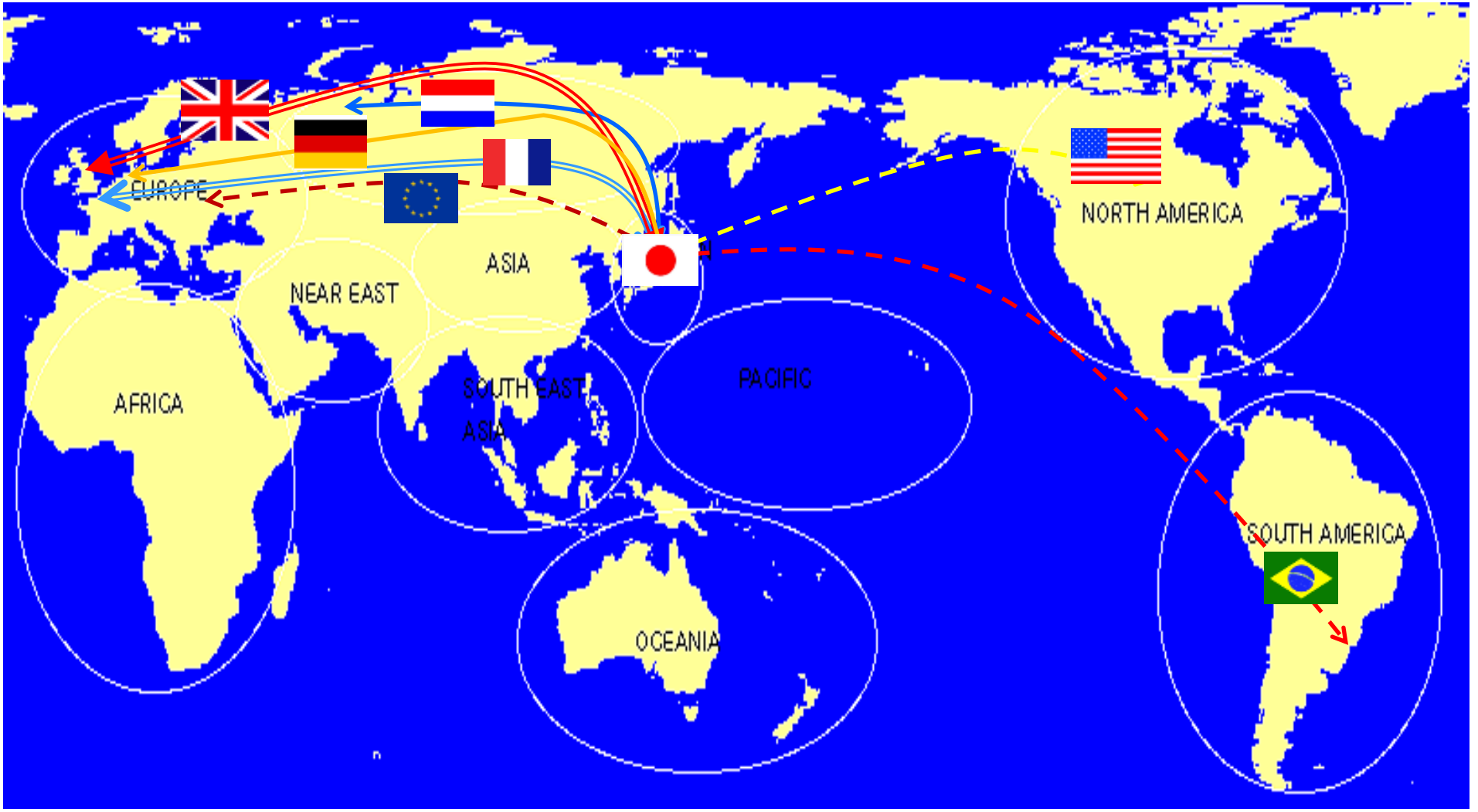
Japan Pharmaceutical Manufacturers Association

JPMA Alliances with EU and American countries



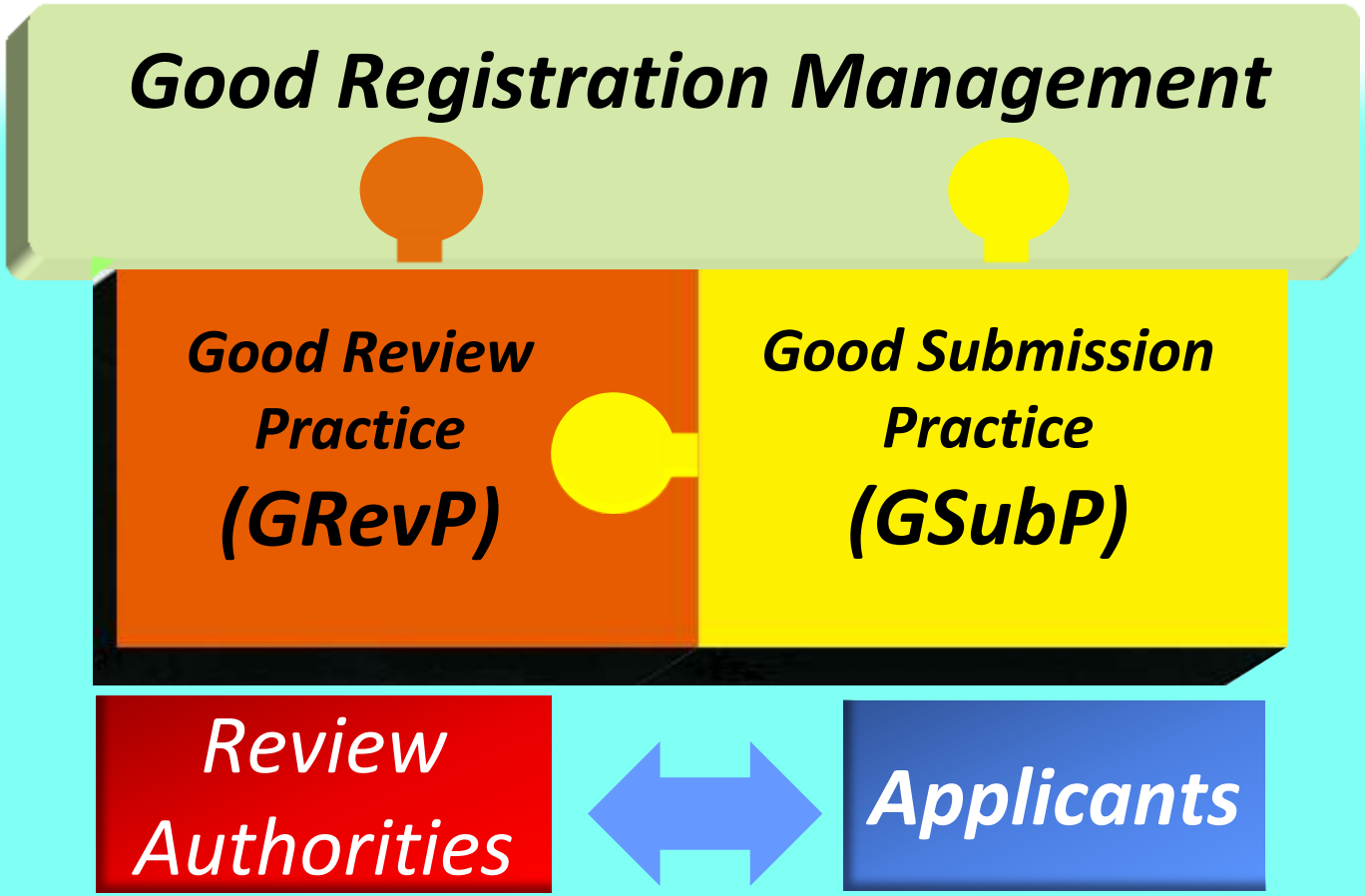
JPMA alliances in Asian countries

http://apac-asia.com/

Mutual Success for Review Authorities and Applicants

JPMA

For Acceleration of Drug Registration



I C H

JPMA

ICH harmonisation for better health

ICH Members and Observers

(after Lisbon meeting, June 2016)

Members:

- Founding Regulatory: EC, MHLW/PMDA, FDA
- Founding Industry: EFPIA, JPMA, PhRMA
- Standing Regulatory: Swissmedic, Health Canada
- Industry: IGBA, WSMI

Standing Observers: WHO, IFPMA

Observers: Regulatory authorities, RHIs, international industry pharmaceutical organisations, international organisations with an interest in pharmaceuticals

See http://www.ich.org/about/membership.html for details

Requests for ANVISA on NDAs

JPMA

Regulatory Convergence

We respect ANVISA's efforts made for regulatory convergence with the international guidelines , including ICH and PIC/S.

We expect that ANVISA will continue to make further progress on the regulatory convergence and regulatory cooperation with PMDA.

Specific Requests relating to NDAs

JPMA

Favorable regulatory environment
for the **Value of Innovation**
made by the pharma industry

Regulatory Timeline

Shorter review period for NDAs

Transparency

Information disclosure on NDA review

Efficiency of NDA

Utilize the clinical data conducted in Japan

Thank you for your attention