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Asia Regulatory Professionals Association

JACK WONG –

FOUNDER OF ARPA

Regulatory Affairs - APAC

9:30-10:30am

28 Feb 2025

09.30 - 10.30 Regulatory Overview of the Key Growth Markets in the APAC Region

Speaker: Jack Wong, CEO and Founder at Asia Regulatory Professionals Association (ARPA), Singapore

- Innovative pathways for quicker registration
- Developing effective regulatory strategies for APAC
- Case studies: Accelerating product launches in markets like Vietnam, South Korea, and China

Jack Wong

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Summary

1. More than 26 years experience in Pharma and MedTech sector
2. Founder of Asia Regulatory Professionals Association (ARPA) with more than 7000 members www.ARPAedu.com
3. Author of Medical Regulatory Affairs Handbook (3rd Edition now)
4. Adjunct Professor/Lecturer in Chinese University of Hong Kong, Hong Kong University, National University of Singapore and Tohoku University Japan
5. CEO of RNAscence (a Biotech start-up spin off from Nanyang Technological University and National Skin Centre Singapore) www.BioRNA.sg

王龍

- 亞洲法規事務專業人員協會會長
- 《醫療監管事務》作者（第三版）
- 新加坡国立大学, 香港中文大學 及香港大學法規事務 兼任副教授/客座講師
- 日本東北大學亞洲醫療法規事務研究院士
- 瑞纳生物科技 行政总裁

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Asia Regulatory Professional Association

Ivy Che

Summary

1. A member of Asia Regulatory Professionals Association (ARPA)
2. Be interested in data science and learning regulatory

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About ARPA

- **Asia Regulatory Professionals Association** aims to **raise the standard and social recognition** of Regulatory Professionals as part of Healthcare team.
- Established 1 Jan 2010
- **Partner for Advisory, Education, Publication and Community support**

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ARLG – Asia Regulatory Leaders Group

Deep Thinking Time

Warm up question

How to know regulatory requirement in Asia? For example, do you need to do this test or not?

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Introduction to Asia Drug Regulatory

(Lots of opportunity but very diverse and dynamic)

Aspect	Explanation	Relevance to Generic Drugs
Regulatory Goals	Ensure safety, efficacy, and quality of generic drugs.	Requires proof of bioequivalence and robust manufacturing data.
Role in Asian Healthcare	Lower costs and improve access to medicines.	High demand in Asia due to large populations and disease burden.
Challenges in Asia	Diverse and complex regulatory systems.	Country-specific variations require tailored strategies for faster approvals.

Challenges in Generic Drug Approvals

Category	Details	Example
Diverse Regulatory Frameworks	Unique country requirements without harmonization.	China's dossier vs. Vietnam's ACTD.
Long Approval Timelines	Delays due to clinical trial requirements and capacity constraints.	China, Korea requires extensive local data.
High Data Standards	Stringent requirements for bioequivalence and manufacturing quality.	WHO Prequalification recognized only in Vietnam but not China. (local testing & local trails impact approval time)

Innovative Regulatory Pathways

Pathway	Key Features	Impact	Example
Abbreviated Approval	Focus on bioequivalence as the primary evidence of safety and efficacy instead of extensive clinical data.	Saves time by skipping redundant clinical trials.	US FDA ANDA model used as a reference in Korea.
Reliance Pathways	Regulatory agencies leverage approvals from trusted bodies like WHO PQ, US FDA, or EMA.	Accelerates approval by reducing the need for repeat evaluations.	WHO PQ pathway adopted in Vietnam.
Priority Reviews	Assigns accelerated timelines for drugs addressing critical public health needs or shortages.	Reduces review time by prioritizing high-impact applications.	China's Priority Review reduced oncology drug approval to 7 months.
Harmonized Frameworks	Use of a common regulatory standard across regions to avoid duplicative submissions.	Streamlines the approval process for multiple countries.	ASEAN ACTD framework simplifies applications in Southeast Asia.
Conditional Approvals	Temporary approval granted for urgent drugs, with ongoing post-marketing surveillance requirements.	Enables faster access to essential medicines in emergencies.	COVID-19 treatments in Korea.

Vietnam Regulatory Strategy

Aspect	Details	Impact
Regulatory Authority	**Vietnam Ministry of Health (MOH)**, specifically the **Drug Administration of Vietnam (DAV)**.	MOH and DAV regulate pharmaceutical products, ensuring their safety, efficacy, and quality.
Approval Pathways	- **Fast-Track Approval** for urgent health needs.- **Conditional Approval** for new generics used in public health emergencies.	Speeds up approval for drugs addressing urgent needs, such as epidemic drugs or emergency-use generics.
Key Requirements	- **Bioequivalence studies** for generic drugs.- Evidence of **safety and efficacy** from major international agencies like WHO or US FDA.	Ensures generics meet high safety and efficacy standards, reducing the need for duplicative trials.
Reliance Pathways	**Reliance on WHO PQ and international agencies (e.g., US FDA)** approval data.- **Mutual Recognition Agreements (MRAs)** with certain countries.	Reduces the time and cost by leveraging the approval data from reputable international regulatory agencies.
Harmonization Efforts	Adherence to **ICH guidelines** for pharmaceutical registration and Good Manufacturing Practices (GMP).	Alignment with ICH standards facilitates global submission processes and ensures high-quality drug registration.
Approval Timeline	- **Standard approval**: Around **12 months**.- **Fast-Track**: Typically **6–8 months** for urgent drugs.	Fast-track approval pathway greatly shortens time-to-market for critical drugs.
Strategic Tips	- Use **Fast-Track Approval** for generics addressing public health needs.- Leverage **WHO PQ and US FDA data** to streamline the approval process.- Prepare for **bioequivalence studies** early in the process to minimize delays.	Helps reduce approval time by focusing on priority health issues and leveraging international data.

Korea Regulatory Strategy

Aspect	Details	Impact
Regulatory Authority	**Ministry of Food and Drug Safety (MFDS)**	Oversees all pharmaceutical regulations, ensuring the safety, efficacy, and quality of drugs in Korea.
Approval Pathways	- **Fast Track** for critical or urgent drugs, especially for epidemic or pandemic situations.- **Conditional Approval** for emergency-use drugs that require post-marketing surveillance.	Speeds up approval for drugs addressing urgent public health issues, reducing review time for generics.
Key Requirements	- **Bioequivalence studies** to demonstrate that the generic drug performs similarly to the reference drug.- **Clinical trial data** or evidence of safety and efficacy from foreign regulatory bodies like WHO or US FDA.	Bioequivalence is mandatory, but clinical trial data can be waived if the drug has already been approved by major international regulators (e.g., US FDA, EMA).
Reliance Pathways	- **Reliance on global regulatory agencies**: Uses approvals from international bodies (e.g., WHO PQ, US FDA, EMA).- **Mutual Recognition Agreements** (MRAs) with countries like the US, EU, and Japan.	Reliance on international approval data reduces duplication of trials, saves time, and lowers costs for generics.
Harmonization Efforts	- **ICH (International Council for Harmonisation)** guidelines are followed for drug registration, safety, and efficacy standards.	Adherence to ICH standards helps ensure global consistency in regulatory practices, easing approval in multiple markets.
Approval Timeline	- **Standard approval** timeline: Typically 12–18 months for generics.- **Fast Track** timeline: **6–8 months** for critical drugs (e.g., antiviral or emergency-use generics).	Fast Track significantly shortens approval timelines, especially for urgent health crises.
Strategic Tips	- **Leverage Fast Track for high-demand generics or those addressing public health crises.** - **Use reliance on international approvals (e.g., US FDA, WHO PQ) to streamline the process.** - **Test tips case studies !!**	**Strategic use of Fast Track and international data can reduce approval time and cost. Focus on bioequivalence and regulatory recognition for a faster market entry.**

China Regulatory Strategy

Aspect	Details	Impact
Regulatory Authority	National Medical Products Administration (NMPA).	Oversees drug approvals, implements national guidelines, and ensures safety and quality standards.
Approval Pathways	- Priority Review for unmet medical needs.- Conditional Approval for urgent use.	Accelerates approval for high-priority or critical drugs.
Key Requirements	- Local bioequivalence studies.- Compliance with Quality Consistency Evaluation (QCE).	Ensures that generics meet the same quality and efficacy as the reference drug.
Reliance Pathways	Limited reliance on foreign approvals (e.g., FDA, EMA). WHO PQ not recognized.	Requires duplicative testing and evaluations, increasing time and cost.
Harmonization Efforts	Aligning with ICH guidelines for Good Manufacturing Practices (GMP) and dossier submissions.	Simplifies global submissions for manufacturers targeting both China and ICH-member regions.
Timeline for Approvals	- Standard review: 12–18 months.- Priority Review: 6–8 months.	Priority Review significantly reduces approval time for critical drugs.
Local Trials	Mandatory local clinical/bioequivalence trials for generics, even if foreign data exists.	Adds cost and time but ensures product alignment with local population needs.
Data Protection Policies	Data exclusivity for new drugs lasts 6 years. Generics cannot reference this data during that time.	Protects innovator drugs, creating delays for generic entry.
Strategic Tips	- **Multicentre studies** - **Focus on Priority Review pathways** - **Standard development tips !!** - **Product standard tips !!**	- **Helps streamline the process and mitigate delays.**

Deep Thinking Time

Let's solved Test problem and Standard problem

What if you keep on fail local test?

What if your product does not meet local standard?

China Regulatory Strategy – Greater Bay Area

Guangdong-Hong Kong-Macao Greater Bay Area (9 cities in Guangdong province-HK-Macao)

Drug and medical device can be used in Greater Bay Area if this product launched in Hongkong government hospital (not need product registration in HK) with recognized medical needs;

5 hospitals in Greater Bay Area considered as pilot;

The real-world data used in Greater Bay Area can support product registration;

The product used in HK should be same with the one used in 5 hospital

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Education

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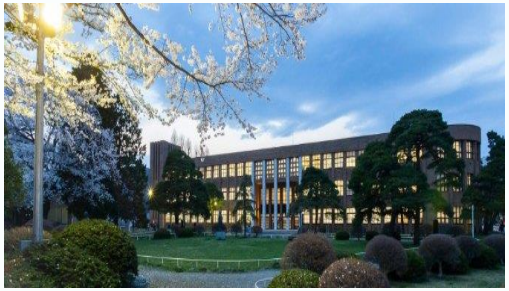
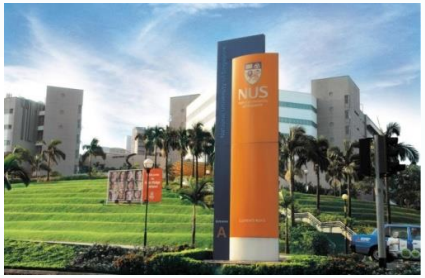
Undergraduate and postgraduate courses in Universities





Education - TaiwanFDA

Education – Vietnam

RAEA – Regulatory Affairs Education Alliance

RAEA
Regulatory Affairs
Education Alliance

About RAEA

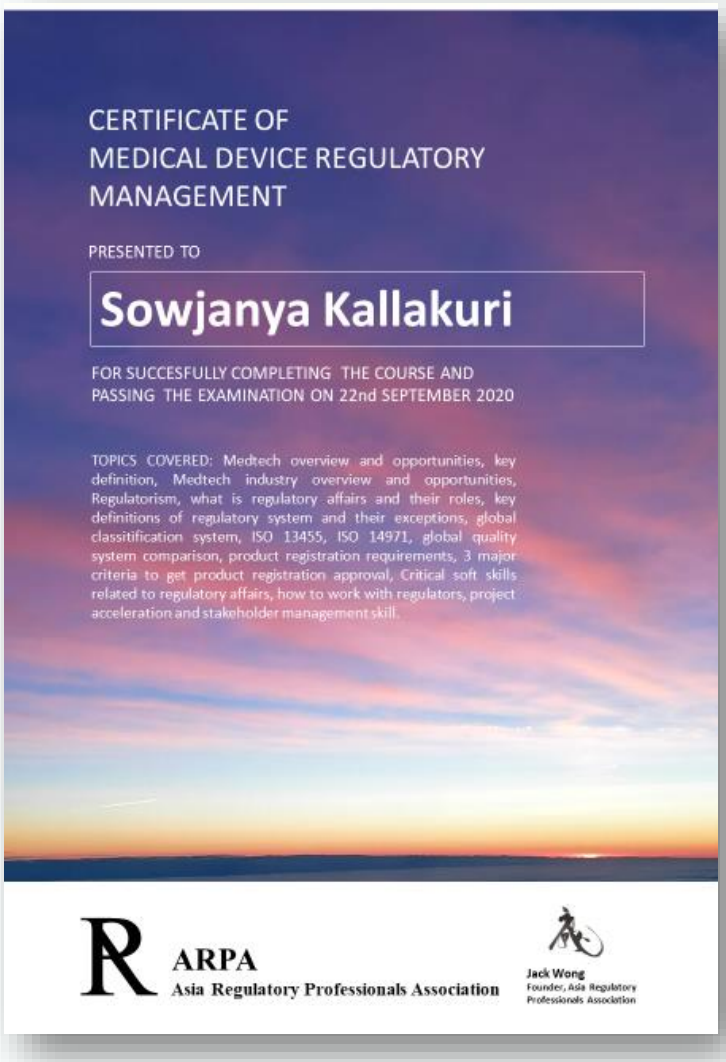
- ❑ We intended to create a group of universities and education institutes which has RA course or want to have RA course
- ❑ Established 18 Aug 2022

We aim to
- share good practice on RA teaching syllabus including teaching materials (***value to teachers***)
- provide wider RA knowledge and network to students e.g. internship, exchange, rotation program (***values to students)***
- gather RA teaching experts (from academic, industry, government and certification bodies) in different countries as our Teachers or partners (***create talent pool***)
- develop RA trainings fit for student and research. Of course industry and government are welcome to join our trainings (***create more training***)
- Regulatory Affairs scope RAEA aims to cover are all regulatory science and soft skills for all healthcare products including medical device, pharmaceuticals etc **(RA scope focus)**

RAEA
Regulatory Affairs Education Alliance

Chairman	Chinese University of Hong Kong	Prof. Raymond Tong
Secretary	ARPA (Asia Regulatory Professionals Association)	Prof. Jack Wong
Founding Members		
Australia	University of Sydney	Dr Orin Chisholm
China	YeeHong Business School, Shenyang University	TBC
Hong Kong	Hong Kong University, Pharmacy department	Ass. Prof Aviva Chow
Hong Kong	Chinese University of Hong Kong	Prof. Raymond Tong
India	SIES (School of Business Studies)	Dr Shuchi Midha
Japan	Tohoku University	Prof Saijo Yoshifumi
Korea	KIST (Korea Institute of Science & Technology)/ HongNueng Innopolis	Dr. Dae-Shin Kang
Korea	KIST (Korea Institute of Science & Technology)/ HongNueng Innopolis	Dr. Sung-Hun Kwon
Korea	KIST(Korea Institute of Science & Technology), BioCenter	Dr. Hyung-Min Kim
Korea	Kyunghee University(Department of Business Administration)	Prof. KT Jung, Kyunghee
Malaysia	Universiti Malaysia Perlis	Associated Prof. NASHRUL
Singapore	NanYang Technological University	Prof. Jack Wong,
Singapore	National University of Singapore	Prof. Mark Chong
Singapore	Temasek Polytechnic	Adrian Danker (TBC)
Thailand	Chulalongkorn University	Ornsiree Junchaya (TBC)
Vietnam	Hanoi University	TBC

Online courses



Online Courses

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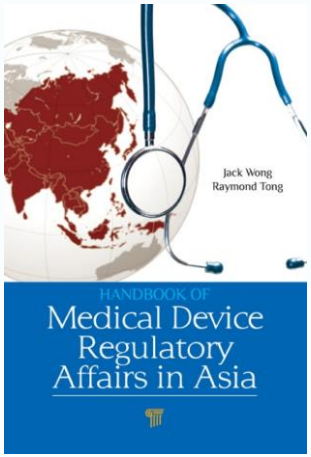
Publication

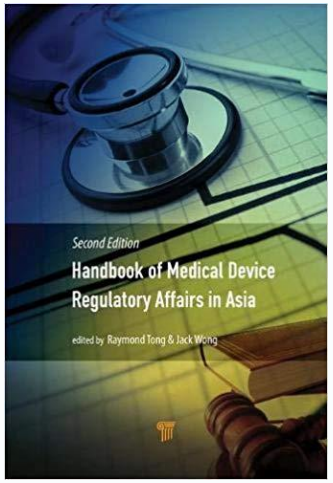
Publications

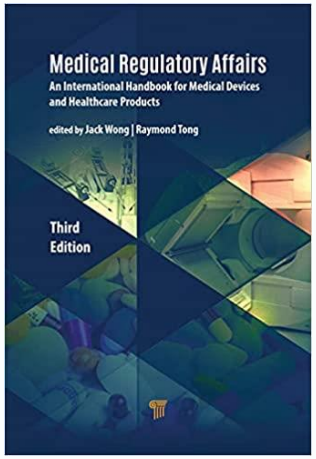
Regulatory Textbook

- To develop the professional, the very first Asia Regulatory textbook was developed
- Name of book: **Handbook of Medical Device Regulatory Affairs in Asia**
- We got support and writers from the following organisations to write the book (AHWP, WHO, US FDA, EU, Japan PMDA etc.)

RA book







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Community

University Scholarship

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Register No

ASK ARPA RESOURCES EDUCATION COMMUNITY

Qianna Chung:

“ With the Asia Regulatory Professionals Association Enrichment Award and summer placement at HKAPI, I hope to gain precious insight into the pharmaceutical industry of Hong Kong and pursue my passion of being an industrial pharmacist through exposing to the working environment of the organization. I hope to build connections with various pharmaceutical companies and explore local policies by carrying out healthcare-related researches. ”

Community Development

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Community Development

ARPA supports handicapped individuals to learn and work as regulatory professionals.

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Summary

ARPA introduction
1. Join the free membership
2. Build your RA knowledge
3. Build your RA network

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