

日本を魅力ある臨床開発環境とするための 人材育成の強化

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日本の臨床開発環境強化に必要な人材とは

第3回創薬・先端医療WG（3月16日）提出資料より一部改編

人材育成と配置の強化

国際共同治験・臨床試験で戦える人材・施設基盤の強化

1. 国際的に通用する治験責任医師(PI)・臨床試験の計画・実施に発言力を持つキーオピニオンリーダー(KOL)の育成
国費によるKOL養成プログラム(臨床開発者養成ワークショップ、海外派遣etc)を創設して中長期的に育成
2. CRC、治験・臨床試験事務局の人材育成と配置の強化
国費によるCRC育成プログラムや国家的な認定資格制度を構築
症例集積の期待できる大規模病院に治験・臨床試験専任チームを配置するための財政支援を実施
3. 創薬・先端医療技術関連人材の産官学間の人材交流の活性化：専門性の強化につながる
クロスアポイント制度の拡充
産官学の人材流動性を高めるためのPMDAと民間との給与格差の是正
4. 卒前・卒後教育における臨床開発教育の体系的な導入
薬学の卒前・卒後教育において、医薬品・医療機器の開発(含むデータサイエンス、治験、GMP/QMS)に関する教育を充実させるなど創薬人材の育成を強化
医学・看護学等の卒前・卒後教育においても、医薬品・医療機器開発(含むデータサイエンス)に関する教育を必須化

米国における臨床開発人材の育成

米国臨床腫瘍学会ASCO・米国癌学会AACR 共催
METHODS IN CLINICAL CANCER RESEARCH



Primary Menu

**1996年に開始、現在に至るまで20年間、
年1回開催され、がん領域の臨床開発人材を育成し続けています**

**臨床試験の方法論、薬剤開発の流れ・法規などを学び、
自分の診療で感じている課題を解決する
プロトコルとIC (Informed Consent) 文書まで作成する**

AACR/ASCO Methods in Clinical Cancer Research Workshop

July 26-31, 2026
The Hythe
Vail, Colorado

standard course for learning about clinical trial design."

"This was the best training experience I ever had. Fantastic mentors and colleagues. I didn't think it was possible to learn so much in less than a week! Thank you all so much!"

<https://vailworkshop.org/>

"This is the best workshop that I have

我が国の創薬力強化にはGMP教育も重要

【医薬品等の開発・生産体制強化に向けて求められること】

- 新技術の導入に関し、規制要件を整理するとともに、査察当局の協力枠組みであるPIC/Sや医薬品規制 調和国際会議 (ICH) 等の活動を通じた国際規制調和を進める
- アジアへの規制理解を進めるPMDAアジア医薬品・医療機器トレーニングセンターにより国際規制調和 の成果の普及を図る
- 競争力強化 ・実生産設備を利用した実践的な研修プログラムなどを通じて、製造人材を育成し確保する

日本成長戦略会議（第3回）資料 2 官民投資ロードマップ素案の「創薬 先端医療 18. 感染症対応製品」より
<https://www.cas.go.jp/jp/seisaku/nipponseichosenryaku/kaigi/dai3/shiryoku2.pdf>

【現状】

- アジア諸国では、未だ、規制当局における査察官等の査察レベルが十分ではなく、アジアでの医薬品製造の品質確保のためにも査察官のレベル向上が求められている。
- この点については、
 - 規制当局間のトップ会合においても各国のリーダーから日本からの支援が求められている。
 - PMDAアジア医薬品・医療機器トレーニングセンターを活用したアジア規制当局へのGMP査察官の教育と査察技術の向上のための支援が求められている。



**我が国の創薬力強化、医薬品等における経済安全保障の確保のためにも、
戦略的に我が国がリーダーシップをとり、
アジア諸国へのGMP活動のレベル向上を図ることが急務**

日本が主導するアジアにおける GMP製造人材の育成プロセスと育成基盤の構築

アジアのGMP査察官は、トレーニングの機会が少なく、調査能力が低い傾向がある

日本市場に品質の良い医薬品がすみやかに供給される

- ・日本（PMDA）はPIC/S活動を通して集積した多くの知見を保有
- ・日本がアジアの当局に対してトレーニングの機会と知見を提供
- ・GMP調査員の育成をリード

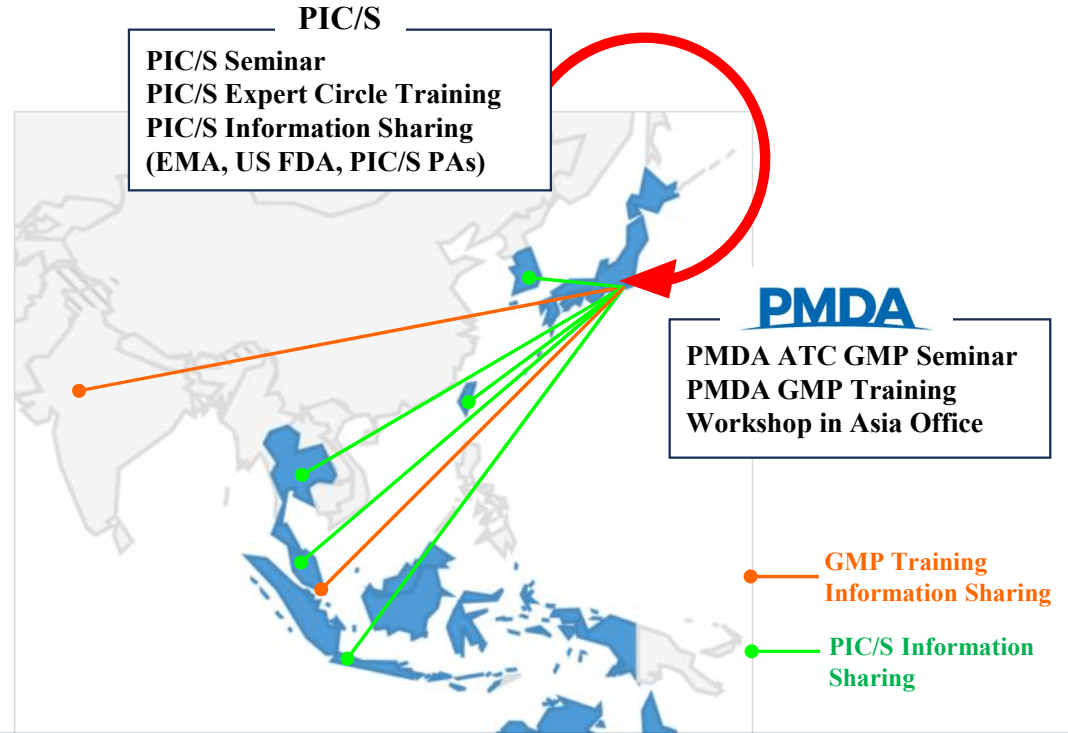
アジアの医薬品製造所のGMP管理能力が向上

アジアのGMP調査員の調査能力が向上

アジアのGMP調査員の育成を日本がリード

↓
アジア全体の医薬品製造のレベルアップ

↓
日本の創薬力強化及び医薬品経済安全保障の確保



日本が享受するベネフィット

1. 日本のプレゼンスが高まり、日本のGMP調査結果がアジアのGMP当局に受け入れられる
2. アジアの製造所に、日本が開発した先端生産技術を導入
3. 日本の優れた医薬品シーズを、アジアの友好国において安価に製造
4. 医薬品経済安全保障上、特定国に依存した製造への懸念が解消 5

Strengthening Human Resource Development to Make Japan an Attractive Environment for Clinical Development

Pharmaceuticals and Medical Devices Agency (PMDA)

Chief Executive

Yasuhiro FUJIWARA M.D., Ph.D.

Disclaimer: The views expressed in this presentation are those of the author and do not necessarily reflect the official views of the PMDA



Building the Talent Base for Japan's Clinical Development Ecosystem

Strengthening Human Resource Development and Deployment

Adapted from materials submitted to the 3rd Drug Discovery and Advanced Medical Technology WG (March 16, 2026)

Global Clinical Trial Capacity Building

- Development of **internationally competent** principal investigators (PIs) and **key opinion leaders (KOLs)** with **influence** over the **planning and conduct of clinical trials.****
Establish a publicly funded KOL development program (e.g., clinical development workshops, overseas dispatch programs, etc.) for medium to long-term development.
- Strengthening the training and deployment of **CRCs** and clinical trial/research **office** staff.**
Establish a publicly funded CRC training program and a national certification system.
Provide financial support to deploy dedicated clinical trial/research teams at large hospitals expected to enroll substantial no. of cases.
- Promoting **personnel exchange among industry, government, and academia** in drug discovery and advanced medical technology fields for leading to enhanced expertise.**
Expand cross-appointment systems.
To increase personnel mobility across industry, government, and academia, correct salary disparities between PMDA and private sector.
- Systematic introduction of clinical development education in undergraduate and postgraduate education.**
Pharmacy education should strengthen training in pharmaceutical and medical device development (including data science, clinical trials, and GMP/QMS), thereby fostering drug discovery talent.
Likewise, integrate pharmaceutical and medical device development, including data science, into mandatory undergraduate and postgraduate education for medicine, nursing, and related health professions.

Training of Clinical Development Personnel in the United States

Co-hosted by the American Society of Clinical Oncology (ASCO) and the American Association for Cancer Research (AACR)

METHODS IN CLINICAL CANCER RESEARCH



An AACR/ASCO Workshop on

Methods in Clinical Cancer Research

July 26-31 | Vail, CO

AACR American Association for Cancer Research

ASCO AMERICAN SOCIETY OF CLINICAL ONCOLOGY

Primary Menu

1996 — launched, and continuing for 20 years to date, this program has been held once a year, continuously training clinical development personnel in the field of oncology

About Workshop

Learn clinical trial methodology, the drug development process, and relevant regulations, and work to resolve issues encountered in your own clinical practice — going as far as drafting the protocol and IC (Informed Consent) documents

AACR/ASCO Methods in Clinical Cancer Research Workshop

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Participants:

"Amazing experience, the most

trial design."

"This was the best training experience I ever had. Fantastic mentors and colleagues. I didn't think it was possible to learn so much in less than a week! Thank you all so much!!"

"This is the attended. It has provided me with the

<https://vailworkshop.org/>

Strengthening Development and Manufacturing Capacity for Medical Products in Japan

[What Is Needed to Strengthen Medical Product Development and Manufacturing]

- Clarify regulatory requirements for new technologies and advance international regulatory harmonization through PIC/S, ICH, and other global initiatives.
- Promote the dissemination of international regulatory harmonization outcomes through the PMDA Asia Training Center for Pharmaceuticals and Medical devices Regulatory Affairs (PMDA-ATC).
- Develop and retain manufacturing talent through hands-on training using commercial-scale production facilities.

From Document 2 of the 3rd Japan Growth Strategy Council, "Draft Public-Private Investment Roadmap, Drug Discovery and Advanced Medical Care, 18. Infectious Disease Response Products"

<https://www.cas.go.jp/jp/seisaku/nipponseichosenryaku/kaigi/dai3/shiryoku2.pdf>

[Current Situation]

- In many Asian countries, regulatory inspection capacity remains insufficient. Enhancing inspector capabilities is critical to ensuring the quality of pharmaceutical manufacturing throughout Asia.
- On this point,
 - Leaders from across Asia have sought Japan's support, including at high-level meetings of regulatory authorities.
 - The PMDA-ATC is leveraged to train GMP inspectors and strengthen inspection capabilities across Asian regulatory authorities.



To strengthen Japan's drug discovery capabilities and secure economic security in medical products, Japan must take a strategic leadership role in elevating GMP standards across Asia.

Japan-Led Capacity Building for GMP Manufacturing in Asia

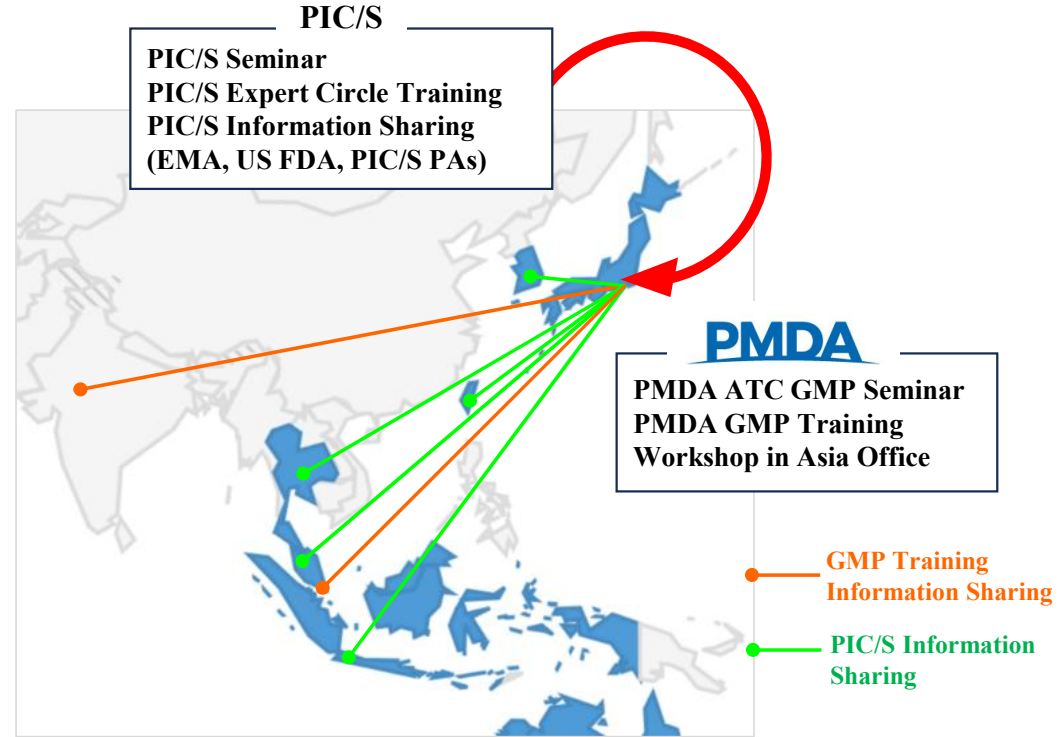
Many GMP inspectors in Asia lack adequate training opportunities, contributing to gaps in inspection capacity

High-quality pharmaceuticals are supplied to the Japanese market in a timely manner

- Leverage PMDA's extensive expertise gained through PIC/S activities.
- Provide training opportunities and technical knowledge to Asian regulatory authorities.
- Lead regional capacity building for GMP inspectors.

GMP management capabilities at pharmaceutical manufacturing sites across Asia are strengthened

Enhanced GMP inspection capacity across Asia



Japan Leads Capacity Building for GMP Inspectors in Asia



Elevating Pharmaceutical Manufacturing Standards Across Asia



Strengthening Japan's Drug Discovery Capabilities and Ensuring Pharmaceutical Economic Security

Benefits for Japan

1. Greater regional influence and recognition of PMDA GMP inspections
2. Expansion of Japanese advanced manufacturing technologies across Asia
3. Cost-efficient production of innovative Japanese medicines (seeds) in partner countries
4. Enhanced pharmaceutical economic security through diversified manufacturing networks