Activities of GMP sub-Committee in JPMA Quality & Technology Committee

日本製薬工業協会（製薬協）品質委員会

March 29th 2010

GMP Sub-Committee

JPMA Quality & Technology Committee

Tsutomu Watanabe

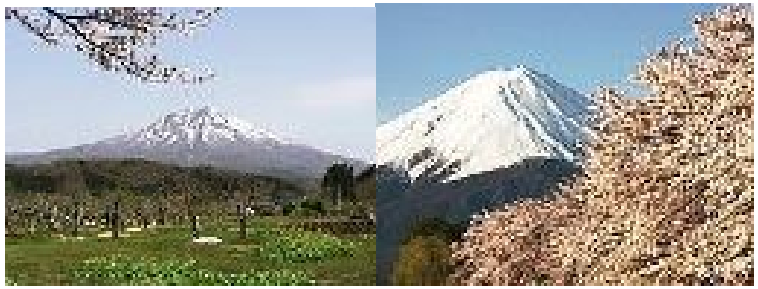
Acknowledgment of Japan

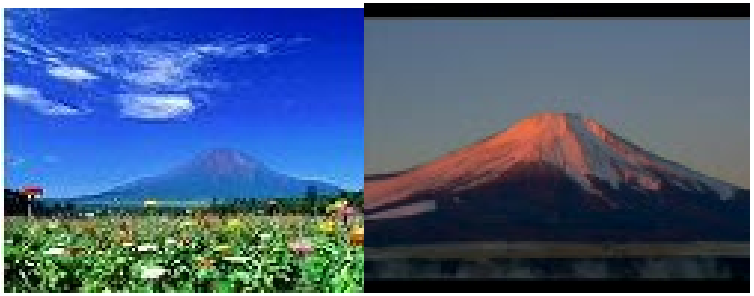
- Great Earthquake on 11th March -

We would like to take this opportunity to thank you for Chinese kind considerations and supports which you have provided us with over the past 20 days.

March 29, 2011

Japan and JPMA





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- **1. Introduction of JPMA**
- **2. Activities**

  Activities of the GMP sub-committee

  (Activities for ICH, as well as for MRA and PIC/S)
- **3. Future Activities**

  Major Tasks and Projects

1. Introduction of JPMA

(Japan Pharmaceutical Manufacturers Association)

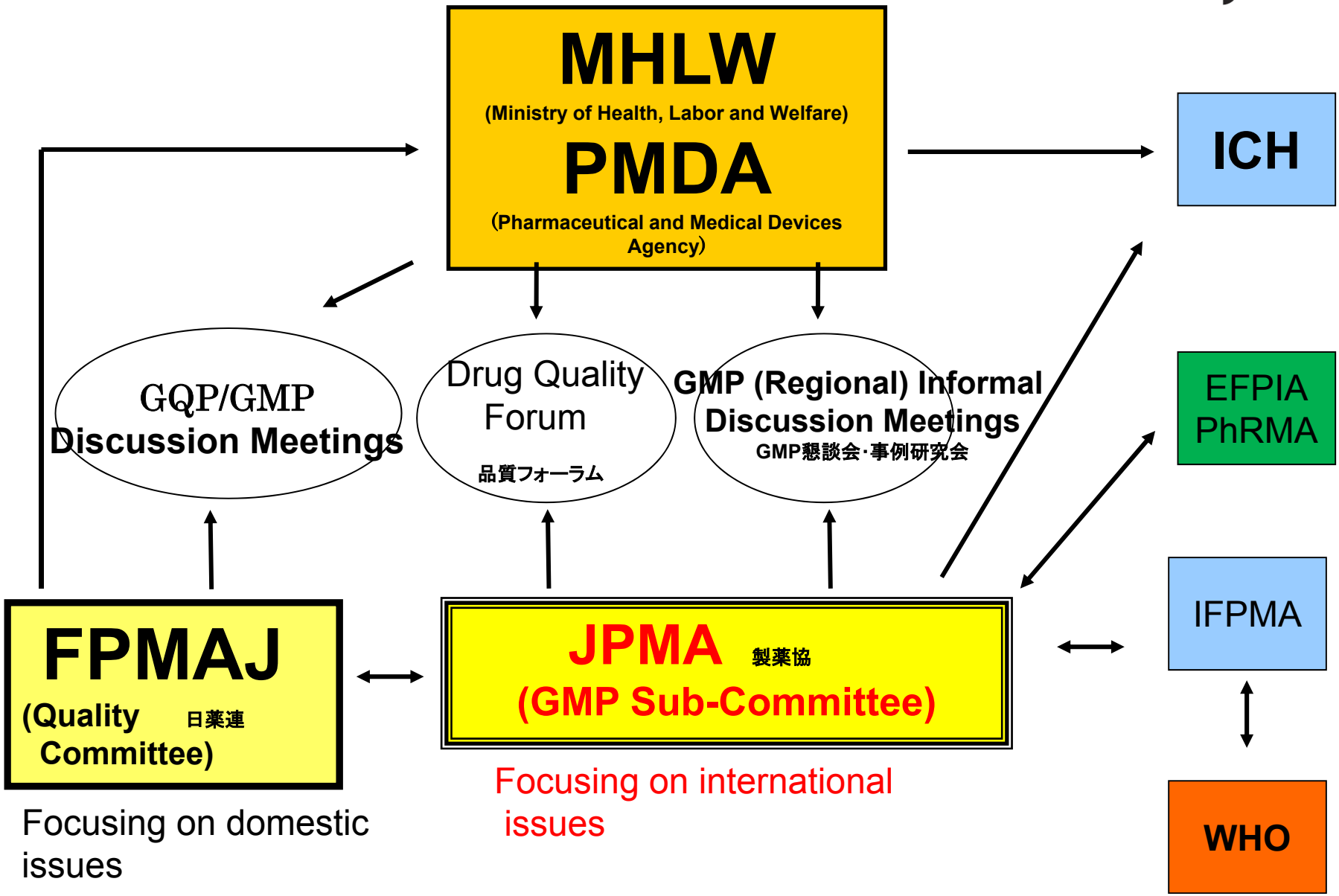
- **The JPMA was founded in 1968 with the motto of "realizing patient-oriented medical care." Since then, it has been contributing to global medical care through the development of revolutionary new pharmaceuticals intended for prescription drugs. Presently, the JPMA has 67 members (as of Jan. 2011), and these pharmaceutical companies focus on research and development.**
- **JPMA is an official members for ICH cooperating with PhRMA and EFPIA.**

  PhRMA: Pharmaceutical Research and Manufacturers of America
  EFPIA : European Federation of Pharmaceutical Industries' Association
  ICH :International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use

- **Also a member of IFPMA**

  IFPMA: International Federation of Pharmaceutical Manufacturers Associations

1. Introduction of JPMA
- Relationship with Authorities -



1.Introduction of JPMA
- Positioning of JPMA in J. Pharmaceutical Associations

The JPMA is a member of FPMAJ which consists of the above regional and industrial bodies.
Quality Standing Committee in FPMAJ : JPMA: 5/ 23 members

***FPMAJ 日薬連**

***FPMAJ: The Federation of Pharmaceutical Manufacturers' Association of Japan**

< Industrial Bodies（14）>

- **JPMA 製薬協**
- JGA (Japan Generic Medicines Association) ジェネリック
- JDSPA (Japan Direct-Selling Pharmaceutical Manufactures Association) 直販メイカー協議会
- JSMI (Japan Self- Medication Industry) OTC医薬品協会

etc.

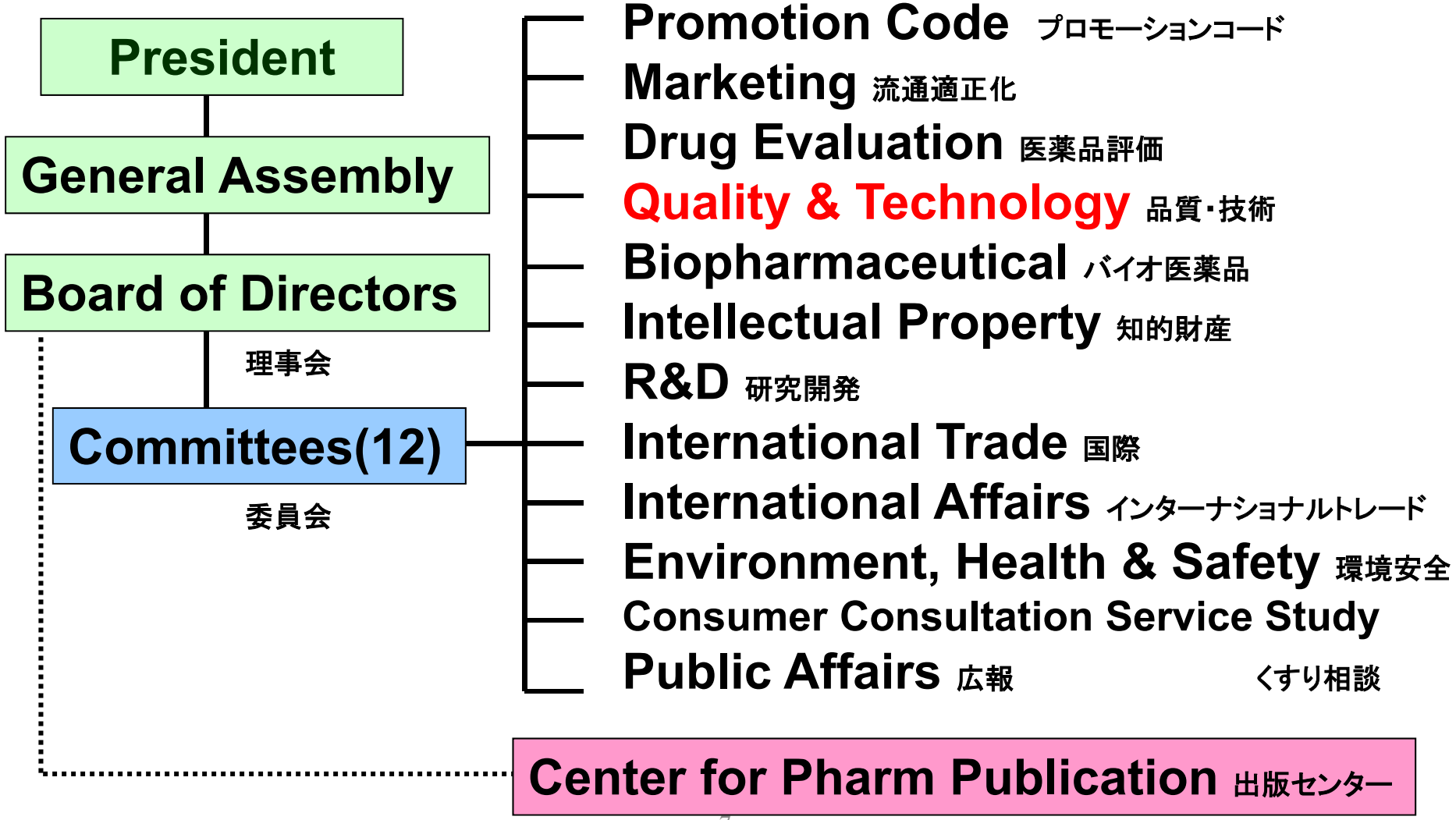
< Regional Bodies（19）>

- PMAT (Pharmaceutical Manufacturers' Association of Tokyo)
  東京医薬品工業協会
- OPMA (Osaka Pharmaceutical Manufacturers Association)
  大阪医薬品協会

etc.

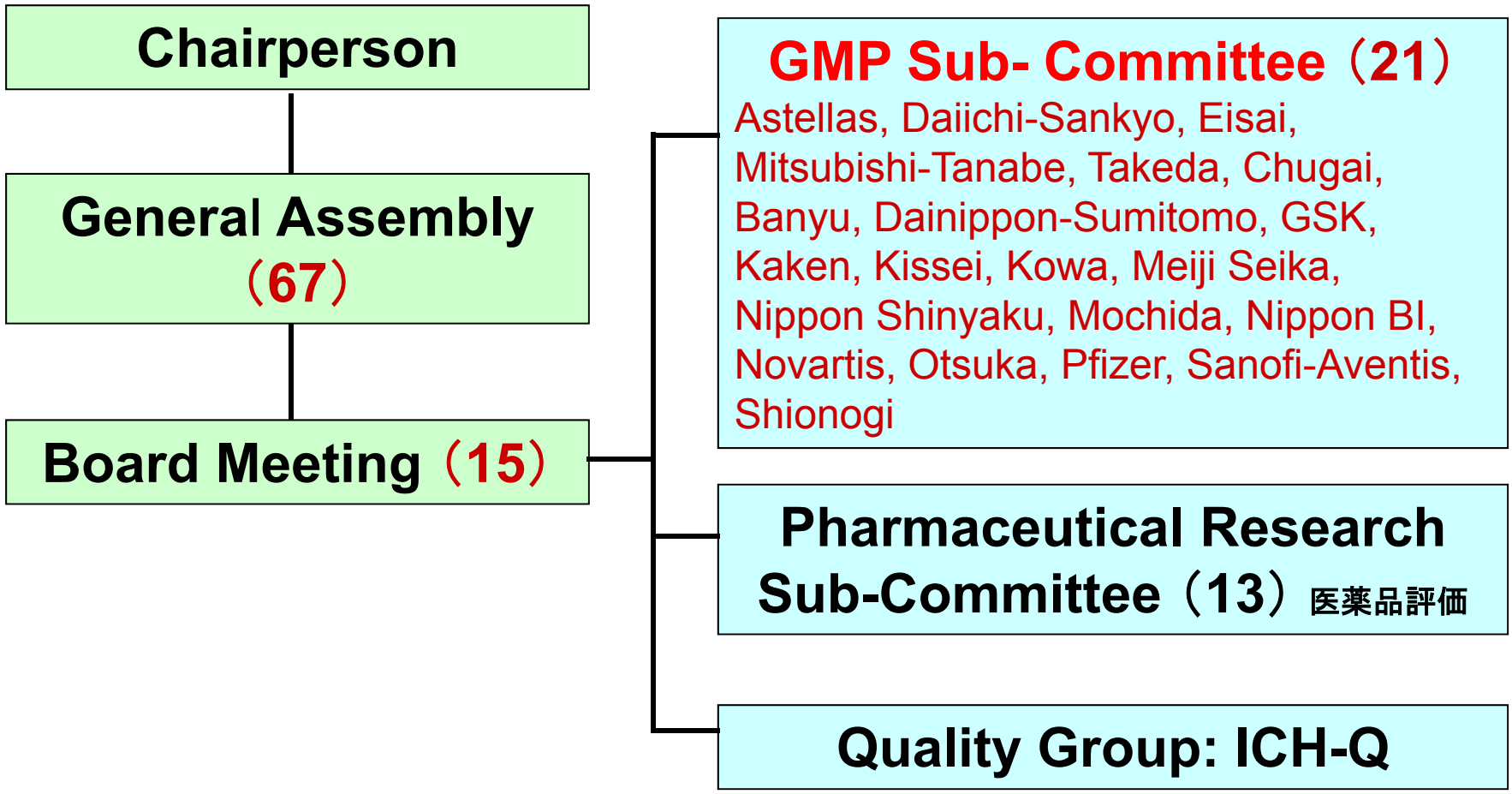
1. Introduction of JPMA

- Organization of JPMA -



1. Introduction of JPMA

- Organization of JPMA Quality & Technology Committee (as of Jan. 2011) - 品質技術委員会組織



2. Activities

- Active Projects by the JPMA GMP sub-committee (21 staff members) GMP専門部会プロジェクト

Current ongoing projects	
GMP Case Study Workshop/ Seminars	JICWELS GMP training programs 国際厚生事業団
GMP News /collecting overseas information	Consideration of the introduction of CSV
GMP Informal Discussion Meetings	GDP/Counterfeit
Mutual Recognition Agreement /PIC/S	Relationship with Asian Countries
International Guidance Watcher (WHO/FDA Watcher)	Comparison of EU/USA GMP requirements for biologics
Support for the ICH/EWG and other working groups	Collaboration with the FPMAJ
Support for the Q11 working group	Gap analysis Working Group (with PMDA) … PIC/S GMP vs. Domestic GMP

2. Activities

- GMP History of Japan & - JPMA/JGMP Guideline -

JPMA

- 1962 FDA (Enforcement of GMP)
- 1963 FDA (Enactment of c-GMP）
- 1964 FDA (Enforcement of c-GMP)
- 1969 WHO (Adoption)
- 1970 EU EFTA （Enactment of c-GMP）
- 1971 UK （GMP Guideline）
- 1972 JPMA (Investigation of GMPs)
- 1973 JPMA (Enactment of JPMA-GMP)
- 1974 MHLW (Publication)
- 1976 MHLW (Enforcement of J-GMP; Notification of Director)
- 1980 MHLW (Legislation of J-GMP; Ministerial Ordinances - Recommendation)
- 1994 MHLW(Revision of J-GMP ; Ministerial Ordinances - Requirement)
- 2005 MHLW (Revision of J-PAL;GQP/GMP)

製薬協 GMP自主基準

2. Activities

- Meetings & Publications -

< Regular Conference & Activities >

1. GMP News GMPニュース
2. GMP Informal Discussion Meetings GMP懇談会
3. GMP Case Study Workshop Seminars GMP事例研究会
4. Drug Quality Forum 品質フォーラム

GMP News

The first edition July.1,197
The 95th edition Oct.31,2010

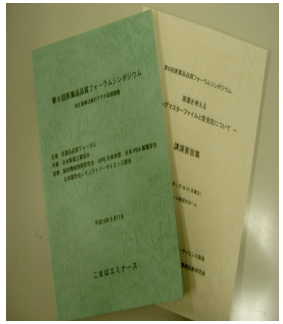
< Publications >

Comparison with US-GMP, EU-GMP and J-GMP

Record of GMP Case Study Workshop Seminars

Study of MRA

GMP Glossary



Guidelines (Proposal) for GMP of Drug Products

2. Activities

- Meetings & Publications -

< GMP Meetings>

< GMP Case Study Workshop Seminars >

Year	Revision of laws	Theme (host cities: Tokyo/Osaka)
1980	GMP Ordinance (Software and hardware)	1. Methods of testing f 2. Usage of protocols 3. Efficient use of test
1981	GMP explanations	Outline of the "GMP exp
1982	Compilation of GMP Case Studies	"Compilation of GMP C GMP seminars (FPMAJ)
		How the "Compilation o and the explanation of t
1983	-	Injection drugs, solid or
	GMP explanations	Matters relating to quali detecting outliers
1984	-	Analysis and testing co
1985	Compilation of GMP Case Studies	1. Reprocessing 2. Clea product items
1986	-	Abnormal processing
1987	PV Guide (FDA)	Understanding how qua
1988-1990	GMP for active substances	Manufacturing control (preparations)

<GMP Informal Discussion Meetings >

Year	Revision of laws
1974	GMP (notification)
1975	GMP administrative instructions
1976	GMP explanations
1977	·
1978	GMP explanations (revision)
1979	Revised Pharmaceutical Affairs Law (October) (Legislating GMP)

Year	Trends in ICH, etc.	Main theme
1999 (26th)	-	Improvement in reliability of the quality of pharmaceutical products
2000 (27th)	-	Improvement in reliability of the quality of pharmaceutical products
2001 (28th)	Q7	Reliability assurance in the quality of pharmaceutical products in relation to globalization
2002 (29th)	-	Latest news surrounding GMP (International mutual recognition of pharmaceutical products, electronic records and electronic signatures)
2003 (30th)	-	Quality systems in the 21st century - future perspective of GMP in Japan - (ICH GMP special symposium)
2004 (31th)	PIS/S, CSV	Establishment of quality systems for pharmaceutical products toward the 21st century (Revised Pharmaceutical Affairs Law, quality engineering, Part 11, PAT, etc.)
2005 (32th)	-	Responses to new regulations and the establishment of quality assurance systems
2006 (33th)	ICH Q8, Q9	Establishment of the management systems for manufacturers, including overseas manufacturing plants (including active substances)
2007 (34th)	ICH Q10 (invite opinions)	"Collaboration" between marketing businesses and manufacturing businesses - Each company's actions for change control and deviation processing, etc. -

2. Activities

- ICH Activities -

JPMA

- Striving to understand GMP trends in various countries, especially in the U.S. and Europe, as well as WHO GMP, and taking appropriate actions and making suggestions for the international harmonization, such as ICH, etc. 3極・WHOと協力しGMPの推進とICHの推進

< Project >

- Promoting implementation of ICH topics through Q-IWG activities, and responding to the new topic, Q11
- Continuously participating in Q-IWG Considering additional Q&As
- Q-trio (Q8;Sep.2006, Q8(R2);Jun.2010, Q9;Sep.2006, Q10;Feb.2010) Considering to have a training/workshop on the 3 main GMPs (USA-GMP, J-GMP, EU-GMP) at Q-IWG
- Discussing with the MHLW to consider the training/ workshop as part of the activities for Q-IWG

2. Activities

- PIC/S and MRA -

JPMA

Discussing with related organizations about mutual recognition of international GMPs (MRA, PIC/S) and contributing to their progress.
Providing cooperation with the MHLW regarding joining PIC/S.

(1) Having arranged an opportunity for the chairperson of PIC/S to explain the current status of PIC/S to MHLW and PMDA (June 2006)
(2) Gave a lecture on the importance of MRA as well as joining PIC/S (Pharmaceutical Affairs Experts Training Program in 2007)
(3) Held a joint study meeting about PIC/S (Oct.14, 2008&Nov.6.2009) MHLW, PMDA, JPMA (International sub-committee, GMP sub-committee)
(4) Created a new reference, a comparison of the 3 major GMPs, "USA-GMP, J-GMP, and EU-GMP" (December 2008)
(5) Formulated the Japanese version of the GDP Guidelines (Reference: WHO and EU Recommendation/Guidelines)
(6) Gave a lecture on the importance of joining PIC/S (Pharmaceutical Affairs Experts Training Program in 2009)
(7) Kick-off Meeting of Working Group of 'GAP Analysis between PIC/S GMP/Annex' (MHLW, PMDA, NIHS, FPMAJ; July 29, 2010)

OBSERVERS TO PIC/S

PIC/S（Jan.2011）

JPMA

39 AUTHORITIES

PIC/S: Pharmaceutical Inspection Co-operation Scheme. Scheme (not Convention)/ Between Agencies(not countries)
An informal arrangement (not a formal treaty)/ Has no legal status

2. Activities

- Recent Submission of PIC/S -

JPMA

- Applicants being assessed for membership from:

  Taiwan, Thailand, Indonesia, Slovenia ,Iran, United Kingdom / Vet, New Zealand, Philippines

  (9 countries)

- Authorities/Agencies showing interest in joining PIC/S. from:

  China/ Hong Kong, Saudi Arabia, Japan, South Korea, Russia, Turkey

  (6 countries)

- Adoption of PIC/S - Example: Taiwan -

Year	1976	2004	2009-
Adoption	—	CGMP	PIC/S
Manufactures	825	161	150（Prospect）

3. Future Activities
- Major Tasks and Projects -

JPMA

1. **ICH Q Trio:** Qトリオの普及と活性化

Responding to and making suggestions about various issues in relation to ICH international harmonization

(1) Dissemination of Q-trio

(2) Activities for Q-trio

What will happen to the approval application and reviewing systems if they are to reflect ICH Q-trio?

2. **MRA・PIC/S:** MRAとPIC/Sの進捗

Discussing with related organizations about mutual recognition of international GMPs (MRA・PIC/S) and contributing to their progress.

(1) Comparison of J-GMP, EU-GMP, and USA- GMP for biopharmaceuticals バイオ医薬品の3極比較

(2) Providing cooperation to MHLW for Japan's joining PIC/S to promoting Japan's participation in PIC/S

(3) Expanding the application of MRA

3. Future Activities
- Major Tasks and Projects -

3. Corporation with other Organizations:

Implementing international cooperation projects that relate to GMP and responding to various related issues

(1) Providing cooperation to GMP training programs by JICWELS

(2) Providing support for the Asian sub-committee in the International Committee, JPMA

(3) Communication between Japan and Indonesia, Japan and Korea, Japan and Thailand, and Japan and Taiwan, and the introduction of Taiwan PIC/S

(4) Corporation with EFPIA & PhRMA

- Accelerated Drug Approval Program

- Decrease of No. of Inspections

- Deregulations

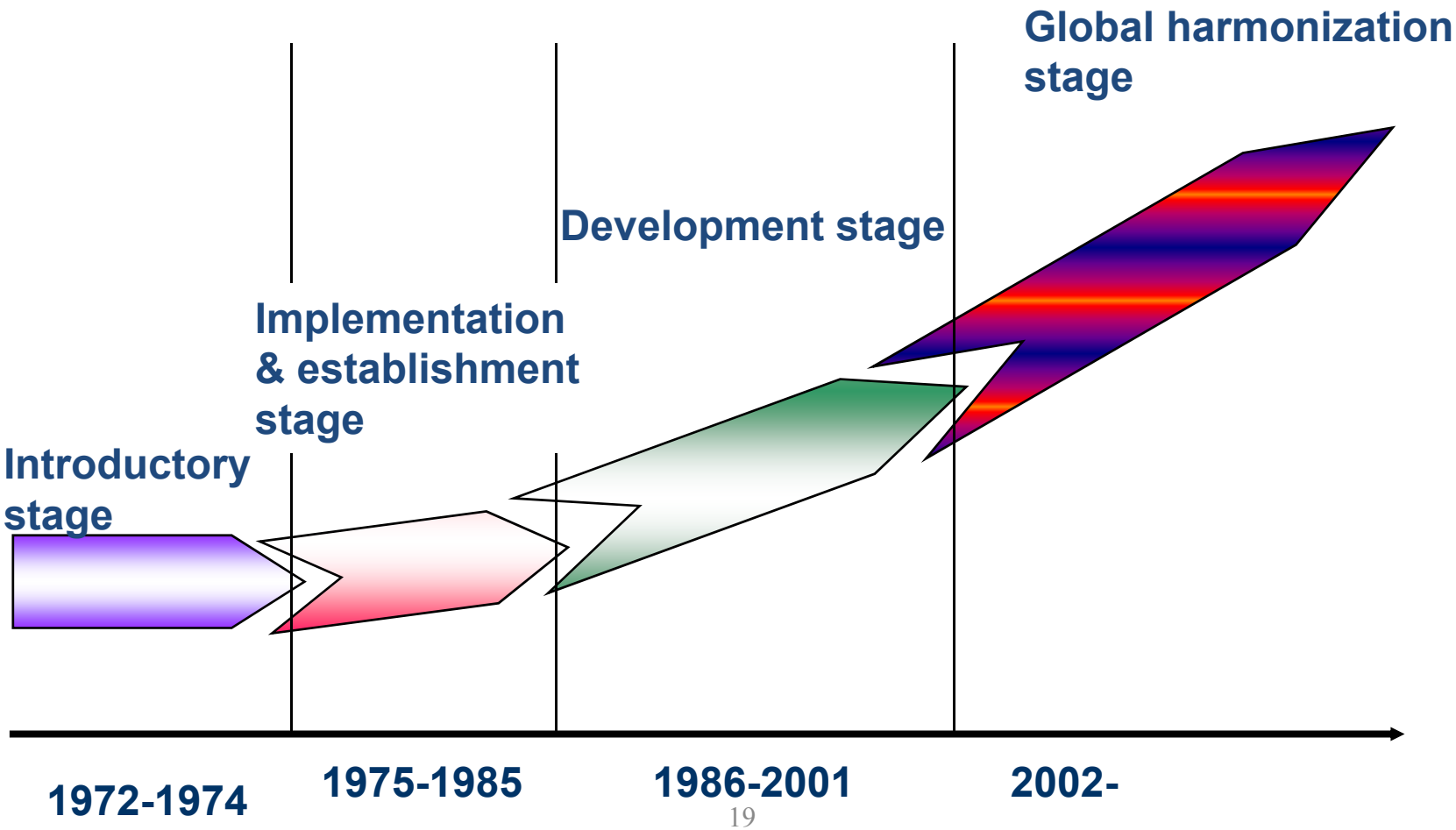
Efficient use of limited resources for quality assurance of Pharm Industry.

Classification of GMP inspections by a risk-base approach.

(From the manufacturing facilities that produce drug products with lower risks to those with higher risks.)

3. Future Activities

- Major Tasks and Projects -



Thank you for your attention.

我的演讲就到此为止，谢谢大家！

ご清聴有り難うございました。

Back Up

2. Activities (past to present)

- Introduction of Quality & Technology Committee

- GMP Committee (sub-committee) GMP専門部会

- In 1969, in response to the WHO recommendation to member countries to adopt GMP, the special committee of the JPMA has created "J-GMP."
- In 1973, the GMP Committee (present GMP sub-committee) began its activities. The committee has now been conducting various activities for 38 years.

製薬協GMP 自主基準

1. GMP News

（GMP study for only JPMA member）

GMPニュース

VOL. 1 NO. 1

1976年7月1日

内容

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会員の投稿を歓迎します

本誌は，製薬協会員各会社間のGMPに関する情報・自由な意見の交換を目的に発行されているものです。投稿は下記にお寄せ下さい。
〒103 東京都中央区日本橋本町3-3(製薬ビル)
日本製薬工業協会「GMPニュース係」

GMPニュースの発行にあたって

日本製薬工業協会会理事長　松　下　[illegible]

現在のわが国の薬事行政は，一時代前の警察的なものから，国民に対して積極的に有効かつ安全で高品質の医薬品を提供することを目的とする福祉行政の方向へと，大きく転換して来ている。特に，ここ10年来，医薬品製造承認の基本方針の策定，一般用医薬品の承認基準の制定，医薬品再評価の実施など多くの行政措置がなされたが，その中でも，2年前に公示され今年4月から施行されたGMPは，事柄は地味であるが，薬事行政としては，一時期を画するものであると言ってよいと思われる。

もちろん，GMPという構想自体は，すでに1969年にWHOが加盟国に勧告し，各々国が実施に移しているところであるが，わが国のGMPについてとりわけ特徴的と考えられるのは，業界団体である製薬協が，国の施策に先がけて，自主基準であるGMPを策定し，会員会社がその遵守を申し合せ，厚生省もまたその趣旨を踏まえて，法的規制でなく行政指導と金融面の助成という助長行政の形でその推進を図っていることである。どの商品でもそうであるが，特に医薬品は，その性格上，多数の中の一つでも欠陥のあることが許されない商品であり，従って，規格に合った均一の品質を確保するためには，製造の各工程における自主的な管理が不可欠の要件である。その意味で，わが国におけるGMP確立の推進力となった製薬協の特別委員会，GMP委員会の功績は，大きく評価されてよいであろう。

ともあれ，医学薬学は日進月歩である。薬

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The first edition　July.1,1976

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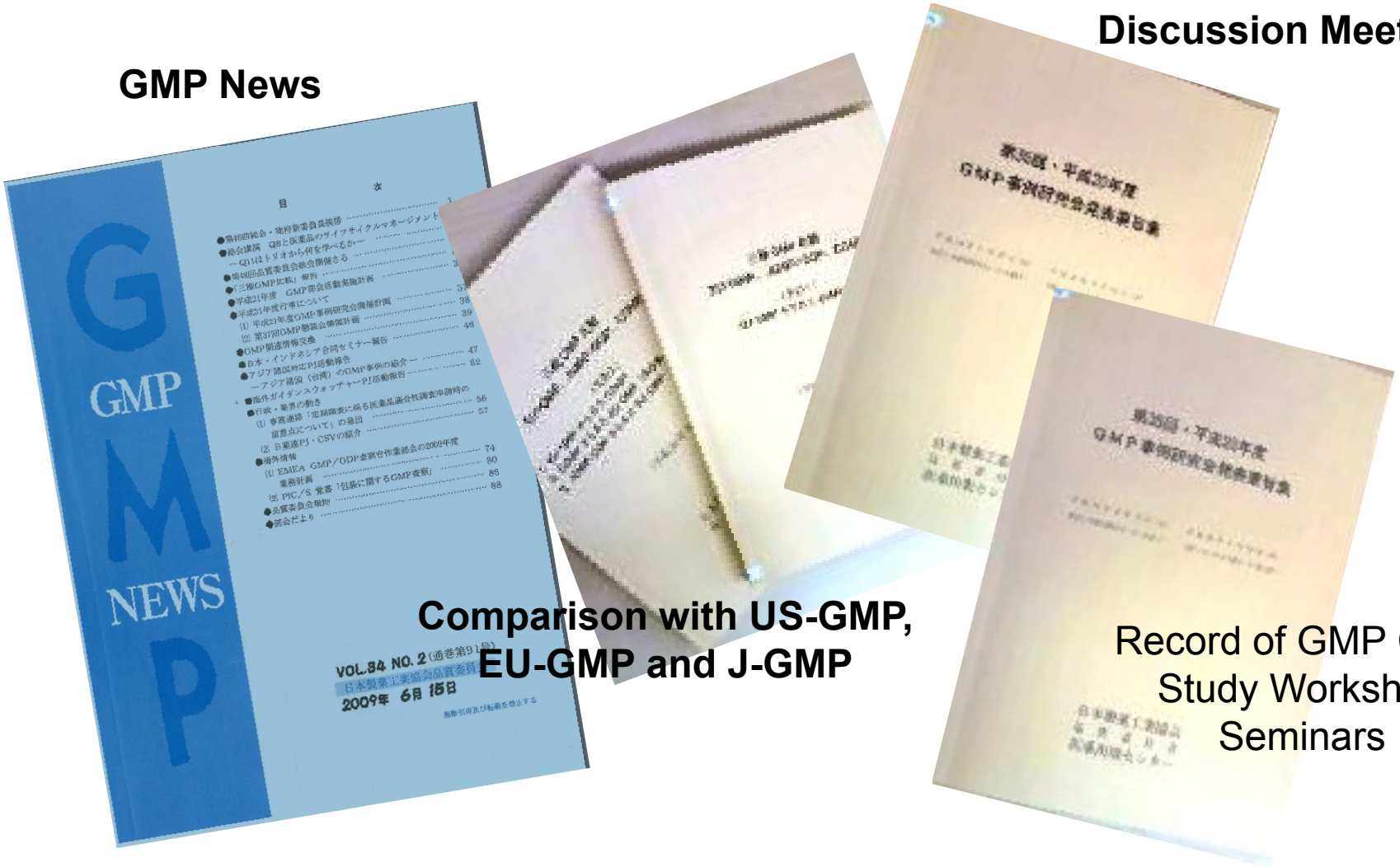
The 95th edition Oct.31,2010

Published matter by Quality & Technology Committee

JPMA

GMP News

Text of GMP Informal Discussion Meetings



Comparison with US-GMP, EU-GMP and J-GMP

Record of GMP Case Study Workshop Seminars

Published matter

JPMA

GMP Glossary

Study of MRA

Guideline (Proposal) for GMP of Drug Products

2. Activities

- PIC/S and MRA -

1. **Joint meeting EFPIA/PhRMA/ JPMA**
   (At JPMA Jun.2009)
   Theme：The Global GMP Inspection Landscape

2. **Joint meeting EFPIA/JPMA**
   (At JPMA July 1, 2010
   & Nov. 12, 2010)

2. GMP (Regional) Informal Discussion Meetings

GMP施工前－GMP説明会

JPMA

Before GMP regulations/ordinances were established

Year	Revision of laws	Theme (host city)
1974	GMP (notification)	GMP Case Study Workshop Seminars (JPMA)
1975	GMP administrative instructions	
1976	GMP explanations	
1977	・	Issues that relate to laws (Tokyo, Nagoya, Osaka)
1978	GMP explanations (revision)	Manufacturing and quality control (Tokyo, Nagoya, Osaka)
1979	Revised Pharmaceutical Affairs Law (October) (Legislating GMP)	Manufacturing control (Tokyo, Nagoya, Osaka)
		1. Issues on the records of corrected charge-in 2. Issues on guidance in prefectures 3. Various issues on subdivided packaging processes

After GMP regulations/ordinances were established GMP施工後-GMP説明会

Year	Revision of laws	Theme (host cities: Tokyo/Osaka)
1980	GMP Ordinance (Software and hardware)	1. Methods of testing foreign particulate matters 2. Usage of protocols 3. Efficient use of tests
1981	GMP explanations	Outline of the “GMP explanations”
1982	Compilation of GMP Case Studies	“Compilation of GMP Case Studies” and future actions GMP seminars (FPMAJ)
		How the “Compilation of GMP Case Studies (Vol.2)” has been received and the explanation of the contents
1983	-	Injection drugs, solid oral preparations
	GMP explanations	Matters relating to quality tests and methods of retesting in cases of detecting outliers
1984	-	Analysis and testing control systems using computers
1985	Compilation of GMP Case Studies	1. Reprocessing 2. Cleaning confirmation at the time of changing product items
1986	-	Abnormal processing
1987	PV Guide (FDA)	Understanding how quality control is conducted by material suppliers
1988-1990	GMP for active substances	Manufacturing control (focusing on process validation of solid oral preparations)

Full revision of the Pharmaceutical Affairs Law (2005) 薬事法改正後- 説明会

JPMA

Year	Revision of laws	Theme (host cities: Tokyo/Osaka)
2003 (31th)	Compilation of GMP Case Studies	Commissioning manufacture in Japan and technology transfer - Current situations and future actions -
2004 (32th)	GMP/GQP ordinances	**Future actions for change control and quality assurance**
2005 (33th)	**Enforcement of the Revised Pharmaceutical Affairs Law**	**Quality assurance systems for pharmaceutical products after the enforcement of the revised Pharmaceutical Affairs Law**
2006 (34th)	Compilation of GMP/GQP Case Studies	**Management of overseas manufacturing plants (including active substances)**
2007 (35th)	-	Collaboration between marketing businesses and manufacturing businesses **- Focusing on change control and deviation control-**
2008 (36th)	-	**Deviation control and preventive actions**

Revised GMP/validations 改正GMPバリデーション説明会

Year	Revision of laws	Theme (host cities: Tokyo/Osaka)
1991-1992	CSV	Responses to the “Drug GMP Monitoring Guid
1993	Revised GMP	Guidelines for adequate computer-operated manufacturing plants of pharmaceutical products
1994	-	Responses to the revised GMP
1995	Validation standards	Responses to GMP/validations
1996		Manufacturing support system (air/water) Cleaning validation
1997	-	Prevention of deficiencies and control systems
1998	-	Self-inspections and internal audits
1999	GMPI	Validation, education and training
2000	-	Actual change control at manufacturing plants
2001	-	Deviation control at manufacturing plants
2002	Revised Pharmaceutical Affairs Law	Computerized operation control in GMP and future actions

Full revision of the Pharmaceutical Affairs Law (2005) 薬事法改正後- 説明会

Year	Revision of laws	Theme (host cities: Tokyo/Osaka)
2009 (37th)	-	**Activities pertaining to corrective actions and preventive actions - the concept of CAPA and issues on the use of CAPA-**
2010 (38th)	-	**Review, after 5 years from the enforcement of the revised Pharmaceutical Affairs Law**

GMP Informal Discussion Meeting (s) ; is not a meeting in order to make conclusions, but is the one to help companies improve quality assurance through candid gathering among members.

3. GMP Case Study Workshop Seminars

GMP事例研究会

JPMA

Year	Trends in ICH, etc.	Main theme
1999 (26th)	-	Improvement in reliability of the quality of pharmaceutical products
2000 (27th)	-	Improvement in reliability of the quality of pharmaceutical products
2001 (28th)	Q7	Reliability assurance in the quality of pharmaceutical products in relation to globalization
2002 (29th)	-	Latest news surrounding GMP (International mutual recognition of pharmaceutical products, electronic records and electronic signatures)
2003 (30th)	-	Quality systems in the 21st century - future perspective of GMP in Japan - (ICH GMP special symposium)
2004 (31th)	PIS/S, CSV	Establishment of quality systems for pharmaceutical products toward the 21st century (Revised Pharmaceutical Affairs Law, quality engineering, Part 11, PAT, etc.)
2005 (32th)	-	Responses to new regulations and the establishment of quality assurance systems
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2007 (34th)	ICH Q10 (invite opinions)	"Collaboration" between marketing businesses and manufacturing businesses - Each company's actions for change control and deviation processing, etc. -

3. GMP Case Study Workshop Seminars

GMP事例研究会

Year	Trends in ICH, etc.	Main theme
2008 (35th)	-	Conduct application case studies on ICH Q-trio and promote studies for further implementation of GMP
2009 (36th)	-	Examples of activities by the companies pertaining to corrective actions and preventive actions in GMP
2010 (37th)	-	Approaches to international GMP requirements