

Bulletin of Japan Society of Quality Assurance

日本QA研究会

アジア QA フォーラム特集号

Asia QA Forum Memorial Issue

Asia
Quality
Assurance
Forum



July 5 – 6 ,2013, Tokyo, Japan

*Oct.2013
Special Issue*

Bulletin of Japan Society of Quality Assurance

Asia QA Forum Memorial Issue

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Chairperson of Asia QA Forum Organization Committee
Yoshikazu Hasegawa

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POST-FORUM NOTES

Post-Forum Notes

The Asia QA Forum was established by the joining of 7 societies from seven Asian countries based on an initiative of JSQA, and the first International Forum has been successfully held. The presentations by each speaker from their respective countries were very useful for the participants. These successes gave me great pleasure. I heartily give my thanks to all participants from the Asian countries. The first General Council Assembly was held by the attendance of the representatives of the 7 societies after the signing ceremony of the establishment of the Asia QA Forum. In the conference, we held discussions and achieved the results through mutual consent about the next International Forum schedule and the host Society with the participants' cooperation. Moreover, we also achieved consensus regarding the candidate host societies of the third and the fourth International Forums. This shows the strong expectation and enthusiasm for the Asia QA Forum.



The drafting of the establishment of the Asia QA Forum goes back to June, 2010. When I was in Seoul giving my lecture in the Summer Seminar of KSQA, it was the first opportunity for me to have discussions about the establishment of the Asia QA Forum with the secretary members of KSQA. Establishment of the Asia QA Forum was assumed by the joint proposal of JSQA/KSQA. I persuaded JSQA Board members to propose the establishment of the Asia QA Forum at the 3rd Global QA Conference (3rdGQAC) sponsored by JSQA in Kyoto in November, 2011 and I proposed it to the participants from the Asian countries. And this proposal was agreed to by all the representatives of Asian QA Societies, a monitoring authority officer and a scientific society in Asia. By this, the establishment of the Asia QA Forum gained more and more momentum.

Since then, pharmaceutical products development has been globalized, and it has been revealed that we can no longer develop pharmaceutical products without Asia. In the Asian countries, introducing GXP regulations has been advanced and several QA Societies have been established in sequence and are active. That is why the participants from each Asian country in the 3rdGQAC showed strong interest and expectation in the drafting of the Asia QA Forum. Therefore they supported the proposal for establishing the Asia QA Forum and also for holding the International Forum as an effective means of information exchange among Asian QA Societies.

This is a small first step of the Asian QA forum that started in Seven Societies in Seven Asian countries. However, the Asia QA forum now contributes QA people in many Asian countries for QA training, improves QA skills and is active. I pray that the Asian people will be brought a higher level of quality development and production in GXP in the future.

Yoshikazu Hasegawa

Chairperson of Asia QA Forum Organization Committee

Report on the 1st Council Assembly

1

Keep the Quality Up, We Asia!

Yoshikazu Hasegawa
JSQA Asia QA Forum Organization Committee
Chairperson

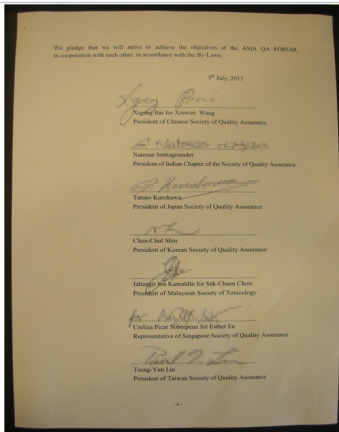
Keep the Quality Up, We ASIA!

Member Forum of Asia QA Forum

2

- Chinese Society of Quality Assurance
- Indian Chapter of the Society of Quality Assurance
- Japan Society of Quality Assurance
- Korean Society of Quality Assurance
- Malaysian Society of Toxicology
- Singapore Society of Quality Assurance
- Taiwan Society of Quality Assurance

Keep the Quality Up, We ASIA!



Keep the Quality Up, We ASIA!

3

Conclusion of the 1st Council Assembly

4

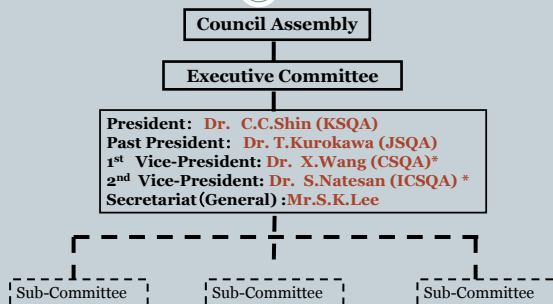
- 2nd International Forum in 2015
Korean Society of Quality Assurance
- 3rd International Forum*
Chinese Society of Quality Assurance
- 4th International Forum*
Indian Chapter of the Society of Quality Assurance

*: a tentative decision

Keep the Quality Up, We ASIA!

Asia QA Forum New Organization

5



*: tentative assignment

Keep the Quality Up, We ASIA!

Asia QA Forum

6

*Keep the Quality Up,
We Asia!*

Thank you for your attention

Keep the Quality Up, We ASIA!



PHOTO ALBUMS

<Registration>



6



<Signing Ceremony>



<Opening Remarks>

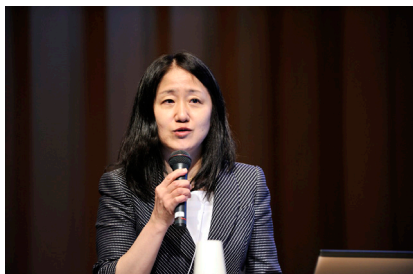
Tatsuo Kurokawa, President of JSQA, Keio University



<Keynote Lecture>

Chair : Tatsuo Kurokawa, President of JSQA, Keio University

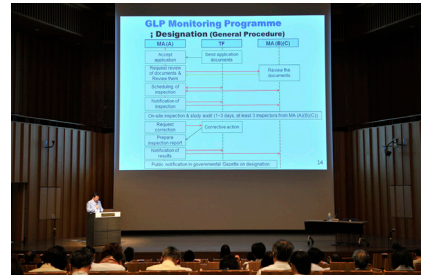
Seiko Miyazaki, Office of Conformity Audit, Pharmaceuticals and Medical Devices Agency (PMDA)



<GLP Session>

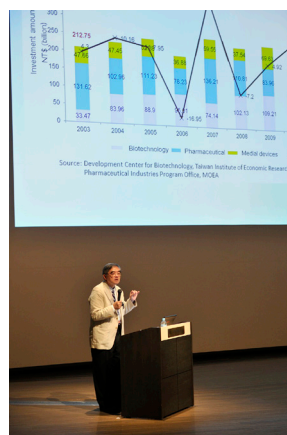
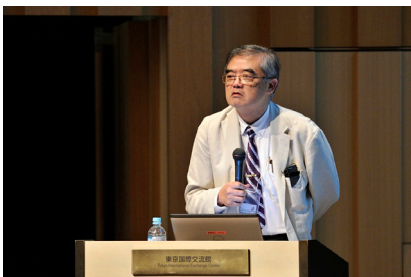
Chair : Yoshikazu Hasegawa(RIKEN GENESIS/JSQA)

Chun-Chul Shin(Korea : KSQA) President of KSQA, Korea Institute of Toxicology



Chair : Yasuhide Kouchi(TAIHO PHARMACEUTICAL CO., LTD./JSQA)

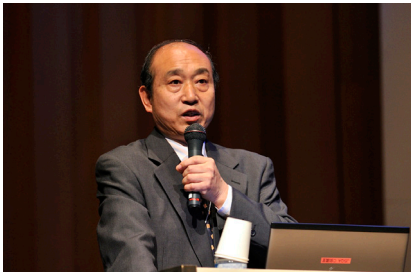
Tsung-Yun Liu(Taiwan : TSQA) President of TSQA, Veterans General Hospital-Taipei



<GLP Session>

Chair : Fujun Chen(Mitsubishi Chemical Medience Corporation/JSQA)

Xigeng Bai(China : CSQA) Vice President of CSQA, Safety Evaluation Center, Shenyang Research Institute of Chemical Industry



Chair : Fujun Chen(Mitsubishi Chemical Medience Corporation/JSQA)

Qi Zhao(China : CSQA) Shenyang Research Institute of Chemical Industry



<Pharmacovigilance(GVP)Session>

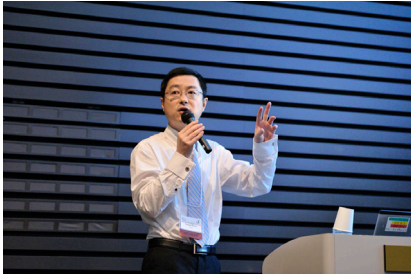
Chair : Tetsuya Saito(Pfizer Japan Inc./JSQA), Ayami Komatsu(Japan Tobacco Inc./JSQA)
Wenhong(Charles) Li(Singapore) Merck Pte. Ltd.



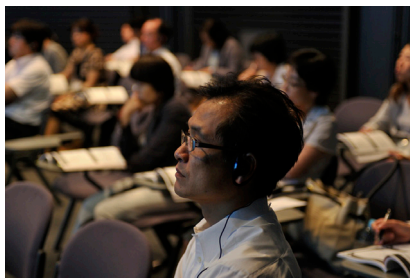
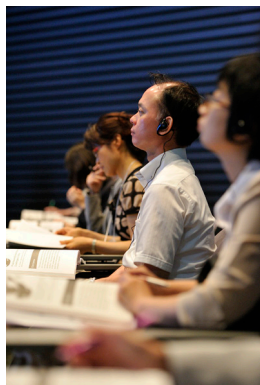
<Pharmacovigilance(GVP)Session>

Chair : Tetsuya Saito(Pfizer Japan Inc./JSQA) , Ayami Komatsu(Japan Tabaccon Inc./JSQA)

Tianxun Wang(China) Rundo International Pharmaceuticals Research & Development Co., Ltd.



14



<GCP Session>

Chair : Tadaki Nagasawa(ASKLEP Inc./JSQA)

Toshiyoshi Tominaga The Food and Drug Evaluation Center, Osaka City University Hospital



Masahiro Tohkin Graduate School of Pharmaceutical Sciences, Nagoya City University



<GCP Session>

Noriaki Suzuki (CMIC Co., Ltd./JSQA)



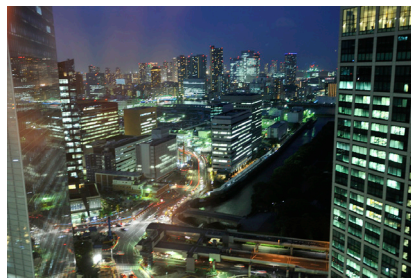
Panel Discussion (Panelists : Speakers and JSQA member)



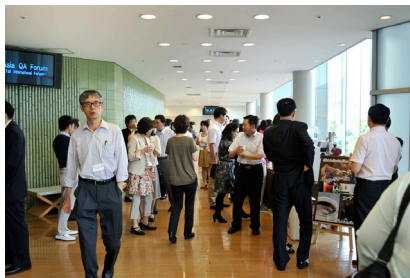
<Banquet>



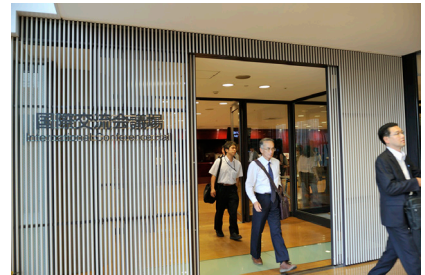
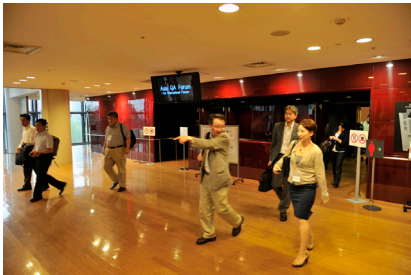




<Coffee Break>



<Closing Ceremony>



The background of the page is a light green gradient with a pattern of stylized green leaves and clovers. The leaves are of various sizes and are scattered across the page, with a higher concentration in the top and bottom borders. The clovers are also scattered, adding to the natural theme. The overall effect is a soft, fresh, and natural aesthetic.

GREETINGS

Attending the 1st Asia QA Forum

KSQA President Chun-Chul Shin

A growing number of regulatory submissions are made world-wide, and preclinical and clinical studies for drug development are requested to be performed internationally. Thus, it is becoming ever more important to understand each countries' regulations, interpretation of those regulations and views of the respective regulatory authorities. QA professionals all over the world gather in conferences and forums to exchange updates on regulations and current industry standards. The SQA Annual Meeting is a good example where regulatory inspectors and industry experts in GLP, GCP and GMP come together to promote global harmony and development. Nowadays, Asian counties are taking on bigger roles in the drug development pathway and making its presence in the global arena. Therefore, it is most important for QA professionals from Asian counties to participate in the transaction and harmonization of the global trend.



It was my pleasure, therefore, to participate in the first Asia QA Forum held in Tokyo, Japan on July 5th. The cool breeze in Odaiba greeted me as I met various QA professionals from 8 different Asian countries. This being the first Asia QA Forum, much was focused on getting to know the GLP regulations for each country and their own way of compliance. After a heartfelt welcome from JSQA president Dr. Tatsuo KUROKAWA, Dr. Seiko Miyazaki, inspector from PDMA, gave us insight into the importance of the Asia QA Forum with her lecture on harmonization of Asian drug development regulatory authorities. Dr. Tsung-Yun Liu, President of TSQA explained the current regulatory authority's organization of Taiwan and its monitoring system, and Dr. Jahangirbin Kamaldin, a GLP inspector of Malaysia avidly explained to us his experience of the Malaysian GLP monitoring system. ICSQA President Dr. Natesan Settiagounder specifically described the history of GLP inspection in India and its current status while CSQA Vice-chair Mr. Xigeng Bai professed the status of China's GLP certification and some of the major findings. The real life experiences and examples of the lecturers were more realistic and direct beyond any expectations. Based on a status analysis from those much appreciated lectures, I believe they presented a direction for Asian QA professionals to follow. The dinner banquet prepared by JSQA afterwards was as much of a delight as the lectures.

I was deeply impressed how perfectly the Asia QA Forum has been organized despite being the first. I would like to express my gratitude for Dr. Y. Hasegawa and Ms. Satoko Takahashi who have worked so hard to organize this forum.

With great honor, the 2nd Asia QA Forum will be held in Korea hosted by KSQA. The 2nd Asia QA Forum is scheduled to be held in July of 2015 under the title "Continuing Efforts for Quality in Asia". Based on what we have learned from the first Asia QA Forum hosted by JSQA, KSQA will make efforts to host another great Asia QA Forum. Thank you.

2nd International Forum

Asia Quality Assurance Forum

JULY 2 (THU) and JULY 3 (FRI), 2015*

KOREA



SEOUL



HOSTED BY KSOA
HONGKONG QUALITY ASSURANCE

** Tentative*



SCHEDULE FOR KEY DATES

- **August, 2013 – Jan, 2014**
 - Call for Plenary, Keynote, Lecturers
 - Call for Symposium Proposals
- **4th Quarter of 2014**
 - Listing Plenary, Keynote, Invited Lecturers
 - Call for Paper (oral and poster presentation)
- **1st Quarter of 2015**
 - Early Registration

Subject To Change



LECTURES and SESSIONS

MAIN THEME:
"Continuing Efforts for Quality in Asia"

➤ **SESSIONS**

- Plenary and Keynote Lectures
- Concurrent Sessions
- Panel Discussion
- Symposium

Subject To Change

SEE YOU 2015!!

WITH EXCITEMENT



AND TRANQUILITY

Watch out for upcoming news on our website! -----
<http://www.kqa.or.kr>

The background of the page is a light green color with a pattern of stylized, overlapping green leaves and four-lobed clover-like shapes. The pattern is more dense at the top and bottom edges, fading towards the center. The word "APPENDIX" is centered in the middle of the page in a bold, black, serif font.

APPENDIX

Greetings

Dear Delegates,

Welcome to Tokyo and also the first conference of the Asia QA Forum.

On behalf of Japan Society of Quality Assurance (JSQA), it is my great pleasure to welcome you all to this conference.

This month marks the founding of the Asia QA Forum. As the president of JSQA, I am really pleased and honored to have this memorial establishment of the Asia QA Forum and its first conference here in Tokyo.

The keywords of this conference are “Keep the quality up, We Asia”. We invited our members to submit their keywords suggestions. We adopted these words, as they express our intention to enhance advancement of quality assurance among Asian countries.

I sincerely hope that the Asian QA Forum organization and its international conferences will eventually expand to provide wonderful opportunities for the member countries to exchange information and discussion of various topics and problems concerning quality assurance in the Asian region. Also, the international conferences of Asia QA Forum will advance the knowledge and skills of a lot of regulatory personnel, pharmaceutical companies, CROs, etc. from Asian countries, as they collaborate for mutual understanding of the quality assurance systems.

During the preparation of this conference, we have encountered a number of difficulties, which have been overcome one-by-one, with the help of many people here - directly and indirectly. Finally, I would like to thank all of you who are participating in this conference. I believe you will find that the First International conference of the Asia QA Forum will be extremely informative and valuable for all of us.

Best wishes,

A handwritten signature in black ink, reading "T. Kurokawa". The signature is written in a cursive style and is underlined with a thick black line.

Tatsuo Kurokawa

President of Japan Society of Quality Assurance

ACKNOWLEDGMENTS

Sponsorship:

Thanks go to the following sponsors:

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- Shin Nippon Biomedical Laboratories, Ltd.
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- CTC Laboratory Systems Corporation
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The Organizing Committee of the Asia QA Forum 1st International Forum:

Yoshikazu Hasegawa	Chairman of the Asia QA Forum 1st International Forum RIKEN GENESIS CO., LTD.
Takashi Furuya	Vice President of JSQA, Tsumura & Co.
Keiji Samura	Director of GLP Division, Huntingdon Life Sciences Ltd.
Mikiko Kuwabara	Director of GLP Division, Toray Industries, Inc.
Tadaki Nagasawa	Director of GCP Division, ASKLEP Inc.
Tatsuya Saito	Director of GQP/GVP/GPSP Division, Pfizer Japan Inc.
Yasuhide Kouchi	TAIHO PHARMACEUTICAL CO., LTD.
Kazumi Tokoro	Astellas Pharma Inc.
Yoichi Matsushita	DAIICHI SANKYO CO., LTD.
Noriaki Suzuki	CMIC Co., Ltd.
Shoko Inoue	Actelion Pharmaceuticals Japan Ltd.
Fujun Chen	MITSUBISHI CHEMICAL MEDIENCE CORPORATION
Seiichi Hata	CMIC Co., Ltd.
Teiki Iwaoka	CAC ExiCare Corporation
Makiko Azuma	Japan Society of Quality Assurance (JSQA)
Satoko Takahashi	Japan Society of Quality Assurance (JSQA)

MEETING INFORMATION

Date:

Friday, July 5 - Saturday, July 6, 2013

Venue:

Tokyo International Exchange Center Plaza HEISEI
Tokyo Academic park, 2-2-1 Aomi, Koto-ku, Tokyo, Japan
Phone: 03-5564-3030
http://www.jasso.go.jp/tiec/plazaheisei_e.html

Organizer:

Japan Society of Quality Assurance (JSQA)

Official Language:

English and Japanese
Simultaneous interpretation will be provided in English and Japanese for oral presentations.

Registration Desk:

All congress materials will be available at the conference registration desk.
Also, please feel free to contact them in case you need any additional information or assistance.

Opening hours:

Friday, 5 July, 2013	9:30-17:00
Saturday, 6 July, 2013	9:00-16:00

Lunch:

Lunch will not be provided during the conference period. However, there are many different types of restaurants near the conference center. We encourage you to explore this area and visit some restaurants. As to the detailed information, please see the "Lunch Map" (page 6,7).

Coffee Break:

Drink service will be available in the foyer of the International Conference Hall (3F).

Friday, 5 July, 2013	16:25-16:40
Saturday, 6 July, 2013	10:50-11:10 and 16:00-16:15

Banquet:

Time and Date: 18:30-20:30, Friday, July 5, 2013

Venue: *The Shiosai Banquet Hall (25th floor)*, Royal Park Shiodome
1-6-3 Higashi-Shinbashi, Minato-ku, Tokyo 105-8333
Phone : +81-3-6253-1111
Directions to the hotel: Please see the page the "Access Map" (page 8,9).

Fee: 6,000 Japanese Yen

*An advanced reservation is necessary to participate. Tickets cannot be purchased at the venue.

*Please be sure to bring your ticket and name badge with you at the Banquet Hall.

Name Badge:

All participants are kindly requested to wear their name badges at all times during the congress including the Banquet.

Internet:

Internet access will not be available in the conference center.

Prohibitions

*Photography, video recording, sound recording are prohibited within the Meeting venue.

*Please refrain from eating or drinking in the conference rooms.

(International Conference Hall and Media Hall)

*The conference hall is non-smoking. But you can smoke in the designated smoking area.

Mobile phones

Participants are kindly requested to keep their mobile phones turned off while attending the sessions in the meeting rooms.

Secretariat:

Japan Society of Quality Assurance (JSQA)

Mita-kokusai Bldg. 6F, 1-4-28, Mita, Minato-ku, Tokyo 108-0073, Japan

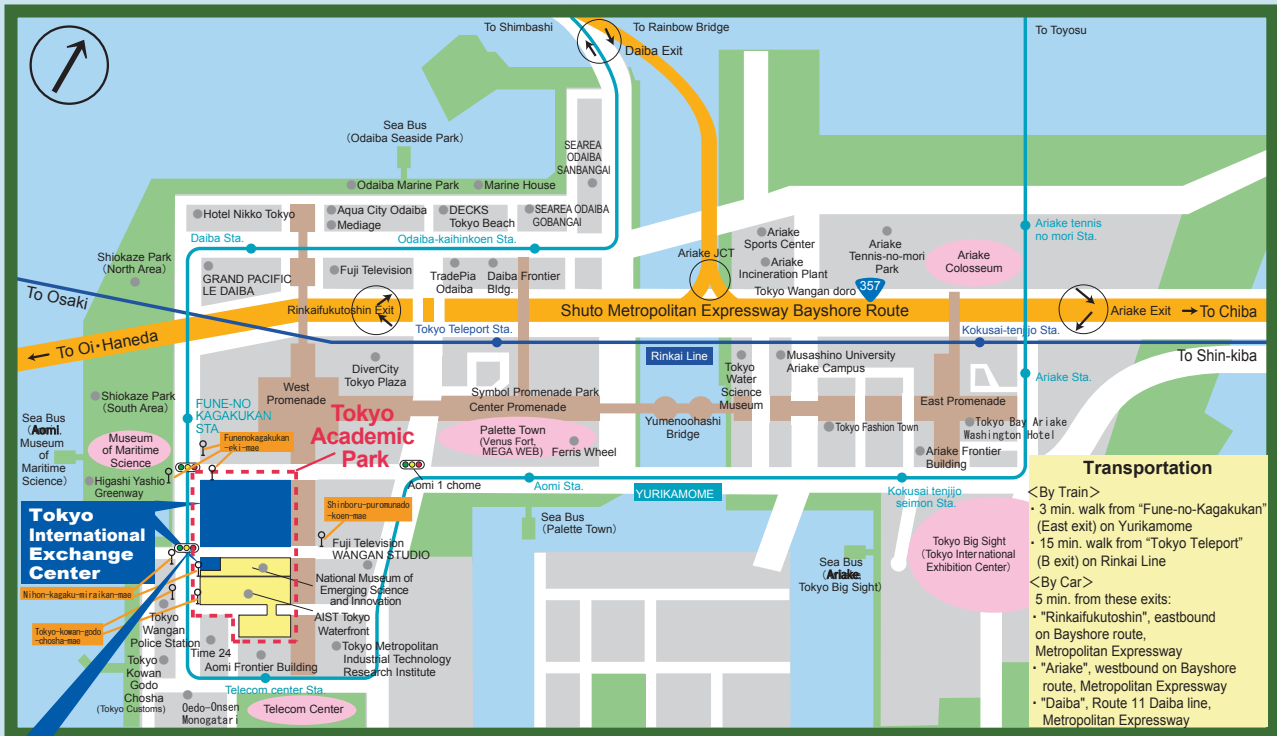
Phone: +81-3-6435-2118

Facsimile: +81-3-6435-2119

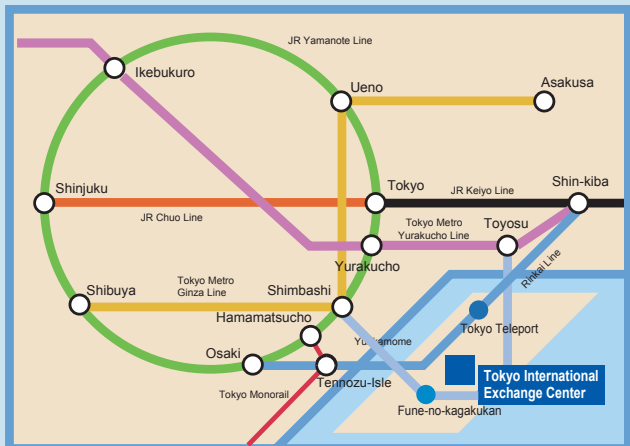
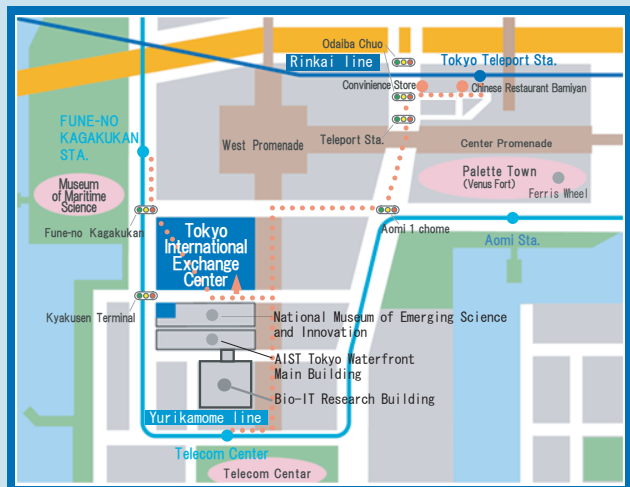
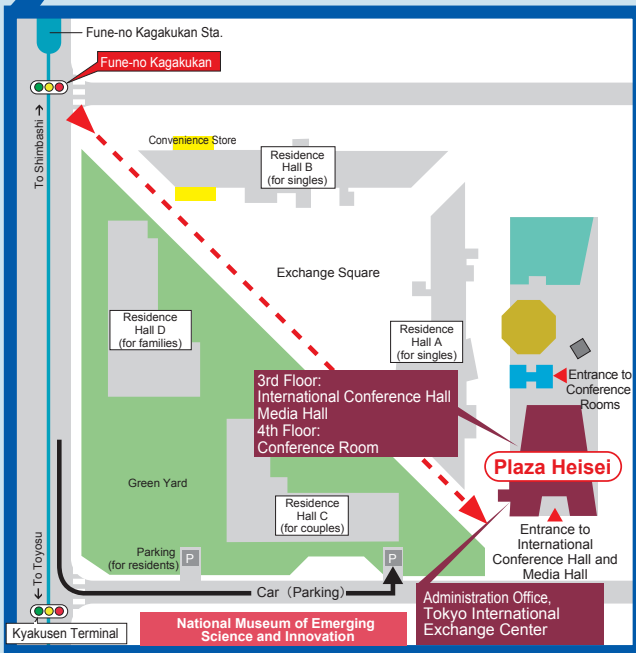
E-mail : asiaqaforum_japan@jsqa.com

URL : <http://www.jsqa.com/1staqafc/>

Tokyo International Exchange Center access map

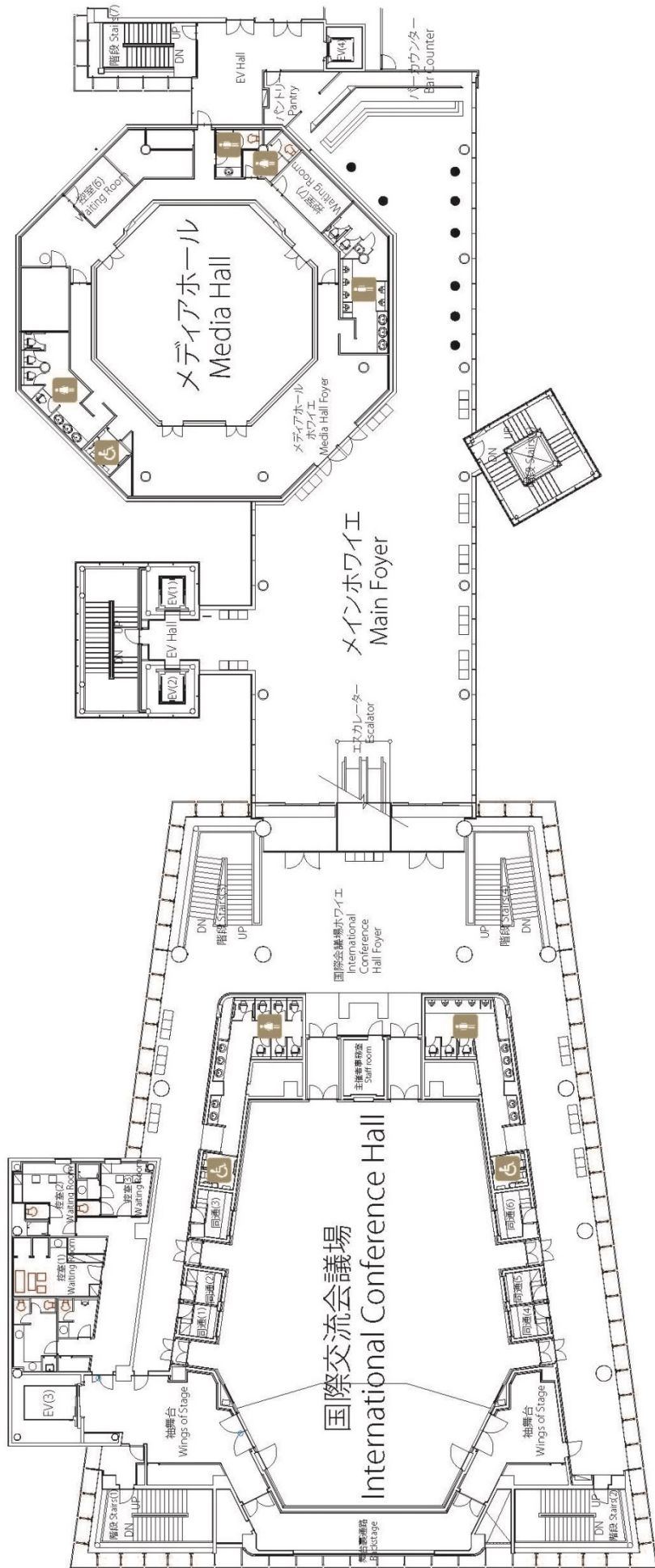


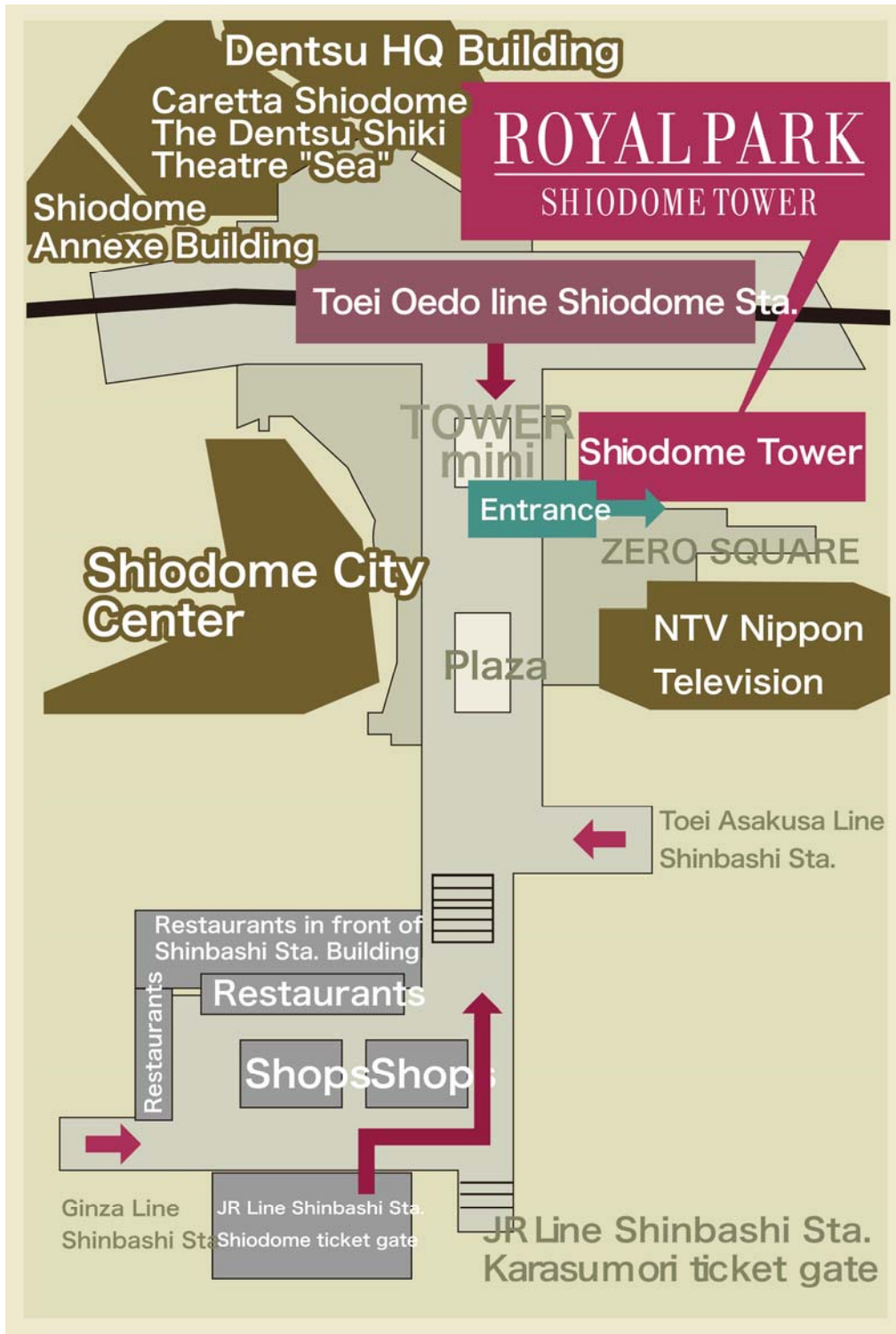
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Tokyo International Exchange Center
PLAZA HEISEI
 2-2-1 Aomi, Koto-ku, Tokyo 135-8630 Japan

3F





【PROGRAM】**Friday, July 5, 2013**

Simultaneous interpretation will be provided in English and Japanese

Opening Remarks and Keynote Lecture **13:30-14:30**
at International Conference Hall

Opening Remarks

13:30-13:45 Tatsuo Kurokawa, President of JSQA, Keio University

Keynote Lecture

Chair: Tatsuo Kurokawa, President of JSQA, Keio University

13:45-14:30 Seiko Miyazaki, Office of Conformity Audit, Pharmaceuticals and
Medical Devices Agency (PMDA)*"Strengthening Cooperation among Asian Drug Regulatory Authorities"***GLP Session **14:45-17:30****
at International Conference Hall

Topics: Current GLP situation, findings and authority's instruction and its background

14:45-15:35 Chair: Yoshikazu Hasegawa (RIKEN GENESIS/JSQA)

Chun-Chul Shin (Korea:KSQA) (45min, Q&A 5min)

President of KSQA, Korea Institute of Toxicology

"Recent GLP update in Korea"

15:35-16:25 Chair: Yasuhide Kouchi (TAIHO PHARMACEUTICAL CO., LTD./JSQA)

Tsong-Yun Liu (Taiwan:TSQA) (45min Q&A 5min)

President of TSQA, Veterans General Hospital-Taipei

"The current Taiwan GLP and the monitoring system"

16:25-16:40 Coffee Break

16:40-17:30 Chair: Kazumi Tokoro (Astellas Pharma Inc./JSQA)

Jahangir bin Kamaldin (Malaysia) (45min Q&A 5min)

STANDARDS MALAYSIA GLP Inspector

Advanced Medical & Dental Institute, Universiti Sains Malaysia

*"Tips from International Experience for Effective GLP Inspectors &
Compliance Programme in Malaysia"*

Pharmacovigilance (GVP) Session

14:45-16:25

at Media Hall

Chair: Tatsuya Saito (Pfizer Japan Inc./JSQA), Ayami Komatsu (Japan Tobacco Inc./JSQA)

14:45-15:35 Wenhong (Charles) Li (Singapore) (40min, Q&A 10min)

Merck Pte. Ltd.

"Pharmacovigilance Audit and Challenges in Asia"

15:35-16:25 Tianxun Wang (China) (40min, Q&A 10min)

Rundo International Pharmaceuticals Research & Development Co., Ltd.,

"Quality Assurance in China/China pharmaceutical industry"

【PROGRAM】**Saturday, July 6, 2013**

Simultaneous interpretation will be provided in English and Japanese

GLP Session**9:30-12:30**

at International Conference Hall

- 9:30-10:10 Chair: Keiji Samura (Huntingdon Life Sciences/JSQA)
Vinita Sharma (India) (35min, Q&A 5min)
National GLP Compliance Monitoring Authority, Department of Science &
Technology, Government of India
*"Indian GLP Compliance Monitoring System - Inspection and certification
Practices (Monitoring Authority Stand Point of View)"*
- 10:10-10:50 Chair: Yoichi Matsushita (DAIICHI SANKYO COMPANY, LIMITED/JSQA)
Natesan Settiagounder (India:ICSQA) (35min, Q&A 5min)
President of ICSQA, Advinus Therapeutics Limited
*"The Concrete Indian GLP System and the Instruction and Findings in the
Authority's Inspection"*
- 10:50-11:10 Coffee Break
- 11:10-11:50 Chair: Fujun Chen (Mitsubishi Chemical Medience Corporation/JSQA)
Xigeng Bai (China:CSQA) (35min, Q&A 5min)
Vice President of CSQA, Safety Evaluation Center, Shenyang Research
Institute of Chemical Industry
"Chinese GLP System and Main findings"
- 11:50-12:30 Chair: Fujun Chen (Mitsubishi Chemical Medience Corporation/JSQA)
Qi Zhao (China:CSQA) (35min, Q&A 5min)
Shenyang Research Institute of Chemical Industry
"The 5 Bathes Analysis Study in GLP system"

GCP Session

14:00-17:00

at International Conference Hall

Chair: Tadaki Nagasawa (ASKLEP Inc./JSQA)

- 14:00-14:40 Toshiyoshi Tominaga (35min, Q&A 5min)
The Food and Drug Evaluation Center, Osaka City University Hospital
"Future strategy for Japan on Asian clinical trials -Strategy around Quality of Japanese Clinical Trials-"
- 14:40-15:20 Masahiro Tohkin (35min, Q&A 5min)
Graduate School of Pharmaceutical Sciences, Nagoya City University
"Comparative Studies of Pharmacokinetics among East Asian Populations and Caucasian"
- 15:20-16:00 Noriaki Suzuki (JSQA) (35min, Q&A 5min)
CMIC Co., Ltd.
"Current Situation of Conduct of Clinical Trials and Local Regulations in Korea, China, and Taiwan from the Perspective of Auditors"
- 16:00-16:15 Coffee Break
- 16:15-17:00 Panel Discussion (Panelists: Speakers and JSQA member)

Closing Ceremony

17:00-

at International Conference Hall

Closing Ceremony and handover to KSQA

ASIA QA FORUM

Member's Pledge

5th July, 2013, Tokyo, Japan

1. Background of Forum Organization

In Asian countries, GXP quality assurance activities have moved from the early stage to the advancing stage and QA associations have been locally organized in succession. Meanwhile, research and development as well as manufacturing and marketing of pharmaceuticals and other products have been globalized and activities with attention to other countries had become necessary. In quality assurance activities as well, it has been increasingly realized that it is important to exchange information and discuss various problems concerning quality assurance not merely in each Asian country but also in Asia as a whole in an effort to standardize quality assurance and elevate its quality.

As an approach to deal with quality assurance in the Asian region, JSQA (Japan Society of Quality Association) and KSQA (Korean Society of Quality Association) proposed the organization of the ASIA QA FORUM and drafted the purposes of its organization at the 3rd GQAC (3rd Global Quality Assurance Conference) and obtained support for the proposal from the countries participating in the 3rd GQAC – China, Taiwan, Thailand, India, Malaysia and Singapore. In 2013, JSQA convened a general meeting for the organization of the ASIA QA FORUM and obtained similar support for its proposal to hold an international meeting of the ASIA QA FORUM.

With the above support obtained, the ASIA QA FORUM is organized to provide opportunities for exchange of information and discussion of various problems concerning quality assurance in the Asian region to promote mutual understanding about quality assurance and elevate its quality.

2. Purposes of Organization

- 1) To provide opportunities for exchange of information about GXP quality assurance in Asian countries.
- 2) To provide opportunities for discussion of various problems concerning GXP quality assurance in Asian countries.
- 3) To provide opportunities for mutual assistance and cooperation for solution of various problems concerning GXP quality assurance in Asian countries.

3. Basic Policy for Organization and Activities

- 1) The ASIA QA FORUM is a confederation of QA associations or other associations having interest in quality assurance in Asian countries that have agreed to its articles of association and signed to join this Forum.
- 2) The ASIA QA FORUM has no fixed secretariat or organizational structure and collects no admission fee.
- 3) The member associations sponsor an international meeting of this Forum in each Asian country by turns.

By-Laws of ASIA QA FORUM

Adopted on 5th July, 2013

1. NAME

The name of the organization shall be the “THE ASIA QUALITY ASSURANCE FORUM”. The official abbreviation of this name shall be “ASIA QA FORUM”.

2. PURPOSE AND STATUS

2-1 Purpose

The purpose of the Forum shall be to foster co-operation among Asian countries and promote progress in quality assurance in GXP in the region, in particular by sponsoring “The International forum on Asian Quality Assurance”.

2-2 Status

ASIA QA FORUM shall be the coalition of QA Society and Party related GXP in the Asian region.

3. MEMBERSHIP

3-1 Members

ASIA QA FORUM recognizes two member categories: Member Forum, and Associate Member Forums.

3-2 Member Forum

Any Quality Assurance Society in the Asian region shall be eligible to become a Member Forum of ASIA QA FORUM.

3-3 Associate Member Forum

Any Quality Assurance Society in the world may become an Associate Member Forum of ASIA QA FORUM.

3-4 Rights

Member Forum shall have the right to participate in the scientific and business affairs of ASIA QA FORUM, and to receive notice of, and send delegates to attend and vote at the Council Assembly as stated in By-Laws 4-4.

Associate Member Forum shall have the right to participate in the scientific and business affairs of ASIA QA FORUM.

3-5 Application

Application for membership shall be sent to the Secretariat ASIA QA FORUM no later than three months before the Council Assembly at which it is to be considered. The application is subject to review and decided as provisional participation by the Executive Committee. A decision of the official participation will be made at the most recent Council Assembly. The provisional participation in each membership has the same rights in By-Laws 3-4.

3-6 Expulsion

Any Forum shall be subject to expulsion from ASIA QA FORUM by a resolution at the Council Assembly when it is judged that Forum causes serious damage to ASIA QA FORUM.

4. COUNCIL

4-1 Councilors

The Council shall consist of persons hereafter called Councilors, which shall be the representative of each Member Forum.

4-2 Number

The number of Councilors shall be the number of Member Forum which is approved by the Council Assembly.

4-3 Term

Councilors shall serve for a two-year term and be eligible to serve for more than one term.

4-4 Meeting

The Council shall meet concurrently with each International Forum of ASIA QA FORUM and on other occasions as decided by the Council. Such meeting shall be called a "Council Assembly". Each Associate Member Forum may send one Observer to attend the Council Assembly. In special circumstances, the President may summon an extraordinary Council Assembly at any time. This extraordinary Council Assembly can be carried out by mail communication. The President is obliged to summon such a meeting upon receipt of written request by at least one-third of the Councilors.

5. EXECUTIVE COMMITTEE

5-1 Constitution

The Executive Committee shall consist of a President, 1st Vice-President, a Past-President (i.e., the immediately preceding President) a Secretary-General, and Subcommittee Chairpersons (if available). A President's Society becomes a host

society of the International Forum. A Past-President becomes an ex-President. 1st Vice-President's Society becomes a next host society of the International Forum. The members of the Executive Committee other than the Subcommittee Chairpersons shall be authorized by the Councilors from among the Council membership at a Council Assembly. The Subcommittee Chairperson shall be nominated by the President as stated in By-Laws 5-4.

5-2 Term

Executive Committee members shall serve a two-year term. All members may serve for three consecutive terms. Each member position may serve in that position for only one term. Members who have finished their allowable terms of service are eligible for re-nominate after an absence of one or more terms.

5-3 Vacancies

If a member of the Executive Committee resigns his/her office, or is absent from his/her office without reasonable excuse for six months, or is suspended or expelled from ASIA QA FORUM, the Executive Committee shall declare his/her office vacated and demand a deputy representative to a member forum, and may appoint a successor in his/her place to hold office until the next Council Assembly.

5-4 Subcommittees

If the President finds it appropriate and if the Executive Committee agrees, the President may establish a subcommittee to be assigned specific activities and nominate a Councilor as chairperson of such subcommittee.

6. DUES

6-1 Holding International Forum

All Member Societies shall perform holding of International Forum according to decision of the Executive Committee as duty every country to which a member society belongs.

6-2 Fiscal Responsibility

The host Member Society shall be responsible for all income and expenses for the International Forum.

6-3 Dispatch Responsibility

If possible, a Member Society shall dispatch a speaker for the International Forum when the host Member Society shall request it. A Member Society shall bear the transportation expenses necessary for dispatch, including the air fare. The host Member Society shall waive the accommodation and registration expenses for a dispatched speaker.

7. SECRETARIAT

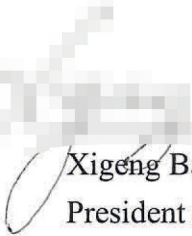
The Secretariat Office shall be in the host Member Society. The Council Assembly may recognize an ASIA QA FORUM Secretariat Office to carry out the business of the forum of ASIA QA FORUM in the host Member Society.

8. BY-LAWS AMENDMENTS


By-Laws Amendments shall be made by the Council. Amendments may be considered only at the Council Assembly. Proposed amendments must be sent to the Secretary-General no later than six months before the Council Assembly at which they are to be considered. The Secretary-General shall send the proposed amendments to all Member Societies at least two months before the Council Assembly. At the Council Assembly, two-thirds of the attendees must cast supporting votes to amend the By-Laws.

We pledge that we will strive to achieve the objectives of the ASIA QA FORUM, in cooperation with each other, in accordance with the By-Laws.


5th July, 2013



Xigeng Bai for Xiuwen Wang
President of Chinese Society of Quality Assurance




Natesan Settiagounder
President of Indian Chapter of the Society of Quality Assurance




Tatsuo Kurokawa
President of Japan Society of Quality Assurance



Chun-Chul Shin
President of Korean Society of Quality Assurance



Jahangir bin Kamaldin for Sek-Chuen Chow
President of Malaysian Society of Toxicology



Creliza Picar Sobrepena for Esther Ee
Representative of Singapore Society of Quality Assurance



Tsung-Yun Liu
President of Taiwan Society of Quality Assurance

**Asia QA Forum Establishment Meeting
Signing Ceremony and 1st Council Assembly
Meeting Minutes**

Friday, 5th July 2013

12:15 p.m.- 1:15 p.m.

Level 4, Room 103

*Tokyo International Exchange Center Plaza HEISEI,
Tokyo, Japan*

Asia QA Forum Establishment Meeting & Signing

Date & Time: July 5th, 2013, 12:15 p.m. - 12:35 p.m.

Agenda:

- Welcome/Call to Order by Dr. Kurokawa
- Confirmation of Member's Pledge including By-Laws
- Signing Ceremony
- Taking photos

Participants

- **IL Je Yu, Dr.**, (Korea); Past President of the Korea Society of Quality Assurance
- **Chun-Chul Shin, Dr.**, (Korea), President of the Korea Society of Quality Assurance
- **Bai Xigeng, Mr.**, (China); Vice-President of Chinese Society of Quality Assurance
- **Natesan Settiagounder, Dr.**, (India); President of Indian Chapter of the Society of Quality Assurance
- **Tsung-Yun Liu, Dr.**, (Taiwan); President of the Taiwan Society of Quality Assurance
- **Jahangir bin Kamaldin, Dr.**, (Malaysia); Deputy Representative of Malaysia Toxicology Society
- **Creliza Picar Soberpen, Ms.**, (Singapore); Deputy Representative of Singapore Society of Quality Assurance
- **Tatsuo Kurokawa, Dr.**, (Japan); President of Japan Society of Quality Assurance
- **Shigeo Watabe, Dr.**, (Japan); Vice-President of Japan Society of Quality Assurance
- **Yukio Fujino, Mr.**, (Japan); Vice-President of Japan Society of Quality Assurance
- **Takashi Furuya, Mr.**, (Japan); Vice-President of Japan Society of Quality Assurance
- **Keiji Samura, Dr.**, (Japan); Director of GLP of Japan Society of Quality Assurance
- **Yoshikazu Hasegawa, Mr.**, (Japan); Chairperson of Asia QA Forum Organization Committee in JSQA

Minutes of Asia QA Forum Establishment Meeting & Signing

- Welcome/Call to Order by Dr. Kurokawa
JSQA President Dr. Kurokawa gave his appreciation for the representative of each

Society from Asian countries joining in the Asia QA Forum and talked about hopes of cooperating by each group of Asian countries for the future improvement of the Quality Assurance within Asia.

- Confirmation of Member's Pledge including By-Laws , and the Signing Ceremony
With regards to the contents of the Asia QA Forum Member's Pledge, the document confirmation was carried out in this meeting. All participants agreed with the Asia QA Forum Member's Pledge and signed it as the representative of each group.

Asia QA Forum 1st Council Assembly

Date & Time: July 5th, 2013 12:40 p.m.- 1:15 p.m.

Agenda:

- Welcome/Call to Order by Mr. Hasegawa
- Host country /Society approval of the 2nd International Forum
- Host country (Society) approval of the 3rd International Forum

Participants: Same as the previous meeting except for Dr. Kurokawa. He was absent from this meeting due to a conflicting schedule.

Minutes of Asia QA Forum 1st Council Assembly

Mr. Hasegawa took the chairman's responsibility instead of Dr. Kurokawa in this meeting. Dr. Samura took the secretary's responsibility in this meeting.

Agenda 1 was the approval of the 2nd International Forum. KSQA (Korea Society of Quality Assurance) proposed holding the 2nd International Forum of Asia QA Forum in Korea sponsored by KSQA. Dr. Shin explained the KSQA's proposal (cf. attached slides). KSQA was the Co-Proposer of the Asia QA Forum establishment. According to their proposal the 2nd International Forum of Asia QA Forum will be held on July 2nd and 3rd, 2015 in Seoul, Korea. The KSQA Board decided it was their responsibility, as the Asian QA Forum Co-Proposer, to hold the 2nd International Forum. All participants approved the KSQA proposal.

Agenda 2 was the selection of holding Society/Country for 3rd International Forum.

Two Societies expressed their hope of holding the 3rd International Forum. These were CSQA (Chinese Society of QA) and ICSQA (Indian Chapter of Society of QA). Mr. Bai and Dr. Natesan explained their intentions about holding the 3rd International Forum in their respective countries. The participants understood that these two Societies were capable of holding the 3rd International Forum. After discussion, it was agreed that if there are more than two Societies which want to hold the 3rd International Forum, at first it is necessary for them to explain their opinions and plans and they must talk with each other to determine which Society holds it first. If they cannot decide the order, then the drawing of lots is proposed for the final decision.

As a result of such discussion, it was temporarily agreed that CSQA held the 3rd International Forum in China temporarily. In addition, it was also temporarily agreed that ICSQA would hold the 4th International Forum in India temporarily.

In the international conference, it needs a large amount of budget for holding the conference. Therefore these two societies were requested to obtain each organizational approval of this temporarily decision. Mr. Bai will inform their final decision to ICSQA and Asia QA Forum Executive Committee as soon as possible after getting the CSQA Organizational decision on this matter. ICSQA will hold the 3rd International Forum if, for any reason, CSQA cannot hold the 3rd International Forum. We will get the final decision at the 2nd Council Assembly in Seoul Korea in 2015.

As the result of these decisions, the Executive Committee Organization in the 2nd term of Asia QA Forum is as follows.

President: Chun-Chul Shin, Dr., (Korea); President of KSQA
Past President: Tatsuo Kurokawa, Dr., (Japan); President of JSQA
1st Vice President: Bai Xigeng, Mr., (China); Vice-President of CSQA
2nd Vice President: Natesan Settiagounder, Dr., (India); President of ICSQA
Secretariat General: Sung Kwon Lee, Mr., (Korea) KSQA Secretariat-General

Tatsuo Kurokawa, Dr.,
President of JSQA
President of Asia QA Forum

Participants

164 participants from 7 countries/region

Country/Region	Participants#
Japan	141
Korea	10
China	4
Taiwan	3
India	2
Singapore	3
Malaysia	1

Bulletin of Japan Society of Quality Assurance
Asia QA Forum Memorial Issue

Tatsuo Kurokawa, President of JSQA

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