

*Bulletin of Japan Society of Quality Assurance*

# 日本QA研究会

3rd GQAC 記念特集号

3rd Global QA Conference Memorial Issue



*Feb.2012  
Special Issue*

# Bulletin of Japan Society of Quality Assurance

## 3rd GQAC Memorial Issue

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# **ADDRESS**

## Address



Thank you very much for the cooperation of all of you, the related persons and participants to ensure that the 3rd Global Quality Assurance Conference (3rd GQAC) ended successfully, with no problems.

The 1st GQAC was held by SQA and then the 2nd GQAC by BARQA. This time we held the 3rd GQAC in Japan, for the first time, under JSQA sponsorship.

The program for each session was devised mainly by GLP, GCP, and Post Marketing divisions to aim at Quality Assurance not only in Japan, the U.S. and Europe, but also in Asia. As a result, the QA associations in Asia have agreed to get together and begin to hold the Asia QA forum. We believe that we were able to take the first step toward the structure for cooperation on QA of global GXP by taking advantage of the GQAC.

We organized the 3rd GQAC using the Japanese fan as the conference logo and concentrated on a particular period in Japanese history in order to have the participants feel the traditional Japanese culture. Moreover, we know that all the participants enjoyed the Japan Night where we organized the events, including braiding, Sake tasting, calligraphy, tea ceremony and origami, to allow them to feel and experience the real Japan and also to enjoy the congress bag, etc.

We are pleased if you recall pleasant memories of the 3rd GQAC with this memorial JSQA Journal.

Takashi Furuya  
Vice Chairman  
JSQA 3rd GQAC Steering Committee

## 御挨拶

3rd GQACステアリングコミッティ  
副議長 古家 孝之

3rd Global Quality Assurance Conference(3rd GQAC) は関係者、参加者の皆様のご協力により無事に終了したことを厚くお礼申し上げます。

GQACはSQA、BARQAと開催され、今回JSQA主催により初めて日本で開催いたしました。開催にあたっては、各セッションのプログラムはGLP、GCP、製造販売後の各部会が中心となって構成し、日米欧の三極のみならずアジアにおける信頼性保証を検討することも目的としました。その結果、アジア圏のQA団体が集まりアジアQAフォーラムを立ち上げて開催する方向性となりました。GQACをきっかけとして世界的なGXPの信頼性保証の協力体制につながる一歩が踏み出せたものと考えます。

今回は扇を3rd GQACのイメージロゴマークとして使用するなど、日本ならではのよさを皆さんに感じていただきたく、開催地、開催期間にもこだわった企画運営を行ないました。また、組み紐、利き酒、書道、お茶、折り紙などを通じて日本を体験し、感じてもらうJapan Nightや、選べるコンgresバックなど、参加者の皆さんに楽しんでいただけたものと思います

本記念号で皆様の3rd GQACでの楽しかったご記憶を思い出していただければ幸いです。





**PROGRAM AT A GLANCE**

 Sunday, 13 November

**14:00 - 17:30** Room A GQAC Pre-Conference Symposium on Computerized System (GCP)  
*Current & Future of Clinical Data Standards – “CDISC Makes You Happy!”*  
**17:30 -** Sakura Welcome Reception

 Monday, 14 November

Main Hall				Annex Hall
<b>10:00 - 12:00</b> Opening Remark <i>Dr. Akira Takanaka</i> Special Lectures <i>Mr. Yoshiharu Habu</i> <i>Dr. Andrew Waddell</i>				<b>9:00 - 17:00</b> Exhibition /Poster
Main Hall	Room A	Room D	Room B1	
<b>14:00 - 17:00</b> Asian Session (GCP)  <i>Quality Assurance of Asian Clinical Study Data for the Regulatory Mutual Acceptance among Asian Countries and GCP Inspections Conducted by Asian Regulatory Authorities</i>	<b>14:00 - 18:00</b> Asian Session (GLP)  <i>GLP in Asian Countries</i>	<b>14:00-17:10</b> Concurrent Session GMP/QQP  <i>GMP and/or GQP Regulation / ICH Q Trio Approach Laboratories</i>	<b>14:00 - 15:40</b> Concurrent Session GLP (1)  <i>International Interpretation of GLP / GCLP</i>	<b>16:00 - 17:45</b> Concurrent Session GMP for Investigational Products  <i>Quality Assurance on Investigational Products - Interface between GMP and GCP -</i>
<b>18:00-20:00</b> Sakura & Swan Japan Night				<b>12:10 - 13:50</b> Poster with Short Oral Presentations  <b>13:30 - 14:00</b> Poster Discussion

 Tuesday, 15 November

Main Hall	Room A	Room D	Room B1	Annex Hall
<b>9:00 - 12:00</b> Concurrent Session GCP (1)  <i>Discuss GCP Compliance Clinical Trial from the “Risk ” Standpoint</i>	<b>8:50 - 12:00</b> Concurrent Session GLP (3)  <i>The Quality of Bioanalytical Studies</i>	<b>9:45 - 12:00</b> Concurrent Session GMP  <i>Audit Check Points on GMP for Investigational Products and Commercial Products</i>	<b>10:00 - 10:50</b> Concurrent Session GLP (2)  <i>International Interpretation of GLP</i>	<b>9:00 - 17:00</b> Exhibition /Poster
<b>14:00 - 17:50</b> Concurrent Session GCP (2)  <i>Quality Control and Quality Assurance in Japan</i>	<b>14:00 - 17:00</b> Concurrent Session GLP (4)  <i>Quality Assurance for Electronic Records in Non-clinical Laboratories</i>	<b>14:00 - 17:35</b> Concurrent Session Pharmacovigilance  <i>Pharmacovigilance Regulation / Pharmacovigilance Quality Assurance</i>	<b>11:00 - 12:00</b> GLP Special Session	
				<b>12:10 - 13:50</b> Poster with Short Oral Presentations  <b>13:30 - 14:00</b> Poster Discussion

 Wednesday, 16 November

Main Hall	Room A	Annex Hall
<b>8:00 - 12:00</b> USA / EU / Japan Session (GCP)  <i>Quality Assurance of Multinational Clinical Studies for Simultaneous NDA Submissions in the Three ICH Regions</i>	<b>9:00 - 12:00</b> USA / EU / Japan Session (GLP)  <i>International Perspective of Pathology Peer Review</i>	<b>9:00 - 11:00</b> Exhibition /Poster
<b>13:00 - 15:00</b> SQA / BARQA / JSQA Joint Symposium (GLP/GCP)  <b>15:00 - 15:30</b> Closing Ceremony		
Kyoto Short Excursion		



3rd Global Quality Assurance Conference

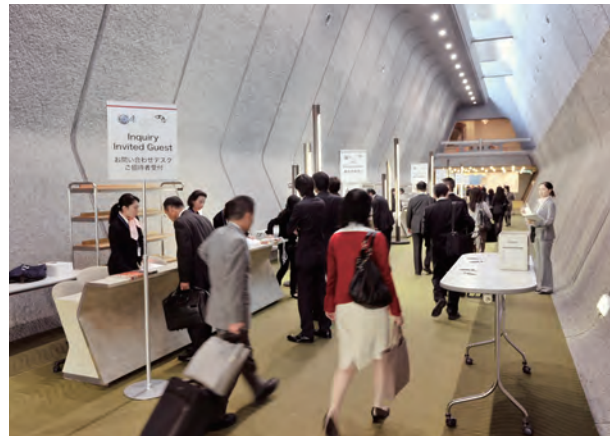


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# **PHOTO ALBUMS**



<Registration>



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<Welcome Reception>

<November 13, 2011>





<Opening Remarks and Special Lectures>

<November 14, 2011>





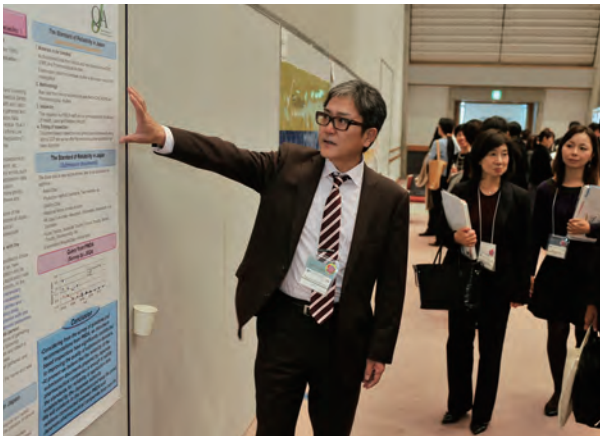
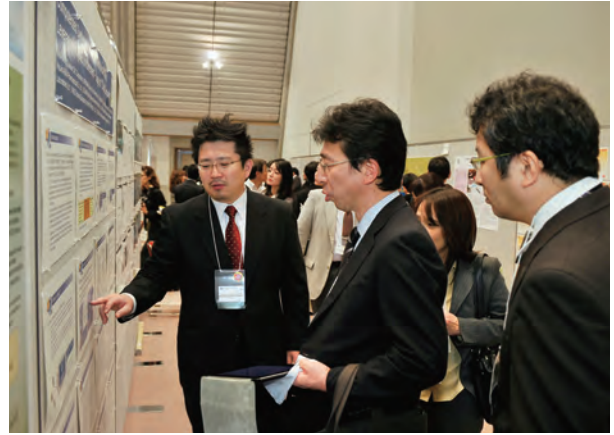
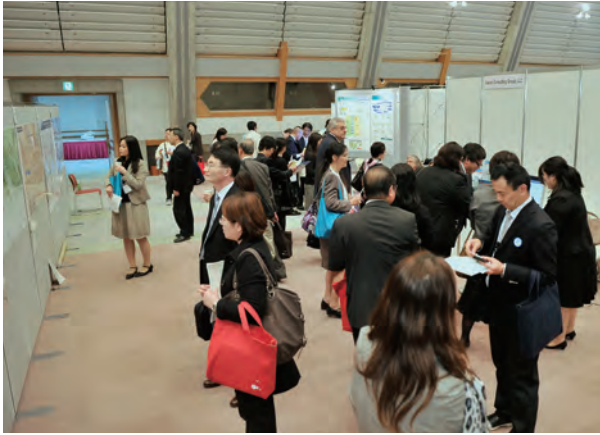
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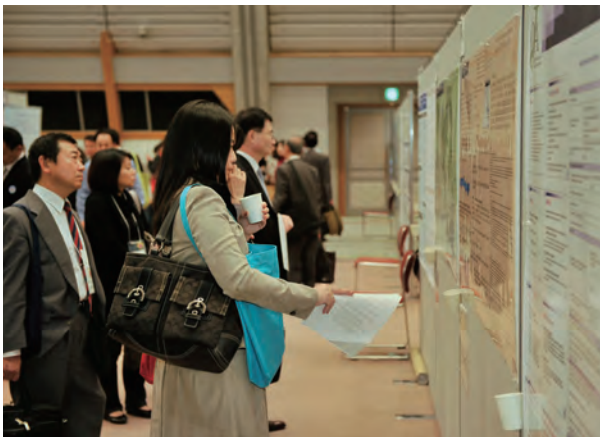


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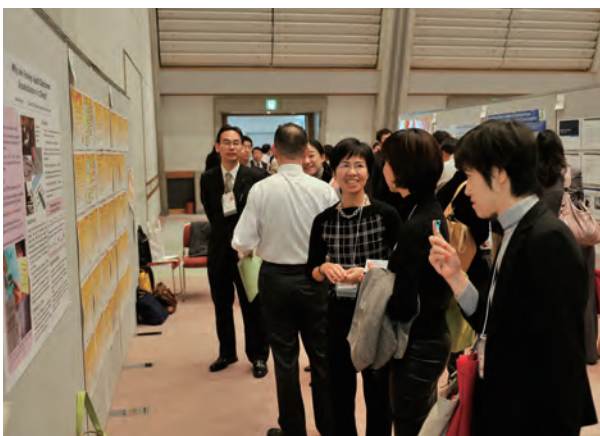
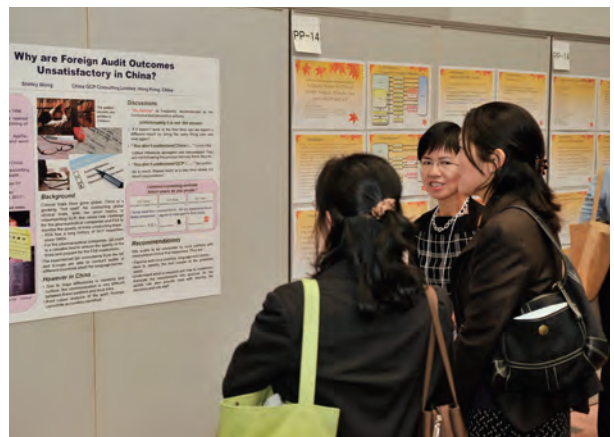
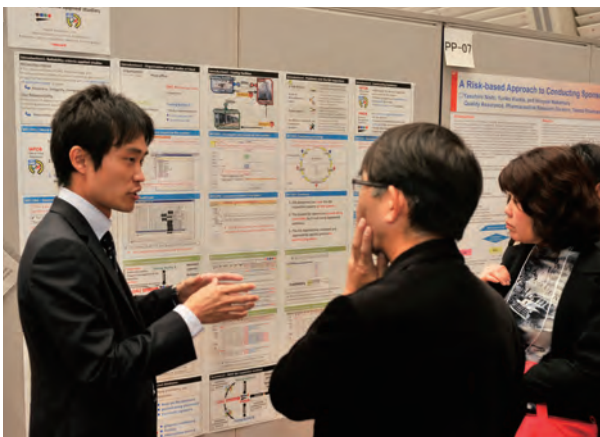
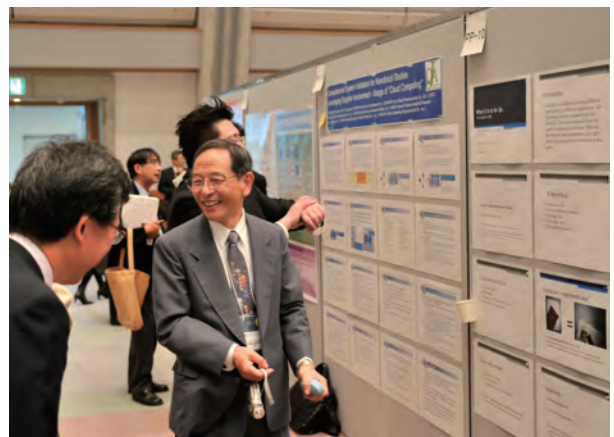
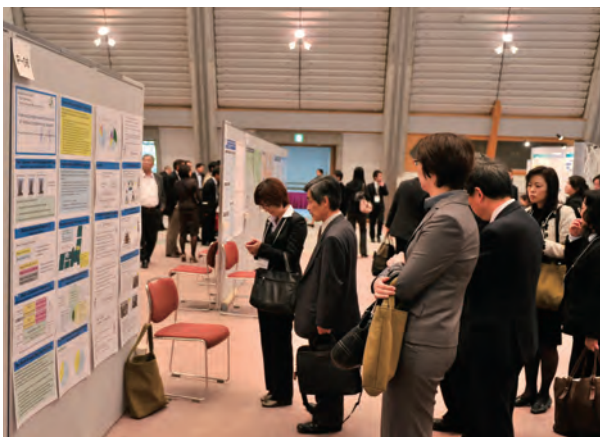
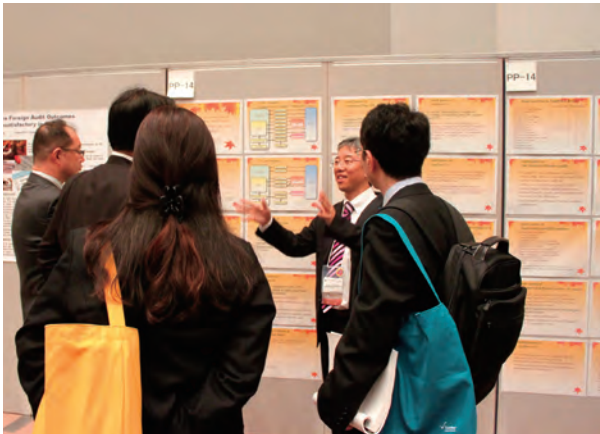


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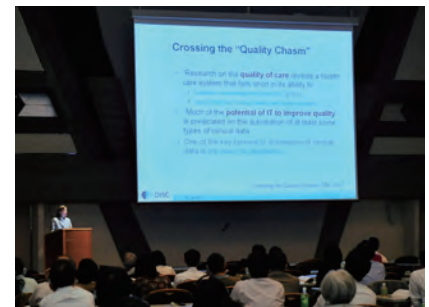


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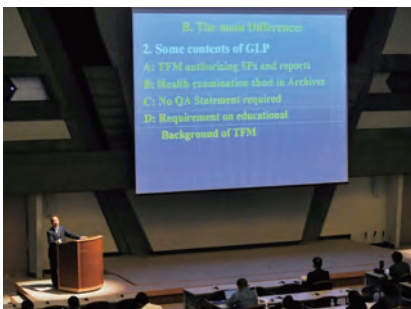






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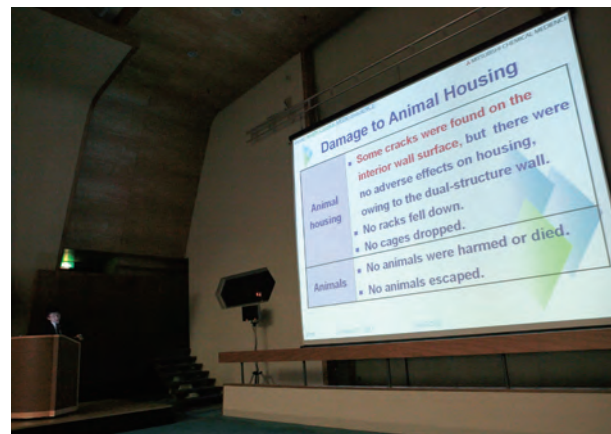
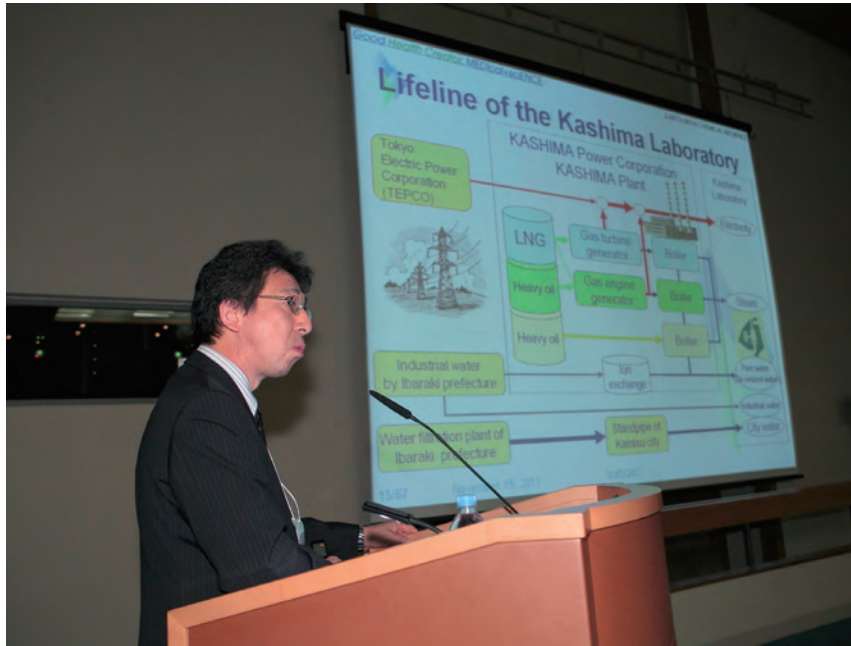


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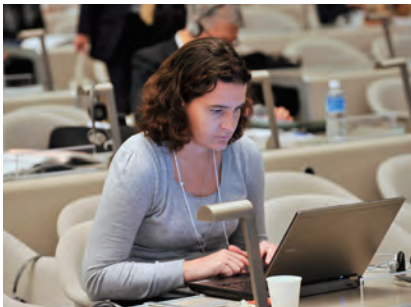
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<Concurrent Session (GMP/GQP)>

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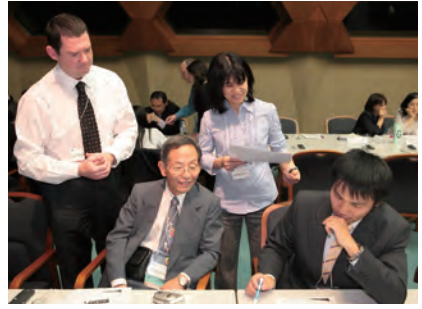
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<GMP Auditor Training>

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<November 16, 2011>







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<November 16, 2011>



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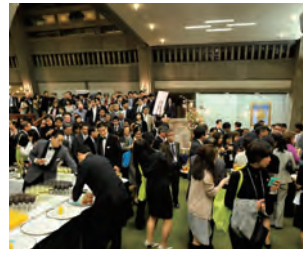
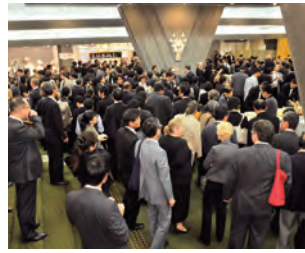


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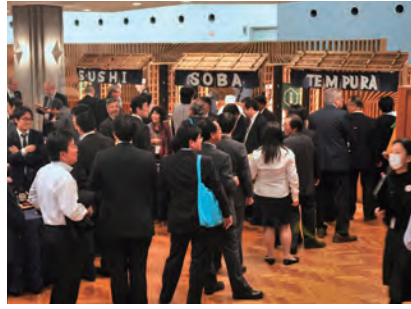
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<Japan Night>

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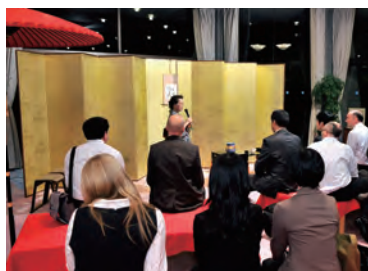


<Japan Night>

<November 14, 2011>



Japanese Tea Ceremony : SADO, CHADO



Japanese Calligraphy : SHODO



Japanese Interlaced Braids : KUMIHIMO



<Japan Night>

<November 14, 2011>

Origami



Japanese Sake Tasting Event : NIHONSHU Tasting





<MoU Signing Ceremony>

<November 13, 2011>

JSQA has developed Memorandum of Understandings (MoU) with the QA organizations in other countries to enhance mutual exchanges and cooperation. During the 3rd GQAC Conference, the tripartite MoU between SQA, BARQA, and JSQA was updated. Also, JSQA has newly developed the direct MoU with SoFAQ, KSQA, and TSQA, which are QA organizations in France, Korea and Taiwan.

SQA/BARQA/JSQA MoU Update



SoFAQ/JSQA MoU



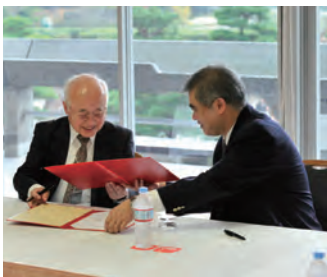
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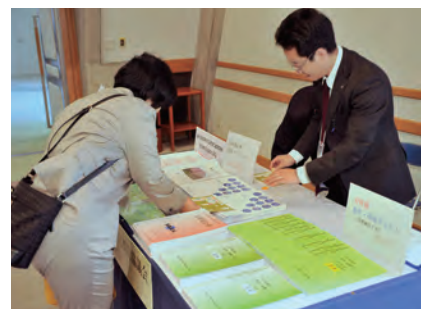
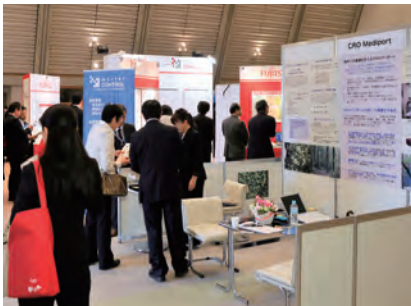
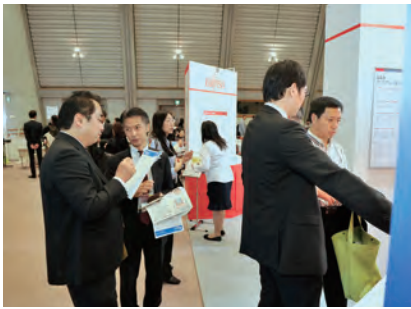
KSQA/JSQA MoU



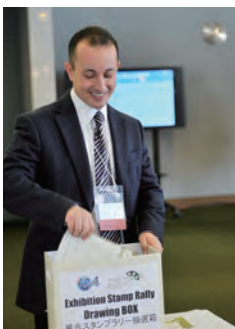
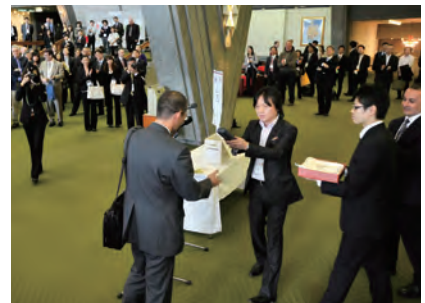
TSQA/JSQA MoU



<Exhibits>



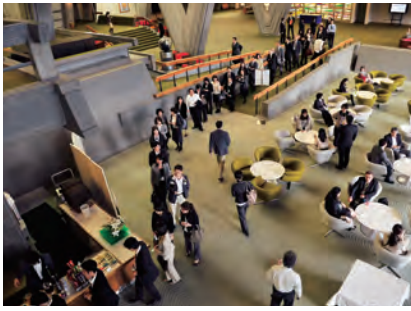
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<Summary/Lunch>



<Summary/Coffee Break>



<Summary>

Certificate of Attendance



Staff



See you again in Las Vegas in 2014 !

The page features a light green background with a central white gradient band. This band is decorated with elegant, flowing white lines that curve across the top and bottom. Interspersed among these lines are stylized white leaf motifs, each with five distinct leaflets. The overall aesthetic is clean, modern, and natural.

## **CLOSING REMARKS**



## Closing Remarks



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Immediately after the 1st GQAC was held and it was decided that the 3rd GQAC would be hosted by JSQA, we estimated that the number of the participants would be just about 1,000, and started to move forward to prepare for the conference step by step. However, on the 11th of March, 2011, the greatest and most horrible earthquake and tsunami ever experienced attacked the Tohoku District of Japan. After the disaster, a number of JSQA members thought that it was extremely difficult to host the conference. They were indeed very skeptical about the number of people who would participate in the 3rd GQAC. Fortunately, however, it turned out that we were able to have 908 participants from 22 countries and regions! In addition, the weather cooperated with us. Finally, the conference ended successfully without any serious problems. I sincerely hope that all the attendees enjoyed the 3rd GQAC conference, its accompanying events, and also the beauty of Kyoto.

For the memorial issue of 3rd GQAC, the photos were selected from more than 6,000 pictures taken by the professionals and also some volunteers. In these photos, everybody looked well and happy. The members of the Public Relations Committee spent a lot of time in selecting photos. I would like to thank Mr. Seiichi Ohba, the chairman of the Public Relations Committee, and other members of the committee for the selection of the photos.

Finally, I would like to take this opportunity to thank all the people who helped us with the conference directly or indirectly.

See you again in Las Vegas in 2014.



Makiko Azuma  
Secretariat of 3rdGQAC  
JSQA 3rdGQAC Steering Committee  
Secretary-general of JSQA Secretariat Office

## 記念特集号発刊にあたって

第3回グローバルQA会議事務局  
3rd GQAC ステアリング・コミッティ  
日本QA研究会 事務局長 東 牧子

2005年米国オーランドで第1回GQACが開催され、第3回大会をJSQAが主催することになった当初、JSQAでは日本大会の参加者数を約1000人と見積もっていました。ところが、2011年3月に日本を襲った未曾有の東日本大震災の後、海外からの参加者が激減する可能性から、会議開催に対して悲観的な意見もあり、参加予定者数を500名と想定するまでになってしまいました。案の定、4月末にスタートした事前参加登録申込も開始直後は申込の不足が非常に悪く、ステアリング・コミッティ内でも随分心配致しましたが、JSQA内はもちろん、SQA、BARQA、各国QA団体や後援団体をはじめ、関連各所に参加呼びかけの願いを繰り返し、最終的に22の国と地域から908名の方にご参加頂くことができました。紅葉の見頃には少し早かったのですが、会期中は素晴らしい好天に恵まれ、盛会のうちに会議を終えることができました。

今回の3rd GQAC記念特集号は、公式写真とカメラボランティアの皆様が撮影して下さった写真を合わせた6000枚の中から写真の選定を行いました。どの写真も皆様が素敵なお顔をされているので、会報用の写真を選ぶ作業に広報委員会の皆様は膨大な時間を使われたことと存じます。大場広報委員長はじめ、委員会の皆様のご尽力に厚く御礼申し上げます。

会議開催当日までには数々の困難に直面致しましたが、無事会議を終了することができて安堵と感謝の気持ちでいっぱいです。故郷京都での3rd GQACは、準備期間も含めて私の人生の中でとても思い出深い貴重な経験となりました。写真の中の沢山の素敵なお顔を拝見して、参加者の皆様もきっと3rd GQACと秋の京都をenjoyして下さったことと感じています。この場を借りて、ご参加頂いた皆様、3rd GQACに温かいご理解とご支援を頂いた全ての皆様に心から御礼申し上げます。本当にありがとうございました。

次回第4回グローバルQA会議は、2014年4月に米国ラスベガスで開催されます。多くの皆様のご参加により、再び盛会な会議となりますことを祈念申し上げます。



The image features a central green rectangular area with a white gradient at the top and bottom. The green area is decorated with white wavy lines and stylized leaf motifs. The word "APPENDIX" is centered in the green area in a bold, black, serif font.

# **APPENDIX**

## WELCOME TO KYOTO

Dear Delegate,

On behalf of JSQA, SQA and BARQA it is my great pleasure to welcome each of you to the 3rd Global QA Conference, hosted by JSQA, and to the remarkable city of Kyoto. As chairman of JSQA, it is my honor to host this memorable conference.

As you already know, the eastern part of Japan suffered tremendous damage from the March 11th earthquake. I would like to express my gratitude to everyone who has supported the relief effort, although recovery is still ongoing. Immediately after the earthquake, it was uncertain whether the conference would take place, but we are honored to have received more than 800 pre-registrations. As a member of the steering committee, I would like to thank each delegate for their attendance.

The theme of the conference is “Toward the Next Generation” taking into account the themes of the first and second GQAC conferences. The program we have put together is a great opportunity to share the latest studies on quality assurance. The Program Committee has carefully chosen hot topics from each GXP, involving government regulatory personnel and QA experts. I thank all members of the Steering Committee and also for the Program Committees for their efforts in successfully organizing the program.

Kyoto is the absolute heart of Japanese culture and is listed by UNESCO as a world heritage site. The 3rdGQAC has planned a “Japan Night” evening as an occasion to encounter some aspects of Kyoto’s traditions and Japanese culture, and are confident that this social event will bring delegates closer together.

In addition, November is the best season to visit Kyoto with the striking Autumn foliage. We hope you will have many opportunities to enjoy this magnificent ancient city.

Once again, thank you all for attending and I know you will find the 3rdGQAC to be a very informative and valuable meeting.

Best wishes,



Akira Takanaka

Chairman of 3rdGQAC

President of Japan Society of Quality Assurance

## ACKNOWLEDGEMENT

### Acknowledgements from Chairman of the JSQA Steering Committee

The JSQA Steering Committee would like to thank SQA and BARQA for their generous and thoughtful help given to JSQA in many respects.

Especially, thanks go to the following persons:

Mr. James A. Ault	President, SQA
Ms. Elliott Graham	Executive Director, SQA
Ms. Leslie Kvasnicka	SQA's Representative to the GQAC Program Planning Committee
Ms. Rachel Hodges	Chairman, BARQA
Dr. Andrew Waddell	Former Chairman, BARQA
Mr. David Weller	Association Manager, BARQA
Mr. Tony Ward	Manager, BARQA

### Supporters:

Ministry of Health, Labour and Welfare (MHLW)  
 Pharmaceuticals and Medical Devices Agency (PMDA)  
 The Federation of Pharmaceutical Manufacturers' Associations of JAPAN (FPMAJ)  
 Japan Pharmaceutical Manufacturers Association (JPMA)  
 Japan Generic Medicines Association (JGA)  
 The Pharmaceutical Manufacturers' Association of Tokyo (PMAT)  
 Osaka Pharmaceutical Manufacturers Association (OPMA)  
 Japan Health Sciences Foundation (JHSF)  
 Japan Association of Contract Laboratories for Safety Evaluation (JACL)  
 Japan CRO Association (JCROA)

### Sponsorship:

Thanks go to the following sponsors:

Sparta Systems Inc.  
 Congress Bags, Banner, Stationery (pens), Advertisement in Delegate Handbook  
 Master Control KK  
 Receptions (Welcome Reception on November 13 and Japan Night on November 14),  
 Advertisement in Delegate Handbook, Stationery (clear file folders)  
 CMIC Co., Ltd.  
 Pocket Program  
 DAIICHI SANKYO Co., Ltd.  
 Advertisement in Delegate Handbook  
 Kowa Co., Ltd.  
 Reception (Welcome Reception on November 13)  
 Shin Nippon Biomedical Laboratories, Ltd.  
 Advertisement in Delegate Handbook  
 InCROM Inc.  
 Advertisement in Delegate Handbook

### Exhibitors:

Thanks to all the exhibitors here at the conference, their support is greatly appreciated.

## THE JSQA STEERING COMMITTEE FOR 3rdGQAC:

Akira Takanaka	Chairman of 3rdGQAC President of Japan Society of Quality Assurance (JSQA)
Takashi Furuya	Vice-Chairman of 3rdGQAC Vice-President of JSQA, Tsumura & Co.
Shigeo Watabe	Vice-President of JSQA, Daiichi-Sankyo Co., Ltd.
Kiyoshi Chiba	Vice-President of JSQA, Kyowa Hakko Kirin Co., Ltd.
Yoshikazu Hasegawa	RIKEN GENESIS CO., LTD.
Mikiko Kuwabara	Toray Industries, Inc.
Akira Nomura	
Masayuki Takezawa	EPS Co., Ltd.
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Kunihisa Akai	Icon Japan
Motoaki Ohsuga	Kissei Pharmaceutical Co., Ltd.
Takeo Ono	Taisho Pharmaceutical Co., Ltd.
Makiko Azuma	Japan Society of Quality Assurance (JSQA) 3rdGQAC Secretariat
Satoko Takahashi	Japan Society of Quality Assurance (JSQA) 3rdGQAC Secretariat

### Program Committee

JSQA GLP Program Committee

JSQA GCP Program Committee

JSQA GQP/GVP/GPSP Program Committee

## MEETING INFORMATION

Date:

Sunday, November 13 - Wednesday, November 16, 2011

Venue:

Kyoto International Conference Center (ICC Kyoto)  
Takaragaike, Sakyo-ku, Kyoto 606-0001, Japan  
Phone: +81-75-705-1234, Fax: +81-75-705-1100  
URL: <http://www.icckyo.or.jp>

Organizer:

Japan Society of Quality Assurance (JSQA)

Co-Organizers:

Society of Quality Assurance (SQA)  
British Association of Research Quality Assurance (BARQA)



Official Language:

English and Japanese

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

Consecutive interpretation will be provided in English and Japanese for poster with short oral presentations.

3rdGQAC Secretariat:

c/o Japan Society of Quality Assurance (JSQA)  
IPB-Ochanomizu Bldg., 3-3-11 Hongo, Bunkyo-ku Tokyo 113-0033, JAPAN  
Phone: +81-3-5840-5561 Facsimile: +81-3-5840-5564  
E-mail : [secretariat@3rdgqac.com](mailto:secretariat@3rdgqac.com)  
Official Website : <http://www.3rdgqac.com>

## SOCIAL EVENTS

### Welcome Reception

After finishing your registration, please join us in the Welcome Reception with light snacks & drinks. We are certain that it provides you a good opportunity to meet with old friends. Refresh contacts and start new networks in a casual atmosphere.

Date and time: Sunday, November 13, 17:30 -

Place: Room “Sakura” (Room has been changed from Swan to Sakura)

Fee: Free for all conference participants

\* Light snacks

\* One ticket for free drink, Cash Bar

### Japan Night “Experiences in Japan”

We welcome all the attendees to “Japan Night” . You could enjoy some tasty foods and Japanese Sake from Kyoto *Fushimi* where is one of the greatest old sake brewing areas Japan.

Special programs (Culture Experience Programs) are also planned for you. We hope these programs will help you understand Japan and some aspects of the traditional culture while socializing with other conference participants.

Date and time: Monday, November 14, 18:00 - 20:00

Place: Room “Sakura” & “Swan” , Lounge

Fee: Free for conference participants

\* Buffet-style

\* Free drink

*You need to pay 100 Yen per cup for the special brand of Fushimi Sake.*

#### *Special Thanks:*

*Special thanks go to Fushimi Sake Brewers Association, Showen Kumihimo, WAK JAPAN Co. for their cooperation to the Japan Night.*

*Our special thanks also should go to many volunteers who cooperated for origami, calligraphy, photography, and language support.*

### Short Excursion “Kyoto Evening Sightseeing Tour”

Kyoto Evening Sightseeing Tour will be held on Wednesday evening, November 16. Participants will visit Kiyomizu Temple, the most iconic temple in Kyoto, a UNESCO world heritage site. Present building with large wooden stage was built in 1633.

Date and time: Wednesday, November 16, 16:00 - 20:00

Place: *Kiyomizu* Temple

Fee: 6,000 Yen

Meeting Time: 15:45 (*The Bus will depart from the ICC Kyoto by 16:00*)

Meeting Place: Entrance Hall of the ICC Kyoto

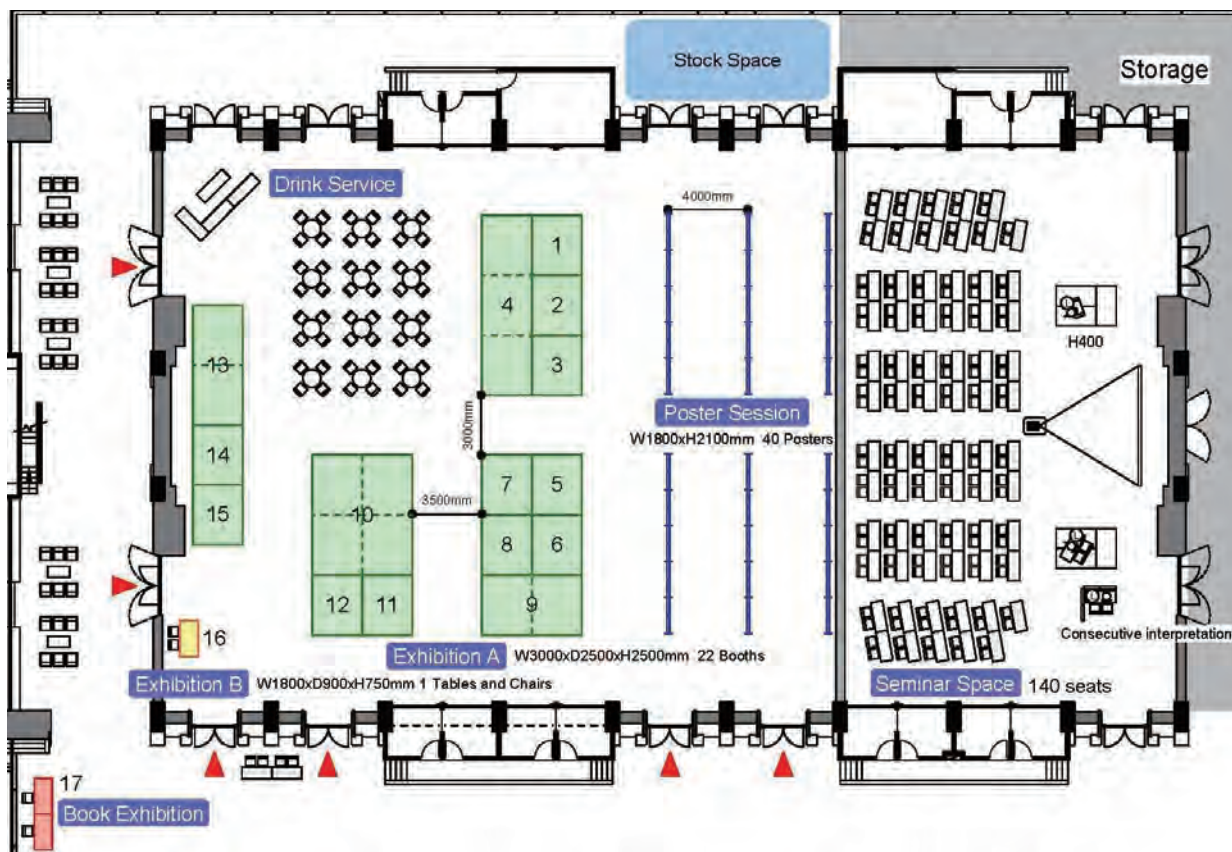


## 3rd GQAC Exhibitors

<u>Exhibitor</u>	<u>Booth</u>
The Society of Quality Assurance (SQA)	1
ADAMAS CONSULTING	2
The University Hospital Clinical Trial Alliance (UHCT Alliance)	3
EPS GROUP	4
Sparta Systems, Inc. / Hitachi Information & Control Solutions, Ltd.	5
Falcon Consulting Group, LLC	6
IT'sQA LLP	7
British Association of Research Quality Assurance (BARQA)	8
Shin Nippon Biomedical Laboratories, Ltd.	9
Fujitsu / MasterControl	10
NextDocs	11
CRO Mediport	12
CTC Laboratory Systems	13
ZigZag Associates Ltd.	14
TMQA	15
Japan Association of Contract Laboratories for Safety Evaluation (JACL)	16
Yakuji Nippo, Ltd.	17

# Exhibit Hall Information

## Annex Hall



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## Exhibit Hours

November 14 (Mon), 2011	9:00-17:00
November 15 (Tue), 2011	9:00-17:00
November 16 (Wed), 2011	9:00-11:00

## Annex Hall

Annex Hall is located at 1st floor of Kyoto International Conference Center.

It is connected to the main building by the corridor. Please take the opportunity to visit the exhibitors and the poster presentations.

## Stamp Rally

The stamp rally will be held during the above exhibits hours.

Collect all stamps from exhibitors and enter to win great prizes!

The draw for the gift will be held in the front of the entrance of the Main Hall at 12:45, November 16.

## POSTER PRESENTATIONS & POSTER DISCUSSIONS

### Poster Presentation with Short Oral Presentation

Short oral presentations are held on November 14 and 15 between 12:10-13:50. Speakers are asked to give the presentation to the audience using power point slides. Time provided for each presenter is 10 minutes. A consecutive interpretation (English and Japanese) is provided.

Monday, November 14, 2011		12:10-13:50, Annex Hall
12:10-12:20	PP-01	Yoshiharu Daiku (Eisai / JSQA) <i>Role of QA in the Validation (Check) of the Apparatus</i>
12:20-12:30	PP-02	Shigeru Johki (Astellas Pharma / JSQA) <i>Quality Assurance for the Final Report-Making Process - How Should We Audit the Final Report without Falling into QC Review? -</i>
12:30-12:40	PP-03	Tsutomu Kimura (Daiichi Sankyo / JSQA) <i>Handling of e-Data Obtained from Instruments for Quantitative Analysis</i>
12:40-12:50	PP-04	Masaki Kudo (Nissan Chemical Industries / JSQA) <i>Current Status of GLP Regulations on Chemical Substances, Pesticides and Veterinary Drugs in Japan</i>
12:50-13:00	PP-05	Ryoichi Takeuchi (Otsuka Pharmaceutical / JSQA) <i>Should All Deviations Be Written in the Final Report?</i>
13:00-13:10	PP-06	Tadahiro Yoshiyama (Chugai Pharmaceutical / JSQA) <i>The Appropriate Operation Controls throughout Its Life Cycle of the System - The Suggestion of the Operational Activity of a Computerized System after the Release -</i>
13:10-13:20	PP-07	Yasuhiro Nishi (Takeda Pharmaceutical) <i>A Risk-Based Approach to Conducting Sponsor's QA Audit on GLP Facilities</i>
13:20-13:30	PP-08	Motohiko Nishio (Yakult Honsha) <i>Constructing Inspection Management Databases for Reliability Criteria Applied Studies</i>
13:30-13:40	PP-09	Toshiki Umetani (Kyowa Hakko Kirin / JSQA) <i>Quality Assurance for Biotechnology - Derived Pharmaceuticals in Preclinical Safety Evaluation</i>
13:40-13:50	PP-10	Akira Nomura (QA Advisor) <i>What It Is to Be QA</i>

Tuesday, November 15, 2011

12:10-13:50, Annex Hall

- 12:10-12:20 PP-11 Daisuke Yamamoto (CAC Corporation / JSQA)  
*Computerized System Validation for Nonclinical Studies Leveraging Supplier Involvement – Usage of “Cloud Computing” -*
- 12:20-12:30 PP-12 Akira Yamazaki (Kyowa Hakko Kirin / JSQA)  
*A Framework for Regulatory Compliance Activities for CSV and Electronic Records Management in Nonclinical Laboratories*
- 12:30-12:40 PP-13 Yumiko Kashiwagi (Mitsubishi Chemical Medience / JSQA)  
*Current Status of GLP Regulations on Pharmaceutical Products in Japan and Other Countries*
- 12:40-12:50 PP-14 Yoshio Inoue (TOYAMA CHEMICAL / JSQA)  
*A Quality System for Clinical Sample Analysis; From the View Point of GCP and GLP*
- 12:50-13:00 PP-15 Shirley Wong (China GCP Consulting)  
*Why Are Foreign Audit Outcomes Unsatisfactory in China?*
- 13:00-13:10 PP-16 Takahito Yamamoto (Merck Serono / JSQA)  
*Communication Gap Faced in the Globalization of Drug Development - What Are the Important Points for Successful Global Auditing? -*
- 13:10-13:20 PP-17 Keiichi Minato (Sparta Systems)  
*The Expanding Role of the Quality Professional Global GMPs and GQPs and Responsibilities of Quality Professionals in the Supply Chain*
- 13:20-13:30 PP-18 Jyoti Sharma (Ministry of Science and Technology)  
*Need of Good Waste Treatment and Disposal Practices*
- 13:30-13:40 PP-19 Hidemitsu Matsunaga (Maruishi Pharmaceutical / JSQA)  
*Improvement of Quality of Submission Documents in Japan - CMC, ADME, Pharmacology Studies -*
- 13:40-13:50 PP-20 Mitsuru Terajima (Kyowa Hakko Kirin / JSQA)  
*The Introductions and Analyses of Document-Based Inspections Results on CMC, ADME and Pharmacology Studies*

**Poster Presentations**

Posters are displayed during the following hours.

November 14 and 15: 9:00-17:00, November 16: 9:00-11:00

- P-01 Yasuhide Kitazaki (Shin Nippon Biomedical Laboratories)  
*IT System Usage and the GLP Facility*
- P-02 Kana Kobayashi (JCL Bioassay / JSQA)  
*Effective Internal Facility Inspection by QAU*
- P-03 Kazunori Sasaki (Shin Nippon Biomedical Laboratories)  
*Perspectives of Archiving*
- P-04 Tomokazu Shigeyama (Shin Nippon Biomedical Laboratories)  
*Requirements and Maintenance of the SOPs in a GLP Facility*
- P-05 Tetsuro Sugimoto (Chugai Pharmaceutical)  
*Major Issues in Applying GCLP Principles to Japanese Clinical Laboratories*
- P-06 Emiko Takeuchi (Teijin Pharma / JSQA)  
*View Exchange toward Resolution of Various Problems by Oneself – Various Trials for the Communication among Members -*
- P-07 Bao-Long Tsai  
(Taiwan Agricultural Chemicals and Toxic Substances Research Institute (TACTRI))  
*An Overview of GLP Implementation at TACTRI in Taiwan*
- P-08 Jianhui Wu (Shanghai Institute of Planned Parenthood Research)  
*How to Avoid Personnel of GLP to Disobey Standard Operating Procedure*
- P-09 Han Yan (Shanghai Institute of Planned Parenthood Research)  
*How to Improve the Correcting Efficiency of Study Director towards the Quality Assurance Personnel's Advice*
- P-10 Tadahiro Yoshiyama (Chugai Pharmaceutical)  
*Bioanalytical Instrument Qualification in GLP Laboratories That Makes Effective Use of the Activities of Suppliers*
- P-11 Elliott Graham (SQA)  
*SQA International Relations Committee- Global Information for the QA Professional*
- P-12 Elliott Graham (SQA)  
*Demystifying RQAP*

- P-13 Hannelie Carstens (International Partnership for Microbicides (IPM))  
*Risk Mitigation in Clinical Research in Africa*
- P-14 Sudheendra Kulkarni (Clinigene International)  
*Vendor Audits for Commercial Software*
- P-15 Aiko Masuda (Bristol-Myers Squibb / JSQA)  
*Are There Any Approvability Differences between FDA and EMA?*
- P-16 Koji Miyake (Dainippon Sumitomo Pharma / JSQA)  
*Result of a Survey by Questionnaire Concerning GCP-Relevant Computerized Systems*
- P-17 Shingo Ohkubo (Genzyme Japan / JSQA)  
*Brush up the Understanding of Risk Management for Clinical Trial*
- P-18 Hiroyasu Yamashita (Dainippon Sumitomo Pharma / JSQA)  
*Global Discussion Project for Supplements of GCQA Guideline for GCP Auditing*
- P-19 Hiroshi Yonezawa (Taiho Pharmaceutical / JSQA)  
*Present State of Methods for Documenting Informed Consent in Japan*
- P-20 Hiroshi Shigeno (UCB Japan / JSQA)  
*Appropriate Product Quality Information Handling Based on Japanese Good Quality Practice Rule, and Effective Usage of PC System*
- P-21 Toshiro Asahina (Merck Serono / JSQA)  
*Mission of Our International Affairs Committee*
- P-22 Chihiro Ishizuka (Toray Industries / JSQA)  
*Education System of JSQA*

**Poster Discussions**

Standard poster presenters will stand by their posters between 13:30 - 14:00, either on November 14 and 15 to answer questions from participants.

Monday, November 14, 2011

13:30-14:00, Annex Hall

**Poster with Short Oral Presenters;**

- PP-11 Daisuke Yamamoto (CAC Corporation / JSQA)
- PP-12 Akira Yamazaki (Kyowa Hakko Kirin / JSQA)
- PP-13 Yumiko Kashiwagi (Mitsubishi Chemical Medience / JSQA)
- PP-14 Yoshio Inoue (TOYAMA CHEMICAL / JSQA)
- PP-15 Shirley Wong (China GCP Consulting)
- PP-16 Takahito Yamamoto (Merck Serono / JSQA)
- PP-17 Keiichi Minato (Sparta Systems)
- PP-18 Jyoti Sharma (Ministry of Science and Technology)
- PP-19 Hidemitsu Matsunaga (Maruishi Pharmaceutical / JSQA)
- PP-20 Mitsuru Terajima (Kyowa Hakko Kirin / JSQA)

**Standard Poster Presenters;**

- P-01 Yasuhide Kitazaki (Shin Nippon Biomedical Laboratories)
- P-03 Kazunori Sasaki (Shin Nippon Biomedical Laboratories)
- P-05 Tetsuro Sugimoto (Chugai Pharmaceutical)
- P-07 Bao-Long Tsai (TACTRI)
- P-09 Han Yan (Shanghai Institute of Planned Parenthood Research)
- P-13 Hannelie Carstens (International Partnership for Microbicides (IPM))
- P-15 Aiko Masuda (Bristol-Myers Squibb / JSQA)
- P-17 Shingo Ohkubo (Genzyme Japan / JSQA)
- P-19 Hiroshi Yonezawa (Taiho Pharmaceutical / JSQA)

Tuesday, November 15, 2011

13:30-14:00, Annex Hall

**Poster with Short Oral Presenters;**

- PP-01 Yoshiharu Daiku (Eisai / JSQA)
- PP-02 Shigeru Johki (Astellas Pharma / JSQA)
- PP-03 Tsutomu Kimura (Daiichi Sankyo / JSQA)
- PP-04 Masaki Kudo (Nissan Chemical Industries / JSQA)
- PP-05 Ryoichi Takeuchi (Otsuka Pharmaceutical / JSQA)
- PP-06 Tadahiro Yoshiyama (Chugai Pharmaceutical / JSQA)
- PP-07 Yasuhiro Nishi (Takeda Pharmaceutical)
- PP-08 Motohiko Nishio (Yakult Honsha)
- PP-09 Toshiki Umetani (Kyowa Hakko Kirin / JSQA)
- PP-10 Akira Nomura (QA Advisor)

**Standard Poster Presenters;**

- P-02 Kana Kobayashi (JCL Bioassay /JSQA)
- P-04 Tomokazu Shigeyama (Shin Nippon Biomedical Laboratories)
- P-06 Emiko Takeuchi (Teijin Pharma / JSQA)
- P-08 Jianhui Wu (Shanghai Institute of Planned Parenthood Research)
- P-10 Tadahiro Yoshiyama (Chugai Pharmaceutical)
- P-11 Elliott Graham (SQA)
- P-12 Elliott Graham (SQA)
- P-14 Sudheendra Kulkarni (Clinigene International)
- P-16 Koji Miyake (Dainippon Sumitomo Pharma / JSQA)
- P-18 Hiroyasu Yamashita (Dainippon Sumitomo Pharma / JSQA)
- P-20 Hiroshi Shigeno (UCB Japan / JSQA)



## ORAL SESSIONS

Simultaneous interpretation will be provided in English and Japanese.

### Sunday, November 13, 2011

Pre-Conference Symposium on Computerized System (GCP) 14:00-17:30, Room A  
Current & Future of Clinical Data Standards – “CDISC Makes You Happy!”

Chair: Yoshio Tsukada (Japan CDISC Coordinating Committee, GlaxoSmithKline)

14:00-14:30 Yoshio Tsukada (Japan CDISC Coordinating Committee, GlaxoSmithKline)  
*“CDISC Makes You Happy!” - Introduction -*

14:30-15:00 Rebecca D. Kush (CDISC)  
*From the Perspective of CDISC Consortium*

15:00-15:30 Osamu Komiyama  
(Japan Pharmaceutical Manufacturers Association (JPMA), Pfizer Japan)  
*To Foster a Discussion on CDISC Standards among Japanese Community*

15:30-16:00 Coffee Break

16:00-16:30 Kazumasa Iwamoto (Eli Lilly Japan)  
*CDISC – A Way to Streamline Clinical Development*

16:30-17:00 Hitoshi Matsui (CAC)  
*Clinical Data Standardization the Current & the Future from CRO Perspective*

17:00-17:30 Hiroyuki Furukawa (Yamaguchi University Hospital)  
*From the Perspective of Medical Institution*

**Monday, November 14, 2011**

Opening Remarks and Special Lectures 10:00-12:00, Main Hall

Opening Remarks

10:00-10:05 Akira Takanaka (President of JSQA / Chairman of 3rdGQAC)

Special Lecture 1

Chair: Shigeki Nakano (Taiho Pharmaceutical / JSQA)  
Hiroshi Yonezawa (Taiho Pharmaceutical / JSQA)

10:05-11:00 Yoshiharu Habu (Professional Shogi Player)  
*Brush Up Your Decision-Making -The Attitude for Selecting the Best Strategy -*

Special Lecture 2

Chair: Seiichi Hata (Cmic / JSQA)  
Takashi Furuya (Tsumura / Vice-President of JSQA)

11:00-12:00 Andrew Waddell (Former Chairman of BARQA / Director of TMQA)  
*Effective Continuing Professional Development of QA Staff*

Asian Session (GCP) 14:00-17:00, Main Hall

Quality Assurance of Asian Clinical Study Data for the Regulatory Mutual Acceptance among Asian Countries and GCP Inspections Conducted by Asian Regulatory Authorities

Chair : Yuji Kumagai (Kitasato University East Hospital)

14:00-14:30 Shinichi Kawai (Toho University School of Medicine)  
*Is There Any Ethnic Difference in Pharmacokinetics among East Asian Countries?*

14:30-15:00 Jong-Pill Park (Korean Food and Drug Administration (KFDA))  
*KFDA Inspection Program and Round Education for Quality of the Clinical Trials*

15:00-15:30 Li Jian Ming (State Food and Drug Administration, P.R. China (SFDA))  
*TBD*

15:30-16:00 Mari Shirotani (Pharmaceuticals and Medical Devices Agency (PMDA))  
*GCP Inspections by PMDA*

16:00-16:30 Coffee Break

16:30-17:00 Panel Discussion

## Asian Session (GLP)

14:00-18:00, Room A

## GLP in Asian Countries

- Chair : Il Je Yu (President of KSQA / Hoseo University)  
Yoshikazu Hasegawa (RIKEN GENESIS / JSQA)
- 14:00-14:05 Yoshikazu Hasegawa (RIKEN GENESIS / JSQA)  
*Greetings and Overview*
- 14:05-14:25 Il Je Yu (President of KSQA / Hoseo University)  
*Current Status and Perspectives of Korean GLP*
- 14:25-14:45 Xigeng Bai  
(Vice-President of CSQA / Shenyang Research Institute of Chemical Industry)  
*Current Status of GLPs in China*
- 14:45-15:05 Siripan Wongwanich (Ministry of Public Health)  
*The Establishment of GLP Program in Thailand*
- 15:05-15:25 Vinita Sharma (Ministry of Science & Technology)  
*GLP Scenario in India*
- 15:25-15:40 Coffee Break
- 15:40-16:00 Tsung-Yun Liu  
(President of TSQA / National Yang-Ming University)  
*The GLP Status in Taiwan*
- 16:00-16:20 Salmaan H. Inayat-Hussain (Universiti Kebangsaan Malaysia)  
*Road to GLP-Compliance: The experience of Melaka Toxicology Laboratory*
- 16:20-16:40 Esther Ee (PPD)  
*Current GLP Status in Singapore*
- 16:40-17:00 Yoichi Sato (Pharmaceuticals and Medical Devices Agency (PMDA))  
*Japanese National GLP Monitoring Programme on Medical Products*
- 17:10-18:00 Panel Discussion: Asia QA Forum

## Concurrent Session GMP/GQP

14:00-17:10, Room D

## GMP and/or GQP Regulation/ICH Q Trio Approach Laboratories

- Chair : Kazuhiko Okamori (Maruho / JSQA)  
Katsuhiko Sawada (Kowa / JSQA)

- 14:00-14:40 Daisaku Sato (Ministry of Health, Labour and Welfare (MHLW))  
*TBD*
- 14:40-15:05 Osamu Takahashi (Mochida Pharmaceutical / JSQA)  
*Customer Audit and Regulatory Inspection for Manufacturers Overseas*
- 15:05-15:30 Diane Clements (C2XL)  
*Botanicals – Back to the Future Medicines?*
- 15:30-15:55 Coffee Break
- 15:55-16:30 Tsukasa Nishihara (The Chemo-Sero Therapeutic Research Institute / JSQA)  
*Identifying the Issues Generated from the Implementation of ICH Q10 by Questionnaire and Responses to Such Issues*
- 16:30-17:10 George G. Kuniholm (BioMarin Pharmaceutical)  
*Implementing ICH Tripartite Harmonized Guidelines Q8, Q9, and Q10*

Concurrent Session GLP (1)

14:00-15:40, Room B-1

International Interpretation of GLP/GCLP

Chair : Roger Chapman (Huntingdon Life Sciences UK)  
Masanori Shindo (Japan Tobacco / JSQA)

- 14:00-14:20 Barbara A. Foy (Monsanto)  
*Brazil's Application of GLPs for Agricultural Products through the Eyes of an American*
- 14:20-14:40 Fábio S.Tagliaferro (Monsanto do Brasil)  
*Challenges of an Interstate Multisite GLP Operation for Residue Field Trials in Brazil*
- 14:40-15:00 Tobin C. Guarnacci (CLINIQUAL)  
*Good Clinical Laboratory Practice (GCLP)  
An Industry Perspective - Introduction, GCP Relevance and Quality Audit Basics*
- 15:00-15:20 Natesan Settiagounder (Advinus Therapeutics)  
*GLP Studies for Global Requirements - Compliance and Exception to Various Regulations: Need for Further Global Harmonization*
- 15:20-15:40 Q & A

Concurrent Session GMP for Investigational Products 16:00-17:45, Room B-1  
Quality Assurance on Investigational Products - Interface between GMP and GCP -

Chair : James A. Ault (President of SQA)

16:00-16:35 Andrew M. Tudor (Pfizer UK)  
*Interface between GMP and GCP*

16:35-17:10 Shinichi Kodato (Chugai Pharmaceutical)  
*Current Status of Interface between GMP and GCP in Japan*

17:10-17:45 Hirofumi Ueda (Pharmaceuticals and Medical Devices Agency (PMDA))  
*GMP Inspection on Investigational Medicinal Products*

**Tuesday, November 15, 2011**

Concurrent Session GCP (1) 09:00-12:00, Main Hall  
Discuss GCP Compliance Clinical Trial from the “Risk” Standpoint

Chair : Masayuki Horie (Graduate School of Nihon University)

09:00-9:30 Masayuki Horie (Graduate School of Nihon University)  
*Where Are We Going? - What Is the Clinical Trial Risk Management For? -*

09:30-10:00 Denis Moulin (Merck Serono Geneva)  
*Quality Risk Management: Development and Implementation of a GxP Approach - First Operational Translation*

10:00-10:30 Katsuyuki Ota (Takeda Pharmaceutical)  
*Approach to Quality Risk Management of Clinical Studies by Our Clinical Quality Assurance*

10:30-11:00 Coffee Break

11:00-11:30 MaryEllen Lander (Falcon Consulting Group)  
*How to Establish a Global Quality Assurance System*

11:30-12:00 Mohamed Oubihi (Biogen Idec)  
*Comparison of GCP Aspects between Japan and Europe and the Impact on Global Clinical Development*

Concurrent Session GLP (3) 08:50-12:00, Room A

The Quality of Bioanalytical Studies

Chair : Hiromi Ohmuro (Musashino University)  
Vanessa E. Grant (Huntingdon Life Sciences UK)

08:50-9:15 Yasuo Ohno (National Institute of Health Sciences)  
*Secure Reliability of Data for New Drug Application in Japan - Non GLP Tests -*

09:15-9:40 C.T. Viswanathan (CT Viswanathan & Associates)  
*The Quality of Bioanalytical Studies*

09:40-10:05 Samantha Atkinson  
(Medicines and Healthcare products Regulatory Agency (MHRA))  
*UK Guidance on Regulatory Compliance for Clinical Laboratories*

10:05-10:25 Stephen B. Rogenthien (Ricerca Biosciences)  
*The Impact of Incurred Sample Reanalysis on Bioanalyses*

- 10:25-10:45 Laurent Bouillot (President of SoFAQ / Sanofi)  
*Which Quality Systems for Non GLP studies*
- 10:45-11:00 Masanori Shindo (Japan Tobacco)  
*Quality Management of Non-GLP Studies for New Drug Application in Japan*
- 11:00-11:15 Coffee Break
- 11:15-12:00 Panel Discussion

Concurrent Session GMP 09:45-12:00, Room D

Audit Check Points on GMP for Investigational Products and Commercial Products

- Chair : Akira Nomura (JSQA )  
Toshihiro Sakakibara (Kyowa Hakko Kirin / JSQA)
- 09:45-10:00 Toshihiro Sakakibara (Kyowa Hakko Kirin / JSQA)  
*Overview*
- 10:00-10:30 Hirofumi Ueda (Pharmaceuticals and Medical Devices Agency (PMDA))  
*GMP Inspection by PMDA*
- 10:30-11:00 John C. Mandy (Pfizer) and Timothy P. Reinhardt (Pfizer)  
*Key check points on GMP audit*
- 11:00-11:30 Kazuhiro Koyama (C&S)  
*Checkpoints of Cleaning and Disinfection of Clean Areas*
- 11:30-12:00 Yasutaka Shinoo (Japan Tobacco / JSQA)  
*Check Points for the Audit/Inspection of Contract Manufacturers and/or External Testing Institutions of the Investigational Drugs*

Concurrent Session GLP (2) 10:00-10:50, Room B-1

International Interpretation of GLP

- Chair : Toshihiko Hara (Astellas Pharma / JSQA)  
Mikiko Kuwabara (Toray Industries / JSQA)
- 10:00-10:20 Shohei Maruno (Shin Nippon Biomedical Laboratories)  
*Improving the Administration of the GLP Facility for Optimum Conduct of a Study*
- 10:20-10:40 Joelle Crouch (AFRIMS)  
*Cultural Considerations in GxP Compliance*

10:40-10:50 Q & A

GLP Special Session

11:00-12:00, Room B-1

Chair : Toshihiko Hara (Astellas Pharma / JSQA)

11:00-11:45 Kaname Takahashi (Mitsubishi Chemical Medience)  
*The GLP Facility Restoration from the 2011 Great East Japan Earthquake Damage*

11:45-12:00 Q & A

Concurrent Session GCP (2)

14:00-17:50, Main Hall

Quality Control and Quality Assurance in Japan

Chair : Hiroe Tsubaki (The Institute of Statistical Mathematics)  
Seiichi Ohba (Quintiles Transnational Japan / JSQA)

14:00-14:20 Hiroe Tsubaki (The Institute of Statistical Mathematics)  
*Role of Quality Management Principle for Drug Development*

14:20-14:40 Satoru Harada (Dainippon Sumitomo Pharma / JSQA)  
*Prospective QC System in Japan toward Next Generation*

14:40-15:00 Tadaki Nagasawa (EPS / JSQA)  
*Prospective QA System in Japan toward Next Generation*

15:00-15:20 Kazuo Yano (Asahi Kasei Pharma)  
*Well-Balanced Quality Assurance System May Trigger to Introduce Risk-Based Approach for Auditing*

15:20-15:40 Coffee Break

15:40-16:10 Cheryl Bissey-Black (Falcon Consulting Group)  
*Quality Control Training For Clinical Trial Personnel*

16:10-16:40 Peter Elfrink (PAREXEL International)  
*Conducting and Hosting an International Audit at a CRO in Japan*

16:40-17:50 Panel Discussion

Concurrent Session GLP (4)

14:00-17:00, Room A

Quality Assurance for Electronic Records in Non-clinical Laboratories



- Chair : Yukari Haramaki (Nihon Waters)  
Chiaki Watanabe (Taisho Pharmaceutical / JSQA)
- 14:00-14:40 Siôn Wyn (Conformity)  
*Data Integrity and Retention - Annex 11 and Part 11*
- 14:40-15:00 Stephanie Taulbee (Pharmaron Preclinical Services Laboratory)  
*How Validation Changes the Way We Do QC and QA*
- 15:00-15:20 Marian M. Mutch (Covance Pharmaceutical R&D (Shanghai))  
*Comparisons of e- Archiving Publications*
- 15:20-15:40 Tomoharu Takada (Nomura Research Institute / JSQA)  
*Key Considerations for Defining the Electronic Data as Raw Data in Japanese Pharmaceuticals*
- 15:40-16:00 Coffee Break
- 16:00-17:00 Panel Discussion

Concurrent Session Pharmacovigilance

14:00-17:35, Room D

Pharmacovigilance Regulation/Pharmacovigilance Quality Assurance

Chair : Tatsuya Saito (Pfizer Japan / JSQA)  
Shuichi Chikada (Daiichi Sankyo / JSQA)

14:00-14:40 Calvin Johnson  
(Medicines and Healthcare products Regulatory Agency (MHRA))  
*The Evolution of Pharmacovigilance and Pharmacovigilance Inspections in the EU*

14:40-15:20 Grace Crawford (ICON Clinical Research)  
*Regulated Pharmacovigilance Systems - How to Ensure Quality to Meet FDA Expectations*

15:20-16:00 Daisuke Tanaka (Ministry of Health, Labour and Welfare (MHLW))  
*Better Safety for Medicinal Products - Pharmacovigilance in Japan -*

16:00-16:25 Coffee Break

16:25-17:00 Genshu Nakamura (Biogen Idec Japan / JSQA)  
*The Comparison of PV Inspections between Japan, US and Europe*

17:00-17:35 Maria Christina Koster (Vigilex)  
*The Creation and Running of a Worldwide Pharmacovigilance QA Unit*

GMP Auditor Training (Basic Course)

14:00-18:00, Room B-1

GMP (IP-GMP) Quality Auditor Training

Trainers : John C. Mandy (Pfizer)  
Timothy P. Reinhardt (Pfizer)  
*GMP (IP-GMP) Quality Auditor Training*

**Wednesday, November 16, 2011**

USA/EU/Japan Session (GCP) 08:00-12:00, Main Hall  
 Quality Assurance of Multinational Clinical Studies for Simultaneous NDA Submissions in the Three ICH Regions

Chair : Koji Kawakami (Kyoto University)  
 Yoshiro Shibasaki (Biomedical Systems)

08:00-08:45 Winifred Ann Meeker-O'Connell (U.S. Food & Drug Administration (FDA))  
*CDER Perspective: Building Quality into Clinical Trial Design, Conduct, and Oversight*

08:45-09:30 Gunnar Danielsson (Medical Products Agency)  
*EMA Perspective: The Path Forward*

09:30-10:05 Emiko Kondo (Pharmaceuticals and Medical Devices Agency (PMDA))  
*PMDA's Approach to Ensure Quality of Clinical Trials*

10:05-10:30 Coffee Break

10:30-10:55 Rita Hattermer-Apostel (Verdandi)  
*QA Strategies for Global Clinical Trials - Points to Consider to Succeed in International Marketing Authorization Applications*

10:55-11:20 Barney Horne (Novartis Pharma)  
*Planning and Implementing Effective Quality Assurance for Global Clinical Trials*

11:20-12:00 Panel Discussion  
 Additional Panelists;  
 Chisato Sato (Pfizer / JSQA)  
 Toshiaki Tamura (Astellas Pharma / JSQA)

USA/EU/Japan Session (GLP) 09:00-12:00, Room A  
 International Perspective of Pathology Peer Review

Chair : Keiji Samura (Hunthindon Life Sciences / JSQA)  
 Junichi Kuranami (Kyowa Hakko Kirin / JSQA)

09:00-9:05 Junichi Kuranami (Kyowa Hakko Kirin / JSQA)  
*Overview*

09:05-9:30 C.T. Viswanathan (CT Viswanathan & Associates)  
*Pathology Peer Review -A Hybrid Perspective*

- 09:30-9:55 Samantha Atkinson  
(Medicines and Healthcare products Regulatory Agency (MHRA))  
*UK Perspective - Pathology Peer Review*
- 09:55-10:20 Toshihiko Asano (Pharmaceuticals and Medical Devices Agency (PMDA))  
*PMDA's Viewpoint on Pathology Peer Review*
- 10:20-10:45 Additional Remarks (1)  
Jeffery A. Engelhardt (Experimental Pathology Laboratories)  
*The Practice of Pathology Peer Review: A Pathologist's Perspective*
- 10:45-11:05 Coffee Break
- 11:05-11:15 Additional Remarks (2)  
Keiji Samura (Huntingdon Life Sciences / JSQA)  
*JSQA's Suggestion*
- 11:15-12:00 Panel Discussion  
Additional Panelists;  
Roger Chapman (Huntingdon Life Sciences UK)  
Munehiro Teranishi  
(Japanese Society of Toxicologic Pathology / Daiichi-Sankyo)

SQA/BARQA/JSQA Joint Symposium (GLP/GCP) 13:00-15:00, Main Hall  
SQA/BARQA/JSQA Joint Symposium (GLP/GCP)

Chair : Shigeo Watabe (Daiichi Sankyo / Vice-President of JSQA)  
Kiyoshi Chiba (Kyowa Hakko Kirin / Vice-President of JSQA)

13:00-13:20 James A. Ault (President of SQA)  
*Looking Forward – What Does the Future Hold for Quality Assurance?*

13:20-13:40 Rachel Hodges (Chairman of BARQA / AstraZeneca)  
*Towards the Next Generation – GLP QA*

13:40-13:55 Akira Takanaka (President of JSQA / Chairman of 3rdGQAC)  
*What Stance Should JSQA Take for Quality Assurance of the Next Generation?*

13:55-14:05 Coffee Break

14:05-15:00 Panel discussion  
Additional Panelists;  
Andrew Waddell (Former Chairman of BARQA / Director of TMQA)

MaryEllen Lander (Former President of SQA / Falcon Consulting Group)  
Tatsuya Kondo  
(Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA))

Closing Ceremony

15:00-15:30, Main Hall

Closing Ceremony and Handover to SQA

## Participants

908 participants from 22 countries/regions

Country / Region	#	Country / Region	#
Japan	754	India	3
USA	37	Singapore	3
China	25	Indonesia	2
UK	25	South Africa	2
Taiwan	12	Australia	1
Korea	10	Belgium	1
Germany	8	Brazil	1
Switzerland	7	Finland	1
Denmark	5	Hong Kong	1
France	4	Malaysia	1
Thailand	4	Sweden	1

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