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:

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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.
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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.icckyoto.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
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

Exhibitor	Booth
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

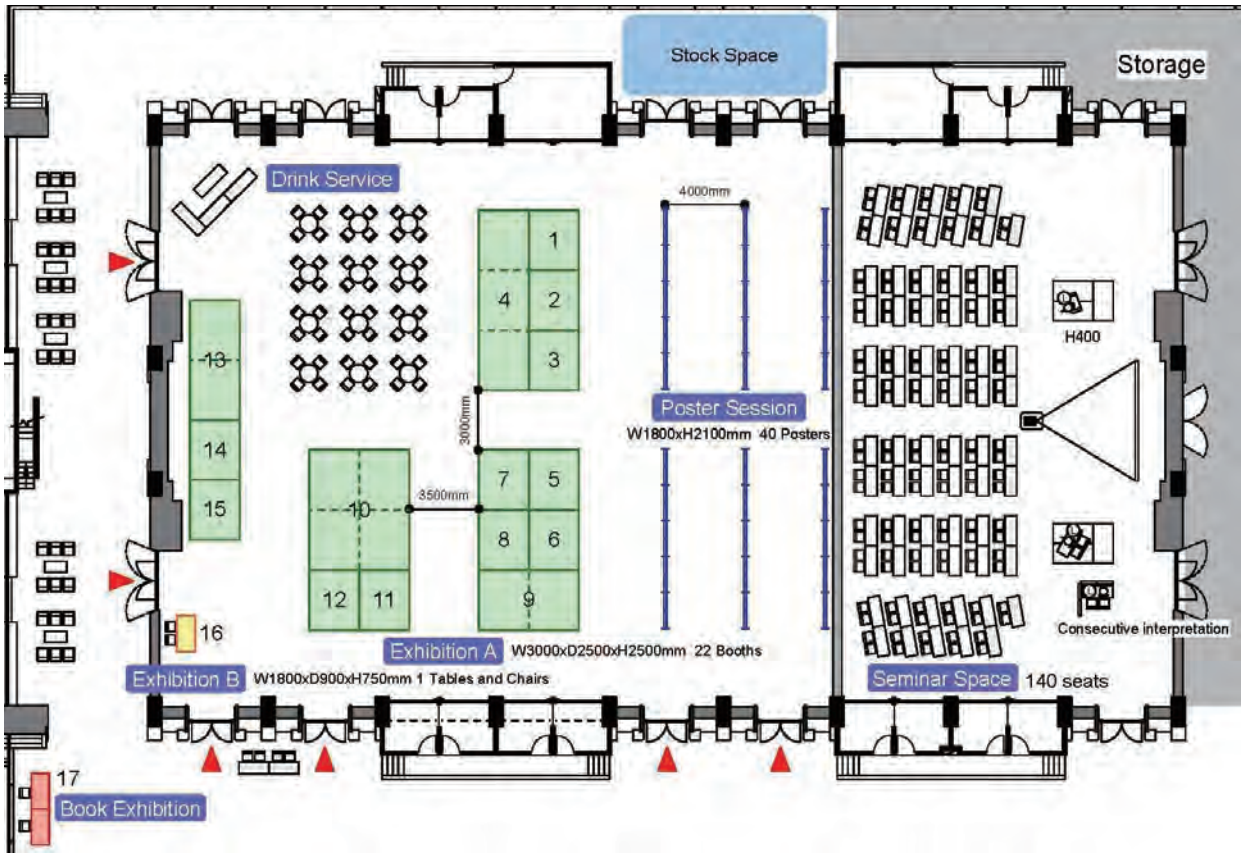

Exhibit Hours

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

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 Yoshiyiama (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 (CLINIQAL)
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 - Pharamacovigilance 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 (Hunthingdon 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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