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