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

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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)

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PP-10 Akira Nomura (QA Advisor)

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