6th Global QA Conference

Day 1 Tuesday 18th February AM : Main Hall

Language: English and Japanese

Simultaneous interpretation service will be available for Japanese and English

10:00 - 10:30 Opening Address

Vanessa Grant	VG Quality Solutions Ltd., Representative of the RQA
Yoshinobu Hirayama, Ph.D.	President of the JSQA
Beth Moulaison	Vertex, President of the SQA

10:30 - 11:30 K-01 Keynote Lecture 1

AI-driven pharmaceutical innovation in Japan

Yasushi Okuno, Professor, Ph.D.

Department of Biomedical Data Intelligence, Graduate School of Medicine, Kyoto University

Chair Yoshinobu Hirayama, Ph.D., President of the JSQA

Professor Yasushi Okuno of Kyoto University as the leading expert of drug discovery research based on RWD and AI, will introduce the current status of application to AI for drug development in Japan. The presentation will include efforts towards the application of AI from upstream (e.g. drug candidate search) to downstream (e.g. diagnosis) in the drug life cycle.

11:30 - 12:30 K-02 Keynote Lecture 2

Medical response to the Great East Japan Earthquake in the Ishinomaki Medical Zone

Tadashi Ishii, Professor, M.D., Ph.D.

Department of Education and Support for Regional Medicine, Tohoku University Hospital

Chair Mikiko Kuwabara, Toray Industries, Inc./JSQA

Professor Tadashi Ishi is a surgeon. He worked at the Japanese Red Cross Ishinomaki Hospital, as the head of the disaster medical team in 2011. In his presentation, he will talk about his experience of how he overcame the difficulties under the extreme conditions immediately after the earthquake.

6th Global QA Conference

Day 1 Tuesday 18th February : Meeting Room1&2, Exhibition building

12:45 - 13:55
Poster including Short Oral Presentations
Language: English

12:45-12:55 **Wolfgang Schumacher** (Schumacher Pharma Consult, Moehlin) / P06★
Data Integrity in the Production Area

12:55-13:05 **Tadahiro Yoshiyama** (JSQA/L-3-1, Chugai Pharmaceutical Co.,Ltd.) / P08★
Best practice of operation management under data-integrity guidelines
- A case study using stand-alone HPLC -

13:05-13:15 **Masaki Aota** (JSQA/L-3-2, Astellas Pharma Inc.) / P11★
Quality Assurance when introducing New Information Communication Technology

13:15-13:25 **Kazumasa Ogawa** (JSQA/L-1-2-B, Nissan Chemical Corporation) / P17★
What's the difference? Good Laboratory Practice for Pharmaceuticals, Agrochemicals and New Chemical Substances in Japan

13:25-13:35 **Smit J. Patel** (Jai Research Foundation) / P18★
Preparing for GLP compliance Inspection

13:35-13:45 **Kiyomi Hirayama** (MSD K.K.) / P22★
Development of Quality Management System (QMS) for Clinical development

13:45-13:55 **Kayo Minegishi** (GlaxoSmithKline K.K.) / P23★
Clinical Quality Management System (QMS) -A Knowledge Management Framework and Approach for Clinical Development-

6th Global QA Conference

Day 1 Tuesday 18th February PM : Meeting Room1&2, Exhibition building

14:15 - 17:45

Oral Presentations

Language: English

14:15-14:45 **Labhu U. Sanghani (Jai Research Foundation)**
Auditing for Data Integrity: Expectations & Experience in GLP”

14:45-15:15 **Wolfgang Schumacher (Schumacher Pharma Consult)**
Validation and Control of Cloud Computing Applications (SaaS)

15:15-15:45 **Sujata Dutta Gupta (Zifo RnD Solutions)**
Data in a fix? A trailblazer’s modus operandi

15:45-16:15 Break

16:15-16:45 **Hanna Preus (Opiant Pharmaceuticals)**
Standard Operating Procedures as part of Quality Management System to ensure quality, compliance and business outcomes.

16:45-17:15 **Jürg Lustenberger (SwissPharmAudit (Schweiz) GmbH)**
Outcome and evaluation of 5 years of experience with a novel QM concept improving Sponsor-Investigator’s compliance with GCP at University Hospitals in Switzerland

17:15-17:45 **Leslie S. Sidor (Biogen)**
How to select the most appropriate effectiveness check for your corrective action

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14:15 - 15:30　C-01

JSQA-JMACCT Collaboration Seminar: Considerations for Using IT Systems in Clinical Trials - Responsibilities as Sites and Sponsors -

Speakers

JMACCT Japan Medical Association Center for Clinical Trials
Shuji Wakai, Clinical Research & Development Division Director
Mayumi Ito, Clinical Research & Development Division Manage

JSQA **Yoko Morimoto**, Medidata

Chair Yoko Morimoto, Medidata/JSQA

According to the globalization and diversification of clinical trials accelerating, in addition to the development of IT technology, the use of various IT systems such as EDC are also progressing in clinical trials and clinical research. Although IT technology has various advantages such as operational efficiency, on the other hand, the quality management of clinical trials has become complicated due to the need to introduce new processes to comply with laws and regulations, especially the quality managements of electronic data and records gains importance.

In this session, on the bases of these situations, we would like to consider what points to keep in mind when using IT systems in clinical trials from both sides, the sponsor and the site.

[Session Overview]

- Japanese regulatory requirements for clinical trials
- Overview of IT systems used in clinical trials
- Role and Responsibility of site/sponsor when using IT systems
- Panel discussions

Area: GCP

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16:00 - 18:05　X-02

Compliance and quality assurance in the integrity of the utilized electrical data in Pharmaceutical industry

Speakers

PMDA **Yoko Tokunaga**, Inspector, Office of Non-clinical and Clinical Compliance

FDA **Eric Pittman**, Program Division Director, Office of Bioresearch Monitoring Operations, Office of Regulatory Affairs

MHRA **Paula Walker, MA, BSc.**, Unit Manager MHRA Inspectorate (GLP/GCP/GPvP)

Chairs Yoko Morimoto, Medidata/JSQA, Shigenori Kaida, Teijin Pharma Limited/JSQA

Lecture and Panel discussion

The electrical data has been common as regulatory data in current pharmaceutical industry, and the generated way of the data has continued to evolve with the development of supporting technologies such as the use of electronic data capture, automation of systems and use of remote technologies. At the same time, various data such as research data, big data, RWD, and Omics collected outside of GxP operations are also utilized widely in the pharmaceutical industry. Under the situation, we need to ensure the quality and the integrity of the data generated and being able to reconstruct activities, and data integrity is getting more and more acute regardless of GLP, GCP, and post-marketing fields.

In this session, regulators presents the current situation in each country with regard to approaches and regulations related generated electronic data in GxP regions, as well as points to consider when using various electronic data in pharmaceutical industry. Also, presenters exchange views about the necessity of global harmonization for compliance and quality assurance of the utilized electrical data.

Presentation : 90 minutes (PMDA, FDA, MHRA : each 30 minutes) Panel discussion : 35 minutes

Area: GxP, Data Integrity, QbD

Audience: Pharmaceutical and medical equipment development personnel

6th Global QA Conference

Day 1 Tuesday 18th February PM : Room Tachibana

Language: English and Japanese

Simultaneous interpretation service will be available for Japanese and English

14:15 – 15:55 X-01

Up-to-date initiatives for promoting clinical trials and Quality Assurance in Asian countries.

Speakers

PMDA Japan	**Rina Takenouchi, Ph.D.** Inspector, Office of Non-clinical and Clinical Compliance
TFDA Taiwan	**Yi-Ting Chen**, Associate Reviewer, Section of Clinical Trial Management, Division of Medicinal Products
NPRA Malaysia	**Nicholas Chun Wei Leow, RPh.**, Senior Principal Asistant Director, Good Clinical Practice (GCP) Compliance Section
India	**Bikash Medhi, MBBS, MD Ph.D.**, Professor,& Additional Medical Superintendent (AMS), Coordinator, PGIMER Pharmacovigilance Centre, Chandigarh
China	**Juncai Xu, MD**, Chief Auditor, Shanghai DrJ Medical Development Co.Ltd
Korea	

Chair Naoki Tsutsumi, AstraZeneca K.K./JSQA

Lecture

Nowadays, clinical trials have increased in complexity and while the variations of the embodiments have spread.

In this session, we will discuss and share the information on clinical trial promotion and quality assurance activities lead by regulatory authorities in Asian countries.

Example

・ Inspection trend,
・ Efficient use of eSource (eMR & EDC, eConsent, ePRO etc)
・ Notes on implementation virtual clinical trials
・ Preparations and achievements for GCP Renovation

Presentations, Questions and Answers by representatives from in Asian countries

Area: GCP, Data Integrity, QbD

Audience:

・Who want to understand of the regulatory requirements of Asian regulatory authorities, the situation of clinical trials and quality control
・Clinical trial sponsor, CRO, medical institution, clinical trial planning such as university and SMO, implementation, quality control, quality assurance department etc.
・Regulatory officials in each country
・Knowledge level: Beginner to experienced person

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Day 1 Tuesday 18th February PM : Room Tachibana

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16:25 – 17:55　L-01

The history behind the FDA GLP　-The case against IBT and Searle-

Speaker　Barbara Munch, Munch GLP Consulting (SQA)

Chairs Vanessa Grant, Director, VG Quality Solutions Limited/RQA

Isao Watanabe, Shin Nippon Biomedical Laboratories Japan/JSQA

Educational Lecture

"Those who cannot remember the past are condemned to repeat it." George Santayana, 1906

This session is an educational lecture about FDA GLP history.

In this session, Barbara Munch will give us stories about the history behind FDA GLP, especially focusing on the case of Industrial Bio-Test and Searle, including recent 483 or Warning Letter. Each section of the GLP was written in direct response to the fraud that was committed.

90 minutes including Q and A

Area: GLP, Educational lecture

Audience: Persons concerned with GLP

6th Global QA Conference

Day 1 Tuesday 18th February PM : Room Hagi

Language: English and Japanese

Simultaneous interpretation service will be available for Japanese and English

14:15 – 15:35 L-02

Points to be noted when outsourcing non-clinical studies (GLP studies, non-GLP studies) to domestic facilities

Speakers

JSQA L4 **Yuka Sugimura**, Daiichi Sankyo Co., Ltd.
Motoko Hidaka, Shin Nippon Biomedical Laboratories, Ltd.
Keiko Hashimoto, TERUMO CORPORATION
Ryoichi Koyama, FUJI YAKUHIN CO., LTD.
Hiroshi Kusuoku, Kao Corporation
Mayumi Ono, Daiichi Sankyo Co., Ltd.
Akiko Tokugi, SANWA KAGAKU KENKYUSHO CO., LTD.

Chairs Takayuki Kato, FUJIFILM Corporation/JSQA, L-4
Sumiko Nagaki, Mitsubishi Tanabe Pharma Corporation/JSQA L-4

Presentation

What do we need to proceed to studies efficiently when outsourcing non-clinical studies (GLP studies, non-GLP studies) to domestic CROs?

We consider it based on the past experiences from the viewpoints of both study contractors and consignors at the session.

Area: GLP and Non-GLP (Standards of Reliability of Application Data)

Audience: Domestic facilities personnel interested in outsourcing/conducting non-clinical studies (GLP studies, non-GLP studies)

6th Global QA Conference

Day 1 Tuesday 18th February PM : Room Hagi

Language: English and Japanese

Simultaneous interpretation service will be available for Japanese and English

16:05 – 18:00 L-03

Points to be noted when outsourcing non-clinical studies (non-GLP, PK and Pharmacology studies) to overseas facilities.

Speakers

Japan	**Hideo Takagi**, JSQA/L-2, Japan Tobacco Inc.
USA (and Hungary)	**Kammie Akers**, SOLVO Biotechnology (a Charles River Company)
Global (UK based)	**Chris Clare**, Covance

Chairs Hideo Takagi, Japan Tabacco Inc /JSQA, Masako Chino, Sanofi K.K. /JSQA

Presentation

We investigate the ways to conduct successfully non-GLP studies compliant with Japanese unique regulations "Standards of Reliability of Application Data" in overseas facilities, based on actual experiences from overseas facilities conducting studies outsourced from Japan and actual experiences from Japanese facilities outsourcing their studies to overseas facilities. As mentioned above, we suggest the method for building Win-Win relationship between contractors and consignors based on the current situation of the outsourcing studies at domestic and overseas. Questionnaire survey of problems at the time of outsourcing in and outside Japan is made in advance and we will report survey results at this session.

Hideo Takagi, JSQA/L-2, Japan Tobacco Inc.

Points to be noted when outsourcing non-clinical studies (non-GLP studies) to overseas facilities

Kammie Akers, SOLVO Biotechnology (a Charles River Company)

Meeting Quality Expectations for a Global Clientele

Chris Clare, Covance

What to Expect When Outsourcing Your Studies in China

Area: GLP and Non-GLP (Standards of Reliability of Application Data)

Audience: Overseas CRO personnel interested in conducting Japanese non-clinical studies (mainly non-GLP studies compliant with “Standards of Reliability of Application Data”) at their facilities.

6th Global QA Conference

Day 2 Wednesday 19th February AM : Meeting Room1&2, Exhibition building

9:15 - 11:45

Oral Presentations

Language: English

09:15-09:45 **Yanping Liu** (Covance Pharmaceutical Research and Development (Shanghai) Co. Limited)
How Central Laboratory Confront the Challenge and Opportunity in China

09:45-10:15 **Kazuo Yano** (Tokyo Women's Medical University - Waseda University, Waseda University, Medtronic Japan Co. Ltd.)
Upcoming ISO 14155 revision as global standard for clinical trials of medical devices and main changes

10:15-10:45 Break

10:45-11:15 **Labhu U. Sanghani** (Jai Research Foundation)
Outsourcing of Non-Clinical Studies: Ensure Quality and Compliance for Care, Housing and Containment of Biological Test System

6th Global QA Conference

Day 2 Wednesday 19th February AM : Main Hall

Language: English and Japanese

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9:00 – 10:15 L-04

Promoting quality in research in the academic environment

- Is it a never-ending challenge? -

Speakers

US Academic Delegate (SQA)	**Melissa Eitzen** Director, Regulatory Operations for the Office of Regulated Nonclinical Studies (ORNcS), University of Texas Medical Branch at Galveston
Japanese Academic Delegate	**Iekuni Ichikawa, MD, Ph.D.** Professor of School of Medicine, Shinshu University; Managing Director of Association for the Promotion of Research Integrity (APRIN); Professor of Pediatrics and Medicine, Vanderbilt University

Chair Hiromi Takano-Ohmuro, Visiting Professor, Musashino University, Faculty of Pharmacy

Lectures

It is a tough issue for us to keep the reproducibility or reliability of research integrity, especially in the academic environment. Japanese universities or governmental institutes are not lagging too much behind other countries in this issue, but actually, we don't have an effective educational program of research integrity nor an effective system like ORI in the US in the Japanese academic environment. It is a very serious problem.

The University of Texas Medical Branch (UTMB) has a GLP capable laboratory to conduct regulated studies under the FDA Animal Rule. In this session, Melissa Eitzen of UTMB will give us a lecture about her QA activities in the academic environment, experience of inspections, UTMB's partnership with the FDA to provide data quality and integrity training for the advancement of medical countermeasures in nonclinical and clinical studies, and the situation of other universities' labs in the US and the EU.

We will also have a lecture by Pf. Ichikawa of APRIN as a Japanese academic delegate.

Lecture by Melissa (40min)

Lecture by Pf. Ichikawa as a Japanese Academic Delegate (30min)

Q and A

Area: Academia

Audience: Academic, governmental and clinical researchers and other interested persons, industrial collaborators with academia, persons concerned with Due Diligence, etc.

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Day 2 Wednesday 19th February AM : Room Tachibana

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9:00 – 10:15 / 10:45 – 12:00 L-05

Future of Electronic Archiving

Speakers

US/SQA	**Joseph Whittemore**, Sr. Manager, Enterprise Records & Information Management, Pfizer Inc.
UK/RQA	**Matt Jones**, Managing Director, Digital Quality Associates Ltd.
Japan/R&D Data Archiving Committee	**Akira Yamazaki,** Kyowa Kirin Co., Ltd.

Chairs Vince D'Angelo, Vice President, Global Quality Assurance, Instem PLC, /SQA, RQA
Terukazu Kitahara, Instem Japan K.K. /JSQA

Lecture and panel discussion

Speakers from industry organizations in Japan, the US, and Europe will give a talk on the issue Issues in ensuring data reliability during long-term archive and responding to the spread of data utilization based on new technologies, and finally a panel discussion will be held. The contents of lectures from each organization are as follows:

・R & D Data Archive Committee: This presentation will clarify the issues in long-term storage of measurement instrument data and propose measures to solve the issues.

・SQA:This presentation will introduce a mechanism for automatically classifying and organizing previously archived electronic records.

・RQA: This presentation will explore the positives and challenges of implementing blockchain technology in the life sciences space.

Area: GLP, IT

Audience: Those interested in archive and utilization of electronic records including QA, IT, and archivist.

6th Global QA Conference

Day 2 Wednesday 19th February AM : Room Hagi

Language: English and Japanese

Simultaneous interpretation service will be available for Japanese and English

9:10 – 10:15 / 10:45 – 11:50 X-03

Current status and issues of clinical analysis-related regulations in each country

Speakers

UK/MHRA	**Andrew Gray BSc, Ph.D.** Deputy Director IE&S, Group Manager MHRA Inspectorate
India	**Bikash Medhi, MBBS, MD Ph.D.** Professor,& Additional Medical Superintendent (AMS), Coordinator, PGIMER Pharmacovigilance Centre, Chandigarh
China	**Zhanjiang Du, MSc,** Quality Assurance Manager, Joinn Laboratories China Co Ltd
Japan	**Nakae Hiroki**, **Ph.D.** Japan bio Measurement & Analysis Consortium)

Chair Yoshiaki Yano, IQVIA Services Japan K.K./JSQA

Lecture

Because of judgment in various situation of the drug development, it is required to ensure reliability of the data such as drug concentration, clinical test value, and biomarker, etc.

Since Good Clinical laboratory Practice (GCLP) has been published by BARQA (RQA) in 2003, the concept of GCLP as a quality system for laboratories has been spread from Europe and the US, and GCLP guidance /guideline were issued in each country.

On the other hand, there are quality systems such as ISO15189, ISO17025, CAP and CLIA to ensure the competence of facility to perform required in medical laboratory/technical procedures tests.

In this session, it is expected to understand the differences in regulations and current status reliability of the data to undertake analyses/tests of samples from clinical studies among each country, and to share the issues regarding quality assurance for the analysis/test associated with development of technology.

【Speaker & Lecture】

1) China: Regulation of medical laboratory/technical procedures tests in clinical studies. Handling of study samples, measurement, and reliability of results.

2) India: Regulation of medical laboratory/technical procedures tests in clinical studies.

3) Japan: Differences in regulation of medical laboratory among countries (Europe and the US vs. Japan) and current issue in genetic tests.

4) MHRA: Dr Andrew Gray: Attempts to harmonize GCLP standards in EU countries

Area: GCLP

Audience: People involved in clinical trials, clinical research, and clinical analysis

6th Global QA Conference

Day 2 Wednesday 19th February AM : Room Shirakashi

Language: English and Japanese

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9:00 – 10:15 X-04

The investigational medicinal products GMP in Japan (J-GMP for IMP)

Speaker and Panelist

PMDA Japan **Ryoko Naruse, Ph.D.**
Division Director, Office of Manufacturing Quality for Drugs
Division of Inspection for Drugs

Panelists

JSQA Joint Special Project Group 1 (K-T-1) members
Jun Kosaka, EA Pharma Co., Ltd.
Shiho Matsumura, ZERIA Pharmaceutical Co., Ltd.
Toshiki Watanabe, Bayer Yakuhin, Ltd.
Wakuko Yamaguchi, Nippon Boehringer Ingelheim Co., Ltd.

Chairs Tomoko Izumi, Maruishi Pharmaceutical Co., Ltd. /JSQA K-T-1
Tetsushi Katayama, Sanofi K.K. /JSQA K-T-1

Lecture and Panel Discussion

We would like to invite the specialist from PMDA in order to provide the overseas and Japanese audiences with the opportunity to learn the specific requirements on J-GMP for IMP. At the same time, Japanese pharmaceutical companies (domestic/multinational) will also provide some case studies on J-GMP for IMP.

① Presentation by PMDA
- Positioning, basic principle, purpose of J-GMP for IMP ("GMP for Investigational Products" Pharmaceutical and Food Safety Bureau (PFSB) Notification No. 0709002, dated July 9, 2008)
- Comparison of J-GMP for IMP with GMP ordinance (commercial products) and with GMP overseas
- Perspective of J-GMP for IMP based on Pharmaceutical Quality Systems (PQS)
- Case studies of PMDA inspection for J-GMP for IMP

② Case studies from Japanese pharmaceutical companies
- Technology Transfer
  - Quality Risk Management
- PQS
  - Change Control/Change Management
  - Supplier Management/Outsourcing Management, etc.

③ Comprehensive panel discussion

④ Q & A with floor

Area: GMP, IMP (Investigational Medicinal Products)

Audience: Persons concerned with CMC (from beginner to expert/specialist)

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Day 2 Wednesday 19th February AM : Room Shirakashi

Language: English and Japanese

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10:45 – 12:00 X-05

Embark on the New Tide ! -PV QMS Culture in Europe, Asia and Japan

Speakers

France	**Laurence Richard**
	Head of Development & Operations, Senior Quality Auditor, Audithem
Japan/JSQA	**Yusei Iwasaki**, Hisamitsu Pharmaceutical Co.,Inc. / P-1-B
Japan/JSQA	**Genshu Nakamura**, Biogen Japan Ltd./ P-1-B

Chairs Laurence Richard, Head of Development & Operations, Senior Quality Auditor, Audithem
Teiki Iwaoka, P-1-B / JSQA

Presentation

Comparison of PV QMS Regulation among Regions

・PV QMS required in EU	Laurence Richard (Audithem)
・PV Regulation in China	Yusei Iwasaki (JSQA P1B)
・PV QMS Implementation in Japan	Genshu Nakamura (JSQA P1B)

Area: PV QMS

Audience: PV Professionals, PV QMS Expert

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10:45 – 12:00 C-02-1

Different or Same? GCP Requirements among Regulatory Authorities

-Subject Protection and Informed Consent Process-

Panelists

PMDA Japan	**Tomoko Ohsawa, Ph.D.** Director, Office of Non-clinical and Clinical Compliance
FDA US	**Chrissy J Cochran, Ph.D.**, Bioresearch Monitoring Program Director, Office of Regulatory Affairs
MHRA UK	**Paula Walker MA BSc,** Unit Manager MHRA Inspectorate (GLP/GCP/GPvP)
BfArM Germany	**Gabriele Schwarz**, Head of GCP Inspectorate, Federal Institute for Drugs and Medical Devices

Speakers and Panelists

JSQA	Takahiro Hanai, Daiichi Sankyo Company Limited (Speaker) Junichiro Tomii, PPD-SNBL Japan (Panelist)
RQA	Barney Horne, Worldwide Clinical Trials

Chair Takahiro Hanai, Daiichi Sankyo Company Limited /JSQA

Lecture and Panel Discussion

This session is programmed to mutually understand why different regulatory authorities differ in requirements and levels relating to subject protection and informed consent process, and exchange views the possibility of harmonization in the future.

1) Lecture: JSQA/SQA/RQA

Introduce a summary of gap analysis result among JSQA/RQA/SQA on the regulatory requirements related to the subject protections and the informed consent processes in each region. Explain key unique requirements related to the subject protections and the informed consent processes in each region.

2) Panel Discussion: JSQA & PMDA, SQA & FDA, RQA & MHRA/BfArM

Exchange views on whether there were any areas that could be harmonized in the future or whether differences could be problematic if a regulatory authority in other region carried out a GCP inspection.

Area: GCP

Audience: For responsible persons for clinical trials

6th Global QA Conference

Day 2 Wednesday 19th February PM : Main Hall

Language: English and Japanese

Simultaneous interpretation service will be available for Japanese and English

14:00 – 16:00　C-02-2

Different or Same? GCP Requirements among Regulatory Authorities

-GCP Inspections-

Speakers

PMDA Japan	**Tomoko Ohsawa, Ph.D.** Director, Office of Non-clinical and Clinical Compliance
FDA US	**Chrissy J Cochran, Ph.D.**, Bioresearch Monitoring Program Director, Office of Regulatory Affairs
MHRA UK	**Paula Walker MA BSc,** Unit Manager MHRA Inspectorate (GLP/GCP/GPvP)
BfArM Germany	**Gabriele Schwarz**, Head of GCP Inspectorate, Federal Institute for Drugs and Medical Devices

Chairs Angelika Tillmann /RQA, Takahiro Hanai, Daiichi Sankyo Company Limited /JSQA

Lecture

The purpose of each regulatory GCP inspection is the same for a compliance check on GCP and protocol requirements, but the inspection requirements and approaches are slightly different (unique) among regulatory authorities based on the changing of circumstance of clinical trial environment and technology in each region. This session is programmed to mutually understanding why each regulatory authority provides such unique and new GCP inspection requirements and approaches.

Lecture: PMDA, FDA, MHRA, BfArM（each 25min）

PMDA：Implementation of ICH E6R2 in Japan

FDA：Restructure of the FDA BIMO inspection office and approaches for inspection of virtual trials

BfArM：New European GCP inspection approaches for the assessment of data integrity in the light of the use of new technologies

MHRA：MHRA GCP inspection approaches in the Digital and Adaptive Design Environment

Area: GCP

Audience: For responsible persons for GCP inspections in multi international studies

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16:30 – 18:00 C-02-3

Different or Same? GCP Requirements among Regulatory Authorities

-Data Integrity in Clinical Trials-

Panelists

PMDA Japan	**Tomoko Ohsawa, Ph.D.** Director, Office of Non-clinical and Clinical Compliance
FDA US	**Chrissy J Cochran, Ph.D.**, Bioresearch Monitoring Program Director, Office of Regulatory Affairs
MHRA UK	**Paula Walker MA BSc,** Unit Manager MHRA Inspectorate (GLP/GCP/GPvP)
BfArM Germany	**Gabriele Schwarz**, Head of GCP Inspectorate, Federal Institute for Drugs and Medical Devices

Speakers and Panelists

JSQA	**Kazuma Sekiguchi**, CRO Mediport Co.,Ltd.
SQA	**Stephanie Branche**, QA Branche of clinical research, LLC
RQA	**Robrecht Tistaert**, PPD

Chair Takahiro Hanai, Daiichi Sankyo Company Limited /JSQA

Lecture and Panel Discussion

The complex and diversified clinical trials are being conducted in the world, however, there are no globally harmonized regulations focusing on the Data Integrity in GCP area.

The session is programmed to introduce some Data Integrity issues and risks in clinical trials, and exchange views what regulations / guidance should be developed in each region in the future, and what reliability assurance activities should be undertaken by the sponsor, CRO, and medical institution.

1) Lecture: JSQA,RQA, SQA

Introduce some examples of data integrity issues and risks in each region

JSQA Clinical trials using wearable devices

SQA Data integrity issues-wearable devices

RQA Audit trail review in clinical trials

2) Panel Discussion: JSQA & PMDA, SQA & FDA, RQA & MHRA/BfArM

Exchange views what kind of regulations / guidance need to be developed or harmonized in the future, and what kind of reliability assurance activities need to be undertaken by the sponsor, CRO, and medical institution for Data Integrity issues and risks in clinical trials.

Area: GCP, Data Integrity

Audience: For responsible persons for clinical trials

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Language: English and Japanese

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14:00 – 15:55 / 16:25 – 17:25　L-06

What has changed by issuing OECD Advisory Document No.19?

Speakers and Panelists

PMDA Japan	**Kenji Nakano, Ph.D.** Inspector, Office of Non-clinical and Clinical Compliance
FDA US	**Charles Bonapace, Ph.D.**, Director, Division of New Drug Bioequivalence Evaluation, Office of Study Integrity and Surveillance
MHRA UK	**Andrew Gray BSc, Ph.D.** Deputy Director IE&S, Group Manager MHRA Inspectorate
ANSM France	**Thomas Lucotte**, Trials and Vigilances Department, Inspection directorate
NATA Australia	**Louise Calder**, Accreditation Manager, GLP Program Adviser
FAMIC Japan	**Hitoshi Shibata**, Technical Staff, Agricultural Chemicals Inspection Station

Chairs Hitoshi Someya, Ph.D.
Director of GLP Inspection, Office of Non-clinical and Clinical Compliance / PMDA
Yoichi Matsushita, BioSafety Research Center Inc./JSQA

Lecture and panel discussion

Upon the publication of OECD AD No. 19 (hereinafter AD19), request PMDA, FDA, MHRA, ANSM, NATA and FAMIC to introduce what perspectives they conduct compliance inspections and cases etc. (findings from the inspection) relating to AD19.

During the panel discussion, each panelist will answer the questions about AD19 which JSQA offered them in advance, and discuss the differences and common understandings by including opinions from the floor.

・Description of purpose: Chairperson, Yoichi Matstushita (5 minutes)
・AD 19 Commentary: Chairperson, Hitoshi Someya, Ph.D. (20 minutes)
・Viewpoint of compliance inspection & introduction of indicated cases or comments relating to AD19　(60 minutes)

1) PMDA　Kenji Nakano, Ph.D. (15 minutes)
2) MHRA　Andrew Gray BSc, Ph.D. (15 minutes)
3) FDA　Charles Bonapace, Ph.D. (15 minutes)
4) ANSM　Thomas Lucotte (15 minutes)
5) NATA　Louise Calder (15 minutes)
6) FAMIC　Hitoshi Shibata (15 minutes)

・Break time (30 minutes)
・Panel discussion (60 minutes) Answer to questions and discuss (1 question / 0 minutes, 6 questions)

Area: GLP

Audience: Researchers and related parties interested in GLP

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Day 2 Wednesday 19th February PM : Room Hagi

Language: English and Japanese

Simultaneous interpretation service will be available for Japanese and English

14:30 – 16:00 / 16:30 – 17 : 50　X-06

Current status of regenerative therapeutic products and Quality Assurance

Speakers

PMDA Japan	**Shinichi Noda, Ph.D.** Principal Reviewer, Office of Cellular and Tissue-based Products
Japan	**Masayo Takahashi M.D., Ph.D.**, President, Coporation VisionCare
Taiwan/TSQA	**Wei-Yu Lo, Ph.D.**, TSQA Director and Director of Service , Division of Protech Pharmaservices Corporation
Japan/JSQA	**Masato Shiozaki,** JCR Pharmaceuticals Co., Ltd/JSQA

Chairs JSQA International Affairs Committee (Asahina, Ito, Iwaoka, Tamura, Makizaki)

Lecture

① Current status of application of regenerative therapy products and consideration points PMDA（40min)

② Current status and issues of clinical study(research) using iPS cell(considering Quality and Regulation)（50min)
Masayo Takahashi,M.D.,Ph.D.(President, Coporation VisionCare)

③ Current status and future issues of clinical study(research) regenerative therapeutic products and regulation -in each region/country in Taiwan.（40min)
TWei-Yu Lo, Ph.D.(TSQA Director and Director of Service ,Division of Protech Pharmaservices Corporation)

② The advanced case of approved regenerative therapeutic product（40min)
Masato Shiozaki(Pharmacovigilance Department, Quality Assurance Division, JCR Pharmaceuticals Co., Ltd)

Area: Regenerative therapeutic products

Audience: Healthcare worker, persons engaged in Academia, CRO, SMO and manufacturing industry.

6th Global QA Conference

Day 2 Wednesday 19th February PM : Room Shirakashi

Language: English and Japanese

Simultaneous interpretation service will be available for Japanese and English

14:00 – 16:00 L-07

Role of QAU at the testing facility in the event of a disaster

Speakers

Japan **Kasai Noriyuki, DVM, Ph.D.**, DJCLAM, Professor Emeritus, Tohoku University

US **Joelle Crouch**, RxGen, Inc./Saint Kitts Biomedical Research Foundation

Chairs Hiromi Takano-Ohmuro, Visiting Professor, Musashino University, Faculty of Pharmacy

Emiko Takeuchi, Teijin Pharma Limited /JSQA

Lecture

What kind of response and record can be accepted as QA when disasters and serious deviations occur?

Based on the cases of large disasters (experience stories), we will consider how to cope with disasters and deviations and what measures can be taken in case of emergency.

It is assumed that lectures will be given by an inviter and/or a public offering (especially targeted to the Asian area where there are many disasters).

Kasai Noriyuki:3.11Great East Japan Earthquake, Dealing with the damage and its aftermath in Animal facility of Tohoku University

Joelle Crouch: A Caribbean CRO and the Annual Threat of Hurricane Season

Area: GxP, BCP

Audience: QA and researcher with GxP testing facility and animal testing facility

6th Global QA Conference

Day 2 Wednesday 19th February PM : Room Shirakashi

Language: English and Japanese

Simultaneous interpretation service will be available for Japanese and English

16:30 – 18:00 L-08

"SAMURAI"and "Quality Assurance"

Speakers

JSQA JSQA Members (L-5), Ken Kawaguchi, Kazumi Yoshida, Kazuhiro Urata

Chairs Ken Kawaguchi, Toray Research Center, Inc /JSQA

Kazumi Yoshida, Ishihara Sangyo Kaisha, Ltd /JSQA

Presentation

We aim to improve reliability of studies in GLP and "the Standard for the Reliability of Application Data (e.g. Article 43)" which is a Japanese unique system, and we are working on issues arising daily.

In this session we give a tile "SAMURAI" and "Quality Assurance" because we would like to tell more people about our activities through traditional Japanese culture and Samurai spirit.

We will introduce the results of discussions on how to deal with problems occurring in daily QA activities from the viewpoint of particularly important "7 virtues", namely "Rectitude", "Courage", "Benevolence", "Politeness", "Veracity", "Honor" and "Loyalty".

We hope you find informative some hints in this session when suffering from resolving problems about reliability of study.

Area: GLP

Audience: QAs, QCs, and SDs in GLP-compliant studies and reliability criteria studies (for beginners)

6th Global QA Conference

Day 3 Thursday 20th February AM : Main Hall

Language: English and Japanese

Simultaneous interpretation service will be available for Japanese and English

9:00 – 9:45　X-07

Basics in keeping Quality

Speaker　　**Andrew Waddell**, TMQA (RQA)

Chairs Vanessa Grant, Director, VG Quality Solutions Limited / RQA

Shigeo Suzuki, MSD K.K /JSQA

Lecture

Basics in keeping quality is common and important not only in auditing but in any event around quality. Sp Speaker is ex-RQA President teaching at Medical School of Edinburgh University. He worked in CRO Inveresk Research as the Quality & Training Head. He had the audit experience of more than 30 years. He was responsible for training in BARQA and RQA.

3rdGQACLecture: “Effective Continuing Professional Development of QA Staff”

5thGQAC Closing Session: “We’re no’ awa’ tae bide awa’ (we are not away to stay away) ”

Area: GxP

Audience: Auditor＆Auditee in GLP, GCP, and in PV

6th Global QA Conference

Day 3 Thursday 20th February AM : Main Hall

Language: English and Japanese

Simultaneous interpretation service will be available for Japanese and English

10:10 – 12:10　X-08

GxP Regulatory Roundtable

Panelists

MHLW Japan	**Ryo Iwase**, Office of International Regulatory Affairs, Pharmaceutical Safety and Environmental Health Bureau
PMDA Japan	**Tomoko Ohsawa, Ph.D.** Director, Office of Non-clinical and Clinical Compliance
FDA US	**Chrissy J Cochran, Ph.D.** Bioresearch Monitoring Program Director, Office of Regulatory Affairs
MHRA UK	**Andrew Gray BSc, Ph.D.** Deputy Director IE&S, Group Manager MHRA Inspectorate
BfArM Germany	**Gabriele Schwarz**, Head of GCP Inspectorate, Federal Institute for Drugs and Medical Devices
ANSM France	**Thomas Lucotte**, Trials and Vigilances Department, Inspection directorate
NATA Australia	**Louise Calder**, Accreditation Manager, GLP Program Adviser
TFDA Taiwan	**Yi-Ting Chen**, Associate Reviewer, Section of Clinical Trial Management Division of Medicinal Products
NPRA Malaysia	**Nicholas Chun Wei Leow, RPh.**, Senior Principal Asistant Director Good Clinical Practice (GCP) Compliance Section
India	**Amaresh Tumbagi**, Additional Drugs Controller and Licensing Authority, Office of the Drugs Controller for the state of Karnataka,India

Chairs　Beth Moulaison, Vertex / President of SQA
Barney Horne, Worldwide Clinical Trials / RQA
Yoko Morimoto, Medidata / JSQA
Naoki Tsutsumi, AstraZeneca K.K. / JSQA

Panel Discussion

Panelists are invited from regulatory agencies in Japan, US, Europe and Asia and discuss the questions collected in advance through JSQA, SQA and RQA.

Area: GxP

Audience: All participants