6th Global QA Conference

Poster Presentations

Venue: Exhibition building

Posters are displayed during the following hours;

February 18 and 19, 9:00 - 17:00, February 20, 9:00-10:30

Poster discussion：February 19, 12:10 - 13:50

★Poster including Short Oral Presenter

P01 **Yangyang Zhi** (Shanghai InnoStar Bio-tech Co., Ltd., InnoStar)
Digitization of inspection report

P02 **Mari Yamaguchi** (JSQA/L-1-1-B, Otsuka Pharmaceutical Factory, Inc.)
Use of external electronic data storage facilities in GLP

P03 **Tadahiro Yoshiyama** (Chugai Pharmaceutical Co.,Ltd.)
QAU contribution to ensure data integrity as the GLP study environment changes - Evaluation of external facilities related to cloud system operation/ Support for system construction for data integrity -

P04 **Catherine Tai Liang** (Charles River)
How to define an Effective Data integrity governance program that shows quality is on your mind?

P05 **Isao Watanabe** (JSQA/ L-3-2-A, Shin Nippon Biomedical Laboratories, Ltd.)
Consideration of appropriate management of the GLP computerized system for data integrity - To identify focus points for education -

P06★ **Wolfgang Schumacher** (Schumacher Pharma Consult, Moehlin)
Data Integrity in the Production Area

P07 **Yoshito Okabayashi** (JSQA/ L-1-1-C, Shionogi & Co., Ltd.)
Identification of gaps with MHRA's "GXP" Data Integrity Guidance in GLP facility management in Japan and its countermeasures

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

P09 **Masahiro Ootani** (JSQA/ L-3-1, Japan Blood Products Organization)
Presentation Title Promotion of computerization of raw data - Will electronic data contribute to improvements in non-clinical studies? -

P10 **Shugo Tabuchi** (Shin Nippon Biomedical Laboratories, Ltd.)
Equipment management according to intended use and processing capacity - Level classification -

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

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P12 **Ryo Okumura** (JSQA/L-3-1, Kissei Pharmaceutical Co., Ltd.)
The future of GLP brought about by new IT technologies
- Prospects of innovation for GLP data storage based on blockchain technology -

P13 **Hayao Okamura** (JSQA/L-1-1-D, Kaken Pharmaceutical Co., Ltd.)
Application of risk-based approach in process-based QA inspection

P14 **Terukazu Kitahara** (JSQA/L-T-S, Instem Japan)
Issues and proposal for SEND from the perspective by quality assurance

P15 **Emiko Takeuchi** (JSQA/L-T-D-1, Teijin Pharma Limited.)
Utilization of QAU in test facilities in case of non-stationary situations such as disasters.

P16 **Emiko Takeuchi** (JSQA/L-T-D-2, Teijin Pharma Limited.)
Damage and Countermeasures for Nonclinical Testing Facilities Due to Disasters

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

P18★ **Smit J. Patel** (Jai Research Foundation)
Preparing for GLP compliance Inspection

P19 **Yasuhide Kitazaki** (Shin Nippon Biomedical Laboratories, Ltd.)
Risk-based assessment in facility inspections at GLP facilities: Aiming for effective and efficient QA inspections of facilities

P20 **Hideo Takagi** (JSQA/L-2, Japan Tobacco Inc.)
Points to be noted when outsourcing non-clinical studies (non-GLP studies) to overseas facilities

P21 **Kai Shen Yoong** (Clinical Research Malaysia)
Is GCP Refresher Training Effective- Perspective from Malaysia

P22★ **Kiyomi Hirayama** (MSD K.K.)
Development of Quality Management System (QMS) for Clinical development

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

P24 **Mikiko Kuwabara** (JSQA/K-T-3, Toray Industries, Inc.)
Japan NDA Registration of Regenerative Medicines - From 2017 to the Present -