The vision and mission of the Japan Society of Quality Assurance

Vision statement:

The Japan Society of Quality Assurance (JSQA) contributes to the improvement of the health and welfare of people by disseminating relevant information, developing human resources, and presenting appropriate suggestions on specialized information concerning the quality assurance of drugs, medical devices, regenerative medicine products, agricultural chemicals, and chemical substances, etc.

Mission statements:

1. To examine quality assurance relating to drugs, medical devices, regenerative medicine products, agricultural chemicals, chemical substances, etc., and present the study reports.

2. To provide opportunities for in-depth study and training necessary for the development of human resources involved in quality assurance.

3. To make proposals to the Japanese and overseas industries, governments and academia, from the viewpoint of quality assurance specialists, utilizing trust and co-operation.

QA Japan Society of Quality Assurance

QA Japan Society of Quality Assurance
Nihonbashi Life Science Building., 2-3-11 Nihonbashi-Honcho, Chuo-ku, Tokyo 103-0023, JAPAN
TEL : +81-3-6435-2118 FAX : +81-3-6435-2119
URL : https://www.jsqa.com/en

The Japan Society of Quality Assurance (JSQA) works not only on study group activities, but also conducts seminars, training modules, and international meetings, as shown below;

Study group activities

Each of the three divisions sets study themes and appoints study groups/subgroups for each theme. The members investigate the study themes to develop their knowledge and skills. The outcomes of the investigation are compiled as specific deliverables, such as brochures, CDs, and the website.

Seminars & training modules

To develop the knowledge of the members, JSQA holds seminars with invited speakers of the regulatory authorities, etc. To facilitate further understanding of QA works, JSQA provides step-wise training courses for QA personnel from beginners to experts according to experience and skill levels.

Global activities

JSQA holds a Global Quality Assurance Conference (GQAC) with SQA (Society of Quality Assurance; US) and RQA (Research Quality Assurance; UK) every 3 years to understand the worldwide situation related to GxP and quality assurance of drugs and medical devices etc.

In recent years, the GxP systems have rapidly been introduced in Asian countries. Many clinical and non-clinical studies are conducted in the Asian countries, except Japan. However, it is not easy to obtain GxP information in Asian countries, when compared with European and American information. JSQA organized an Asia QA Forum with other associations in Korea, China, Taiwan, India, Singapore and Malaysia. The first forum was held in 2013 in Japan, and it will be held every 2 years in various Asian countries.

GLP Division

The GLP division investigates quality assurance for non-clinical studies. Major study themes are i) GLP regulations related to drugs, medical devices, agricultural chemicals, chemical substances and so on, ii) quality management for non-GLP studies and iii) computer systems used in non-clinical studies. The GLP division also has regional study groups which discuss any topics related to quality assurance for non-clinical studies in Eastern and Western Japan. This does not include study groups which focus on one of the above-mentioned themes.

GCP Division

The GCP division addresses the latest selected problems and issues an order to improve the knowledge and the skill levels of the members engaged in quality assurance of clinical studies, standardize interpretations through information sharing and present suggestions to member companies and relevant parties. The main focused areas are quality management system, methodology of auditing, computerized system, relationship among stake holders of clinical studies and inspection by health authorities. It also provides a variety of training courses for QC/QA personnel of member companies.

GQP/GVP/GPSP Division

The GQP/GVP/GPSP division works to improve levels of quality and quality management as defined by MHLW ordinances on GQP (Good Quality Practice), GVP (Good Vigilance Practice) and GPSP (Good Post-marketing Study Practice). The main focused areas are self-inspection techniques, QA techniques in GQP, GMP, GVP and GPSP operations, investigation of the cases of inspection by regulatory authorities, education of personnel in charge of self-inspection.

Joint Special Project Groups

Joint special project groups are organized for every study theme which needs to be examined beyond the specific division, such as quality control of the medical supplies from development to manufacture, the reliability of the lab data in clinical studies, new regulation correspondence in the regenerative medicine products and so on. They have led to a broad discussion by members who have different specialties, since people in any division can participate in them.

Communication with related authorities, organizations, etc. in Japan

The JSQA exchanges opinions with not only regulatory authorities, but also various associations and societies.

Communication with overseas QA organizations

JSQA has established a Memorandum of Understanding (MoU) with RQA, SQA, CSQA, SoFAQ, KSQA, TSQA, GQMA, SARQA, SEGCIB and CQAF, and cooperates mutually with them by sending lecturers as representatives to each other's general meetings, developing guidelines, and exchanging opinions on GxP. JSQA will further promote exchanges with European, American and other Asian quality assurance-related organizations during this term.

Information transmission via the JSQA's website

We provide our activities and outline of research findings on the website. We also provide English translations as reference material to aid the understanding of Japanese laws and regulations, and much more.
For more information, visit

https://jsqa.com/en/english/