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.

Japan Society of Quality Assurance

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The Japan Society of Quality Assurance (JSQA)

In addition to study group activities, JSQA organizes seminars, training programs, and international meetings, as outlined below;

Study Group Activities

Each of the three divisions establishes study themes and forms study groups or subgroups for each theme. Members investigate these themes to enhance their knowledge and skills. The outcomes of JSQA activities are made available on the JSQA website or presented at conferences.

Deliverables

Based on research themes established for each two-year term, each group discusses and prepares deliverables, which are made available electronically through the JSQA website. These deliverables are used in the day-to-day operations of individual members and personnel at member companies.

Training Programs and Case Study Sessions

JSQA offers training programs organized by its divisions and committees to help participants deepen their understanding of quality assurance operations. Designed for participants ranging from beginners to experienced professionals, these programs support step-by-step learning according to participants' experience and skill levels.

JSQA also holds case study sessions in which cases collected from survey data and information provided by member companies are analyzed and shared among participating companies.

These activities are intended for registered participants from JSQA member companies and are delivered in formats appropriate to the content, including video-based learning, lectures, and group work.

Committee Activities

Under the Board of Directors, JSQA establishes committees and other bodies responsible for activities such as organizing General Meetings, supporting educational and international initiatives, and maintaining and administering the GLP-QAP Registration System.

GLP Division

The GLP Division examines issues related not only to GLP studies for pharmaceuticals, medical devices, agricultural chemicals, and other products, but also to non-GLP studies, including quality testing of pharmaceuticals, pharmacology studies, and pharmacokinetic studies, as well as the reliability of regulatory submission data.

For non-clinical studies, the Division collects case examples related to GLP compliance inspections and document-based conformity reviews of regulatory submission data in Japan, and considers issues and possible measures concerning study reliability. The Division also monitors the latest overseas regulatory trends, discusses emerging issues, and analyzes differences in regulatory requirements and practices.The Division also focuses on methods for ensuring the reliability of electronic data and documents created and managed using computerized systems. In addition, it provides timely training programs on GLP and non-GLP topics to support the development of personnel involved in ensuring the reliability of non-clinical studies.

GCP Division

The GCP Division examines timely issues and topics to improve the knowledge and technical skills of members primarily engaged in quality assurance for clinical trials and clinical research involving pharmaceuticals and medical devices. It also promotes the standardization of interpretations through information sharing and provides recommendations to member companies and other relevant stakeholders.The Division addresses a wide range of topics, including the implementation of quality management systems, audit techniques and audit case studies, computerized systems, relationships with stakeholders, including personnel at medical institutions, overseas regulatory information, and inspection cases in Japan and overseas, including GCP compliance inspections.The Division also provides training courses for QA and QC personnel and actively supports their professional development.

GQP/GVP/GPSP Division

The GQP/GVP/GPSP Division collects information on domestic and overseas regulations and ICH trends related to post-marketing activities. Based on this information, the Division identifies timely issues and prepares deliverables that support reliability assurance for post-marketing GxP activities, including GQP, GMP, GVP, and GPSP. The Division addresses key topics such as self-inspection and audit techniques, pharmacovigilance, post-marketing documents, surveillance and studies, quality events, manufacturing site audits, and inspection case studies. It also exchanges views with regulatory authorities and industry organizations and provides training programs for personnel involved in post-marketing GxP activities.

Joint Special Project Groups

Joint Special Project Groups are established for research themes that need to be addressed across divisions, such as quality control of pharmaceuticals from development through manufacturing and the reliability of laboratory data in clinical trials.

Because members may participate regardless of their division, these projects provide opportunities for broad discussion among participants with diverse expertise.

Internationalization and Collaboration with Overseas QA Organizations

JSQA co-hosts the Global Quality Assurance Conference (GQAC) every three years on a rotating basis with the Society of Quality Assurance (SQA, United States) and the Research Quality Association (RQA, United Kingdom). The conference aims to promote international mutual understanding of GxP operations and approaches to reliability assurance for pharmaceuticals, medical devices, and related products, bringing together regulators and quality assurance professionals from pharmaceutical companies, CROs, and other organizations around the world.

In addition, JSQA has entered into Memoranda of Understanding (MoUs) with QA organizations in Europe, the United States, and Asia. JSQA promotes mutual cooperation through exchanges such as dispatching speakers to general meetings and other events, developing guidelines, and exchanging views on GxP.

Interaction with Regulatory Authorities and Related Organizations

JSQA regularly exchanges views with regulatory authorities and relevant industry organizations in the fields of pharmaceuticals, medical devices, agricultural chemicals, and related areas. Through these interactions, JSQA seeks to deepen mutual understanding and build constructive relationships.

Information Dissemination via the JSQA website

JSQA disseminates a wide range of information to member companies and individual members through its website.

For more information, visit

https://jsqa.com/en/