Activity Summary of the 11th Term (May 2012 – March 2014)	
Special Project Group	Common Special Project Group 1: GMP/CMC group
Theme	Quality assurance relating to GMP and CMC

(Summary)

Common Special Project 1 was set up as a cross-working group activity of the Japan Society of Quality Assurance (JSQA) to widely examine what quality assurance relating to GMP and CMC should be in April 2006. The project is now in its fourth term.

In the third term (Year 2010 – Year 2011), we discussed about two themes of "Think of gaps with own individual companies with a focus on Q10 among ICH Q Trio <Group A>" and "Contract-based operation management <Group B>," with the group task of "Examination of what quality assurance relating to GMP and CMC should be," and both groups presented the results of their operations at the 3rd Global Quality Assurance Conference (GQAC), and also complied the results as deliverables. Group B was also engaged in the organization of the GMP session at the 3rd GQAC held in November 2011.

In this term (Year 2012 – Year 2013), we discussed about four themes "Examination of case examples to solve various questions pertinent to GMP for Investigational Medicinal Products/GMP for Drug Products <Group A>," "Examination of Issues to Operate ICH Q10 <Group B>," "Examination of GMP-related education and training <Group C>," and "Investigation of Q&A of PIC/S GMP Guide (the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme Guide to GMP)<Group D>," with the group task of "Examination of what quality assurance relating to GMP and CMC should be," and compiled the results as deliverables. Group B will present the results of their research at the 4th GQAC scheduled in the US in April 2014.

In the current GMP/CMC world, there is a pressing need to get PIC/S and ICH Q Trio (particularly Q10 as QA activities) entrenched in organizations. In this term, we could discuss about a number of themes among as many as about 50 members at meetings including morning meetings, and this greatly advanced the understanding of PIC/S and ICH Q10. As event programs of group activities, we held an interim debrief session as well as a one-day camp-based meeting as in the previous term, and also had an end-of-term by-group debrief session at the final regular meeting. Furthermore, we could not hold lecture meetings in the previous term but had those four times in this term. The lectures by outside professionals were highly beneficial to activation of our subsequent group activities.

Nevertheless, our activities in this term have not caught up with the activities undertaken by our senior staffs belonging to the GLP program committee, GCP program committee, and post-marketing program committee. However, we could be engaged in discussions and activities based on a wide range of themes in this term, and therefore believe that we could build a base for our group activities which is appropriate as the Common Special Project. In the next term, we would like to further improve the way we operate our meetings and carry out higher-quality and more productive group activities.

Activity Summary of the 11th Term (May 2012 – March 2014)	
Special Project Group	Common Special Project Group 1: GMP/CMC group Subgroup A
Theme	Examination of case examples to solve various questions pertinent to GMP for Investigational Medicinal Products/GMP for Drug Products

(Summary)

Corporations engaged in the manufacture and development of drugs are required to comply with the "Standards for Manufacturing Control and Quality Control for Investigational Products" (Pharmaceutical and Food Safety Bureau Notification No. 0709002 dated July 9, 2008) (hereinafter, "GMP for Investigational Medicinal Products" as well as the "Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs" (Ministry of Health, Labour and Welfare [MHLW] Ministerial Ordinance No. 179 dated December 24, 2004) (hereinafter, "GMP for Drugs Products"). However, there are not a few cases, in which people have a variety of questions in the interpretation and operation of the GMP for Investigational Medicinal Products and the GMP for Drug Products in the course of their daily activities. Under these circumstances, Group A recruited questions mainly pertinent to the GMP for Investigational Medicinal Products and the GMP for Drug Products from participating members, had discussions about the questions, and created the answers among the participating members. We expect this Q&A paper to be of some help to deepen the understanding of the GMP for Investigational Medicinal Products and the GMP for Drug Products and appropriately operate these guidelines.

This examination of case examples was summarized by Group A after a great deal of consideration based on the information obtained up to November 2013, and is not an official opinion of regulatory authorities or JSQA. In the actual operation, it is advisable to consider the "Ministerial Ordinance on Standards for Quality Assurance for drugs, Quasi-drugs, Cosmetics and Medical Devices" (MHLW Ministerial Ordinance No. 136 dated September 22, 2004), GMP Case Examples (2013 edition) released on December 19, 2013, and others. Please also note that the interpretation of the questions and the answers can change due to a future change in regulations etc.

Activity Summary of the 11th Term (May 2012 – March 2014)	
Special Project Group	Common Special Project Group 1: GMP/CMC group Subgroup B
Theme	Examination of Issues to Operate ICH Q10

(Summary)

Four years are soon about to pass since the notification of ICH Q10 was released, and many pharmaceutical companies in Japan are currently working on the introduction of ICH Q10.

ICH Q10 is constructed based on ICH Q7 and ISO9001. Major elements described in ICH Q10 are nearly the same as requirements in ISO9001; however, as far as Risk Management and Knowledge Management (KM) are concerned, there are no corresponding requirements in ISO9001.

Particularly, KM is the concept first introduced in ICH Q10 among regulations and guidelines for drugs, and information which can be used for reference is limited. "Management Responsibilities" which are listed as well-defined requirements in ISO9001, have not been explicitly reflected to the conventional GMP Ordinance or GQP Ordinance.

Under these circumstances, we decided to examine "Management Responsibilities" and "KM," which participating members found it difficult to interpret in the process of introducing ICH Q10, as one of the activities of Common Special Project 1 in the previous term (10th term). We worked with a focus on establishment of easy-to-understand explanation of "Management Responsibilities," and consequently could not examine "KM" adequately in the previous term. Thus, we aimed to understand "KM" and examine a tangible practical method in this term (11th term).

Since there is no description about a tangible method to practice "KM" in ICH Q10, we attempted as a first step to learn a general concept of KM, such as what KM is, what approach is available, and how it is utilized. We then began learning "Information," "Knowledge," and "KM," keywords for KM that were ranked lowest in terms of the level of recognition consistency among participating members, expanded the area of our research to KM in corporate management, and made efforts to understand the "Theory of Organizational Knowledge Creation" which was developed by Nonaka, Takeuchi, et al. and are widely recognized as the basic theory of KM. In the process of learning the "Theory of Organizational Knowledge Creation," we deepened the understanding of the concept of the SECI model, which is the process of tacit-to-explicit knowledge conversion and knowledge creation, through workshops by outside lecturers.

After taking the above process, the members had a common view, then investigated the movement of knowledge in the development and production of drugs using the SECI model as an analytical flame, and eventually examined points to consider in the introduction of KM to the quality system for drugs.

Activity Summary of the 11th Term (May 2012 – March 2014)	
Special Project Group	Common Special Project Group 1: GMP/CMC group Subgroup C
Theme	Examination of GMP-related education and training

(Summary)

The GMP Education Study Group (hereinafter, Group C) worked on what education and training should be, taking into consideration a setup of the curriculum of JSQA-sponsored "GMP Basic Course."

As an activity for Section 2 "Questionnaire on Introduction Education," in order to start working on a curriculum, Group C first investigated the actual status of each company about conducting an introductory education, and then carried out a questionnaire, which was planned for use as a reference to design subsequent continuous education and stratified education.

As an activity for Section 3 "Curriculum Draft," Group C planned to embody the introductory education scheme constructed based on the questionnaire results about the curriculum of "GMP Basic Course." In this term, however, this activity was left at the level of curriculum draft, and the creation of documents such as manual will be continued as a task for the next term.

Activity Summary of the 11th Term (May 2012 – March 2014)	
Special Project Group	Common Special Project Group 1: GMP/CMC group Subgroup D
Theme	Investigation of Q&A of PIC/S GMP Guide

(Summary)

The following items are currently gaining prominent attention under circumstances surrounding Japanese pharmaceutical companies and GMP.

- The MHLW submitted an application to be a PIC/S member in 2012, which is currently under examination, and Japan will be given the approval in 2014.
- Japanese pharmaceutical companies are needed seeking appropriate measures to apply the PIC/S GMP Guide.
- Compliance with the PIC/S GMP Guide is required to manufacturing sites for release of commercial and investigational medicinal products to PIC/S member nations and to conduct overseas clinical studies.

In light of these situations, hoping to fully understand the PIC/S GMP Guide and take appropriate measures, Group D set the theme of "Investigation of PIC/S GMP Guide and creation of its Q&A"

Fifteen members constituting joining Group D are engaged in various responsibilities in their companies, including those related to investigational medicinal products, commercial pharmaceutical products, QC testing, and computer system, thus these members were quite appropriate to investigate the issues from both the aspects of investigational and commercial medicinal products as well as from the support system point of view.

The investigation and preparation of Q&A covered Part 1 (Medicinal Products), Annex 8 (Sampling of starting and packaging materials), Annex 11 (Computerised systems), Annex 13 (Manufacture of investigational medicinal products), Annex 15 (Qualification and validation), and Annex 19 (Reference and retention samples) of the PIC/S GMP Guide. Group D gathered questions mainly focused on the members' uncertain points , and discussed the validity of the questions, then considered and prepared the answers to the questions.

A conscious effort was made in the preparation of the answers so that they could be utilized in actual practice. In addition, considering the further understanding of our answers, the group decided to add actual case examples to support the answers, and incorporated the actual examples collected in GMP/CMC group.

This Q&A paper is the outcome of the investigation among Group D members, and we have not checked the compatibility with MHLW Office Communication "GMP Case Examples" (dated December 19, 2013); however, we expect each company to utilize this as a current reference to apply to the PIC/S GMP Guide.

Activity Summary of the 11th Term (April 2012 – March 2014)	
Special Project Group	Common Special Project Group 2
Theme	QA methodology at Central/Analytical Laboratories for Clinical Trials − Examination of Problems/Suspicious Case Examples, Retention of Materials, and Checkpoints in Auditing −

(Summary)
Quality assurance of contract laboratories including central laboratories, pharmacogenetic laboratories conducting analysis of clinical samples (Good Clinical Laboratory Practice; GCLP) is drawing attention in the US and Europe, and JSQA has also been working on this topic as a Common Special Project since 2008. Due to recent changes in the regulations (GCP Ordinance, guidance, etc.), the quality assurance of analyses of samples from clinical trials and storage of records have been reinforced as the related investigator sites (trial facilities), sponsors, etc. are working to respond to these changes.

Then, as the tasks of Common Special Project 2 for this term, we continuously worked on the theme of the previous term, “QA methodology in Contract Research Organizations Including Central/Analytical Laboratories,” and also in view of recent environmental changes, set the specific themes for our activities as listed below, and worked on each theme.
Group 1: Collection and Examination of GCLP-related Problems/Suspicious Case Examples
Group 2: Checkpoints for Auditing the Quality Assurance of Laboratory Data
Group 3: The Facility Records to be Retained at Central/Analytical Laboratories
Group 4: Checkpoints for Auditing of Analysis on Imaging Tests
Through this project, we have been attempting to present specific case examples by using questionnaires, and are working on the above tasks so that our work outcomes can be helpful for individual audit operations.
We hope that our work outcomes can also be contributed to JSQA members’ daily audit operations.