GQP/GVP/GPSP Division, Activity Summary of the 14th Term (April 2018– March 2020)	
Study Group	**Study Group 1: GVP**
Subgroup	**P-1-A**
Theme	**Investigation of GVP self-inspection methods -Effective self-inspection based on each company's situation-**

Based on the current situation surrounding post-marketing safety management, Subgroup A, Study Group 1 of the Post-marketing Division, reviewed notifications, including "Appropriate Implementation of the Duties Held by the Three Officers within Marketing Authorization Holders of Medicinal Products" and "Thorough Compliance in Post-marketing Safety Management Duties of Marketing Authorization Holders (Re-request for thorough dissemination)" and the past deliverables. As a theme in the 14th term, we then selected "Investigation of GVP self-inspection methods—Effective self-inspection based on each company's situation—" to train GVP self-inspectors and upgrade their skills and investigated the methods for GVP self-inspection.

To check the self-inspection method of each group member company, the actual situation of self-inspection was investigated for each item according to the GVP Ministerial Ordinance, examples were presented by each company, and effective methods were selected. The self-inspection methods were then summarized, and questions and problems reported by each company were used as tips to discuss them in detail. The items included in this deliverable were extracted from the investigated items.

For items with different actions among companies and items with unclear materials checked, especially requiring discussion among members, we used experiences in inspections for marketing business license and successful improvements at each company to investigate checking methods from perspectives of both the GVP Ministerial Ordinance and effective GVP Self-inspection.

We also focused on ambiguities included in the GVP Ministerial Ordinance and summarized them in a column.

We hope that our deliverable will help you all improve your GVP duties and self-inspections.

GQP/GVP/GPSP Division, Activity Summary of the 14th Term (April 2018– March 2020)	
Study Group	**Study Group 1: GVP**
Subgroup	**P-1-B**
Theme	**Proposal of the PV QMS in Japan**

To improve the deliverable of the 2014–2015 term, “Points to Keep in Mind and Checklist for Undergoing Global Inspections,” Subgroup B (P-1-B), Study Group 1, in the Post-marketing Division of the Japan Society of Quality Assurance (JSQA) developed the deliverable, “Risk Analysis for Findings to be Identified during PV Inspections and Audits by Foreign Authorities” in the 2016–2017 term. This deliverable summarized matters that are likely to be identified as findings during PV audits and inspections and their features, precautions, and other information for each region, Japan, the United States, or Asian countries, in reference to Europe with the detailed definition of pharmacovigilance (PV) activities. Through these activities, we considered that the Quality Management System (QMS) should be well understood and the organization should be established to respond to globalized audits and fulfill our responsibilities to each stakeholder. As the theme of the 14th term, we thus selected the QMS for PV in Japan to understand the concept of QMS and establish the system on the basis of the Europe GVP Modules and summarized the results of the investigation.

The QMS provides means and methods for quality maintenance and improvement; the PV QMS supports quality improvement in pharmacovigilance activities and has an impact on the safety of patients using drugs. With the globalization of the pharmaceutical market, the pharmacovigilance system is also increasingly globalized. Furthermore, PV inspections by local regulatory authorities and PV audits by affiliated companies are also increasing. In Japan, however, the PV QMS is still under development.

Considering the PV QMS to be an important activity for the entire society, Subgroup B, Study Group 1, in the Post-marketing Division proposed how the PV QMS should be promoted in Japan and the precautions and summarized the results in a deliverable.

This deliverable contains the information for better understanding of the PV QMS and guidance for introducing each PV QMS for the following matters:

- Organization
- SOP
- Record preparation and management
- IT system
- Education
- Collaboration with outside partners
- Monitoring (determination of key performance indicators [KPIs])
- Audit and self-inspection
- Issue Management & Corrective Action and Preventive Action (CAPA)
- Management review

This deliverable will provide helpful hints about how the PV QMS should be developed in Japan. We hope that the deliverable will contribute to further improvement in the reliability of PV activities in each company.

GQP/GVP/GPSP Division, Activity Summary of the 14th Term (April 2018– March 2020)	
Study Group	**Study Group 1: GVP**
Subgroup	**P-1-C**
Theme	**Examination of the self-inspection method for the Safety Management Operational Department, etc.** **- Notification of considerations for the three officers: collection of the safety management information -**

Continuing from the preceding term, Subgroup C of Study Group 1 (hereinafter referred to as "our group") worked under the theme "Examination of the self-inspection method for the Safety Management Implementation Division, etc." (P-1-D in the 13th term). The objectives of our group activity were to establish and propose audit and self-inspection methods for ensuring the accuracy, completeness, and preservability of duties for collecting the safety management information in the Safety Management Operational Department (hereinafter referred to as "the Operational Department") and other departments.

Because of failures to report the safety management information, notifications requiring thorough compliance have been recently issued in succession. With advances in computer/network technologies, such as the Internet, the safety management information sources have become more divergent. Based on such a situation, our group determined to investigate the quality assurance methods for the Operational Department, as well as other departments handling the safety management information.

Our consideration was mainly based on the information notified in paragraph 4 "Matters Concerning Safety Management Duties" of the "Appropriate Implementation of the Duties Held by the Three Officers within Marketing Authorization Holders of Medicinal Products (hereinafter referred to as "the Notification of Considerations for the Three Officers") which was issued as PSEHB Notification No. 0626-3, June 26, 2017.

We conducted a "Factual survey on self-inspections for the Safety Management Operational Department, etc." (hereinafter referred to as "the factual survey") among 86 companies belonging to the Post-marketing Division of the Japan Society of Quality Assurance. Responses were obtained from 47 companies about the information that can contain the safety management information, departments that can obtain the information, and the scope and methods of self-inspections.

[Information that can contain the safety management information]

Many companies have various routes to collect the safety management information, including not only spontaneous or proactive reporting from healthcare providers *via* medical representatives (MRs) or call centers but also surveys of healthcare professionals needs, patient support programs, and inquiries *via* the Internet. The result indicated that we should continue to investigate whether the safety management information to be collected can be contained in the

information collected through these routes.

[Departments that can obtain the safety management information]

In many companies, departments that are highly likely to obtain the safety management information are positioned as the Operational Department, and the safety Management Operational Manager has been assigned. Even though departments that are not positioned as the Operational Department, many companies confirm with those departments whether they handle the safety management information. The kind of safety management information that they could handle was also checked in many companies. The results indicated that the content and volume of the information collected by the non-Operational Departments should be checked on a risk basis, and then the information should be included in the inspection as needed.

Regarding the priority and frequency of inspections, it is important to establish a control system in the Safety Management Department (hereinafter referred to as “the Management Department”). So, we should conduct regular self-inspections. Moreover, we should consider extraordinary inspections for appropriate priority and frequency.

[Scope and methods of inspections]

Regarding the “degree of understanding of officers” which is difficult to evaluate only by reviewing documents stored at the Management Department, confirmation through interviews was considered to be one of the effective methods. Also, if the degree of understanding of officers was doubtful from the results of multiple interviews, it was suggested that it should be doubted that the education and training itself was not be properly performed. The point is that the contents of materials used for the education and training are also important items. So we considered it important not only to delegate the training to the Operational Department but also to be actively involved by the Management Department.

Collection of the safety management information, which was investigated in the present term, may be associated with the risk of missing or delayed reporting in each company, which made it difficult to propose the inspection methods clearly.

Although this deliverable has been prepared in reference to the factual survey results as well as on the basis of the Notification of Considerations for the Three Officers and is just a proposal at the present time, we hope that the deliverable will support the self-inspection for the Operational Department.

GQP/GVP/GPSP Division, Activity Summary of the 14th Term (April 2018– March 2020)	
Study Group	**Study Group 2: GPSP**
Subgroup	**P-2-A**
Theme	**Basic GPSP self-inspection methods** **-Events and precautions for outsourcing GPSP operations-** **-Results of a survey of the actual situation for post-marketing database studies-**

Our subgroup worked under the following two themes: “Events and precautions for outsourcing GPSP operations” and “Questionnaire survey for post-marketing database (DB) studies.”

The PSEHB/PED Notification No. 1128-2 issued by the Director of Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, the Ministry of Health, Labour and Welfare allowed us to conduct a consultation for reexamination regulatory inspection for drugs. Many companies consider it beneficial to receive an inspection before reexamination application, and the entire pharmaceutical industry is positively considering to apply for the consultation. Our subgroup shared the information on matters inspected by the Pharmaceuticals and Medical Devices Agency (PMDA) during inspections, and the results revealed a common understanding that relatively more matters were related to the outsourcing of GPSP operations. The results also revealed that each company has working know-how acquired through many experiences of outsourcing-related troubles, and that the person in charge depends on the know-how.

In the 13th term (2016–2017), our subgroup reported a comprehensive self-inspection checklist as the deliverable to check the compliance of operating procedures specified by each company in accordance with the GPSP Ministerial Ordinance. In the present term, we started to visualize the working know-how unspecified in the operating procedures and other rules and discuss the role of quality assurance based on the visualized know-how, because these activities were considered to be new attempts from a perspective different from previous activities.

We collected the “working know-how” gained from experiences of troubles related to outsourced GPSP operations through a questionnaire in our subgroup and categorized the know-how according to the type of operations leading to troubles. We then summarized the know-how and background as precautions for sponsors and vendors.

The big advantage of the precautions presented in this deliverable is that they are based on the trouble cases experienced by each company.

Our group has continuously examined the self-inspection methods from the viewpoint of quality assurance related to GPSP operations. Since the revised GPSP Ministerial Ordinance came into effect, we then focused on the role and methods of the self-inspection for post-marketing DB studies to be conducted in the future.

At an early date in the present term, we decided to conduct a questionnaire survey on the

implementation status of post-marketing DB studies in each company and the methods for self-inspection of study-related operations. We scheduled the questionnaire survey for the latter half of the present term and developed a questionnaire that consisted of the following three parts: “overall,” “post-marketing DB studies,” and “selection of DB providers.”

The questionnaire was distributed to 83 companies belonging to the Post-marketing Division, and responses were obtained from 43 companies. The results of “overall” were analyzed in 43 companies that answered the questionnaire; the results of “post-marketing DB studies” and “selection of DB providers” were analyzed in 11 companies that answered “ongoing” or “under consideration” to the question on post-marketing DB studies. We collected very useful information that reflected the actual situation of the industry at the time when approximately 1.5 years have passed since the revised GPSP Ministerial Ordinance was issued.

We hope that our deliverable will contribute to further improvement in the quality of post-marketing studies in each company.

GQP/GVP/GPSP Division, Activity Summary of the 14th Term (April 2018– March 2020)	
Study Group	**Study Group 2: GPSP**
Subgroup	**P-2-B**
Theme	**Case study of reexamination application data conformity inspections**

New drugs must be reexamined in compliance with Article 14-4 of the "Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics" (hereinafter referred to as the "Pharmaceuticals and Medical Devices Act"). The reexamination application data must be collected in compliance with part of the "Ministerial Ordinance on the Standards for the Conduct of Post-marketing Surveillance and Studies on Drugs"; "Ministerial Ordinance on the Standards for the Conduct of Post-marketing Surveillance and Studies on Medical Devices" (GPSP Ministerial Ordinance); "Ministerial Ordinance on the Standards for Post-marketing Safety Management of Drugs, Quasi-drugs, Cosmetics, Medical Devices and Regenerative Medicine Products" (GVP Ministerial Ordinance); and "Enforcement Regulations of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics" (hereinafter referred to as the "Enforcement Regulations of the Pharmaceuticals and Medical Devices Act"), and "Ministerial Ordinance on Good Clinical Practice for Drugs" and "Ministerial Ordinance on Good Clinical Practice for Medical Devices" (GCP Ministerial Ordinance). The prepared data must also be attached.

Marketing authorization holders are making an effort to assure the reliability of reexamination application data by establishing the organization for complying with the Enforcement Regulations of the Pharmaceuticals and Medical Devices Act and other ministerial ordinances and by developing the procedures for post-marketing studies and post-marketing safety management operations. Only after the prepared reexamination application data are reviewed in a conformity inspection of the Pharmaceuticals and Medical Devices Agency (PMDA) and the applicant receives a notification of "compliant" data can a review of reexamination application data be conducted. Elucidating specific findings identified by the PMDA during conformity inspections may be useful for objective evaluation of their own works and for more reliable works, as well as smooth progression to the review.

Previously, Subgroup B, Study Group 2, in the Post-marketing Division has conducted questionnaire surveys among companies belonging to the Post-marketing Division, collected findings identified during conformity inspections, and fed back the information. In the present term, Subgroup B conducted questionnaire surveys in September 2018 and May 2019 to collect findings identified during conformity inspections conducted between April 2017 and March 2019. The collected cases were classified into the following 14 categories: 1. GVP, 2. outsourcing

management, 3. self-inspection, 4. education and training, 5. storage of documents, 6. re-investigation, 7. procedures, 8. deviations from procedures, 9. data management (DM) / tabulation analysis, 10. computerized system validation (CSV), 11. writing, 12. Basic plan of post-marketing study / risk management plan (RMP), 13. reporting to marketing authorization holders, and 14. others. Based on the results, the background and trends of findings and points to note were investigated. We hope that the investigation results and the individual finding cases will be used for reference in your daily work.

GQP/GVP/GPSP Division, Activity Summary of the 14th Term (April 2018– March 2020)	
Study Group	**Study Group 3: GQP**
Subgroup	**P-3-A**
Theme	**Case study of observations identified by authorities during inspections for manufacturers -Perception gaps between marketing authorization holders and manufacturers-**

Subgroup P-3-A aimed at determining "What are the points to be considered for appropriate management of manufacturing sites?" because most of members were interested in the management and oversight of manufacturing sites and raw material manufacturers. While discussing about GMP-related observations identified by regulatory authorities, it was revealed that the group members had somewhat different ways of thinking about the observations between marketing authorization holders and manufacturers. Then, it was decided not to integrate their opinions forcibly but to discuss it while comparing opinions from both sides and derive an opinion of the group for each case.

At first, 87 cases of observations identified by the Japanese regulatory authorities were collected and were reviewed, mainly focusing on frequent observations. For the reviewed observations, it was considered the reason why the level expected by marketing authorization holders was different from that provided by manufacturers and examined the measures to eliminate the gap.
Among the reviewed observations, the following four topics associated with more gaps were included in the deliverable: (1) validation, (2) supplier management, (3) document retention and control, and (4) manufacturing record control. It also contained problems and opinions which each member has in actual business cases and proposed the points to be checked in audits for manufacturing sites by marketing authorization holders and the points to note in quality management of manufacturing sites by manufacturers, which were summarized for each case.
The members hope that the deliverable will serve as a trigger to promote an interest in the actual conditions and issues of control and supervision of manufacturing sites among persons involved in audits for manufacturing sites as well as all persons related to drug quality assurance work.

GQP/GVP/GPSP Division, Activity Summary of the 14th Term (April 2018– March 2020)	
Study Group	**Study Group 3: GQP**
Subgroup	**P-3-B**
Theme	**A Study on GDP Audits and Supply Chain Management**

This fiscal period started with complicated thoughts about determining when to issue the Japanese GDP Guidelines and the need to start implementing GDP, and Subgroup B in Study Group 3 of the GQP/GVP/GPSP Division groped about as it began a study. Nevertheless, the basic requirements do not differ significantly from those of the PIC/S GDP, so we discussed questions and answers regarding GDP implementation as a prelude to the application of the Japanese GDP Guidelines. Within that context, the "Guideline to Good Distribution Practice (GDP) for Medicinal Products" (hereinafter referred to as the "GDP Guidelines") were issued in December 2018. However, the impression is that many companies are still watching the surroundings, since the GDP Guidelines are not legally binding like GQP ministerial ordinances or GMP ministerial ordinances and since efforts to implement GDPs will take time and effort. Therefore, we thought that surveying member companies and gathering their statuses will be helpful to provide a reference for companies working to implement GDPs.

Survey results indicated that some companies have already started operations in accordance with the GDP Guidelines, but many companies have yet to start operations.

Even though the GDP Guidelines have been issued, most companies that have not started operations are aware of the requirements of the GDP Guidelines but they are unsure of where to start or which approach to use internally and externally.

In addition, this deliverable consists of investigation results against GDP requirements and GDP system examples provided by Oosumi Logistics co., ltd. and JSQA members in order to share them.

The purposes of GDP implementation are "Maintaining product quality" and "Ensuring patient safety." Therefore, procedures for security and communication are required. We recommend making the gap assessment sheets between GDP requirements and current conditions and mapping of the status of GDP implementation. Prioritizing requirements that have yet to be implemented and that are time-consuming or costly is the key to facilitating GDP implementation. That said, one approach to GDP implementation is to start with requirements that have already been implemented or that can be implemented immediately.

The important point is to evaluate and identify the gaps between GDP requirements and current condition in the company in light of product quality and patient safety.

"SOP is the basement of GDP implementation" is our key message. Again, we recommend starting GDP implementation from what you can do, such as reviewing current tasks and procedures related to GDP requirements, because one company took a year and a half to implement GDPs.

We hope that this deliverable helps companies that are implementing GDPs and companies that have yet to do so.

GQP/GVP/GPSP Division, Activity Summary of the 14th Term (April 2018– March 2020)	
Study Group	**Study Group 3: GQP**
Subgroup	**P-3-C**
Theme	**Case study of recalls in GQP/GMP/QMS**

In the 11th term, Subgroup C of Study Group 3 categorized the reasons for recall cases of Class II or III that had been presented on the website of the Pharmaceuticals and Medical Devices Agency (PMDA) between April 2010 and September 2012 (investigated in the preceding term) and determined possible causes of the recalls to investigate measures to prevent recurrences. Since 2012, relevant laws and regulations were greatly changed, including the issuance of the notification of the revised GMP review guidance, participation of Japan in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S), and enforcement of Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. Based on the problem that a manufacturer received an administrative punishment because they had intentionally used a way different from that designated in the marketing approval document to manufacture a product for many years, the Ministry of Health, Labour and Welfare ordered simultaneous inspections of actual manufacturing conditions. Therefore in the 14th term, we classified the reason for recall cases (Classes I, II, and III) of drugs (excluding *in vitro* diagnostics) that had been presented on the PMDA's website between April 2017 and June 2018 into the following categories in a manner similar to that in the previous term: "foreign matters," "contamination," "labeling," "drug product," "manufacturing process," "raw materials," "deviation from the marketing approval document," "GMP violation," and "others." Trends in the reasons for recalls were analyzed by comparing with the previous results. We also discussed the following causes of recalls that were more frequent among those reported between April 2017 and June 2018 or increased as compared with the previous results, "drug product," "raw materials," "deviation from the marketing approval document," and "labeling," and investigated the measures to prevent the recurrence of these recalls. A fishbone diagram was created to examine the causes of recalls and, based on the results, determined the measures to prevent the recurrence of recalls. The main causes of recalls and the recurrence prevention measures are summarized below.

Regarding the cause of "drug product" (responsible for 40% of all recall cases), many products were recalled because out-of-specification was identified (or supposed) at any phase during stability monitoring. Given that any changes over time due to various factors may cause nonconforming products in some lots during market distribution, the need for stability monitoring was reconfirmed. To prevent the recurrence of product-related recalls, it is desirable to fully understand stability-related properties of drug products during the development phase, to regularly review the information accumulated from experiences, and to make efforts to improve the quality of drug products whenever possible.

Regarding the cause of "raw materials," a recall case of Class I occurred because a drug

substance was contaminated by a suspected carcinogen. Recalls related to drug substances among raw materials produce higher risk of health injury and poor product quality than those related to other causes. A problem with one drug substance triggers recalls in multiple marketing authorization holders using the drug substance. To prevent the recurrence of recalls caused by raw materials, it is recommended that the information on changes and quality of raw materials be controlled and audits be conducted for suppliers.

Regarding the cause of "deviation from the marketing approval document," a case of administrative punishment occurred because a product was manufactured in a way different from the designated way, and production and laboratory control records were falsified. The recommended measures to prevent the recurrence of deviation-related recalls included GMP audits (on-site), written requests for checking the actual manufacturing conditions, assessment using annual product review (APR) (for all changes made in processes and test methods), and requests for checking at the time of agreement revision.

The causes related to "labeling" were writing errors and omissions. To prevent the recurrence of labeling-related recalls, the accuracy of confirmation should be increased by double- or triple-checking. Establishing a system for detecting errors and making efforts not to use humans may also be effective.

We also extracted cases related to Part 211 (CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS) of 21 CFR in the FDA Warning Letters issued between January and July 2019 to analyze the trends in cases. The results revealed that the most frequent finding was related to Responsibilities of quality control units, followed by Equipment cleaning and maintenance, Written procedures; deviations, Testing and release for distribution and Testing and approval or rejection of components, drug product containers, and closures.

We hope that the causal analyses using the fishbone diagram and the recurrence prevention measures presented here will be used for reference to avoid recalls and issuance of the Warning Letters.

GQP/GVP/GPSP Division, Activity Summary of the 14th Term (April 2018– March 2020)	
Study Group	**Special Project Group 1**
Subgroup	**P-T-1**
Theme	**Case study of prefectural inspections related to marketing business license (GQP・QMS/GVP)**

The prefectural GQP/GVP inspections related to marketing business license started in 2005. The Japan Society of Quality Assurance established the Special Project Group 1 (hereinafter referred to as "the Project") in the Post-marketing Division in fiscal year 2006 to collect inspection cases from member companies through questionnaire surveys and to provide information for maintenance and improvement of GQP/GVP compliance systems. The Project conducted eight questionnaire surveys during the period from fiscal year 2006 to 2017 and summarized the results in seven Post-marketing Division Reports (No. 07X09, No. 09X01, No. 09X02, No. 10X01, No. 13X04, No. 15X11, and No. 17X10). There have recently been several cases where the "Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics" was violated, including cases where differences were identified between the marketing approval form and the actual manufacturing conditions and cases where adverse drug reactions supposed to be reported were not reported within the specified time limit, although they had been noticed. Under these situations, the notification of "Appropriate Implementation of the Duties Held by the Three Officers within Marketing Authorization Holders of Medicinal Products" (hereinafter referred to as the "Notification for Three Officers") was issued in 2017. In the 9th questionnaire survey in the present term, we also collected cases where the compliance of the Notification for Three Officers had been checked.

The 9th questionnaire survey included inspections conducted between January 2017 and December 2018 and started on February 1, 2019. The questionnaire was distributed to 82 representative member companies of the division, and responses were obtained from 34 companies, and 19 inspection cases were collected from 17 companies (nine cases from Tokyo, seven cases from Osaka, and three cases from other prefectures). Regarding the cases where the compliance of the Notification for Three Officers had been checked, which were newly collected in the present term, responses were obtained from 16 companies, and 10 cases were collected (four cases from Tokyo and six cases from Osaka) after excluding cases where the compliance had not been checked and other cases.

Among the responses, 65 responses (27 related to GQP, 6 related to QMS, and 32 related to GVP) were selected to be findings that should be presented for the members, and 169 responses (98 related to GQP, 6 related to QMS, and 65 related to GVP) were selected to be the review status that should be presented for the members.

The most common answer on GQP-related findings was the agreement with manufacturers (related to GQP Article 7), which was mostly related to unconcluded agreements. The most

common answer on the review status was the assurance of proper manufacturing and quality control (related to GQP Article 10). All answers on QMS-related findings were related to inadequate procedures and records.

The most common answer on GVP-related findings was the collection of safety control information (related to GVP Article 7), which was mostly related to timelines and information sources. The most common answer on the review status was self-inspection (related to GVP Article 11).

In addition to the cases included in the answers to the questionnaire, the Project proposed 68 comments about points to be checked during self-inspection, points to be considered during working, and points to be prepared for smooth inspection, added the section of “editor’s comments” as needed. We hope that these comments will support further improvement and enhancement of the GQP/QMS and GVP compliance system.

GQP/GVP/GPSP Division, Activity Summary of the 14th Term (April 2018– March 2020)	
Study Group	**Special Project Group 2**
Subgroup	**P-T-2**
Theme	**Discussions on Education and Training for Self-inspectors (GVP/ GPSP/ GQP)**

Special Project Group 2 sets up "Discussions on Education and Training for Self-inspectors" as its group theme in the 14th term. The group planned and conducted educational training courses for both JSQA members and non-members, evaluated results of each course after its conduction, and took actions to improve future educational training courses.

This theme has been continued since the 12th term, and 4 members of the 13th term continued to participate in the 14th term group. Considering importance of the group activity, meaning that the group is responsible for providing educational training courses for JSQA members, the chief of the JSQA Post-marketing division participated in all activities of the group.

In the 13th term, we organized a system for efficient planning and delivery despite limited human resources; therefore, creation of this system allowed us to plan and deliver educational training courses in the 14th term in the face of limited human resources.

The first thing that we worked on as the group was to change the drafting of training plans. We drafted an annual training plan for each term in the past, but this time we first drafted a training plan for the 2 years of this term. Based on the 2-year plan, we conducted the following 4 educational training courses. We also planned and conducted training courses with an emphasis on members' wishes in order to sustain the motivation of members. While we were drafting the 2-year plan, each member proposed course contents that we then we discussed, and we decided what courses to conduct based on those proposals. As a result, we planned and conducted 3 new Advanced courses. We conducted the GVP/GPSP Basic course once in the 14th term because we had set up a system to facilitate the regular conduct of courses in the 13th term.

We became aware of some topics for the future in the 13th term. One was insufficient resources in terms of instructors, meaning that there would be performance and operational limits if courses were conducted only by instructors from group members. We invited instructors from the PMDA, non-JSQA member companies, and experts from other groups in Post-marketing division to conduct the 4 courses in the 14th term. Thanks to their support and cooperation, we were able to conduct efficient educational training.

[Advanced course]:

1. Quality Management System -Introduction and Practice-, conducted on October 12, 2018, 69 people participated in the course
2. Response to the MHLW notification regarding the "Triumvirate" -Focusing on branch inspections presupposing intentional malfeasance, conducted on February 4, 2019, 84 people participated in the course
3. Quality Assurance of Post-marketing Database surveys, conducted on November 25, 2019, 81

people participated in the course

[Basic course]:
4. GVP/GPSP Self-inspection Techniques (General introduction), conducted on September 30, 2019, 80 people participated in the course

By conducting the 4 courses above, we were able to provide educational opportunities for about 300 people through JSQA in the 14th term. Surveys of participants in these courses and the lecture indicated that each course was rated highly in terms of participant understanding, course content, and participant satisfaction. Every time we conducted a course, we repeated a review-cycle, meaning that we have discussed lessons learned, identified issues, reviewed our actions, and made improvements. Through the cycle, we efficiently conducted courses with limited human resources and we were able to draw on and pass on our know-how.

We identified the following topics for the future when consistently and routinely conducting educational training courses and developing new courses in the future,:

- Insufficient human resources in the training group (currently Special Project Group 2). Incentives need to be provided for group members as well as their companies, and conditions need to be created to keep motivation high to work for JSQA's educational training by focusing on the planning of educational training courses rather than on course delivery.
- Insufficient human resources in terms of instructors. The content of educational training courses should be enhanced through use of external instructors and to assistance from other groups in the Post-marketing division/other JSQA divisions.
- Conduct courses more efficiently using limited human resources. For know-how knowledge transfer about course conduction between terms, we will archive and transfer our materials to the next project member.

This theme will continue to be discussed in the next term. We hope that more members will be involved in planning and conducting JSQA's educational training and that educational training will be brushed up.