

## Regarding the Completion of the 6th GQAC

Yoshinobu Hirayama, Ph.D.  
President of the JSQA

The 6th Global Quality Assurance Conference (GQAC) was held at Sendai City in Miyagi Prefecture on February 17–20 and was closed with great success. The novel coronavirus pneumonia that emerged in China at the end of last year was gradually spreading to Japan at this period, when people infected with the coronavirus were also found among travelers from China and people who had contacts with Chinese in Japan. Some of the expected participants in the conference either inquired whether or not the conference would still be held or canceled their participation. The Japan Society of Quality Assurance (JSQA) considered that the conference can be convened by taking infection control measures, such as wearing a mask and handwashing, referred by the WHO and the Japanese government's strategic policies and held the conference as scheduled. With the benefit of hindsight, I am glad that the conference was successfully held with the participation of the majority of the expected participants and without catching the virus during the conference. The subsequent increase in the number of cases with community-acquired infection, whose origin could not be presumed, resulted in the cancellation of various events and academic conferences. Thus, I think that if the conference had been planned to be held several days later than the actual date, we would not have held the conference.

The main theme of the conference was “Embark on the New Tide,” and thus, we asked Prof. Yasushi Okuno at the Graduate School of Medicine, Kyoto University, to give a keynote lecture about the introduction of artificial intelligence (AI), which is one of the new tides, into the medical field. In the lecture, he introduced the example that AI created a new self-portrait of Rembrandt by learning many of Rembrandt's paintings. He explained that even if AI learns the equally famous Picasso paintings, AI cannot draw the self-portrait of Rembrandt; that is to say, the correct answer can be obtained only when the appropriate targets are selected for learning. This point shows the importance of the role of quality assurance (QA), and we should take note of this point as QA personnel. He also explained about AI's Blackbox Problem, which means that only the answers are provided without showing the learning process by AI and are compelled to be accepted without understanding the process. He told that, in order to solve this problem, a software that graphically demonstrates what factors and how much these factors contribute to getting to the answers has been developed so that the factors and the degree of contribution of such factors can be presented for the individual answers. His lecture got us to realize that the utilization of AI in the medical fields has been spreading in Japan as well. After the conference, I read a trade paper and knew that the Life Intelligence Consortium (LINC) regarding AI and big data, that was organized mainly by Prof. Okuno, had won the Minister of Health, Labour and Welfare Award at the 2nd Japan Open Innovation Prize by the Cabinet Office. I believe that the lecture was performed by the right person in a timely manner.

Speaking of Sendai, the Great East Japan Earthquake is an inevitable theme. At the start of the opening ceremony, the song “Hana wa Saku (Flowers Will Bloom),” as a symbol of post-disaster reconstruction, was sung by all the participants with the accompaniment of violins played by the persons concerned. I listened attentively to another keynote lecture by Prof. Tadashi Ishii at Tohoku University School of Medicine, who was active in the front lines of the medical field when the earthquake occurred. (He worked as a Miyagi Prefecture disaster medical coordinator at the Ishinomaki Red Cross Hospital during disaster recovery.) The theme of the business continuity plan (BCP) at the time of emergency response was also picked up in one of the sessions. What was interesting to me in his lecture was that the awareness of the persons concerned for disaster prevention had been raised before the onset of disaster by repeating highly practical rehearsals, and all of the persons concerned started taking the appropriate measures at the onset of disaster with the feeling of “At last, the time has come.” instead of “Why the time is now?”. According to his explanation, fortunately, the hospital building had been rebuilt to that of a seismically isolated structure, and land elevation work had been conducted before the onset of disaster so that damages from earthquake and tsunami could be avoided, and thus, the hospital necessarily played a central role in the medical relief measures in the Ishinomaki Medical Zone while the administrative functions were paralyzed. Subsequently, various unexpected difficulties occurred, and the improved measures were accordingly

taken for the difficulties, resulting in the overcoming of the disaster. Currently, this experience has been incorporated into a disaster rehearsal for emergency response. After his lecture, I asked him why the quick measures were possible, and he answered that this is because the Ishinomaki Red Cross Hospital has many staff who are interested in emergency response to disasters. This represents that the response to large-scale disasters was possible precisely because all of the people, goods, and daily training were in place. We should keep this in mind as QA personnel.

In consultation with the OECD, the GLP Working Group Meeting was held together with this conference for the first time in Japan. The regulatory personnel in each country/region who attended the conference participated in the banquet and served as a leader or symposiasts in the conference. I have heard that many orders on the methods of organizing the conference were placed in prior consultation with the OECD, but these orders were handled without any problem because of the Management Office's efforts, which was appreciated by the OECD personnel.

Finally, I would like to thank all members of the steering committee and the executive board who planned and implemented the organization and management of the conference; all members who organized various sessions; all members of overseas QA organizations such as the Society of Quality Assurance (SQA) and the Research Quality Association (RQA) who provided various supports; personnel of the Ministry of Health, Labour and Welfare and the Pharmaceuticals and Medical Devices Agency (PMDA) who supported the dispatch of symposiasts and the contact with the overseas regulatory authorities by providing valuable advices; and, above all, all members of the Management Office who supported the overall management of this conference.

The flag of GQAC was passed on from the JSQA to the SQA. The next GQAC will be held in the suburbs of Washington, D.C., in March 2023. I am looking forward to seeing what new science technology will be incorporated into the world of QA by then.

Ms. Beth Moulaison  
President of the SQA

The 6th Global QA Conference (GQAC) in Sendai, Japan, seems so long ago. Our world has changed tremendously since my visit to Sendai in February as we all cope with the COVID-19 pandemic. I feel tremendously fortunate to have represented SQA at the GQAC. JSQA's program included many relevant presentations with a focus on emerging technology such as Artificial Intelligence and Disaster Recovery. Excellent keynote speakers kicked off this two-and-a-half-day event. In attendance was a diverse set of regulators from around the world providing their opinions on questions submitted by JSQA, SQA and RQA. SQA members provided presentations on various topics. Barb Munch, Melissa Eitzen, and Joseph Whittemore presented on History of the GLPs, Integrating Regulatory Science in an Academic World, and Use of Machine Learning in Support of Electronics Records Management, respectively.

JSQA not only provided meeting attendees with an opportunity to connect, learn, and collaborate, but also planned every detail to gracefully highlight their country and their culture. Each day included special bento boxes for lunch, an opportunity to make your own chopsticks, and local artisans who had special keepsakes available for purchase.

A special event, highlighted by a performance from dancers showcasing traditional Japanese fans, also included performances by several Samurais depicting the famous Masamune Date . It was certainly a tremendous evening enjoyed by all who attended.

I wasn't able to attend the tour of Matsushima area but by all accounts, it was spectacular. JSQA also hosted the SQA staff for a fun night of sushi. They were welcoming and gracious hosts.

At the conclusion of the meeting, Dr. Yoshinobu Hirayama ceremoniously passed the flag to SQA, who will host the 7th Global QA Conference (GQAC) in National Harbor, Maryland, USA, in 2023. We hope to see all of you there and will communicate more about our meeting program when it becomes available.



Mr. Matt Jones  
Chairman's Representative of the RQA

To all our friends in JSQA, and our One Team of Global Quality Professionals. It was an absolute pleasure to represent RQA at the Global Conference in Sendai this year, and it seems a world away from where we are now in the second wave of COVID in the UK. The conference itself was beautifully organised and presented in the city of Sendai, where it was wonderful to see how the area had prospered following the Tsunami, and that normal life had returned, which is reassuring in these strange times.

The conference itself was an excellent forum for exchanging ideas and meeting colleagues from all over the world. It's diverse lectures and workshops gave a truly international flavour and the evening exertainment and social gatherings allowed for time to discuss the hot topics with colleagues and meet new friends and contacts. The city was a beautiful backdrop and gave all the participants a taste of life in Sendai while riding the underground trains and meeting at the conference centre every day.

The mix of topics discussed during the conference were enlightening, showcasing a depth of understanding from the presenters and the audience participation, which always determines the success of a talk, was excellent with many insightful questions and comments. The posters that were displayed and submitted were of a high quality and many of the participants in the conference spent the breaktimes reviewing the content and talking to the authors, with a prize giving at the conclusion.

One of the most enjoyable evenings was the traditional dancing, where we were treated to a flamboyant show by the talented dancers, who even brought some of the conference delegates to join them on the stage.

It so important in these times to ensure that we move forwards together and that all quality communities globally remain in close contact, sharing ideas and innovations to move forward in the world that is forming around us. We should show solidarity to each other and ensure that quality wins through in the race to beat the current pandemic.

Take care, and best wishes from myself on behalf of the RQA Board of Directors, and we look forward to welcoming colleagues to the RQA Virtual Conference this year!



## After the 6th GQAC

Masako CHINO  
Former Vice-President of the JSQA

I was appointed Chairperson of GLP Division in July 2019, and I participated for a short time as a Steering Committee member. I am grateful to everyone for being able to successfully finish the 6th GQAC as Chairperson of GLP Division. Especially in GLP Division, all groups planned sessions and were able to present many posters. In addition, one group received the poster award, and I was very proud to be Chairperson. This shows the deep interest and enthusiasm of the members of GLP Division for this conference.

I participated in the 3rd GQAC in 2011 in Kyoto and organized a session from GLP Division. At that time I asked speakers from Japan and other countries to give a lecture. I explained the contents of the session and considered what to talk about. This made me realize the difficulty of planning. However, at the same time I enjoyed the fun of the planning. At the 6th GQAC, I worked hard to hold a better session by taking advantage of the lessons learned from the 3rd GQAC. I can't say that I was 100% satisfied, but I was able to feel a sense of accomplishment.

At the Olympic Games it is said the participating is more important than winning. I want you to apply this way of thinking to our conference. Get the most out of it by participating in the planning rather than just listening.

Lastly, it was a great honor to be Chairperson of GLP Division for giving the opening speech of the reception, and I would like to thank everyone concerned again.

Toshinori Ueda  
Vice-President of the JSQA

For me, the 6th GQAC started with being dispatched on behalf of former President Kishida to the 5th GQAC held in Edinburgh, UK in 2017, sponsored by RQA. After that, I was dispatched on behalf of the president to the 2018 RQA Annual Meeting in Manchester, the 2019 SQA Annual Meeting in Atlanta and the 3rd EQAC in Dublin. At those conferences, I strengthened my connections with the representatives and secretariats of QA organizations in each country, and I wanted as many people as possible to come to 6th GQAC. At the 3rd EQAC, all the dispatchers performed a skit to publicize the 6th GQAC. Immediately before the event, the global epidemic of the new coronavirus began, and I was worried about the event, but it was decided to be held at the discretion of Chairman Hirayama. I think it was a close call. Unfortunately, Chinese people could hardly attend, but none the less I think it was a marvelous conference with more than 500 participants from all over the world. I believe that the efforts of everyone involved, including the Steering Committee and the JSQA Secretariat, have led to its success.

There are many people who I have to thank. In particular, Dr. Chrissy Cochran of the FDA actively cooperated with us, such as introducing the performers from the USA and acting as speaker on many sessions. In addition, both GQAC and also JSQA are really indebted to Dr. Andrew Waddell of the UK. In Japan, we received strong cooperation and advice from the Ministry of Health, Labor and Welfare and PMDA. Study Group 1-B and the Joint Special Project 1 requested by GQP / GVP / GPSP Division had a marvelous session. There are many more things I'd like to write, but please allow me to end by saying. We are deeply grateful to everyone who cooperated.

Yoshiaki Yano  
Vice-President of the JSQA

The theme was 'Embark on the New Tide.' I thought 'Embark or being Swallowed, that is the question.' as new tide is natural phenomenon. I had an anxiety about the situation of quality assurance due to emerging new wearable devices, new clinical study method such as virtual studies, basket studies, etc. and new thoughts about economy. In addition, we need to watch out for troublesome spread of Covid-19 infection.

However, clouds and fog of my mind had disappeared at the 6th GQAC thanks to much communication with people of regulatory agencies, representatives, and members of many quality assurance societies at meetings and realized all the people embarked on new tide and had already prepared for new era. GCP division had some sessions which showed questions about diversities in obtaining informed consent, the inspection method by regulatory agencies, and even requirements in every country. As a result, we could understand that the basic concepts were the same and communication was important to discuss for mutual understanding even though we had got acquaintance each other.

We would appreciate it if all the people could continuously get in touch with and exchange opinions regardless of conference period, so that we can get knowledge and foster a friendship.

We are grateful to you all for your contribution to the 6th GQAC and friendship such as knowledge sharing and talking. I am looking forward to seeing you again. Thank you very much indeed.