

## **Regarding the Completion of the 6th GQAC**

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.

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Chairman of JSQA 6th GQAC Steering Committee

President of the Japan Society of Quality Assurance

## 第 6 回 GQAC を終えて

6thGQAC ステアリング・コミッティ 議長

一般社団法人日本 QA 研究会

会長 平山佳伸

仙台にて第 6 回 GQAC を 2 月 17 日～20 日の日程で開催し、成功裏に終了しました。昨年末に中国で新型コロナウイルス肺炎が発生し、徐々にその流行域が拡大し、日本でも中国からの旅行者や中国人との接触者の中に感染者が見られるようになってきた時期であり、参加予定者の中からも開催するのかどうかの問い合わせがあったり、参加を控える方も出てきていました。JSQA では、WHO や日本国政府の対応方針を参考に、マスクや手洗いの実施による感染予防体制をとることにより、開催可能と判断し、実施しました。結果論ではありますが、大多数の方に参加して頂き、感染者も出すことなく終了し、開催してよかったと考えています。その後は感染源が推測できない市中感染の事例が増加し、各種のイベントや学会が開催中止に至っており、時期的にはギリギリであったかと考えています。

本会のテーマは、「Embark on the New Tide」で、新しい潮流のひとつ、AI（人工頭脳）の医薬分野への導入について京都大学大学院医学研究科の奥野恭史教授に基調講演をお願いしました。講演の中で、奥野教授は、新たなレンブラントの自画像をレンブラントの過去の絵画を多数学習した AI が創作した事例を紹介され、同じ名画であるからといってピカソの絵を学習しても、レンブラントの自画像は描けないこと、すなわち、学習対象が適正でなければ正しい答えは得られないことを話されました。この点は、我々 QA 担当者が自覚しておくべき観点で、QA の役割が重要であることを示しています。また、AI のブラックボックス化問題、すなわち、AI がどのような学習をしたのかわからない状態で答えだけが示され、それを訳もわからず受け入れざるを得ない問題に対応するため、答えに到達する際にどのような因子がどの程度貢献したかを図示するソフトを開発し、個々の答えごとにそれを示すことができるようになっていたことを示されました。AI の医薬分野などへの活用が日本でも浸透してきていることが実感できた講演でした。後日、業界紙で、教授が中心になって組織した AI とビッグデータに関するコンソシアムである LINC（Life Intelligence Consortium）が内閣府の第 2 回オープンイノベーション大賞の厚生労働大臣賞を受賞していたことを知って、時宜と人を得た講演であったと考えています。

仙台といえば、東日本大震災は避けては通れないテーマであり、オープニングセレモニーの冒頭で、震災復興の象徴である「花は咲く」を関係者のバイオリン演奏により全員が合唱し、もうひとつの基調講演として、震災時に医療分野の第一線で活躍された東北大学医学部の石井正教授（震災当時は、石巻日赤病院で県災害医療コーディネーター）の講演を拝聴しました。また、セッションの 1 つに危機対応時の BCP（事業継続計画）も取り上げました。石井教授の話で興味深

かったのは、災害前からかなり実践的な予行演習を繰り返して関係者の意識を喚起している中で、震災が発生し、「何故、今？」という意識ではなく、「来たか」という意識で全員が対応を開始したということでした。幸いにも病院の建物は免震構造に立て替えてあり、盛り土もされて地震と津波の被害を免れたことで、行政機能が麻痺する中で必然的に石巻医療圏の医療救護対応に中心的役割を果たすようになったとのことでした。その後には予期しない様々な困難が発生し、その都度改善を加えて対応することで震災を乗り切ったとのこと、現在はその経験を含めて危機対応の予行演習に組み込んでいるとのことでした。講演終了後、石井教授に対応の迅速さが何故なのか聞いたところ、日赤には災害等の危機対応に関心のある人材が集まっているとの答えがありました。ヒト、モノ、日頃の訓練が揃っていたからこそ大規模な災害に対応が可能だったわけで、我々QAにとっても肝に銘ずべき話でありました。

本会ではOECDと協議し、GLPワーキンググループの会合を併設することになり、ワーキンググループとしても初めての日本開催となりました。出席した各国・地域の規制担当者がバンケットに参加されたり、本会の座長やシンポジストなどとして活躍されたりしました。OECDとの事前協議では運営方法について多くの注文が出されましたが、事務局の頑張りで、問題なく終了し、担当者からは感謝されたとのことでした。

最後に、会の編成や運営を企画し、実行されたステアリング・コミッティや理事会のメンバー、いろいろなセッションを組織された会員の皆様、いろいろな支援を頂いたSQA、RQAなど海外のQA団体の皆様、シンポジストの派遣のみならず貴重なアドバイスと海外規制当局とのコンタクトを支援して頂いた厚生労働省やPMDAの方々、そして何よりも本会の運営全般を支えてくれた事務局の皆様に感謝いたします。

GQACの旗はJSQAからSQAに手渡されました。3年後の3月にワシントンDCの近郊で開催される予定です。その頃にはどのような新しい科学技術がQAの世界に入ってきているのか楽しみです。

## Participants

489 participants from 25 countries

|                |     |                       |   |
|----------------|-----|-----------------------|---|
| Japan          | 386 |                       |   |
| United Kingdom | 21  | Russian Federation    | 2 |
| United States  | 13  | Australia             | 2 |
| Germany        | 9   | Bulgaria              | 1 |
| Taiwan         | 9   | Colombia              | 1 |
| Malaysia       | 7   | Italy                 | 1 |
| Hungary        | 6   | Netherlands           | 1 |
| India          | 6   | Poland                | 1 |
| France         | 5   | Saint Kitts and Nevis | 1 |
| Switzerland    | 4   | Singapore             | 1 |
| Korea          | 3   | Slovakia              | 1 |
| Belgium        | 3   | Spain                 | 1 |
| China          | 3   | Sweden                | 1 |





















