

# First Japanese hospital lab earns CAP accreditation

## Steve Ziolkowski

December 2022—Atsushi Ohtsu, MD, PhD, director of Japan's prestigious National Cancer Center Hospital East, reached a groundbreaking decision with his management team in February 2020: They decided to pursue CAP accreditation. While the CAP has accredited more than 40 laboratories in Japan, this was to be a first for a Japanese hospital. And it was: In September 2022, the CAP advised the cancer center (NCCE) of its success in achieving accreditation and congratulated the team for the excellence of its laboratory services.



Dr. Ohtsu

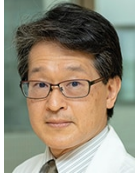
"By maintaining CAP accreditation in the future," Dr. Ohtsu said, "the National Cancer Center Hospital East will provide the highest level of quality patient outcomes. And as a more internationally oriented hospital, we will work to further improve treatment and promote clinical research and development based on our patient-first policy."

After deciding in 2020 to seek accreditation, Dr. Ohtsu's next step was to contact two experts connected to the CAP: former (and now the late) CAP president Gene Herbek, MD, and Mark Colby, president of CGI, the company that has provided CAP support in Japan for more than 30 years. Two days of meetings were arranged, highlighted by education sessions led by Dr. Herbek with a focus on the needs of NCCE laboratory director Genichiro Ishii, MD, PhD, and his department heads.

From the start, Dr. Ohtsu had a series of questions related to NCCE's goals and objectives. He said he wanted his laboratory and pathology services to be on par with those of the best hospitals in the world and asked how CAP accreditation would help achieve this. He also wanted to know how CAP accreditation would help drive best-in-class patient outcomes. Dr. Ohtsu noted that NCCE already had achieved ISO 15189 certification and wondered why international partners favored the CAP as the global standard. He asked, too, about the accreditation process itself and what support was available to help achieve accreditation.

Dr. Herbek addressed Dr. Ohtsu's questions. "First, Dr. Herbek outlined the detailed technical CAP checklists and annual checklist updates as well as the collaborative peer-to-peer nature of the inspection process," Colby recalls. Dr. Herbek also highlighted how each inspector needed certification in the technical specialty they are tasked with inspecting. "Besides these technical aspects, Dr. Herbek also discussed the importance of quality and meaningful communication among the lab and clinical staff, something absolutely essential, often challenging, and emboldened by the CAP requirements," Colby says. Other topics included the need for labs to take responsibility for the quality of point-of-care testing and blood gas procedures even if performed by the nursing staff, the vital nature of proficiency testing for all analytes, and the challenges associated with next-generation sequencing and laboratory-developed testing processes.

Cultural differences exist even in scientific labs, and many of the concepts Dr. Herbek introduced are novel to Japanese laboratories and their staff, which Dr. Herbek understood, Colby says. When answering Dr. Ohtsu's question about why international partners prefer CAP standards over ISO, for example, Dr. Herbek surmised that CAP standards are interpreted the same way worldwide while ISO's standards tend to be perceived differently from country to country, leading to a greater number of variables among institutions—a problem for researchers and government regulators alike.



Dr. Ishii

Dr. Ohtsu and Dr. Ishii were concerned about the more than 2,000 requirements that had to be met for CAP accreditation. One of the NCCE senior staff asked where to even start. Colby explained that CGI has decades of expertise in helping labs that seek CAP and even ISO accreditation. "In the past we used old-fashioned consulting practices, spreadsheets, and now-antiquated project management systems as well as education sessions and such," Colby told them. "This process was mainly manual, not to mention extremely complex, time-consuming, and expensive, and it required tremendous management bandwidth from the labs as well as from our consultants and coaches." However, after a nearly two-decade development period, Colby explained, "most of those old, unwieldy management and education processes had been automated into an online software product called LEAP."

LEAP (Laboratory Education and Accreditation Program) is comprehensive, he said. It involves the entire laboratory staff, and it sets up and manages all projects, educates the staff, and is loaded with a full range of materials ready for customization to meet any hospital's or lab's needs. LEAP is also ongoing so it continually monitors the lab's progress in maintaining its accreditation processes. "LEAP has been designed for any and all labs building systems from scratch, including NCCE's," Colby explained.

Despite the advent of aids like LEAP, NCCE's two-year journey to CAP accreditation was not without struggle. Weeks after starting the process, COVID-19 hit. "While virtual meetings seem commonplace now, at the time everything was all new," Dr. Ishii said. "But we learned fast. We had to."

Projects were established using the Japanese language version of LEAP software, and CGI coaches initiated virtual meetings several times weekly. (They're called coaches because their primary function is to drive the process while technical support is mainly incorporated into LEAP.) As time passed, CGI's technical consultants were finally able to make hospital visits, but even then the process was driven by the software and supported by asking questions and requesting document and process reviews online. After all the projects were assigned, the building of the necessary processes was accomplished with production-line-like efficiency. Nearly two years in, NCCE was ready.

CGI initially did mock inspections virtually, until consultants and coaches were able to visit the hospital. "Laboratory staff seemed surprised when inspectors asked questions of bench technologists regarding their role in maintaining CAP standards," Colby says. "But, to their credit, the NCCE staff soon appreciated that CAP processes aren't merely about documents or the sole concerns of the QA department. CAP accreditation is more about implementing the processes articulated in the documented procedures and about real people having real communication and a meaningful understanding resulting in real actions." Ultimately, it is about reshaping these actions into daily routines, he says, "essentially transforming CAP standards until they become a shared habit." In Colby's experience, this conceptual difference is new to many ISO-centric laboratories, in which document management seems to be at the center of quality control systems.



The laboratory team that made CAP accreditation a reality for the National Cancer Center Hospital East.

NCCE's laboratory and hospital staff were in for even more and bigger surprises when the CAP inspectors arrived.

"One of the greatest things about working with the CAP over the last three decades has been the CAP inspectors," Colby says. The team leader for the NCCE inspection was Richard Scanlan, MD, of the CAP Council on Accreditation. Other members of the team were Robert Baisden, MD (long-time leader of international inspections); Kailash Sharma, MD (microbiology and anatomic pathology); Sainan Wei, MD, PhD (molecular specialist); and Denise Driscoll (CAP senior director of accreditation and regulatory affairs). The full inspection team consisted of nearly 20 technical specialties. "We are here as your peers and colleagues," Dr. Scanlan told a nervous NCCE staff in his opening remarks, "and we hope to learn from you and, where we can, act as teachers and mentors."

The CAP inspectors erased all doubts and jitters during the three-day inspection. Dr. Baisden emphasized the importance of external proficiency testing and taught staff about statistical outliers and how to best evaluate proficiency testing results. Dr. Scanlan, a transfusion medicine expert, explained the use and benefits of new platelet storage techniques in trauma cases. Dr. Wei led her molecular pathology group through the intricacies of validating next-generation sequencing oncology markers using the CAP checklist as a teaching guide, and Dr. Sharma guided staff through the preanalytical requirements for anatomic pathology and suggested areas for improvement. The CAP's Driscoll tied everything together with the laboratory general checklist, answering questions and emphasizing how important it is to understand the benefits of each requirement and the associated risks of noncompliance.

Deficiencies and recommendations were loaded into the LEAP CAPA (Corrections and Preventive Actions) system and a root-cause analysis was performed and plans laid for corrective actions to take place and be reported to the CAP. NCCE received its official notification of CAP accreditation in September 2022.

"Ultimately," Colby says, "the true worth and benefits of CAP accreditation to NCCE, its patients, and research partners is this: that enduring and intrinsic value is best achieved by making CAP principles and practices a daily foundation of the laboratory's culture and CAP standards a shared habit. To me, that is where the magic happens."

*Steve Ziolkowski is a writer focused on Japan and Asia. He was formally the managing director of Oxford University Press, Japan.*