



Professional biobanking education in Korea based on ISO 20387

Jong Ok Kim¹, Chungyeul Kim², Sangyong Song³, Eunah Shin⁴, Ji-Sun Song⁵, Mee Sook Roh⁶, Dong-chul Kim⁷, Han-Kyeom Kim⁸, Joon Mee Kim⁹, Yeong Jin Choi¹⁰

¹Department of Pathology, Daejeon St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Daejeon, Korea

²Department of Pathology, Korea University College of Medicine, Seoul, Korea

³Department of Pathology, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Korea

⁴Department of Pathology, Yongin Severance Hospital, Yonsei University College of Medicine, Yongin, Korea

⁵Department of Pathology, Ewha Womans University Seoul Hospital, Ewha Womans University College of Medicine, Seoul, Korea

⁶Department of Pathology, Dong-A University College of Medicine, Busan, Korea

⁷Pathology Division, Seoul Clinical Laboratories, Yongin, Korea

⁸Professor Emeritus of Pathology, Medical College Korea University, HiLab, HANARO Medical Foundation, Seoul, Korea

⁹Department of Pathology, Inha University School of Medicine, Incheon, Korea

¹⁰Department of Hospital Pathology, Seoul St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Seoul, Korea

To ensure high-quality bioresources and standardize biobanks, there is an urgent need to develop and disseminate educational training programs in accordance with ISO 20387, which was developed in 2018. The standardization of biobank education programs is also required to train biobank experts. The subdivision of categories and levels of education is necessary for jobs such as operations manager (bank president), quality manager, practitioner, and administrator. Essential training includes programs tailored for beginner, intermediate, and advanced practitioners, along with customized training for operations managers. We reviewed and studied ways to develop an appropriate range of education and training opportunities for standard biobanking education and the training of experts based on KS J ISO 20387. We propose more systematic and professional biobanking training programs in accordance with ISO 20387, in addition to the certification programs of the National Biobank and the Korean Laboratory Accreditation System. We suggest various training programs appropriate to a student's affiliation or work, such as university biobanking specialized education, short-term job training at unit biobanks, biobank research institute symposiums by the Korean Society of Pathologists, and education programs for biobankers and researchers. Through these various education programs, we expect that Korean biobanks will satisfy global standards, meet the needs of users and researchers, and contribute to the advancement of science.

Keywords: Biological specimen banks; Standardization; Education; International organization

INTRODUCTION

Biobanking is the collection of a large number of biospecimens containing personal and health information, mainly for health and medical research [1]. Biobank samples include not only

classical archive specimens such as tissues, blood, nucleic acids, and microbiomes, but also virtual specimens such as images and data. In the current global situation, it is imperative to emphasize ethical and legal considerations and to standardize processes. The International Organization for Standardization

Received: September 4, 2024 **Revised:** October 29, 2024 **Accepted:** November 4, 2024

Corresponding Author: Joon Mee Kim, MD, PhD

Department of Pathology, Inha University Hospital, Inha University School of Medicine, 27 Inhang-ro, Jung-gu, Incheon 22332, Korea

Tel: +82-32-890-3981, Fax: +82-42-220-9843, E-mail: jmk@path@inha.ac.kr, jkim@catholic.ac.kr

Yeong Jin Choi, MD, PhD

Department of Hospital Pathology, Seoul St. Mary's Hospital, College of Medicine, The Catholic University of Korea, 222 Banpo-daero, Seocho-gu, Seoul 06591, Korea

Tel: +82-2-2258-1616, Fax: +82-2-2258-1627, E-mail: mdyjchoi@catholic.ac.kr

This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (<https://creativecommons.org/licenses/by-nc/4.0/>) which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

© 2025 The Korean Society of Pathologists/The Korean Society for Cytopathology

(ISO) documents for biobanking (ISO 20387:2018) define biobanks as legal entities or parts of a legal entity, so the whole biobanking process (acquisition and storage, including collection, preparation, and preservation; testing; analysis; and distribution) must be performed within adequate legal boundaries [2]. To establish and administrate biobanks, there is an urgent need to develop and disseminate educational training programs in accordance with ISO 20387. In Republic of Korea, a pilot project for KS J ISO 20387-accredited certification has been implemented, and three institutions have acquired Korea Laboratory Accreditation Scheme (KOLAS) accreditation. The number of institutions seeking ISO 20387 certification in Republic of Korea is increasing, as is the demand for education on biobanking standards. Although an education system or program is mandatory to comply with global standards, specified infrastructure for biobanking personnel in Republic of Korea is insufficient. In this article, we briefly review ISO 20387, KS J ISO 20387, and both international and Korean educational programs for biobanking and offer suggestions for professional programs based on KS J ISO 20387.

OVERVIEW OF ISO 20387

The ISO is a global network of national standards bodies (foremost standards organizations in their countries) composed of 170 members, one per represented country. The name ISO is derived from the Greek *iso*, meaning equal. Though the acronym originally differed across languages, called the IOS in England and the Organization International Denormalization in France, the founders decided to use ISO globally to represent equality, whatever the country and language. The ISO was established in 1946 to support global trade by developing and publishing international standards, driving inclusive and equitable economic growth, advancing innovation, and promoting health and safety to achieve a sustainable future (ISO mission). Currently, there are about 13,500 ISO standards [3].

A *conformity assessment* demonstrates whether a product or service, process, claim, system, or person meets the relevant requirements (ISO/IEC 1700). *Accreditation* is the publication of an official certification by a third party to indicate that a conformity assessment body is qualified to perform a particular conformity assessment task (KSQ ISO IEC 17000) [4]. The International Laboratory Accreditation Cooperation (ILAC) is an international organization of accreditation bodies for calibration laboratories, testing laboratories, medical testing

laboratories and inspection bodies, proficiency testing providers, reference material products, and biobanks. The ILAC can secure the international equivalence of conformity assessments in individual countries based on an agreement under ISO/IEC 17011. The ILAC-Mutual Recognition Arrangement (ILAC-MRA) demonstrates the equivalent competence of conformity assessment bodies. In other words, the accrediting bodies of each country participate in regional and international agreements to assess and certify conformity assessment and demonstrate their eligibility internationally.

ISO 20387 was developed in 2018 to promote confidence in biobanking. It specifies general requirements for biobank competence, impartiality, and consistency, including quality control requirements, to ensure the appropriate collection of biological materials and data. The Republic of Korea introduced ISO 20387 and enacted KS J ISO 20387 in 2019. The development of standard operating procedures (SOPs) for the collection, processing, and storage of samples and data based on ISO 20387 has an important impact on the quality control and future use of bioresources. SOPs are mandatory for the efficient use of bioresources, including human-derived materials. Experts with a biobanking standards education based on ISO 20387 are needed to standardize bioresource quality. ISO 20387 became the exclusive accreditation standard for ILAC in October 2018, following its publication in August of that year (ILAC GA 22.19). In October 2020, biobanking (ISO 20387) activities were included as an Asia Pacific Accreditation Cooperation (APAC)-MRA (Level 3, APAC GA Ballot 2020-02). In November 2021, ISO 20387 was introduced in the ILAC-MRA scope, and related document updates were promoted (ILAC GA resolution 25.09, 2021-11) [5,6]. Then, American Association for Laboratory Accreditation launched a biobanking accreditation program based on ISO 20387 in January 2019. Because biobanks are important research infrastructure for bio businesses, research and discussions about specialized biobanking education are being conducted in Republic of Korea.

OVERVIEW OF KS J ISO 20387

The KOLAS is an accreditation body that evaluates and performs accreditation work on inspection bodies and calibration tests in Republic of Korea under the Framework Act on National Standards and Regulations. The KOLAS has signed an international MRA with ILAC for testing, calibration, and medical testing laboratories, but it has not yet signed an MRA relating

to biobanks. To achieve such expansion, KS J ISO 20387 was enacted by the KOLAS in Republic of Korea in December 2019. KS J ISO 20387:2019, aligned with ISO 20387, *Biotechnology — Biobanking — General requirements for biobanking*, was published as the Korean Industrial Standard in 2019, to promote trust in the operation of biological resource banks. This standard ensures that collected bioresources and associated data are of appropriate quality, and it ensures the eligibility, fairness, and consistent operation of bioresource banks. KS J ISO 20387 consists of general, structural, resource, and process requirements, in addition to quality control systems and annexes. The general requirements involve matters such as impartiality and confidentiality. Resource requirements involve personnel; facilities/dedicated areas and environmental conditions; externally provided processes, products, and services; and equipment. The process requirements include the collection, reception, distribution, transport, and traceability of biological material and associated data, as well as the preparation, preservation, and storage of biological material, quality control, validation and verification of methods, and the management of information and data, nonconforming output, reports, and complaints. The quality management system is based on ISO 9001 and provides two options. Option A lists the minimum requirements for implementing a quality management system in biobanks according to the *principles* of ISO 9001. Option B allows biobanks to establish and maintain a quality management system under the *implemented requirements* of ISO 9001. Under these regulations, it is necessary to introduce and be aware of the ISO 9001 system in KS J ISO 20387:2018.

In October 2022, three institutions, the Korean National Institute of Health (National Biobank of Korea), the National Culture Collection for pathogens, and the Korean Institute of Radiological & Medical Science, received KOLAS accreditation certification [7].

CURRENT STATUS OF OVERSEAS BIOBANKING EDUCATION

In Europe and the Americas, professional biobanking education has expanded since the 2010s in recognition of the need for specialized training and to meet the demand for experts in the growing bioindustry. Biobanking education is largely divided into degree programs and job training courses (Table 1) [8-17]. Degree programs in universities exist mainly in Europe, with six-degree courses available as of 2022.

King's College London in the United Kingdom offers a Master's degree in research biobanking and offers 5-month practical training sessions. The program focuses on the collection and storage of oncology-related bioresources, as well as bioresource preparation, preservation, and staining techniques. Through this course, students can learn how to handle and analyze DNA and tumor cells, but only six to eight first-year students are accepted each year, limiting this opportunity for education [17].

The Master's degree program for biobanking at the Medical University of Graz in Austria offers a five-semester, part-time, English online learning course. The course uses a biobanking curriculum for job training with comprehensive topics comprising introduction and basic knowledge of biobanking, ethics and law, collection and management of samples, risk management and biobanking, biobanking IT, sustainability, budgeting and business planning, epidemiology, quality management and quality control, management and communication, strategy and development, research methods I, research methods II, design and implementation of clinical studies, international biobanking, and managing multidisciplinary teams [8]. Another educational focus includes courses on building and operating biobanks. The Medical University of Graz also offers various 2-day and 4-day biobanking courses [8]. The Université d'Azur in France offers a specialized Master's degree in biobank data management, involving practice-oriented education that includes field practice in a biobank and comprehensive programs on biobanking processes [10].

Lyon Catholic University in France offers a 2-year Master's program that involves both field classes and practice. This degree teaches skills in biobank management and biology for use in positions of responsibility in biobanks [11]. The Universidad Católica de Valencia in Spain teaches field classes for 1 year as a Master's degree [12]. The University of Milano-Bicocca has developed a comprehensive Master's-level curriculum, including 40 online series (webinars), training programs, and staff exchange programs, by integrating with existing curriculums for three semesters.

In addition to universities, network-style organizational institutions such as associations and academic societies offer biobanking job training courses. The Integrated Biobank of Luxemburg, which uses proficiency tests certified by the International Society for Biological and Environmental Repositories (ISBER), offers a three-week seminar for up to 35 students each year in conjunction with the University of Luxembourg [13,17]. The European Biobank Network of human-derived biobanks in

Table 1. Overseas biobanking education

Type	Educational institution	Training courses	Characteristics	Education method	Education period
College degree programs	King's College London (England)	Master's degree in biobanking	Two 5-month practical training sessions, six to eight new students a year Focus on the collection and storage of oncology-related bioresources and sample preparation, preservation, and dyeing technology	Field class, practice	1 yr
	Medical University of Graz (Austria)	Master's degree in biobanking	Online-learning courses in English	Online and in-person seminars (in English)	Five semesters
	Université d'Azur (France)	Master's degree in biobank data management	Overall job training for biobanking, including comprehensive issues 2nd and 4th semesters: internship 1st semester, learn human health-agro-environment, quality in biobanking, bioethics in biobanking, safety and security in biobanking, project management, and technical practice at the biobank Côte d'Azur	Field classes	2 yr
	Lyon Catholic University (France)	Master's degree	3rd semester, biobankonomics, big data for biobanking, networking in biobanking, professional integration, communication and marketing, and success stories in biobanking	Field classes, practice	2 yr
	Universidad Católica de Valencia (Spain)	Master's degree	Biobank management and biology	Field classes	1 yr
	University of Milano-Bicocca (Italy)	Master's degree	Comprehensive curriculum	-	Three semesters
Network-type job training courses	IBBL-Luxembourg University Link	-	On-site biobanking job training	Field classes	3 wk
	Medical University of Graz	Certificate	Data collection, preservation, and data management of samples Theoretical and practical training workshops	Field classes	3 days, 5 days
	BBMRI-ERIC, European Biobank network	Certificate, Master's degree	Annual biobank week conference with information exchange, presentation, and discussions Research infrastructure training program leading to Master's degree at the University of Milano-Bicocca	Staff exchange, webinars, training programs	3–18 mo
	College of American Pathologists (CAP)		Coordinated research infrastructure building enduring life-science services (CORBEL) Systematic and professional education for medical laboratory technologists	Field classes, online	-
			Accredited as a high-quality bioresource provider		
Online-based bio-bank e-learning	ISBER/in partnership with the Canadian Tissue Repository Network	Certificate	Online education and webinar about bioresources and biobanking by pathologists' society	Online	20–30 hr
	CTRNet, UBC Office of Biobank Education and Research	-	Collaboration with ISBER Basic biobanking education program based on ISBER best practices in conjunction with the University of British Columbia for students and research technicians	-	-

BBMRI-ERIC, Biobanking and Biomolecular Resources Research Infrastructure-European Research Consortium; ISBER, International Society for Biological and Environmental Repositories.

Europe holds a Global Biobank Week Conference once a year to exchange information and discuss presentations related to biobanks.

The Biobanking and Biomolecular Resources Research Infrastructure–European Research Infrastructure Consortium (BBMRI-ERIC) is the largest pan-European service-driven infrastructure in health research [18]. The BBMRI-ERIC has operated educational infrastructure projects since 2015. In 2020, with the support of Horizon, it developed a related policy framework recognizing the importance of biobanking education and training. The Research Infrastructure Training Program (RItrain) defines the competencies required by research institutions from initial preparation to the operational stage, links those competency-specific requirements to existing training courses, and culminates in a Master's degree at the University of Milano-Bicocca. The RItrain project is operated by a consortium of leading European research infrastructure institutions such as the European Bioinformatics Institute and the European Clinical Research Infrastructure Network [18].

The Coordinated Research Infrastructure Building Enduring Life-science Service (CORBEL) project has the same nature as RItrain but seeks to build shared services between biological and medical research infrastructures, including the European Marine Biological Resource Center (EMBRC). EMBRC is part of the European Strategic Forum on Research Infrastructure, comprising cross-infrastructure science workflows and a common suite of services in response to the needs of specific users and research infrastructures. The EMBRC is part of a transnational access program and provides standardized services, an innovation desk, a working group on quality management, and training. The CORBEL project focuses on data management and integration, physical access, ethics, and innovation and develops and operates education and training programs through staff exchanges and webinars [19].

The College of American Pathologists (CAP) offers a systematic and professional online and offline curriculum for clinical pathologists and operates an educational program to earn CAP Biobank accreditation. This accreditation is a peer evaluation model that allows students to share knowledge and best practices with other biobank experts through education. If a biobank acquires this accreditation, it will be recognized as an institution that provides high-quality biomaterials. An example of a CAP webinar related to biobanking is the “Biospecimens and Biorepositories for the Community Pathologist” [17].

ISBER, a global biobanking organization, offers online

training courses on the general operation and management of biobanking, dealing with major issues in establishing, maintaining, and accessing biobanking services. The education program includes nine online modules designed to provide “how-to” knowledge for researchers and biobankers and “what is” knowledge for stakeholders (e.g., the public, ethics board members). The nine modules are the overview of research biobanking; governance; ethics, privacy, and security; facility design and safety; quality management and process improvement; informed consent; biospecimen collection and processing; biospecimen storage and distribution; and data systems and records management (Table 2). Module 1 covers general management applicable to overall biobanking, and modules 2 through 9 detail specific biobanking processes [16]. In addition, ISBER provides information about institutions and curriculums that offer biobanking education by country (Table 1). Annual meetings and symposiums have been held for more than 20 years. ISBER offers opportunities for academia, industry, and pharmaceutical companies to learn, connect, discuss, and collaborate with biobankers from six continents, along with education programs on various topics through in-person and online/hybrid gatherings [15].

The Canadian Task Repository Network (CTRNet), jointly with ISBER, offers basic online courses on general operational management of biobanks and standardized biospecimen research methods. These are in-depth courses based on the National Cancer Institute and ISBER operation guidelines in conjunction with the University of British Columbia for researchers, undergraduates, graduate and doctoral students, and research technicians dealing with human-derived specimens (Table 1) [17,20].

Our examination of the status of overseas biobanking education showed that a small number of educational institutions/associations has been providing systematic biobanking education, including practical training and theoretical courses, for a considerable period of time. Those educational programs were developed and distributed with technical and legislative support.

CURRENT STATUS OF BIOBANKING EDUCATION IN REPUBLIC OF KOREA

Within the life research resource management implementation plan, the registration agencies of each ministry operated training and education programs for human resources from 2012 to 2023. The Ministry of Science, ICT, and Future Planning

Table 2. ISBER details on the online module of the biobanking operation management course

Module	Training course	Description
1	Basics of biobanking	Provide an overview of the establishment, maintenance, and use of biobanks
2	Governance	Concept of biobank governance, structure, model development, access and release process management model, and stakeholder interests
3	Ethics, privacy, and security	Ethics, personal information protection, and security standards related to research and biobanking The role of the ethics review board in the operation of biobanks Considerations for the development of security standards related to the use of bioinformation Ethical principles in terms of biobanking procedures and organizational operations
4	Facility design and safety	Physical requirements for biobanks Necessary security measures for the protection of bioinformation and data in facilities Need for backup devices and systems Securing the safety of a biobank's workforce
5	Quality management and process improvement	Defining the quality management role of biobanks Definition of the quality management system Implementation of the quality management system Establishment and maintenance of standard operating procedures for biobanks Importance of process monitoring and continuous improvement
6	Informed consent	Purpose and principles of informed consent Types of informed consent Special considerations in the informed consent process Withdrawal of consent procedures and related documents Considerations for obtaining parental permission and pediatric consent
7	Biospecimen collection and processing	Different types of biospecimens Important considerations for obtaining and processing biospecimens Various processing methods for each biospecimen Considerations for labeling biospecimens
8	Biospecimen storage and distribution	Understanding research support through biospecimen distribution Required steps for biospecimen transport Objectives of material transfer agreements (MTAs) Steps for biospecimen distribution and reception documentation
9	Data systems and records management	Requirements for annotating biospecimens Considerations for choosing databases for biobanks Overview of data types, data standards, data quality, and data access policies Mechanisms for data protection

Source: International Society for Biological and Environmental Repositories (ISBER), <https://www.isber.org> [16].

(currently the Ministry of Science and ICT) conducted workshops on microbial classification, identification, culture technology, sample collection, and preservation, and the Ministry of Oceans and Fisheries held workshops on seaweed collection, classification, and conservation. However, those were one-off educational opportunities focused on specific processes (mainly collection and preserving) in biobank operations. On the other hand, the Korean Disease Control and Prevention Agency under the Ministry of Health and Welfare has regularly offered comprehensive education by segmenting courses for biobank

practitioners into foundational and advanced levels [17]. A new training course for KOLAS biobank assessors began in 2022.

Korean Biobank Project, Korean Disease Control and Prevention Agency

The Ministry of Health and Welfare and the Korean Disease Control and Prevention Agency (formerly the Korean Centers for Disease Control and Prevention) established the Comprehensive Information and Management System for Health and Medical Bioresources in 2007, to secure the collection and use

of human resources at the national level.

In the first phase of the Korean Biobank project (2008–2012), 100 professors and researchers associated with the biobank were trained twice under the theme “Biobank and Bioethics.” The program started with education on bioethics and safety laws related to biobanks and their regularization. That was followed by systemized basic and in-depth education programs. In 2012, the project offered basic courses for new employees (having worked less than 1 year) of 17 human biosource regional banks located at university hospitals and in-depth courses for those who had worked for more than 1 year or had completed the basic courses in the previous year. In addition, the trainees practiced preserving, dyeing, separating, and identifying pathogens using a pathogen management system. Since 2009, the National Biobank of Korea has offered step-by-step training to strengthen the job capabilities of biobank operators [21–23].

In the second phase of the project (2013–2015), the frequency and importance of basic and in-depth training were increased to strengthen the job capabilities of practitioners. Training on the National Biobank Information Management System (BIMS) was conducted independently and regularly. Furthermore, in 2014, the Korean Biobank project offered basic education for new employees and workers of less than 1 year from not only the 17 biobanks at university hospitals, but also those from 55 other biobanks of human-derived products approved by the Ministry of Health and Welfare. This training covered the basic management of biobanks, such as a biobank overview, an introduction to the Korean Biobank project (including BIMS 3.0), ethics related to biobanks and biosources, and the management of biobanks under the Bioethics and Safety Act. A total of 59 trainees completed these training courses [24,25]. Beginning in July 2014, BIMS hands-on education was conducted regularly, and education participation surveys targeting biobank practitioners were conducted every month. As a result, customized education could be offered to users. The training included an introduction to the system’s basic structure and function, biological resource collection, safety inspection, distribution, medical information registration method, resource and medical information batch processing, and basic searches of biosources [25]. BIMS is used by the National Biobank of Korea and the human biosource regional banks at 17 university hospitals (Korean Biobank Network). In 2015, it was extended to 18 new biobanks outside the Korean Biobank Network to facilitate the operation of Korean human-derived biobanks. BIMS 3.0 hands-on education has been conducted every month since July 2015,

and the curriculum was divided into two courses: elementary education and advanced/in-depth education. As of the end of December 2015, education had been offered five times, with 65 trainees participating in the elementary education program and 89 participating in the in-depth education program [26]. In addition, the *Basic Textbook for Human Materials Banking Practitioners* [24] was published and contains the following chapters: overview of biobanking, Korean Biobank Project, biobank ethics and law, Biosources Information Management [BIMS 3.0, One-Stop System Main Function Introduction], biosource quality management (blood, body fluids, tissues, nucleic acids), storage equipment and high-pressure gas safety education, and biobank laboratory safety management [24].

In the third phase of the Korean Biobank project (2016–2020), four educational programs offered monthly hands-on training courses on biosource management for practitioners, biosource quality management, additional courses on biosource quality management, and the operation and update of BIMS. In 2017, the project initiated a biosource quality management program to improve the management ability of new workers by training them to handle human specimens. Three biobanks at university hospitals (Ajou University Hospital, Keimyung University Dongsan Hospital, and Cheonbuk National University Hospital) oversaw this training. Practical training was offered once for 5–6 students, and a total of 80 students completed 13 sessions by the end of 2020 [27–30]. Apart from training on DNA and RNA extraction and quality management using cell lines operated by biobanks, students practiced collection, preservation, RNA extraction (automated equipment and manual methods), and quality management methods for biosources collected by biobanks. In November 2020, Ajou University Hospital and Keimyung University Dongsan Hospital ran three training sessions on quality control using a series of training courses, such as extracting RNA from tissues, measuring quality control values, and analyzing the results [30].

In the fourth phase (2021–2025), the 2021 standard software revision of BIMS (HuBis_Sam) was distributed to 61 of the 75 domestic biobanks to improve biosource management efficiency and user convenience. To carry out the “education and certification support for enhancing expertise” task, the project considered a domestic accreditation system for ISO 20387:2018, an advanced test of biosource quality management proficiency, and the development of biobank education programs [31]. In September 2021, the National Biobank of Korea launched an online education program to revitalize and standardize bio-

bank operations. As a result, four courses and 13 sessions of the National Biobank of Korea's online training began in 2022, and included biobank overview and trends, bioresource management and provision procedures, bioresource collection and assessment of quality control errors, bioresource management facilities and equipment operation, safety management of human resource storage rooms and accident response, and BIMS (HuBis_Sam). In 2022, 326 trainees completed those courses (Table 3) [32].

The National Biobank of Korea regularly holds trainings, forums, and symposiums for continuous education and promotion of biobank experts. In addition, to diversify public relations channels and actively communicate with researchers through mobile-oriented services, the Kakao Talk channel of the National Biobank of Korea (channel name: the National Biobank of Korea of Central Disease Control Headquarters) has been operated since 2021 [30].

Korean National Research Resource Center Project

The Korean National Research Resource Center (KNRRC) originated as a Ministry of Science and Technology specialization promotion project in 1995 and is currently operating as a research resource support project under the Ministry of Science and ICT/National Research Foundation of Korea. It comprises a central research resource center, five base centers, five national purpose-based research resource banks, and 31 research resource banks. It has specialized research resources in various fields, such as bioresources, animals, plants, microorganisms, and fusion materials. The organization helps to discover, collect, and store resources that are difficult for individual researchers to secure. From 2008 to 2019, yearly educational workshops and symposiums were held. For the efficient operation of research resource banks, KNRRC offered training for workers at 30 biobanks. In 2018, educational training was offered on the standardization and certification preparation process necessary for biobank operation [33].

KOLAS biobank education based on KS J ISO 20387

The KOLAS biobank curriculum is for assessors and workers and is divided into new assessor training, internal auditor education, general training, training for special topics, and refresher training. The KOLAS biobank employee training is for practitioners, quality managers, and technical managers. The KOLAS training program, "KS J ISO 20387 Operation Practice _ [KOLAS] KS J ISO 20387 Operation Practice (Biobank)," is

mandatory for staff members, quality managers, and technical managers of a biobank. The purpose is to improve the quality of biobank operations by informing students about the KS J ISO 20387 requirements. These requirements need to be met for authorized institutions to establish a management system and perform tasks in compliance. The training is expected to demonstrate to students the system operator role of the KOLAS, enhance operational capabilities by aligning with KS J ISO 20387 requirements, and maintain and improve in-house quality management systems. The training is completed over 3 days (20 hours) and is organized as follows:

Day 1: Biobank accreditation system, international trends, and KS J ISO 20387 requirements.

Day 2: KS J ISO 20387 requirements, the operation status of biobanks.

Day 3: Method validation, verification, and KOLAS accreditation criteria.

The KS J ISO 20387 Operation Practice_ [KOLAS] KS J ISO 20387 Operation Practice (Biobank) course began in 2023 and offered online lectures in February and July. It is available on the Korea Conformity Laboratories website (<https://www.kcl.re.kr/site/program/education/eduschedule.do?menuid=007002001>) [34].

The training course for assessors is divided into (1) new assessor training and (2) lead assessor training. The new assessor training courses are specified in ILAC-G3 (assessor training guidelines used by accredited organizations) and APAC CBC-002 (assessor curriculum guidelines) documents. Biobank assessors must complete the ISO-IEC-17025 and ISO 20387 courses including training on KS Q ISO/IEC 17011, KS Q ISO 19011, KS Q ISO/IEC 17025, measurement uncertainty, and KS J ISO 20387 (Tables 4, 5) [2,7,35]. The program also includes an introduction to accreditation systems, international trends in conformity assessment systems, the importance of quality assurance and quality management concepts, the standards and interpretation of each accreditation scheme, assessment techniques and practices, metrological traceability, measurement uncertainty, qualification criteria and registration procedures for assessors, and the qualification requirements of KS Q ISO/IEC 17011.6.1.2. The new training course for KOLAS biobank assessors opened in 2022. Maintenance training courses for assessors are currently in preparation for future inclusion in the curriculum [7]. Internal auditors must complete internal auditor training courses (in-person, 3 days [20 hours]) and employee refresher training courses (online) [7].

Table 3. Practical training by the National Biobank of Korea (Ministry of Health and Welfare/Korea Centers for Disease Control and Prevention)

1st phase (2008–2012)	2nd phase (2013–2015)	3rd phase (2016–2020)	4th phase (2021–2025)
2009	2013	2017	2021
First biobank practitioner training for working professors and researchers in the Korean Biobank Network (KBN) (offered two times)	Biobank practitioner training at KBN units – Basic training – In-depth training – Publishing basic textbooks for practitioners at biobanks	Bioresource management training Bioresource quality management training Add training courses on the quality management of human tissue resources BIMS hands-on training	Revised BIMS Distribution of standard software (HuBis_Sam)
2010	2014	2018	2022
Biobank practitioner training – Basic training – In-depth training Pathogen resource bank practical training – Pathogen Management System (PIMS) – Pathogen preservation and dyeing practice	Basic training for the management of biobanks Bio Information Management System (BIMS) practical training	Biobank manager training Practical training for bioinformation users BIMS training Bioresource distribution desk training Practical training for quality management Practical training for blood-derived resource quality management Practical training for tissue resource quality management	Start e-learning education
2011	2015	2019	2023
Biobank practitioner training – Basic training – In-depth training Pathogen resource bank training – PIMS – Separation and identification of pathogen resources	Regular training courses of BIMS 3.0 practice – Monthly courses – Basic/in-depth training Bioresource management training – Basic training – In-depth training – Target expansion to all biobanks approved by the Ministry of Health and Welfare	Biobank practitioner training Biobank practitioner workshop Practical training for users of bioinformation systems Bioinformation system basic/in-depth course Bioresource distribution desk basic course Practical training for tissue resource quality management	The second session of the biobank manager practical training course
2012	-	2020	-
Practitioner training for 17 KBN biobanks	-	Practical training for tissue resource quality management	-
Start regular training for practitioners	Increase in the frequency of training	Overview	Distribution of standard software (HuBis_Sam)
Systematization of educational programs	Independent operation and expansion of BIMS education Expanding training targets in 2015	Separate operation of four training programs Expansion of BIMS education	Development of online education content for biobank manager practical training course in 2022

Table 4. Content of KOLAS training related to ISO 20387

Training type	Module	Courses	Content and structure
Assessor training	1. New assessor training	ISO 17025 (40 hr)	Ethics education International mutual accreditation and conformity assessment system Trends in international conformity assessment and KS Q ISO/IEC 1701 Assessment techniques and skills KS Q ISO 19011 guidelines Certified information integration system KS Q ISO/IEC 17025 requirements description and understanding Nonconformity cases and application practice Roleplay, case assessment Report writing practice Course evaluation
		Measurement uncertainty (20 hr)	Theory of statistics Measurement uncertainty assessment overview Bottom-up and top-down approaches Measurement uncertainty assessment case practice ISO 5725 overview Course evaluation
		ISO 20387 (16 hr)	Bioethics, biosafety ethics education KOLAS biobank accreditation system and international trends according to KS Q ISO/IEC 17011 KS J ISO 20387 requirements: description and understanding Current status and cases of biobank operation Method validation and verification overview Requirement application practice Course evaluation
	2. Lead assessor training	-	Scheduled
Practitioner training	1. New training (20 hr)	-	Ethics education KOLAS biobank accreditation system and international trends KS J ISO 20387 requirements: description and understanding Metrological traceability and overview of SI units Current status and case of biobank operation Method validation and verification overview KOLAS accreditation criteria Course evaluation (60 points or higher)
		2. Maintenance (5 hr, once every 3 yr)	-
Internal auditor training	-	-	KS Q ISO 19011 management system review guidelines Case analysis (practice) Theory 50%, practice 50%

KOLAS, Korea Laboratory Accreditation Scheme.

COMPOSITION OF PROPOSED PROFESSIONAL EDUCATION PROGRAMS BASED ON KS J ISO 20387

The composition of biobanking education based on KS J ISO 20387 is divided into general, structure, resource, process, and quality management system requirements, as shown in Table 5 [35]. For the establishment, maintenance, and quality control of biobanking, we suggest that biobanking practices based on KS J ISO 20387 be applied, and that professional education programs for training professionals include the following.

First, the general operation management course, which deals with quality management, risk management, ethics, and the law of biobanking (based on KS J ISO 20387) is unified into a common education program applicable to all biobanks.

Second, the course about managing bioresources, such as human-derived resources, animals, plants, and microorganisms, applies to resources based on KS J ISO 20387 and provides preservation methods, quality control methods, and deposit sales units.

Third, professional biobanking education from biobanks should be offered with various and systematic curriculums. Training courses should be divided according to the tasks of the operating manager (bank president), quality control manager, practitioner in charge of bioresources from deposit to sale, and an administrative officer in charge of education, and

they should offer a systematic step-by-step curriculum. This program will subdivide educational categories and levels for customized education, including beginner, intermediate, and advanced grades with various educational content.

Fourth, biobanks based on KS J ISO 20387:2018 must be familiar with ISO 9001:2015 to operate the quality management system, so they should offer training courses related to ISO 9001:2015 for quality management systems and certification. They must also be familiar with ISO 17025:2017 for general requirements about the competence of testing and calibration laboratories and accreditation, with ISO 17043:2010 for proficiency test providers, and with ISO 13528:2015 for statistical methods used in proficiency testing by interlaboratory comparison.

Fifth, the expected effect and use plan for professional curriculum developed based on KS J ISO 20387 for biobanking encourages continuous contribution of the Korea Accreditation Support Center, which provides education on assessment specifications for biobank certification that meets the requirements of the international standard. Therefore, it operates under ISO/IEC 17024: 2012 Conformity Assessment–General requirements for models operating certifications of persons, which sets out the principles and requirements for institutions that regularly provide standards training for biobank members and certify surveyor qualifications. In addition, when government-related institutions want to establish professional education institutions for biobanks and provide common standard

Table 5. KS J ISO 20387–based professional training plan

Category	Description	Key content
Basics of biobanking	Overview of the scope, citation standards, terms and definitions, and establishment, maintenance, and use of biobanks	-
General requirements	General requirements such as operating procedures, fairness, and confidentiality	General principles
Structural requirements	The legal status of bioresources, the authority and obligations of banks and members, governance	Organizational structure, responsibilities, authority, legal identity
Resource requirements	Biobank requirements according to components: general matters; personnel (general matters, eligibility, eligibility assessment, and training); facilities/applicable areas and environmental conditions; outside processes; management of products and services; equipment, etc.	Resource management
Process requirements	Biobank requirements according to processes: general matters; collection, receipt, distribution, transportation, tracking, preparation, preservation, and storage of bioresources and related data; quality control of bioresources and data; validation and verification of methods; management of information and data; requirements for nonconforming result reports, complaints, etc.	Material and material information management
Requirements for quality management system	Options, documentation and management of quality management systems, records management, actions to risks and opportunities, improvements, response to nonconforming results, internal audits, and quality management review	Quality management system

education applicable to pan-ministerial biobanks, the Biobank Research Association can cooperate as a specialized institution for establishing an educational system.

Sixth, the following method for providing domestic professional education programs is proposed (Table 6).

- KS J ISO 20387–based SOPs and various educational contents should be developed considering the operational status of each institution and the composition of the national governance system.
- Despite the growing demand for biobanking experts, no university in Republic of Korea offers a biobanking degree program. A biobanking degree program could synergize the knowledge and practices of general biobanking professional education by offering professional on-site/online biobanking education at a university and awarding a Master’s degree within 2 years.
- Universities or other institutions could provide specialized courses and certifications for data quality education through approximately 6 months of on-site and online training. Universities or other institutions with short- and long-term courses could offer certificates through molecular and genetic education classes and practical training during 3 days to 6

- months of on-site practice and field classes.
- A one- to two-day elementary education program that is mandatory for beginners could be administered online (e-learning, webinar, online learning, podcast, etc.), and courses requiring practical training such as quality control and preservation methods could be conducted on-site.
- One- to two-day job training in the form of workshops, seminars, or webinars could be provided for biobanking practitioners to respond to changing biobanking technology and help manage quality control according to the type of biological resources.
- One- to two-day in-depth (advanced) courses at the biobank level could be provided through field classes and hands-on training (in-person seminar format).
- The Korean Society of Pathology Biobank Research Group could continue holding symposiums for pathologists on site and online. Symposium program files have been uploaded annually to the website of the Biobank Research Association of the Korean Society of Pathologists for biobankers and researchers.

Table 6. A proposal for KS J ISO 20387–based professional education programs

Education institution	Characteristics	Completion of training courses	Training method	Period
National Biobank of Korea	SOP renewal based on KS J ISO 20387	-	On-site, online	All the time
	Development and application of international biobanking standards	-	On-site, online	All the time
	Operation of a professional human resource training program	Certificate	On-site, online	All the time
University or other institution of specialized education	Common biobanking professional education	Diploma/certificate	On-site, online	2 yr
	Data quality training	Diploma/certificate	On-site, online	6 mo
	Molecular and genetic education classes and practical training	Certificate	On-site, field classes, practice, course education (short course, long course)	3 days–6 mo
Domestic regional biobanks	Elementary education for beginners	Certificate	E-learning, webinars, podcasts	1–2 days
	Job training for biobanking practitioners	Certificate	Workshops, seminars, webinars	1–2 days
	Group-type in-depth (advanced) courses	Certificate	Field classes and hands-on training	1–2 days
Biobank Study Group of the Korean Society of Pathologists	Symposiums	-	On-site, online	1 day
	Lectures on biobanking	-	Online	All the time
	Education for biobankers and researchers	-	Online	All the time

SOP, standard operating procedure.

EXPECTED EFFECTS OF BIOBANKING EDUCATION IN REPUBLIC OF KOREA

There is a high demand for professional biobanking education, as evidenced by the number of people who completed the National Biobank of Korea's e-learning course in 2022. Domestic accreditation of KS J ISO 20387:2018 for high-quality managed biosources is now required. For this, systematic governance and professional job training are mandatory. Education programs for biobank members, such as operating managers, quality managers, practitioners, and administrators, can facilitate this accreditation. These programs will benefit health and medical research and related industries.

Nonetheless, there are several limitations to implementing the proposed education programs.

- Because no universities in Republic of Korea currently provide programs related to biobanking, continuous interest, commitment, and financial support are required to establish academic biobank courses at the university level.
- Domestic Regional Biobanks are considered the best institutions actively implementing educational programs because they receive national support. It is necessary to encourage these banks to actively implement educational programs for researchers in their regions.
- The Biobank Study Group of the Korean Society of Pathologists needs to continue to implement the education programs it has provided to date.
- Due to the diverse range of job types within biobanks, it is challenging to implement educational programs within a single integrated system. The educational programs for assessors and practitioners provided by KOLAS pertain to many ISO-related programs; however, their focus on biobanking education is limited. As a result, it is challenging to establish a system based on KS J ISO 20387 after receiving practical training and evaluation related to this standard.
- It is desirable for assessor trainers to have practical experience working in and managing biobanks. The participation of doctors, including pathologists, as assessor trainees is low so far, but it is anticipated that pathologists will eventually engage more actively as assessors.

CONCLUSION

Biobank work will become more specialized and systemized

through international certification, and continual and professional education is an essential element for qualified biobank personnel. Biobank education programs need to include an appropriate range of training opportunities to meet the various needs of biobank employees. These could include in-person and online education programs. Certification of completed education courses is necessary to verify the expertise of qualified biobank operators.

The support of tertiary institutions is needed to establish a Master's degree and education program in the field of biobanking that can be implemented at the universities mentioned in this paper.

Ethics Statement

Not applicable.

Availability of Data and Material

All data generated or analyzed during the study are included in this published article (and its supplementary information files).

Code Availability

Not applicable.

ORCID

Jong Ok Kim	https://orcid.org/0000-0002-3632-2998
Chungyeul Kim	https://orcid.org/0000-0002-9636-5228
Sangyong Song	https://orcid.org/0000-0001-5540-6823
Eunah Shin	https://orcid.org/0000-0001-5961-3563
Ji-Sun Song	https://orcid.org/0009-0007-7116-8141
Mee Sook Roh	https://orcid.org/0000-0002-5676-5569
Dong-chul Kim	https://orcid.org/0000-0002-4710-6449
Han-Kyeom Kim	https://orcid.org/0000-0001-6750-8528
Joon Mee Kim	https://orcid.org/0000-0003-1355-4187
Yeong Jin Choi	https://orcid.org/0000-0002-0744-3854

Author Contributions

Conceptualization: HKK. Formal analysis: JOK, JMK. Investigation: CK, SS, ES, JSS, MSR, DCK. Resources: JOK, JMK. Supervision: JMK, YJC. Writing—original draft: JOK, JMK. Writing—review & editing: JOK, JMK, YJC. Approval of final manuscript: all authors.

Conflicts of Interest

E.S., a contributing editor of the *Journal of Pathology and Translational Medicine*, was not involved in the editorial evaluation

or decision to publish this article. All remaining authors have declared no conflicts of interest.

Funding Statement

The Korean Society for Pathologists provided research funding to the Korean Biobank Study Group.

Acknowledgments

We thank to Choonghyun Lee and Kirham Lee in Korea Conformity Laboratories for their advice in writing this article.

REFERENCES

- Annaratone L, De Palma G, Bonizzi G, et al. Basic principles of biobanking: from biological samples to precision medicine for patients. *Virchows Arch* 2021; 479: 233-46.
- ISO 20387 Biotechnology–Biobanking–General requirements for biobanking [Internet]. Geneva: International Organization for Standardization, 2018 [cited 2024 Jan 26]. Available from: <https://www.iso.org/standard/67888.html>.
- Members [Internet]. Geneva: International Organization for Standardization, 2020 [cited 2024 Jan 9]. Available from: <https://www.iso.org/members.html>.
- ISO/IEC 17000:2020(en) [Internet]. Geneva: International Organization for Standardization, 2020 [cited 2024 Jan 26]. Available from: <https://www.iso.org/standard/73029.html>.
- Yoo KO. Overview of the biobank accreditation system (ISO 20387) and KOLAS policy direction. Daejeon: Korea Bioinformatics Center, 2022.
- About ILAC [Internet]. Vejen: International Laboratory Accreditation Cooperation, 1977 [cited 2024 Jan 28]. Available from: <https://ilac.org/about-ilac/>.
- KOLAS education [Internet]. Eumseong: Korea Laboratory Accreditation Scheme, 2001 [cited 2023 Jan 27]. Available from: <https://www.knab.go.kr/usr/edu/inf/RqinsKolasEduSumryInfo.do>.
- Medical University of Graz. International Biobanking Education [Internet]. Graz: Medical University of Graz, 2015 [cited 2023 Jan 11]. Available from: <https://www.medunigraz.at/en/international-biobanking-education>.
- King's College London [Internet]. London: King's College London, 1829 [cited 2020 Jan 11]. Available from: <https://www.kcl.ac.uk/>.
- Universite Cote D'azur. MSc biobanks and complex data management [Internet]. Nice: University Administrative Center, 2002 [cited 2023 Jan 10]. Available from: <https://univ-cotedazur.eu/search?beanKey=&page=&l=1&RH=1410659255029&q=M-Sc+Biobanks+%26+Complex+Data+Management>.
- Lyon Catholic University. Biobank management | graduate [Internet]. Lyon: Lyon Catholic University, 1875 [cited 2024 Jan 25]. Available from: <https://www.ucl.fr/en/academics/our-programmes/biobank-management-graduate/>.
- Universidad Catolica de Valencia. Postgraduate programmes [Internet]. Valencia: Universidad Catolica de Valencia, 2020 [cited 2024 Jan 28]. Available from: <https://www.ucv.es/eng/studies/postgraduate-programmes>.
- Castellanos-Uribe M, May ST, Betsou F. Integrated BioBank of Luxembourg-University of Luxembourg: University Biobanking Certificate. *Biopreserv Biobank* 2020; 18: 7-9.
- BBMRI.at. Courses and educational events [Internet]. Graz: Biobanking and BioMolecular Resources Research Infrastructure, 2023 [cited 2023 Jan 11]. Available from: <https://bbmri.at/courses>.
- ISBER. Events [Internet]. Vancouver: ISBER, 2023 [cited 2023 Jan 21]. Available from: <https://www.isber.org/page/events>.
- Biobank Resource Centre. Essentials of biobanking course [Internet]. Vancouver: ISBER, 2023 [cited 2023 Jan 11]. Available from: <https://biobanking.org/webs/education>.
- Nam S, Lee S. The necessity for standardized biobanking education. *J Stand Certif Saf* 2018; 8: 35-51.
- Litton JE. Launch of an infrastructure for health research: BBMRI-ERIC. *Biopreserv Biobank* 2018; 16: 233-41.
- CORBEL: coordinated research infrastructures building enduring life-science [Internet]. Paris: European Marine Biological Resource Centre, 2015 [cited 2023 Jan 3]. Available from: <https://www.embrc.eu/collaborative-projects/corbel>.
- Essentials of biobanking [Internet]. Vancouver: Canadian Tissue Repository Network, 2023 [cited 2023 Jan 11]. Available from: <https://www.ctrnet.ca/en/education/>.
- Annual report 2009 (11-1352159-000006-10), Korea Biobank Project. Cheongju: Division of Biobank for Health Science, Korea National Institute of Health, 2010.
- 2010 Annual report of National Biobank of Korea (11-1352159-000046-10). Cheongju: Division of Biobank for Health Science, National Biobank of Korea, 2011.
- 2011 Annual report on National Biobank of Korea (11-1352159-000070-10). Cheongju: Division of Biobank for Health Science, National Biobank of Korea, 2012.
- 2013 Annual report on National Biobank of Korea (11-1352159-000070-10). Cheongju: Division of Biobank for Health Science, National Biobank of Korea, 2014.

25. 2014 Annual report on National Biobank of Korea (11-1352159-000070-10). Cheongju: Division of Biobank for Health Science, National Biobank of Korea, 2015.
26. 2015 Annual report on National Biobank of Korea (11-1352159-000070-10). Cheongju: Division of Biobank for Health Science, National Biobank of Korea, 2016.
27. 2017 Annual report on the National Biobank of Korea. Cheongju: Division of Biobank for Health Science, National Biobank of Korea, 2018.
28. 2018 Annual report on the National Biobank of Korea (#11-1352159-000070-01). Cheongju: Division of Biobank for Health Science, National Biobank of Korea, 2019.
29. 2019 Annual report on the National Biobank of Korea (#11-1352159-000070-10). Cheongju: Division of Biobank for Health Science, National Biobank of Korea, 2020.
30. 2020 Annual report on the National Biobank of Korea (#11-1352159-000070-10). Cheongju: Division of Biobank for Health Science, National Biobank of Korea, 2021.
31. Annual report on National Biobank of Korea (2019) [Internet]. Cheongju: National Institute of Health, 2020 [cited 2023 Jan 13]. Available from: <https://nih.go.kr/>.
32. Human resources manager practical training course (2020-1st session) [Internet]. Jincheon: Government e-learning Platform, 2023 [cited 2023 Jan 22]. Available from: <https://kdca.nhi.go.kr/crs/schedule/crsScheduleList.do>.
33. Lee YH. The microorganisms and industry. Seoul: Korea National Research Resource Center, 2010; 8-12.
34. Korea Conformity Laboratories. KCL/Training/Consulting/Proficiency Korea [Internet]. Seoul: Korea Conformity Laboratories, 1998 [cited 2023 Jan 27]. Available from: <https://www.kcl.re.kr/site/program/education/eduschedule.do?menuid=007002001>.
35. KS J ISO 20387:2018 Biotechnology–Biobanking–General requirements for biobanking. Seoul: Korean Standards Association, 2019.