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A Biobank's Journey: Implementation of a Quality Management System and Accreditation to ISO 20387

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Biobanks play an integral role in research and precision medicine by acquiring, processing, storing, and distributing high-quality, clinically annotated biological material. Compliance with biobanking standards and the implementation of quality management systems (QMS) can improve the quality of the biological material and associated data (BMaD). By undergoing third-party assessments, biobanks can demonstrate compliance to these standards and instill confidence in their users. In the 8 months following the publication of the International Organization for Standardization (ISO) 20387:2018 General Requirements for Biobanking standard, the Cornell Veterinary Biobank (CVB) became compliant with the standard requirements, including developing and implementing a QMS. This was achieved through the documentation of all biobanking processes, demonstration of personnel competence, the stringent control of documents and records, and ongoing evaluation of processes and the QMS. Procedures describing the control of documents and records were implemented first to provide a foundation on which to build the QMS, followed by procedures for documenting the identification of risks and opportunities, improvements, and corrective actions following nonconforming outputs. Internal audit and management review programs were developed to verify QMS performance and to monitor quality objectives. Procedures for the governance and management of the biobank were developed, including the following: organizational structure; confidentiality and impartiality policies; facility and equipment maintenance, calibration, and monitoring; personnel training and competency; and evaluation of external providers. All processes on scope were described, along with the validation and verification of methods, to ensure the fitness-for-purpose of the BMaD and the reproducibility of biobanking processes. Training sessions were held during implementation of the QMS to ensure all personnel would conform to the procedures. In April 2019, the CVB underwent third-party assessment by the American Association of Laboratory Accreditation (A2LA) and became the first biobank in the world to receive accreditation to ISO 20387:2018.

Keywords: biobank, quality management, accreditation, standards, ISO

Introduction

High-quality biological material and associated data (BMaD) are fundamental for scientific research and precision medicine benefiting both human and veterinary patients,[1] by supporting valid and reproducible results and accurate and targeted treatments, respectively. The quality of biological material is dependent on numerous factors throughout the life cycle of the samples, from collection to final utilization. Biobanks can help minimize the risk factors and improve the traceability, authenticity, and fitness-for-purpose by providing reliable services for the collection/acquisition, transport, processing, storage, and distribution of BMaD.[2]

By adhering to biobanking conformity assessment standards, including implementing a quality management system (QMS), biobanks are well positioned to provide the consistent quality control and assurance required for research and precision medicine.[3] Implementing standardized practices also helps decrease irreproducibility in research,

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which was reported in 2015 to exceed 50% of all preclinical research and result in an estimated cost of US$28,000,000 per year in the United States alone.[4] Similarly, the human fertility preservation industry would benefit from uniform biobanking practices by incorporating standard requirements in response to several highly publicized catastrophes involving equipment failure, lack of traceability, and personnel error.[5–7]

Biobanks can follow industry guidelines,[8–10] but without conformity assessment to determine if they are adhering to these guidelines, users cannot have assurance of compliance. Conformity assessment can be accomplished by first-, second-, or third-party attestation methods. As related to biobanking, first-party conformity includes self-assessment, self-enforcement, and self-declaration of conformity by biobank internal personnel. Second party includes assessment and attestation of conformity by another party outside of the biobank that has a relationship with the biobank (e.g., biobank client or user). Third party includes assessment and attestation of conformity by an impartial body, such as an accreditation body, which should also be peer evaluated to ensure the validity and impartiality of their assessment and accreditation process.[2] For example, the American Association for Laboratory Accreditation (A2LA) is an accreditation body recognized by the International Laboratory Accreditation Corporation (ILAC) for its compliance with ISO/IEC 17011 (Conformity assessment—Requirements for accreditation bodies accrediting conformity assessment bodies).

Conformity assessments performed by an impartial and objective third party can be preferable to self-assessments or user assessments. Third-party conformity assessments are the most objective and formal means of conformity assessment. Accreditation is awarded when both biobanking processes and personnel competence are assessed to be in conformance with standard requirements, whereas certification, the other form of third-party conformity assessment, does not usually include personnel competence (an exception is ISO 9001 that includes less explicit technical competence requirements than ISO 20387). Therefore, third-party accreditation is the most stringent evidence of conformity a biobank can achieve, which should provide the highest level of assurance to its users for the quality of BMaD produced.[2]

With the publication of the International Organization for Standardization (ISO) standard 20387:2018 General Requirements for Biobanking[2,11,12] in August 2018 and the subsequent announcement by A2LA of its ISO 20387 accreditation program in January 2019, biobanks gained access to third-party accreditation to this standard. As conformity to ISO 20387:2018 includes the implementation of a QMS, BMaD traceability, personnel competence, and documentation of all critical biobanking processes, biobanks accredited to this standard are a favorable option for research institutions seeking services meeting similar quality criteria, along with their funding agencies.

The Cornell Veterinary Biobank (CVB) recognized this advantage, and in its commitment to providing researchers with high-quality BMaD, achieved compliance with the requirements of the standard. The CVB was assessed by A2LA in April 2019, becoming the first biobank in the world to be accredited to an ISO biobanking standard. This article describes how the CVB attained compliance with ISO 20387:2018 and provides perspective on the challenges and opportunities encountered along the way.

Materials and Methods

Institutional involvement

Before the implementation of ISO 20387:2018, the CVB personnel had used its collective biobanking experience to improve BMaD acquisition, collection, processing, preservation, testing, analysis, storage, and distribution procedures to meet or exceed industry best practices, including the National Cancer Institute (NCI) Best Practices for Biospecimen Resources[8] and the International Society for Biological and Environmental Repositories (ISBER) Best Practices: Recommendations for Repositories.[10] The CVB director was a contributing author to the 4th edition of the ISBER Best Practices, and was subsequently recruited as an ISO expert and delegate for Technical Committee (TC) 276: Working Group 2: Biobank and Bioresources, a committee working on the development of ISO 20387. The CVB began implementing compliant practices after the publication of ISO 20387:2018, building upon the strong foundation provided by the ISBER and NCI best practices and using its director's expertise of the normative requirements. This article does not report any research using human subjects.

The first stage of implementation was to establish an intra-university consortium with diverse expertise within the Cornell University College of Veterinary Medicine (CVM). In addition to CVB management consisting of the director, sample collection coordinator, and laboratory coordinator, this committee also included key members of the Cornell University Animal Health Diagnostic Center (AHDC), CVM Information Technology (IT), CVM Human Resources (HR), CVM Facilities, Cornell Environmental Health and Safety, Cornell University Hospital for Animals (CUHA), and CVM Accounting Office.

The AHDC quality assurance manager, who had expertise with implementation of ISO 17025 (General Requirements for Competence of Testing and Calibration of Laboratories) and vast experience as an A2LA assessor, was given a part-time appointment with the CVB to oversee the development of its QMS.

Cornell veterinary pathologists and the histopathology core laboratory at the AHDC have assisted the CVB in tissue sample harvesting and authentication during surgical and postmortem tissue collections. In preparation for ISO 20387 accreditation, these service providers implemented procedures for verification and documentation of individual tissue types, aiding the CVB in meeting requirements for biological material authentication and quality control. Similarly, CUHA clinical and administrative personnel supported the CVB by participating in the collection of BMaD and providing subject expertise and records.

The CVB uses a custom-designed biobank application database as a biobank information management system (BIMS) developed and operating in compliance with ISO/IEC 27001:2013 by CVM IT to accession biological material and capture data. CVM IT was responsible for updating the database to meet ISO requirements, maintaining data security and integrity, and providing documentation of these functions as needed.

CVM HR, CVM Facilities, Cornell Environmental Health & Safety, and CVM Accounting Office contributed records, subject expertise, training requirements, and documentation as needed for compliance with normative requirements.

Developing and implementing a QMS

A QMS was developed as required in Section 8 of ISO 20387 and compiled into a QMS manual. The manual follows the same outline as the ISO standard, with each clause presenting a CVB policy and referencing procedures for how each requirement is met. Procedures relating to the QMS and structural and resource requirements were created, along with detailed documentation of all processes on scope (Table 1). Procedures describing the control of documents and records were implemented first, to provide a foundation upon which the QMS was built and to ensure that all documents generated during the creation of the QMS would be uniform within the CVB.

Preparation for assessment

Between application for ISO 20387 accreditation by A2LA on January 31, 2019 and the assessment visit on April 4, 2019, CVB personnel prepared for assessment by regularly meeting with the quality assurance manager. A documentation packet was submitted to A2LA for on-site assessment preparation. CVB operations were reduced to essential activities during the last 6 weeks before assessment, to allow CVB personnel to focus on finalizing document preparation for accreditation.

Results

Creating controlled documents and records

Between September 2018 and the assessment visit on April 4, 2019, the CVB created over 200 controlled documents in preparation for ISO 20387 accreditation by A2LA. Controlled documents were divided into five types (Table 2). Standard operating procedures (SOPs) were written to provide consistent and uniform instructions for CVB processes. Forms were created as templates to record information related to CVB procedures; forms became controlled records once data was recorded. Charts were used for graphical representations of information or abbreviated summaries of procedures. Manuals were created as detailed instructions for an entire system rather than one process. External documents were also integrated into CVB controlled documents and included equipment manufacturer instruction manuals, external submission forms, external standards, and external references for other controlled documents.

Controlled documents were categorized by process to facilitate organization and storage: collection (COL), data management (DM), distribution (DIS), equipment (EQM), management (MG), preparation and preservation (PP), quality control (QC), QMS, reception (REC), storage (STR), traceability (TRC), and transport (TRP). The documents were controlled in accordance with a detailed QMS SOP; in addition to a descriptive title, each document received a unique identifier consisting of the document type, category, identification number, and version (Table 3). The unique identifier was displayed in the document header or footer along with the issue and effective dates and page numbers. Forms, charts, manuals, and external documents affiliated with a specific SOP were identified based on that SOP category and identification number (Table 3).

All controlled documents were saved electronically in a secure cloud-based storage application maintained by Cornell IT, allowing biobank personnel to access files both locally and remotely. Paper copies of SOPs, charts, and manuals were embossed with a CVB seal indicating the number of printed copies. A master document list was generated to track each controlled document along with its unique identifier, current version, corresponding ISO 20387 sections, issue and effective dates, and the personnel responsible for

Table 1. Overview of the Cornell Veterinary Biobank Quality Management System Manual

Manual section	*Corresponding ISO section*	*Content*
General requirements	4	Impartiality and confidentiality
Structural requirements	5	Organizational structure
Resource requirements	6	Personnel responsibilities Personnel training and competency Facilities Equipment maintenance and calibration External providers
Process requirements	7	Life cycles of biological materials and associated data Specific procedures for collection, reception, transport, preparation, preservation, testing, analysis, storage, and distribution Traceability Validation and verification of methods Data management Material and data certificates (reports) Nonconforming output Complaints
Quality management system	8	Control of documents and records Identification of risks and opportunities Corrective actions following nonconforming outputs Internal audits and quality management review

Table 2. Types and Number of Controlled Documents Created During Preparation for ISO 20387 Accreditation

Document type	*Abbreviation*	*Number*
Standard Operating Procedure	SOP	76
Form	FORM	68
Chart	CHT	43
Manual	MAN	2
External Document	EXD	29
	TOTAL	218

creating, reviewing, and approving the current version. Records of obsolete versions were maintained. The master document list also indicated the storage location of paper and electronic copies.

Records were maintained predominantly using the CVB database, but also using electronic or paper forms, laboratory notebooks, electronic records from external software, and copies of external records. Record maintenance, including corrections, was performed following a strict procedure. A record master list was created to index all CVB records and the corresponding electronic location of each record type and category folder.

A corrective action report (CAR) form was created to document nonconforming output and other events that could adversely affect the quality of CVB products or services. The form was designed to record pertinent information of the nonconformity, cause analysis, corrective actions taken, risk assessment, and the monitoring and effectiveness of the corrective actions. An action item report form was created to document possible improvements identified proactively and not in reaction to a nonconformity. Information recorded in this form included a summary of the action item, associated risks, opportunities for improvement, action plan and progress summary, target date, and follow-up statement. CARs and action items were recorded in master lists to facilitate management and overview. Monthly meetings were held to review new CARs and action item records. Additional forms were created to record the results of internal audits and management reviews.

Each process listed on the CVB scope was described using SOPs, charts, and manuals to ensure correct and uniform performance by CVB personnel. Forms were created to facilitate data capture. As risks were identified using CARs and action items, these controlled documents were updated and training events took place to ensure relevant personnel were informed and in compliance.

Governance and management of the CVB

An organizational chart was created to define the CVB management structure and its place within the CVM (Fig. 1). CVB position descriptions were created detailing personnel roles, responsibilities, and authority within the organization.

Training records were created for each CVB employee to document training events and personnel competency. Cornell HR archived documentation relating to degree certificates, licenses, and other pre-requirements of each position. Cornell Environmental Health and Safety kept information related to required and recommended safety training for CVB employees.

An equipment master list was created to document and track information for critical CVB equipment. For each piece of equipment, this list documented the CVB unique identifier, manufacturer, model designation, physical location, and maintenance or calibration dates. Records detailing maintenance and calibration of equipment were maintained, and dates of calibration were displayed on equipment according to detailed SOPs. Forms were created to monitor the temperatures of various sample storage locations, as well as ambient temperature and humidity.

An external provider master list was produced to document approved external providers, their applicable processes, services or products, contact information, and quality certification.

Preparation for assessment

All biobank-related processes (acquisition, collection, preparation, preservation, testing, analysis, storage, and distribution) performed by the CVB were included in its scope of accreditation, which can be viewed in the A2LA directory of accredited organization.

A normative requirement matrix was created, in which each clause of the ISO 20387 standard was listed with a corresponding document or record referenced; this allowed CVB personnel to become familiar with the ISO 20387 requirements and how they were met by the CVB, as well as to identify which documents were missing. Action items for the creation of these documents were assigned to the appropriate biobank members and monitored to completion.

Table 3. Examples of Controlled Document Identification Nomenclature

Title	*Document type*	*Category*	*ID*	*Version*	*Unique identifier*
Organizational chart	Chart	QMS	003	1	CVB-CHT-QMS-003-V01
Tissue data capture form	Form	Reception	002–01	2	CVB-FORM-REC-002-01-V02
Monitoring refrigerator and freezer temperature	SOP	Equipment	007	1	CVB-SOP-EQM-007-V01
Refrigerator and freezer temperature log	Form	Equipment	007	1	CVB-FORM-EQM-007-V01
Traceable Refrigerator/Freezer Thermometer Plus 4730—instructions	External	Equipment	007–01	1	CVB-EXD-EQM-007-01-V01

QMS, quality management system.

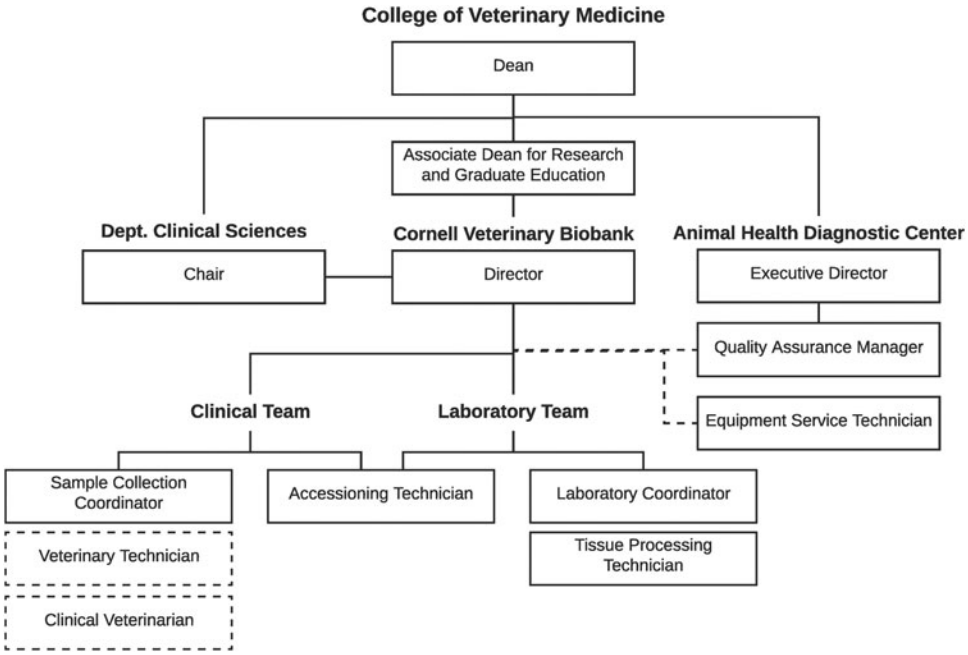

FIG. 1. Organizational chart of the CVB in relation to the Cornell University College of Veterinary Medicine. *Dashed lines* represent positions with part-time appointments to the CVB. CVB, Cornell Veterinary Biobank.

An internal audit of the CVB was performed by the quality assurance manager, where controlled documents and records pertaining to processes submitted on scope for accreditation were examined. This allowed the CVB personnel to identify nonconformities, document them in CARs, and address them as necessary. The first annual management review occurred shortly thereafter; topics reviewed included internal and external changes, fulfillment of objectives, suitability of policies and procedures, outcome of recent internal audits, external assessments, provider/recipient/user feedback, effectiveness of implemented improvements, adequacy of biological materials and associated data, results of risk identification, and other relevant factors. Action items were created as appropriate.

The documentation packet submitted to A2LA before the assessment visit included the on-site assessment preparation form (FM8102), the technical staff matrix, a subcontractor competence form, the CVB organizational chart, the equipment master list, and all QMS documents referenced in FM8102. In addition, the CVB submitted reports from the recent internal audits and management review, the list of proposed materials and processes on scope with corresponding sample life cycle charts, floor plans of CVB facilities, and a full catalog of banked biological materials.

Assessment

The CVB underwent an assessment visit on April 4 and 5, 2019, consisting of a QMS and technical review by A2LA assessors. During the QMS review, the CVB was asked to provide evidence of compliance for each clause of the ISO 20387 standard. Personnel from AHDC, CVM IT, CVM HR, CUHA, and CVM Accounting Office were asked to briefly participate to provide records for pertinent sections of the standard; these departments had been notified in advance and had been asked to be available during the assessment.

During the technical review, the assessor witnessed a tissue collection from harvest and preservation through to transportation, processing, and storage; the controlled documents and records related to these procedures were examined. A vertical audit of randomly selected sample records was performed including the above processes and the sample traceability during the entire life cycle from collection to distribution. A second part of the technical review included a vertical audit of the life cycle of randomly selected DNA samples from acquisition (as blood) through to processing, testing, storage, and distribution by reviewing supporting records and documents. The aim of the technical review was to evaluate the traceability, technical competence, appropriate use of equipment, and accurate description of processes listed on scope. Personnel listed in the technical staff matrix were interviewed with regard to their assigned processes.

Deficiencies

After the QMS and technical reviews, the A2LA assessor team provided the CVB with a list of four deficiencies identified during the assessment that needed to be addressed within 40 days for accreditation to be granted. CARs were opened for each deficiency; upon satisfactory completion of the corrective action, a copy of the report along with supporting evidence was submitted to A2LA for review.

Upon acceptance of the submitted evidence as satisfactory by the A2LA review committee, CVB was granted accreditation to ISO 20387 on April 23, 2019.

Discussion

Following the publication of ISO 20387 in August 2018, the CVB developed and implemented a QMS, became compliant with the standard for all its processes, and received accreditation by A2LA in 8 months. This unusually expedient timeline was accelerated by a number of contributing factors that may not be available to all biobanks. First, the Director of the CVB was part of the ISO working group that creates these standards and therefore had in-depth knowledge of the document before its publication. Second, the CVB was assisted by a quality assurance manager who had extensive experience

with ISO 17025, which is similar to ISO 20387, and as an accreditation assessor to that standard; this enabled the efficient development and implementation of the QMS and facilitated the adherence to the normative requirements. Third, as a core resource of the CVM, the CVB received significant support from the College and University, as leadership recognized the benefits of compliance and accreditation to an international standard for both the CVB and the users of its products and services. Although compliance with ISO 20387 and subsequent accreditation would be possible without these three factors, the CVB recognizes that they contributed to the short duration of the preparation steps. It is therefore recommended that other biobanks seeking accreditation allow for a longer timeframe and solicit support from quality assurance managers with knowledge of other ISO standards such as ISO 9001 (Quality Management) or ISO 17025.

The CVB's objectives in seeking accreditation by an independent and objective third party were to improve biobanking operations and increase stakeholder acceptability, as well as confidence in the overall program, products, and services. The CVB was able to meet its accreditation objectives and experienced improvements in operational efficiency, increased researcher interest, new financial support awarded by the National Institute on Aging, and effective marketing resulting in increased philanthropy and participation from BMaD providers.

The implementation of a QMS as part of compliance with ISO 20387 had accompanying benefits. The initial documentation of biobanking processes gave CVB personnel an opportunity to identify and address risks and areas of improvements. Once the QMS was implemented, regular data audits allowed for the detection of nonconforming records more efficiently, which led to an improvement in CVB processes. Furthermore, yearly quality management reviews help improve biobank operations, as a review of corrective actions spanning an extended time frame allows for risk patterns to be detected and for more efficient risk mitigation rather than relying on case-by-case solution of nonconformities.[13] Another benefit of implementing a QMS was the development of a controlled document system that allows for the rapid identification of required documents while maintaining control of content and distribution. In addition, CVB personnel learned to properly assess external providers to ensure that external processes and services would not negatively impact the traceability, authenticity, and fitness-for-purpose of the biobank's BMaD.

Compliance with ISO 20387 provided unforeseen benefits to CVB's response to the COVID-19 pandemic. ISO 20387 requires a contingency plan based on risk assessment to avoid the loss of BMaD in the event of natural and human-made disasters. Having contingency and disaster protection plans in place has allowed the CVB to efficiently adapt to new and rapidly changing conditions to its biobanking activities during the COVID-19 pandemic. Although not originally designed for pandemic response, the CVB disaster protection plan provided a strong foundation to address novel challenges such as supply chain disruption, restricted access to facilities, and long-term shutdown. Competency gained by biobank personnel working in compliance with ISO 20387 increased CVB's ability to develop and implement new procedures in a more efficient manner, thereby minimizing the impact of pandemic-related challenges on biobanking operations.[14]

Conversely, maintaining an ISO 20387-compliant QMS has increased the documentation required for each process and has added new extensive processes such as data audits and report creation. This requires biobank personnel to be adaptable as they find balance between meeting the normative requirements and operating efficiently with limited resources. One example was the creation of a hybrid record system consisting of both electronic and paper records, allowing for continued material and data traceability, while being flexible enough to accommodate CVB process and data management limitations. Another challenge was the need to educate both users/researchers and external providers on normative requirements so they could better understand the changes in processes. The CVB has found both users/researchers and external providers to be generally receptive to these changes once the requirements have been explained along with the increased benefits achieved from being ISO 20387 compliant.

Interpretation of the normative requirements also varied among the members of the intra-university consortium. As the ISO implementation guidelines were not yet published, the CVB proceeded using its collective best judgment; some of the deficiencies received were a result of the A2LA assessors having a different interpretation than that of the CVB. The publication of the ISO implementation guidelines may resolve some of these ambiguities and help other biobanks implement the standard in a more uniform manner.[15] In addition, maintaining accreditation by A2LA is a continuous process with yearly assessments. One year after the initial assessment, the CVB will undergo a surveillance on-site visit to ensure that compliance to the standard has been maintained. In particular, it will focus on the aspects related to the deficiencies received during the initial assessment. On year 2, A2LA will perform a renewal assessment visit, similar to the original visit, and will complete an in-depth assessment of the biobank's QMS and processes on scope. On year 3, an annual review is completed off-site by A2LA. This 2-year cycle of renewal assessment and annual review will then repeat, ensuring the continued compliance with ISO 20387.

Accreditation to ISO 20387 can be achieved by all types of biobanks, including human, animal, plant, and microorganism, regardless of size or equipment availability.[2] This flexibility is possible because the standard does not set requirements for how the processes should be performed, but rather how they should be described and recorded, with a large emphasis on the QMS.[15] Before the publication of ISO 20387, biobanks traditionally obtained certification to ISO 9001 (Quality Management), or accreditation to ISO 15189 (Medical Laboratories—Requirements for Quality and Competence), and/or ISO 17025 (General Requirements for Competence of Testing and Calibration of Laboratories), and demonstrated first-party compliance with ISBER Best Practices through their Self-Assessment Tool.[16] This new standard was created to fill a gap in international biobanking standards,[17] and intended to be implemented either independently or as a complement to ISO 9001, 15189, and 17025.[15]

Receiving accreditation by an ILAC-recognized third party such as A2LA informs clients that the CVB adheres to international standards and can provide an unbroken chain of traceability for biological material processed by competent personnel using validated processes and calibrated equipment. This in turn allows users/researchers to perform reliable experiments using appropriate biological materials and processes, which yields repeatable and trustworthy results.[18] In

an industry where sample underutilization is a widespread concern,[19] implementation of QMS practices that increase the integrity and value of biological materials and samples can only be beneficial.[20] In addition to ensuring data traceability and integrity, the standardized collection of pre-analytical data for biobanked samples is conducive to the implementation of the Biospecimen Reporting for Improved Study Quality (BRISQ) recommendations, which advocate for the publication of key pre-analytical factors that influence experimental outcomes and reproducibility.[21] Similarly, standardization of biobank processes is paramount to ensuring uniform, reliable, and predictable sample quality in multisite and long-term studies.[22] As biobanking is an integral part of precision medicine,[23,24]compliance with ISO 20387 in addition to ISO 15189 helps ensure that the development of new diagnostics and treatments is based on accurate and fit-for-purpose BMaD, and that patient samples are being banked using a dynamic system that constantly evolves to reduce risks and implement improvements.[25]

A review of the ISBER Self-Assessment Tool completed by 62 biobanks between 2015 and 2017 revealed that 43% do not have a QMS in place,[16] which suggests that much progress is needed within the international biobanking community to achieve standardization. As more users/researchers become educated to the benefits of standardized processes in biobanking,[26,27] including consistency and reliability of BMaD, they may request evidence of this compliance,[28] which in turn will encourage biobanks to achieve accreditation to biobanking standards. By voluntarily and proactively seeking accreditation to ISO 20387, and educating their users on the benefits of a QMS, biobanks can share the benefits experienced by the CVB and increase user satisfaction and confidence in their biobanking products and services.

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