INTRODUCTION

Effective biobanking is underpinned by standardization and best practices. Biobanks should follow international standards and best practices to ensure the biospecimens they store are fit for research purposes and the results of studies conducted using biospecimens are reproducible. One key international standard that provides confidence in biobanking and plays a role in the standardization of biobanking activities is ISO 20387:2018. It specifies the technical and quality requirements for the competence, impartiality, and consistent operations of biobanks. ISO 20387 compliance applies to all biobanks storing biological materials from multicellular organisms, such as humans and microorganisms, for research and development.

For quality biobanking management, ISBER Best Practices (BP) serve as one of the key documents to supplement the ISO 20387:2018 standard, harmonizing scientific, technical, legal and ethical issues. ISBER BP enable biobanks to develop standardized methodologies for collection, handling, storage, retrieval, and distribution of specimens, enabling them to provide high-quality specimens that meet necessary regulatory and ethical requirements.

ISO 20387:2018 and ISBER BP: COMMONALITY

Biobanking guidelines vary widely from one biobank to another; however, biobanks find it challenging to implement the various standards and best practices. Some of the commonalities between ISO 20387 and ISBER BP are listed in Table 1 below.

Table 1: Some of the requirements of international biobanking standards and ISBER BP

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Description</th>
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<tr>
<td>Training of biobank personnel</td>
<td>Biobanks should maintain a record of all materials and supplies used to perform the biobank procedures on a daily basis. Biobanks should also maintain a record of the vectors, catalog number, lot number, and expiration dates of the materials and supplies used.</td>
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<tr>
<td>Instrument calibration and maintenance</td>
<td>Biobanks should use equipment whose uncertainty intervals are provided by manufacturer's specifications or other criteria. Biobanks should perform calibration reading twice before and after calibration. Biobanks should also check the date of alarm of the source of the equipment performing the calibration, the valid range number of the contratual equipment, and the ISBER followed to perform the calibration.</td>
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<tr>
<td>Data security</td>
<td>Biobanks should ensure that the entire biospecimen data is backed up on a secure remote server daily or at regular intervals depending on the frequency of data modification to prevent data loss. To ensure data integrity, only authorized personnel should be allowed access to confidential records and documents. The access rights should be assigned based on the level of access permitted by the ISBER. Based on the staff roles, some individuals may be able to view only the sample availability and others may be able to edit and enter sample data.</td>
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<tr>
<td>Chain of Custody (CoC)</td>
<td>Biobanks should maintain a CoC for biobank specimens as it is transferred from one individual to another. The label should have an ID that can be used to uniquely identify each sample in the biobank. If Protected Health Information (PHI) is present in the system, then only authorized individuals should be able to generate an ID. A unique ID should be assigned to each shipment for easy tracking. The electronic shipping log should keep track of shipping details such as the shipment ID, shipment source and destination, type of document shipped, Material Transfer Agreements (MTA), the date of shipment, and the date on which the shipment was received or rejected.</td>
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ROLE OF INFORMATICS IN ACHIEVING ISO 20387:2018 AND FOLLOWING ISBER BEST PRACTICES

To keep track of the recommendations under the international standards and BP, a need was felt to automate the processes of securing specimen data, patient consents and anonymization. LIMS or an information management system offers an automated solution to meet the various requirements of specimen management. An information management system or a LIMS can prove to be an indispensable tool.

Some of the ways in which an information management system can help biobanks in automating workflows and quality management, to render biobanks, an information management system or a LIMS can prove to be an indispensable tool.

1. Managing all internal and external documents, such as SOPs, Material Transfer Agreements (MTA). An information management system helps ensure that the documents are controlled, periodically reviewed, the revision history of documents is tracked to help staff always identify and refer to the latest version of a document.
2. Reporting: The biobank information management system should have the capability to generate various reports, such as inventory reports, clinical trial samples, and audit reports, to support the biobank workflow. For example, if EHR/Health Information (PHI) is present in the system, then any authorized individuals should be able to generate such reports. PHI should be in place for the use and destruction of PHI. An information management system should prevent unauthorized access to PHI.
3. Sample tracking: Biobanks should be able to trace the containers in which the samples are stored and their exact storage locations in freezers.
4. Ensuring data security is one of the important requirements of ISO 20387 and ISBER BP. The biobank information management system must ensure secure storage and transmission of data because it stores confidential data of patients. Additionally, biobanks must enter into a service-level agreement with the service providers to ensure that the data is backed up, archived, and any changes of data loss is reported. The information management system should enable biobank managers to assign role-based data access to the biobank staff, preventing unauthorized data access.

CONCLUSION

Biobanks should meet the requirements of ISO 20387 and follow best practices for promoting confidence in biobanking and for assuring the quality of specimens. Though the requirements can be fulfilled through manual processes, LIMS or an information management system offers an automated solution to meet the various requirements of ISO 20387 and ISBER BP. A cloud-based information management system enables biobanks to securely store samples, including PHI, and share data in real-time. Furthermore, it helps biobanks meet the quality standards so that they can provide high-quality specimens for advanced research and drug discovery.