ICS 07.080
CCS C 40

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 37864-2019

General requirements of quality and competence for biobank

Issued on: August 30, 2019 **Implemented on: August 30, 2019**

Issued by: State Administration for Market Regulation, China National Standardization Administration

Table of Contents

1 Scope 1
2 Normative references 1
3 Terms and Definitions 1
4 General requirements 6
4.1 General 6
4.2 Impartiality 7
4.3 Confidentiality 7
5 Structural requirements 7
6 Resource Requirements 8
6.1 General 8
6.2 Personnel 8
6.3 Infrastructure/Special Site and Environmental Requirements 9
6.4 Externally provided processes, products and services 9
6.5 Equipment 10
7 Process Requirements 11
7.1 General 11
7.2 Collection of biological samples and related data 11
7.3 Receiving and distributing biological samples and related data 11
7.4 Transport of biological samples and related data 12
7.5 Traceability of biological samples and related data 13
7.6 Preparation and preservation of biological samples 13
7.7 Storage of biological samples 13
7.8 Quality control of biological samples and related data 14
7.9 Confirmation and verification of the method 15
7.10 Information and Data Management 15
7.11 does not match output 15
7.12 Reporting requirements 16
7.13 Complaint 17
8 Management requirements 17
8.1 Method 17
8.2 Quality Management System Document Information Record (Method A) 18
8.3 Quality Management System Document Control (Method A) 18

8.4 Record (Method A) 18
8.5 Risk Prevention Measures (Mode A) 18
8.6 Improvements (method A) 19
8.7 Corrective Action (Method A) 19
8.8 Internal Audit (Method A) 19
8.9 Quality Management Review (Method A) 20
Appendix A (Normative) Document Requirements 21
Appendix B (Informative Appendix) Implementation Guide for Appendix A 23
Appendix C (informative) Quality Management System Options 27
Foreword
8.1 Method 17
8.2 Quality Management System Document Information Record (Method A) 18
8.3 Quality Management System Document Control (Method A) 18
8.4 Record (Method A) 18
8.5 Risk Prevention Measures (Mode A) 18
8.6 Improvements (method A) 19
8.7 Corrective Action (Method A) 19
8.8 Internal Audit (Method A) 19
8.9 Quality Management Review (Method A) 20
Appendix A (Normative) Document Requirements 21
Appendix B (Informative Appendix) Implementation Guide for Appendix A 23
Appendix C (informative) Quality Management System Options 27
Foreword

Appendix C (informative) Quality Management System Options 27

Reference 28

Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard uses the translation method equivalent to ISO 20387.2018 "General requirements for biological samples stored in biotechnology biological samples." The documents of our country that have a consistent correspondence with the international documents referenced in this standard are as follows.

---GB/T 7408-2005 Data element and exchange format information exchange date and time

representation (ISO 8601.2000, IDT)

This standard has made the following editorial changes.

--- Change the standard name to "General requirements for quality and capabilities of biological sample libraries." This standard is proposed and managed by the National Biological Sample Standardization Technical Committee (SAC/TC559).

This standard was drafted. Biochip Shanghai National Engineering Research Center, Guangdong Provincial Hospital of Traditional Chinese Medicine, China National Accreditation Service for Conformity Assessment, Fudan University Affiliated Tumor Hospital, Peking Union Medical College Hospital, Zhongshan Hospital of Fudan University, China Center for Disease Control and Prevention, Nanjing Gulou Medical Institute, Fudan University, Xinhua Hospital affiliated to Shanghai Jiao Tong University School of Medicine, Renji Hospital affiliated to Shanghai Jiao Tong University School of Medicine, Shanghai Core Super Biosciences Technology Co., Ltd., Shanghai Pharmaceutical Clinical Research Center, Jiangsu Cancer Hospital, Shanghai First Maternal and Child Health Hospital, Zhejiang Cancer Hospital, Shenzhen Huada Life Science Research Institute, Eastern Hepatobiliary Surgery Hospital, National Institute of Health and Family Planning Science and Technology, People's Liberation Army General Hospital, Day Tianjin First Central Hospital, Tianjin Medical University Cancer Hospital, Sun Yat-sen University Cancer Center, Peking University Affiliated Tumor Hospital, Air Force Military University Xijing Digestive Disease Hospital, China Institute of Metrology.

The main drafters of this standard. Yan Hengjun, Chen Qubo, Yan Peijun, Zhang Xiaoyan, Li Junyan, Xu Jingman, Guo Dan, Li Ka, Ye Qing, Xu Medie, Wei Qiang, Du Xiang, Sun Menghong, Yang Yajun, Wang Weiye, Kang Xiaonan, Zhang Kehao, Du Lili, Zhang Yong, Yan Liangliang, Zhou Xuexun, Yin Rong, Li Qian, Zheng Zhiguo, Xu Xun, Li Qiwei, Yang Yuan, Gao Huafang, Zhao Xiumei, Zheng Hong, Wang Zhenglu, Li Haixin, Jia Weihua, Zhang Lianhai, Nie Yongzhan, Yao Haizhen, Wang Jing.

General requirements for quality and capabilities of biological sample banks

1 Scope This standard specifies the general requirements for the capacity, fairness, and continuous operation (including quality control) of biological sample banks to ensure biological samples and numbers.

According to the quality.

This standard applies to all institutions engaged in the preservation of biological samples, including the preservation of multicellular organisms (eg humans, animals, etc.) for research and development.

A library of biological samples of fungi and plants) and microorganisms. Biobank users, regulatory agencies, peer assessment organizations, and accredited organizations can use this Standards to confirm or recognize the capabilities of a biological sample bank.

This standard does not apply to biological samples for food, seed production, analysis and treatment.

Note 1. International, national and regional regulations or requirements also apply to specific provisions of this standard.

Note 2. Institutions that collect and use human samples for diagnostic and therapeutic purposes first comply with ISO 15189 and other clinical standards.

2 Normative references The following documents are indispensable for the application of this document. For dated references, only dated versions apply to this article.

Pieces. For undated references, the latest edition (including all amendments) applies to this document.

ISO 8601 data element and exchange format information exchange date and time representation (Dateelementsandinterchange formats-Informationinterchange-Representationofdatesandtimes)

3 Terms and definitions The following terms and definitions apply to this document.

3.1 Registration accession/logging Record new biological samples and/or related data.

3.2 Get acquisition The act of obtaining ownership and/or regulatory power of the sample and/or related data.

3.3 Related data associateddata Accessory information for biological samples, including but not limited to research data, phenotypic data, clinical data, epidemiological data, and biological sample processing The data obtained by the process, etc.

3.4 Sample identification The process of determining the authenticity of a sample by determining the properties of the biological sample at a certain level by a specific technical means/document.

3.5 Biological sample bank biobank The legal entity or part of the biological sample collection (3.6).

GB/T 37864-2019 (General requirements for quality and capabilities of biological sample banks)

ICS 07.080 C40 National Standards of People's Republic of China General requirements for quality and capabilities of biological sample banks Generalrequirementsofqualityandcompetenceforbiobank (ISO 20387.2018, Biotechnology-Biobanking-Generalrequirementsforbiobanking, IDT)

Published on.2019-08-30 2019-08-30 implementation State market supervision and administration China National Standardization Administration issued Content Foreword III

1 Scope 1