SAMPLE MANAGEMENT SYSTEM

1. INTRODUCTION

The purpose of this Sample Management System is to ensure that our sample management process is compliant, efficient, safe, and of controlled quality. This system applies to all employees of SRS Nutrition Express B.V. (hereinafter referred to as "SRS") and Xi'an Europeherb Biotechnology Co., Ltd. (hereinafter referred to as "Europeherb"), regardless of their department or responsibilities, and it is the responsibility of all employees to comply with and enforce the provisions of this system.
SRS and Europeherb are committed to producing and providing high-quality products and services, including food, nutritional supplements, and related health and beauty products. To ensure the quality, safety, and compliance of our products and to meet regulatory requirements, we recognize the importance of sample management. This system will provide us with a framework to ensure that the handling and management of all samples meet the highest standards and can effectively track and record the sample processes.

In the context of this introduction, we commit to:

- Comply with all relevant regulations and standards, including food safety, drug regulations, and health product regulations.
- Ensure that our sample management process is not only compliant but also of high quality and traceability.
- Provide necessary training and support to employees to ensure that they understand and adhere to this system.
- Continuously improve our sample management practices to adapt to changing industry standards and regulatory requirements.
- This Sample Management System will be a key tool in ensuring quality and compliance. We look forward to active participation from all employees in adhering to the provisions of this system to achieve our common goals.

2. DEFINITIONS

In this system, the following terms are defined as follows:

2.1 Sample

A sample refers to raw materials or original components obtained from suppliers or other sources for use in product manufacturing or processing. This includes but is not limited to various raw materials, such as chemicals, food ingredients, raw pharmaceutical materials, and more.

2.2 Sample Identification Number

A sample identification number is a unique set of identifiers used to label and track each raw material sample. This number typically includes the following information:
Sample source: Indicates the source of the sample, such as supplier name, batch number, and more.
Sample type: Indicates the type or category of the sample to facilitate differentiation between different types of raw materials.
Number sequence: A combination of characters and numbers used to uniquely identify each raw material sample.

2.3 Sample Label

A sample label is attached to each raw material sample and includes the sample identification number, collection date, collector, and relevant information. Labels must be legible to ensure the traceability and identification of samples. Labels typically include the following information:

- Sample identification number: A combination of characters and numbers used to uniquely identify each raw material sample.
- Collection date: Indicates the specific date on which the sample was collected to understand the sample's timeliness.
- Collector: Identifies the individual or team responsible for collecting the raw material sample.
- Relevant information: Any additional information, such as supplier information, purchase date, batch number, and more.

2.4 Sample Storage

Sample storage refers to the physical or digital storage of raw material samples to ensure their stability and integrity. This includes, but is not limited to, the management of the following:
Physical storage: Storing raw material samples in designated storage areas, temperature-controlled equipment, or containers to prevent contamination,

degradation, or damage.
Digital storage: Storing digital samples (such as related documents, batch information, etc.) in a secure, backup digital environment to ensure data integrity and security.

2.5 Sample Tracking

Sample tracking is the process of recording the entry, storage location, usage, and disposal of raw material samples. Tracking raw material samples is to ensure that each sample can be accurately identified, located, and tracked to meet the purposes of quality control, compliance, and supply chain management.

2.6 Sample Testing

Sample testing is the process of sending raw material samples to third-party laboratories (such as Eurofins, SGS Laboratories, etc.) for testing, analysis, or verification. Sample testing typically involves submitting samples to the laboratory and collecting test results to ensure the quality and compliance of raw materials.

2.7 Sample Retention

Sample retention refers to the practice of retaining samples of each batch of raw materials for at least two years before selling the batch. This is done for future retesting and tracking in case of any issues. The purpose of sample retention is to ensure.

3. RESPONSIBLE PARTIES AND RESPONSIBILITIES

3.1 Sample Manager

The Sample Manager plays a critical role in the management of raw material samples. The following are the main responsibilities of the Sample Manager:

- Sample Collection and Labeling: Responsible for coordinating and executing the collection and labeling of raw material samples, ensuring that each sample has a unique sample number and clear labels.
- Sample Storage: Responsible for arranging and overseeing the physical

storage of raw material samples, including selecting appropriate storage conditions and containers to ensure the stability and integrity of samples.

- Sample Tracking: Recording the entry, storage location, and usage of each raw material sample to ensure traceability and compliance.
- Sample Testing: Assisting in the preparation and management of the sample testing process, including liaising with third-party laboratories and collecting test results.
- Sample Retention: Responsible for maintaining the sample retention repository, including proper storage, recording, and retention of samples for future retesting and tracking.

3.2 Department Manager

Department Managers assume supervisory and auditing responsibilities in the management of raw material samples to ensure compliance and quality control. The following are the main responsibilities of Department Managers:

- Supervision and Enforcement: Overseeing the sample management practices within the department to ensure compliance with the provisions of the Sample Management System.
- Quality Control: Ensuring compliance with quality control procedures for raw material samples to meet product manufacturing and compliance requirements.
- Training and Support: Providing employee training and support to ensure their understanding and compliance with the requirements of the Sample Management System.
- Compliance Review: Assisting in regular reviews and evaluations of the compliance and effectiveness of the Sample Management System and driving improvements.

3.3 Employees

All employees have a responsibility to comply with and enforce the provisions of the Sample Management System. The following are the main responsibilities of employees:

- Sample Handling: Responsibly handling raw material samples in compliance with the requirements of the Sample Management System, including collection, labeling, storage, tracking, testing, and disposal.
- Training Participation: Actively participating in employee training programs to ensure an understanding and adherence to the requirements of the Sample Management System.
- Issue Reporting: Reporting any issues, anomalies, or quality concerns related to raw material sample management to facilitate issue resolution

and improvement.

- These responsible parties and their duties will contribute to efficient management and supervision of raw material samples throughout the supply chain while maintaining compliance and quality control.

4. SAMPLE COLLECTION

4.1 Collection Procedure

4.1.1 Sample Sources

The collection of raw material samples should begin with traceable sources. Here are some examples of sample sources:

- Suppliers: Samples obtained from suppliers should undergo careful inspection and selection to ensure they meet product quality and compliance requirements before collection.
- Production Batches: For received raw materials, samples should be collected based on production or supply batch to ensure samples represent the quality of specific batches.
- New Product Development: In the new product development phase, raw material samples should be collected according to the research and testing requirements.
- Quality Issue Investigation: If quality issues or complaints arise, samples should be collected based on the nature of the problem for investigation and analysis.

4.1.2 Collection Methods

The methods for collecting raw material samples should be chosen based on the nature and source of the samples. Here are some possible collection methods:

- Sampling Equipment: Use appropriate sampling equipment such as containers, bottles, bags, etc., for sample collection.
- Sampling Tools: Use suitable tools like scoops, tongs, tubes, etc., for collecting solid or liquid samples.
- Collection Procedures: Follow standardized collection procedures to ensure sample consistency and repeatability.
- Collection Locations: Collect samples in appropriate locations to avoid external contamination.

4.2 Recording and Labeling

4.2.1 Sample Numbers

Each raw material sample must be assigned a unique sample number to ensure traceability and identification. Sample numbers typically include the following information:

- Sample Source: Indicates the source of the sample, usually the supplier's name or identifier.
- Sample Type: Indicates the type or category of the sample for easier differentiation of different types of raw materials.
- Number Sequence: A combination of digits or letters used to uniquely identify each raw material sample.
- Sample number assignment should start at the initial stage of sample collection and should follow consistent naming conventions. This ensures the continuity of identification throughout the entire sample management process.

4.2.2 Sample Labels

Every raw material sample must have a clear, readable sample label attached to ensure the uniqueness and traceability of the sample. Sample labels should include the following information:

- Sample Number: The label must prominently display the sample number for tracking and identification.
- Collection Date: Indicates the specific date of sample collection for understanding the sample's timeliness.
- Collector: Identifies the individual or team responsible for collecting the raw material sample.
- Relevant Information: Any additional information, such as supplier information, purchase date, batch number, etc.

4.3 Collection Procedure Compliance

During the collection of raw material samples, strict adherence to the provisions of this system is necessary to ensure compliance and quality control. Employees should receive relevant training to understand the requirements of the collection procedure to ensure the proper collection and labeling of samples.

4.4 Collection Records

Accurate collection records must be maintained for each raw material sample, including information such as sample source, collection date, collector, and sample number. These records should be stored properly and provided to relevant parties for tracking and auditing when needed.
These detailed guidelines and procedures will help ensure that the collection process of raw material samples is compliant, traceable, and of high quality. Employees should consistently adhere to these regulations to maintain the quality of samples and the integrity of data.

5. SAMPLE LABELING

5.1 Sample Numbers

Each raw material sample must be assigned a unique sample number to ensure its distinct identification and traceability. Sample numbers are a core element of sample management and typically include the following information:

- Sample Source: Indicates the source of the sample, often the name or identifier of the supplier.
- Sample Type: Indicates the type or category of the sample for easier differentiation of different types of raw materials.
- Number Sequence: A combination of digits or letters used to uniquely identify each raw material sample.

Sample number assignment should commence during the initial stages of sample collection and should follow consistent naming conventions. This ensures the continuity of identification throughout the entire sample management process.

5.2 Sample Labels

Each raw material sample must have a clear, readable sample label attached to ensure the uniqueness and traceability of the sample. Sample labels should include the following information:

- Sample Number: The label must prominently display the sample number for tracking and identification.
- Collection Date: Indicates the specific date of sample collection for understanding the sample's timeliness.

- Collector: Identifies the individual or team responsible for collecting the raw material sample.
- Relevant Information: Any additional information, such as supplier information, purchase date, batch number, etc.

Sample labels should be robust, durable, and remain legible during storage and transportation. Labels should be correctly affixed to or attached to the sample containers to prevent detachment or damage.

5.3 Label Consistency

To ensure the consistency of sample labeling, clear labeling procedures should be established, and employees should be trained to comply with these procedures. This includes guidelines on how to assign sample numbers, complete labels, and record information on the labels. Employees should consistently follow these procedures to ensure the correct labeling of samples.

5.4 Label Review and Maintenance

In the sample management process, sample labels should be regularly reviewed to ensure they remain clear and consistent with sample records. If labeling errors or wear are discovered, labels should be corrected or replaced promptly to prevent confusion or difficulties in sample tracking.

These detailed guidelines and procedures will help ensure that the labeling of raw material samples is accurate, consistent, and traceable. Label accuracy is crucial for quality control and compliance.

6. SAMPLE STORAGE

6.1 Physical Storage

6.1.1 Storage Conditions

The physical storage conditions for raw material samples should be determined based on the characteristics and requirements of the samples. Here are some common examples of storage conditions:

- Temperature Control: Some raw materials may need to be stored at specific temperatures to ensure their stability. In such cases, temperature-controlled equipment should be used to maintain the appropriate temperature.
- Humidity Control: Some raw materials are sensitive to humidity and should

be stored in either low or high humidity environments. Humidity control equipment can be used to maintain the desired humidity levels.

- Light Protection: Light can have adverse effects on certain raw materials. These samples should be stored under light-avoiding conditions, such as using opaque containers or storing them in a dark environment.

6.1.2 Container Selection

Raw material samples should be stored in appropriate containers to ensure they are not contaminated, degraded, or damaged. Container selection should consider the following factors:

- Material Compatibility: The container material should be compatible with the sample to prevent material cross-contamination.
- Sealability: Containers must have good sealing to prevent the entry of external air, humidity, or contaminants.
- Label Adherence: Container surfaces should be able to adhere sample labels and maintain label clarity.

6.2 Digital Storage

6.2.1 Data Storage Environment

In addition to physical storage, digital samples (such as related documents and batch information) also require an appropriate storage environment. Here are some considerations for digital sample storage:

- Security: Digital samples must be stored in a secure digital environment to prevent unauthorized access, modification, or loss.
- Backup: Regular backups of digital samples should be made to prevent data loss or damage.
- Access Control: Access to digital samples should be restricted and managed through access control and permission management to ensure that only authorized personnel can access them.

6.3 Recording and Tracking

6.3.1 Recording Storage Locations

Accurate records of the storage locations for each raw material sample must be maintained. These records should include information such as storage unit, shelf number, refrigeration room, or digital storage file path to facilitate the locating and retrieval of samples.

6.3.2 Expiry Date Management

The expiry dates of raw material samples should be carefully recorded, and

appropriate actions should be taken as the expiry date approaches. Expired samples should be promptly disposed of or updated to ensure sample quality and compliance.

6.4 Temperature Monitoring

If raw material samples require storage at specific temperatures, temperature monitoring devices should be installed to regularly monitor and record storage conditions. This allows for the timely detection of temperature anomalies and the implementation of measures to prevent sample damage.
These detailed guidelines and procedures will help ensure that both the physical and digital storage of raw material samples meet requirements and can be accurately tracked and retrieved when needed. Proper storage conditions are crucial for ensuring sample quality and traceability.

7. SAMPLE TRACKING

7.1 Entry and Exit Records

7.1.1 Sample Receipt and Dispatch Records

Detailed records must be maintained for each entry and exit of raw material samples. This includes the following information:

- Sample Number: Identifying a unique number for each sample.
- Entry and Exit Date and Time: Recording when samples entered or exited the storage area or laboratory.
- Source and Destination: Indicating the source of the sample (e.g., supplier or department) and its destination (e.g., laboratory or testing facility).
- Receiver Information: Recording information about the personnel or contractors responsible for the sample's receipt and dispatch.

7.1.2 Acknowledgment and Acceptance

Acknowledgment and acceptance must be conducted when samples enter or leave the storage area or laboratory. This includes:

- Acknowledgment Records: Recording the name and signature of the personnel who acknowledged the sample to confirm that the received sample matches the records.
- Acceptance Records: Recording the name and signature of the personnel responsible for the sample's acceptance to confirm the sample's integrity and compliance.

7.2 Storage Location Tracking

7.2.1 Storage Location Records

The storage location of each raw material sample must be clearly recorded. This includes information such as shelf number, storage unit, refrigeration room location, or digital storage file path. Storage location records should be updated regularly to ensure accurate tracking of samples.

7.2.2 Storage Location Identification

Storage areas should have clear identifications to assist employees in quickly locating samples. Identifications should include shelf numbers, area names, or digital storage folder names. These identifications should match the storage location records.

7.3 Usage and Operation Tracking

7.3.1 Sample Usage Records

Usage of raw material samples must be recorded. This includes the purpose for which the sample was used, the usage date, and information about the user. These records help ensure compliance with sample usage and can be used to track sample history.

7.3.2 Operation Records

If any operations are performed on the sample during the handling process, such as sub-sampling, mixing, or processing, detailed information about these operations must be recorded. This includes the operation date, information about the operator, and the nature of the operation.

7.4 Disposal Records

7.4.1 Sample Disposal Records

When raw material samples reach their storage expiration date or are no longer needed, they must be disposed of following prescribed disposal procedures. Disposal records should include:

- Sample Number: Identifying the sample to be disposed of.
- Disposal Date: Recording when the sample was disposed of.
- Disposal Method: Describing how the sample was destroyed, recycled, or archived.
- Information of the Person Responsible: Recording information about the

employee executing the disposal.

7.5 Tracking Audits

Regular tracking audits and verifications should be conducted to ensure that all sample tracking records are accurate, complete, and compliant. Any issues or inconsistencies found should be promptly addressed and corrected.
These detailed guidelines and procedures will help ensure that the sample tracking process for raw materials is accurate and traceable, meeting quality control, compliance, and research requirements. Sound tracking procedures are essential for maintaining the integrity and quality of sample data.

8. SAMPLE SUBMISSION

8.1 Submission Procedure

8.1.1 Lab Selection

Before submitting raw material samples for testing, an appropriate third-party laboratory must be selected, one that possesses the required testing capabilities and qualifications. Consider the following factors when selecting a lab:

- Qualifications and Certifications: Ensure that the laboratory has the relevant certifications and qualifications to perform the required tests.
- Testing Capabilities: Evaluate whether the lab has the equipment and expertise to conduct the necessary tests.
- Historical Record: Review the lab's historical records to understand the accuracy and reliability of their testing.
- Schedule: Negotiate an appropriate testing schedule with the lab to ensure timely results.

8.1.2 Sample Preparation

Prior to submission, samples must be prepared according to the requirements of the laboratory. This includes ensuring that the sample labels are clear and legible, and using appropriate packaging and transport methods to prevent sample contamination or damage.

8.2 Submission Records

8.2.1 Record Sample Information

During submission, detailed information about the sample must be recorded, including the sample name, number, collection date, source, and any other relevant information. This helps ensure sample tracking and its association with test results.

8.2.2 Record Submission Date

The submission date of the sample should be recorded to track the progress and schedule of the testing.

8.3 Testing Reports

8.3.1 Test Results

Once the laboratory provides testing results, a thorough review of the report is necessary. The testing report should include test results, methods, standards, units, and any key comments.

8.3.2 Result Evaluation

Based on the testing results, an assessment of the quality and compliance of the raw material must be made. If any issues or anomalies are discovered, appropriate actions, such as discontinuing use or investigating the cause, should be taken.

8.4 Conclusion and Records

8.4.1 Record Test Results

The results of laboratory testing should be recorded in files for future reference and auditing. The records should include sample information, submission date, test results, and conclusions.

8.4.2 Conclusion and Decision

Based on the testing results and conclusions, decisions must be made, including whether to accept the raw material, whether further testing is required, or whether other actions need to be taken.

By ensuring the compliance and detail of sample submission procedures and records, a company can maintain the quality and compliance of raw materials,

meeting regulatory requirements and customer expectations. Sample submission is a crucial step in ensuring a company provides high-quality products and must be handled with care and continuous improvement.

9. SAMPLE RETENTION

9.1 Purpose of Retention

The primary purpose of sample retention is to ensure that raw material samples can still be accessed and tested when needed in the future. This helps meet regulatory requirements, address quality issues, and conduct further research and analysis.

9.2 Retention Procedure

9.2.1 Sample Selection

When retaining samples, it is essential to choose which samples need to be preserved based on their importance and potential risks. Typically, each batch of raw material samples should be retained, but selection can be made based on actual circumstances.

9.2.2 Sample Preparation

Before retention, it must be ensured that sample labels are clear and legible, and appropriate packaging and storage conditions are used to prevent sample contamination or damage.

9.3 Sample Storage

9.3.1 Storage Conditions

Samples should be stored properly based on their nature and requirements. This may include refrigeration, freezing, drying, or other specific conditions. Storage conditions should be clearly indicated on the sample labels.

9.3.2 Storage Location

The company should designate specific storage locations to ensure samples are easy to access and manage. Storage locations should meet specified environmental conditions, such as temperature, humidity, and security.

9.4 Sample Tracking

9.4.1 Sample Labeling

Each sample must be clearly labeled, including the sample's name, number, collection date, and storage conditions. This helps ensure sample tracking and traceability.

9.4.2 Record Entry and Exit

Record the entry and exit of each sample, including the date, reason, and personnel involved. This helps track sample usage and ensures sample integrity.

9.5 Sample Retention Period

The company should specify the retention period for each sample. In general, raw material samples should be retained for at least two years, but in some cases, longer retention periods may be required based on regulations and company policies.
Through a compliant sample retention procedure, the company can ensure the traceability and compliance of raw materials, addressing potential quality issues and regulatory requirements. Sample retention not only helps in problem-solving but also provides essential data for future research and improvements.

10. SAMPLE DISPOSAL

10.1 Disposal Procedure

10.1.1 Disposal Decision

Before deciding to dispose of raw material samples, careful consideration must be given. Some factors to consider include:

- Expiration Date: Check the sample's expiration date to ensure expired samples are not used.
- Usage Status: Determine if the sample has been completely used or if there are remaining portions.
- Quality Issues: If there are quality issues or abnormalities with the sample,

consider how to dispose of it.
- Regulatory Requirements: Comply with all applicable regulations and legal requirements to determine if special disposal procedures are necessary.

10.1.2 Disposal Methods

Different disposal methods can be chosen based on the nature of the sample and the reason for disposal, including some examples:
- Destruction: Some raw material samples need to be destroyed to prevent improper use or potential hazards.
- Recycling: Recyclable samples can be recycled and reused following sustainability principles.
- Archiving: Some samples may need long-term storage in designated archival areas for future reference or audit.

10.2 Disposal Records

10.2.1 Record Disposal Information

Detailed records must be maintained for each disposed raw material sample to ensure disposal is compliant. These records should include the following information:
- Sample Number: Identifying the sample being disposed of.
- Disposal Date: Recording when the sample was disposed of.
- Disposal Method: Describing how the sample was disposed, such as destruction, recycling, or archiving.
- Information of the Person Responsible: Recording information about the employee performing the disposal, including their name and signature.

10.2.2 Disposal Audits

Disposal records should undergo regular audits and reviews to ensure that all disposals are compliant. Any non-compliant disposals should be addressed and corrected promptly.

10.3 Safety and Environmental Considerations

10.3.1 Safety

Safety factors must be considered when disposing of samples. Employees should follow safety procedures during the disposal process to ensure there are no hazards or accidents.

10.3.2 Environmental

Environmental considerations are essential for sample disposal. Environmental regulations should be followed to ensure that sample disposal does not have adverse effects on the environment. If there are specific environmental requirements, disposal must be conducted according to the prescribed procedures.

11. TRAINING AND AWARENESS

11.1 Training Plan

11.1.1 Training Content

To ensure that employees understand and comply with the sample management system, the company should develop a comprehensive training plan. Training content should include the following aspects:

- Overview of the Sample Management System: Introduce employees to the purpose, importance, and scope of the sample management system to establish their understanding of the system.
- Sample Collection Procedures: Provide detailed instructions on how to correctly collect raw material samples, including sourcing, methods, and labeling requirements.
- Sample Storage and Labeling: Explain how to store samples in both physical and digital environments and label them correctly.
- Sample Tracking: Describe how to record sample entry and exit, storage locations, usage, and disposal to ensure sample tracking and traceability.
- Sample Usage and Disposal: Introduce how to use and dispose of samples in compliance with usage procedures, disposal decisions, and safety considerations.

11.1.2 Training Methods

Training can be conducted through various methods, including but not limited to:

- Classroom Training: Provide in-person training sessions to allow employees to interact and ask questions.
- Online Training: Offer online training courses, allowing employees to complete training at their convenience.
- Training Manuals and Materials: Provide training manuals, information booklets, and reference materials for employees to consult at any time.

11.2 Awareness Building

11.2.1 Awareness Activities

In addition to training, the company should conduct awareness activities to ensure that employees remain sensitive and vigilant regarding the sample management system. This includes:

- Internal Notifications: Communicate the latest information and important updates about sample management to employees through internal notifications, emails, and communication channels.
- Periodic Reviews: Regularly review the system and procedures to ensure their continued effectiveness and make suggestions for improvements.
- Sharing Success Stories: Share success stories related to compliant sample management to inspire employees and encourage compliance.

11.2.2 Questions and Support

The company should establish support channels so that employees can ask questions, report issues, or seek assistance. This may include setting up a sample management system consultation hotline, email support, or regular question and answer sessions.

11.3 Training Records and Assessment

11.3.1 Training Records

The company should maintain records of each employee's training, including the training content they have received, dates, and training assessment results. This helps track employees' training history and compliance.

11.3.2 Training Assessment

After training, training assessments should be conducted to ensure that employees have understood the training content. Assessments can take various forms, such as tests, surveys, or practical exercises. Employees should achieve a passing score to pass the training.

Through training and awareness-building, the company can ensure that employees understand the sample management system and comply with its requirements in their daily work. This helps maintain the integrity, quality, and compliance of sample data.

12. DOCUMENT RECORDS

12.1 Types of Documents

The company should maintain various types of document records as required by the sample management system. These document types include but are not limited to:

- Sample Collection Records: Recording the collection date, source, quantity, and identification of each raw material sample.
- Sample Storage Records: Documenting the sample's storage location, storage conditions, and relevant identifications.
- Sample Tracking Records: Keeping records of sample entry, usage, storage locations, and disposal.
- Training Records: Recording the content of training that employees have received, training dates, and training assessment results.
- Awareness Building Records: Documenting awareness-building activities, notifications, and employee participation.
- Review and Audit Records: Maintaining records of regular reviews, audits, and improvement suggestions regarding the sample management system.

12.2 Document Management

12.2.1 Document Storage

All documents related to the sample management system should be stored following a consistent document management procedure. This includes storing documents in designated physical locations or digital storage systems to ensure easy access and retrieval.

12.2.2 Document Indexing

The company should maintain a document index or directory to allow employees to quickly locate and access the required documents. The index should include the document's name, location, date, and relevant descriptions.

12.3 Document Retention

12.3.1 Retention Period

Different types of documents should be retained for a specified period of time as per regulations, contractual requirements, and company policies. The

sample management system should specify the retention period for each document type.

12.3.2 Document Disposal

Once documents reach their retention period, the company should follow prescribed document disposal procedures. This may include document archiving, digital document archiving, or secure disposal of paper documents.

12.4 Document Backup

To prevent document loss or damage, the company should implement a document backup strategy. This includes regularly creating copies of digital documents and storing backups in secure locations for recovery when needed.

12.5 Document Access and Security

12.5.1 Access Permissions

The company should establish document access permissions to ensure that only authorized personnel can access and modify documents. This includes encrypting digital documents and securely storing physical documents.

12.5.2 Document Security

To ensure the integrity and confidentiality of documents, the company should implement appropriate security measures such as password protection, access log recording, and document transmission encryption.
Effective document management ensures that document records related to the sample management system are correctly retained, protected, and accessible. This helps meet compliance and regulatory requirements while maintaining data integrity and traceability.

13. CHANGE MANAGEMENT

13.1 Change Identification

13.1.1 Change Requests

Any employee can submit change requests concerning the sample management system. Change requests should detail the nature, reasons, and impacts of the proposed changes.

13.1.2 Change Evaluation

Upon receiving a change request, a change evaluation should be promptly conducted. The purpose of the evaluation is to determine the necessity, compliance, and impacts of the proposed change.

13.2 Change Approval

13.2.1 Change Committee

The company should establish a change committee composed of representatives from various departments responsible for reviewing and approving change requests. Committee members should include quality control, compliance, safety, and technical experts.

13.2.2 Change Approval

The change committee should review change requests and decide whether to approve them based on the nature, compliance, and impacts of the change. Approval decisions should be documented and communicated to relevant parties.

13.3 Change Implementation

13.3.1 Change Planning

Once a change is approved, a change plan should be developed, including an implementation schedule, responsible individuals, and resource requirements.

13.3.2 Change Notification

All affected employees should be promptly notified of the change and receive training or guidance to ensure they understand the new requirements of the sample management system.

13.4 Change Records

13.4.1 Change Documentation

Each change should have corresponding documentation, including change requests, approval decisions, change plans, and implementation records.

13.4.2 Change Review

Regular change reviews should be conducted to ensure that the

implementation and effects of changes align with expectations. If issues or inconsistencies are identified, corrective actions should be taken and documented.

13.5 Change Closure

13.5.1 Change Evaluation

Once a change has been implemented and evaluated over a period, its effects should be assessed to determine whether the expected objectives have been met.

13.5.2 Change Closure Records

Change closure records should include an evaluation of the change's effects, a description of any follow-up corrective actions, and the decision to close the change. This ensures the successful implementation and compliance of changes.

Through effective change management, the company can ensure that the sample management system continues to adapt to changing needs and regulatory requirements. The change management process should be transparent, traceable, and compliant to maintain the effectiveness and integrity of the system.

14. COMPLIANCE AND REVIEW

14.1 Compliance Maintenance

14.1.1 Compliance Monitoring

The company should establish a compliance monitoring mechanism to ensure that all aspects of the sample management system comply with applicable regulations, laws, and standards. This includes food safety regulations, quality standards, and environmental regulations, among others.

14.1.2 Compliance Training

Employees should receive training on compliance to understand their responsibilities in sample management and how to comply with applicable regulations and policies.

14.2 Regular Reviews

14.2.1 Review Planning

The company should establish a regular review plan to ensure the effectiveness and compliance of the sample management system. The review plan should include the frequency, scope, and participants in the review.

14.2.2 Review Process

The review process should include the following steps:

- Document Review: Review sample management system documents to ensure alignment with actual operations.
- Operational Review: Inspect employee operations in sample management to ensure compliance.
- Risk Assessment: Evaluate potential compliance risks and take appropriate measures to reduce risks.
- Change Review: Review any changes related to the sample management system to ensure their compliance and effectiveness.

14.3 Review Records and Reports

14.3.1 Review Records

Detailed records should be created for each review, including the review date, scope, participants, and identified issues.

14.3.2 Review Reports

Based on the review records, review reports should be prepared to summarize the results of the review, issues, and suggested improvement measures. The review reports should be submitted to relevant parties and the progress of improvements should be tracked and monitored.

14.4 Improvement Measures

14.4.1 Improvement Planning

Based on review results, the company should establish improvement plans that describe in detail how identified issues will be addressed, inconsistencies corrected, and the efficiency of the sample management system enhanced.

14.4.2 Improvement Tracking

Improvement plans should include tracking and monitoring the

implementation and effectiveness of improvement measures. This ensures that issues are addressed and compliance is maintained.
Through compliance monitoring and regular reviews, the company can ensure the compliance of the sample management system and continuously improve its efficiency. Review and improvement are critical steps in continuous improvement to adapt to changing needs and regulatory requirements.

15. EMERGENCY SITUATIONS

15.1 Emergency Definition

The company should clearly define what situations are considered emergencies to ensure that employees can quickly identify and respond to these situations. Emergencies may include but are not limited to:

- Chemical Spills: For example, leaks of hazardous raw materials that may lead to exposure to dangerous substances.
- Fires: Fires that may threaten employee safety and sample integrity.
- Natural Disasters: Such as earthquakes, floods or hurricanes, which may cause significant damage to sample storage and facilities.

15.2 Emergency Plans

15.2.1 Emergency Teams

The company should establish emergency teams composed of trained employees responsible for responding to emergencies. Team members should have a clear understanding of their roles and responsibilities.

15.2.2 Emergency Procedures

For different types of emergencies, the company should develop detailed emergency procedures. These procedures should include the following:

- Emergency Notification Procedures: Outlining how to promptly notify all affected employees and authorities.
- Safety Evacuation Procedures: Describing how employees should safely evacuate hazardous areas and specifying evacuation assembly points.
- Hazardous Material Handling Procedures: Providing instructions for handling hazardous materials, especially in the case of chemical spills.
- Fire Response Procedures: Covering fire alarms, fire extinguisher use, and calling for help, among other steps.
- Natural Disaster Response Procedures: Creating relevant response plans

based on the type of natural disaster.

15.2.3 Emergency Equipment and Resources

The company should provide necessary emergency equipment and resources to support operations during emergency situations. This may include fire extinguishers, first aid kits, communication devices, and protective gear.

15.3 Emergency Drills

15.3.1 Regular Drills

The company should conduct regular emergency drills to ensure that employees are familiar with emergency procedures and can act swiftly during emergency situations. Drills should simulate various types of emergencies.

15.3.2 Drill Evaluation

After each drill, an evaluation should be carried out to determine the effectiveness of the drill and areas that may need improvement. Improvement plans should be established and implemented.

15.4 Emergency Communication

15.4.1 Internal Communication

The company should establish an internal communication system to ensure that employees receive timely information and instructions during emergency situations. This can include emergency notifications, walkie-talkie systems, and email notifications, among other methods.

15.4.2 External Communication

The company should set up external communication channels to connect with emergency services and authorities and provide necessary information to external stakeholders.

Through well-developed emergency plans and training, the company can minimize the risks of potential emergencies while ensuring the safety of employees and samples. Regular updating and practicing of emergency plans are essential to maintaining preparedness for emergency situations.

APPENDIX

APPENDIX A: SAMPLE RETENTION MANAGEMENT PROCEDURE

1. Samples are arranged to be sent with each batch.
2. Register sample information: Chinese and English product name - batch number - specification - color - packaging material.
3. Arrange for samples to be sent to Europeherb or SGS third-party testing organizations for analysis.
   3.1. Routine testing includes content, moisture, ash content, heavy metals, and microbiology.
   3.2. Periodic testing includes ETO, PAHs, PAs, pesticide residues, and solvents.
   3.3. Additional testing may be conducted as needed.
4. The remaining samples are kept for long-term retention.
   4.1. Quantity of samples retained: 50g.
   4.2. Sample storage conditions:
      4.2.1. Sample cabinets are stored in a well-ventilated, dry, and light-avoiding place, with conditions similar to the storeroom (humidity $\leqslant$ 75%).
      4.2.2. Indoor temperature and humidity are monitored, and air conditioning is provided in the cool storage room.
5. Storage of Retained Samples
   5.1 Retained samples are sealed tightly, intact, and each retained sample should have a label that includes the product name, specification, batch number, source, retainer, and retention date for easy identification.
   5.2. Retained samples are stored according to the specified conditions for each product type.
   5.3. Retained observation samples are stored in an organized manner.
   5.4. Storage period: Finished products - 1 year after the expiration date.
   5.5. The retainer checks temperature and humidity every morning and afternoon (except on holidays) and maintains records.
   5.6. Retained samples are not for sale or personal use; any transfer of non-inspection samples must be documented and approved by the Head of the Quality Department.
   5.7. Any abnormalities discovered during the retention period shall be reported to the QC Supervisor in a timely manner and handled in accordance with the "Laboratory Deviation Handling Procedure."
   5.8. Samples are observed and checked at specified times, with records made (including properties, moisture, and content determination) and recorded in the ledger.

5.9. The retainer summarizes the retention observations annually, evaluates the stability of expiring samples, and submits the written materials to the QC Supervisor and Head of the Quality Department. After review, they are archived by QA.

5.10. Testing and expiration date calculation for retained samples are conducted according to the "Product Stability Test Management Procedure."

6. Sample Disposal

6.1. Samples that have exceeded the retention period are regularly disposed of. The Sample Retention Administrator records the name, specification, quantity, and reason for disposal in the "Disposal Ledger." After approval by the Head of the Quality Department, QC personnel are responsible for disposal. Disposal method: abandonment.

6.2. Two individuals must be present during disposal, with one person conducting the disposal and the other supervising while keeping records.

APPENDIX B: SAMPLE MANAGEMENT DOCUMENT TEMPLATES

Appendix B includes templates for various sample management documents such as sample collection records, sample storage records, and sample usage records. These templates are provided for employees to ensure the consistency and compliance of document records.

Cabinet	Product Name	Sample Registration Date	Quantity	Factory	Factory Batch Number	Our Company's Batch Number	Contract Order Number

APPENDIX C: TRAINING RECORD FORM

Appendix C contains a training record form used to document the training content, dates, and training assessment results for employees. This helps in tracking employees' training history and compliance.

Training Sign-In Sheet for [Date] of [Month] 2023

Company Name: Xi'an Europeherb Biotechnology Co., Ltd.

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Time	[Date] of [Month] 2023, XX:XX AM - XX:XX AM		Location	Company Meeting Room	
Training Content			Trainer		
No.	Signature	Department/ Position	No.	Signature	Department /Position

Note: This form is a general form applicable for attendance at various meetings held by different departments.