



UKJAS Accreditation Pvt Ltd
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Om Kaveri CHS Ltd, Nagindas
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Ref UKJAS /CO/ADM/2023-24/00

PRESENTS

Dtd: 30/09/2024

5 DAYS LEAD AUDITOR TRAINING PROGRAMME
CLASSROOM & DISTANCE LEARNING COURSE
ISO 20387 ACCREDITATION OF BIO BANKS TO ENSURE BIOLOGICAL
MATERIAL AND COLLECTIONS TECHNICAL SERVICES

Dear Sir,

As is widely known, UKJAS Accreditation Pvt. Ltd conducting various technical courses inviting interested personnel/technocrats for enhancing & fine-tuning of the skill.

UKJAS Accreditation Pvt. Ltd organizing **5 Days Lead Auditor Training Programme** Classroom & online Training course for ISO 20387 ACCREDITATION OF BIO BANKS TO ENSURE BIOLOGICAL MATERIAL AND COLLECTIONS TECHNICAL SERVICES

ISO INTRODUCTION

The standards published by ISO undergo changes periodically, to reflect the best-suited practices over the changing times. ISO series of standards

For a business unit to successfully set up and ISO 20387 ACCREDITATION OF BIO BANKS TO ENSURE BIOLOGICAL MATERIAL AND COLLECTIONS TECHNICAL SERVICES Or get maximum benefits from an established management system, auditors within the organization have to be trained to assess the system against ISO 20387 ACCREDITATION OF BIO BANKS TO ENSURE BIOLOGICAL MATERIAL AND COLLECTIONS TECHNICAL SERVICES They must also be able to assess their suppliers required management system to support own Quality Initiative.

To increase professionalism, quality auditors also seek formal registration with the IAF-AB (UK) one of the prerequisites for such registration requires the quality auditors and practitioners to successfully complete an IAF-AB (UK) approved auditor training.

a) OBJECTIVE OF THE COURSE:

The objective of the course is to illustrate the importance of the **5 Days Lead Auditor Training Programme** role, skills and competency in bearing the ultimate responsibility for the effective performance of the audit team. A practical and intensive course for training quality professionals to External, Internal and manage third and second party audits of a ISO 20387 ACCREDITATION OF BIO BANKS TO ENSURE BIOLOGICAL MATERIAL AND COLLECTIONS TECHNICAL SERVICES. Course describes how to plan and perform an audit, report findings, conduct opening and closing meetings and establish follow-up action. You will understand by the end of the course



How regular auditing by an audit team directed by a competent internal auditor is the foundation of an effective ISO 20387 ACCREDITATION OF BIO BANKS TO ENSURE BIOLOGICAL MATERIAL AND COLLECTIONS TECHNICAL SERVICES

On completion of the course you will have the necessary skills and the experience to Internal Audit and manage your own audits. The learning process will include a Series of tutorials, exercises, culminating in both practical and written examination. Delegates will be supplied with a bound set of comprehensive course notes.

b) COURSE CONTENTS:

- Introduction to ISO 20387 ACCREDITATION OF BIO BANKS TO ENSURE BIOLOGICAL MATERIAL AND COLLECTIONS TECHNICAL SERVICES Vocabulary & understanding definitions
- Introduction to ISO 20387 ACCREDITATION OF BIO BANKS TO ENSURE BIOLOGICAL MATERIAL AND COLLECTIONS TECHNICAL SERVICES Need for Internal Quality Audits
- Auditing Techniques
- Conducting Internal Quality Audits
- Course Examination with minimum 70% passing marks.

Day 1: Introduction to ISO 20387 and Audit Fundamentals

- **Session 1: Overview of ISO 20387**
 - Purpose and scope of ISO 20387
 - Importance of biobanks in research and healthcare
 - Key terms and definitions relevant to biobanking and ISO 20387
- **Session 2: Understanding Biobanking**
 - Overview of biobank functions and processes
 - Types of biological materials and data collected
 - Regulatory frameworks and ethical considerations in biobanking
- **Session 3: Principles of Auditing**
 - Fundamental principles of auditing (integrity, fair presentation, due professional care, confidentiality, independence, and objectivity)
 - The role and responsibilities of auditors in biobanking
- **Workshop:**
 - Group discussion on the significance of ISO 20387 in enhancing quality and reliability in biobank operations

Day 2: ISO 20387 Requirements for Biobanks

- **Session 1: Management System Requirements**
 - Overview of management system requirements in ISO 20387
 - Establishing quality objectives and policies for biobanks
 - Documentation requirements and record-keeping for biobanks
- **Session 2: Personnel Competence and Training**
 - Importance of qualified personnel in biobanking
 - Competency requirements and training programs
 - Evaluating and ensuring personnel competency
- **Session 3: Biological Material Management**
 - Collection, processing, storage, and distribution of biological materials

- Implementing procedures for quality control and assurance
- Tracking and traceability of biological samples
- **Workshop:**
 - Case study analysis on effective biological material management in a biobank

Day 3: Planning and Conducting the Audit

- **Session 1: Audit Planning**
 - Objectives and components of an audit plan for biobanks
 - Determining audit scope, criteria, and resources
 - Developing effective audit checklists specific to biobanking processes
- **Session 2: Conducting the Audit**
 - Steps in executing an audit (opening meeting, evidence collection, closing meeting)
 - Techniques for effective interviews and observations in biobanking settings
 - Collecting and verifying evidence related to compliance with ISO 20387
- **Session 3: Identifying Non-Conformities in Biobanking Practices**
 - Types of audit evidence and evaluation techniques
 - Identifying and documenting non-conformities in biobanks
 - Assessing the significance of findings and potential impacts on research and data integrity
- **Workshop:**
 - Role-playing exercise to practice conducting audit interviews with biobank staff

Day 4: Reporting, Follow-Up, and Continuous Improvement

- **Session 1: Audit Reporting**
 - Structure and elements of an effective audit report for biobanks
 - Best practices for presenting findings and recommendations
 - Communicating effectively with stakeholders and regulatory bodies
- **Session 2: Follow-Up Procedures**
 - Importance of follow-up actions in the audit process
 - Monitoring and verifying corrective actions taken in biobanks
 - Evaluating the effectiveness of implemented improvements
- **Session 3: Continuous Improvement in Biobanking Practices**
 - Tools and techniques for promoting continuous improvement
 - Building a culture of quality and compliance within biobank operations
 - Integrating lessons learned from audits into biobank management systems
- **Workshop:**
 - Group activity on developing a continuous improvement plan based on audit findings in biobanking

Day 5: Practical Application and Examination

- **Session 1: Case Studies and Best Practices**
 - Review of successful ISO 20387 implementations in various biobank settings
 - Discussion of challenges and effective strategies in managing biological materials and data
- **Session 2: Mock Audits**
 - Conducting mock audits in small groups using prepared scenarios related to biobanking
 - Peer feedback and discussions on audit performance and findings
- **Session 3: Examination and Certification**
 - Written examination to assess understanding of course content
 - Feedback session and discussion of exam results

- Issuance of certificates for successful participants

Additional Notes:

- **Materials Provided:**
 - Course handbook
 - Copies of ISO 20387 standard
 - Access to online resources, templates, and discussion forums
- **Assessment:**
 - Continuous assessment through participation in workshops and group activities
 - Final examination to evaluate understanding of course content

Target Audience:

- Auditors, quality assurance professionals, biobank managers, researchers, and individuals involved in the management of biological materials and data in biobanks.

For detail of contents refer our website at www.ukjas.com

c) WHO SHOULD ATTEND:

- 1) All employees whose work responsibility directly affects ISO 20387 ACCREDITATION OF BIO BANKS TO ENSURE BIOLOGICAL MATERIAL AND COLLECTIONS TECHNICAL SERVICES
- 2) Those individuals willing to take up external auditing as a future profession by becoming an independent auditor.
- 3) Those who intend to enroll themselves to IAF-AB (UK) Registration Schemes of ISO 20387 ACCREDITATION OF BIO BANKS TO ENSURE BIOLOGICAL MATERIAL AND COLLECTIONS TECHNICAL SERVICES
- 4) Management Representatives responsible for effective implementation and execution of ISO ISO 20387 ACCREDITATION OF BIO BANKS TO ENSURE BIOLOGICAL MATERIAL AND COLLECTIONS TECHNICAL SERVICES

d) FACILITIES:

All facility for delegates covering lecture hall, tea and lunch will be arranged by Client or if you are attending the course at UKJAS Offices. UKJAS institute will arrange the above facility.

e) COURSE DETAILS:

Detail program of every days training course will be sent / given on the first day to the delegates on registration.

f) DURATION:

Five days Lead Auditor Training Programme ISO 20387 ACCREDITATION OF BIO BANKS TO ENSURE BIOLOGICAL MATERIAL AND COLLECTIONS TECHNICAL SERVICES [Timings: 10.00 am to 6.00 pm]

FEES:

- g) 5 Days Lead Auditor Training program of ISO 20387 ACCREDITATION OF BIO BANKS TO ENSURE BIOLOGICAL MATERIAL AND COLLECTIONS TECHNICAL SERVICES and any other program is Rs 25000+18% GST**
Payment should be made by Cheque / DD in favor of **“UKJAS Accreditation Pvt Ltd, Mumbai**

Indian overseas bank

BANKERS DETILS FOR EFT/ECS/RTGS/NEFT PAYMENT

Sr. No.	Name	Details
1.	Name of Beneficiary	UKJAS ACCREDITATION PVT LTD
2.	Name of Bank	Indian overseas bank
3.	Bank Branch	Station Road, Palwal Branch, Haryana
4.	Bank Branch Code	1667
5.	Account No	166702000000340
6.	RTGS/NEFT / IFSC Code	IOBA 0001667
7.	Account Type	CURRENT
8.	MICR code	110020106
9.	SWIFT code	IOBAINBB089
10.	Email Id	info@ukjas.com
11.	PAN No.	AVZPS7816G
12.	GST No.	27AVZPS7816G1ZN

We hereby declare that the particulars given above are correct and complete.
Thanking You

Step for Admission:

1. Select the course, you want.
2. Choose Classroom/Distance Learning
3. Pay the fees by ECS/RTGS/NEFT to our Indian overseas bank
4. Send transaction ID/Deposit Slip along with duly filled Registration form
5. Get Confirmation of your admission by email. Admission is based on first cum first serve basis.
6. Currently Classroom training is only available at Mumbai and your office premises/factory, if there are more than 4 participants in the same city/ factory. For outside student, Guest house facility is available of Rs 300/per day in Mumbai depends on seat availability; otherwise all ranges of hotels are available near to our institute.
7. Other cities student, who doesn't want to come Mumbai, can opt for Distance Learning Mode. Syllabus is the same. You will be given course material by email and we will recommend some books, which you can buy. Three month time will be allowed to study the course material and for any doubts and faculty interaction can be done one to one on Skype is: six sigma _quality and whatsapp video call on 8275879725 on Sunday between 5.00 to 8 pm. If you want training online we can share presentation on www.ukjas.com with live presentation. Live presentation Rs 1500 will be charged extra. You can attend from any cities around the world.

h) **VENUE:**
Client Office
Or
UKJAS Accreditation Pvt Ltd
B-401, New Om Kaveri CHS Ltd, Nagindas Para, Next to Shiv Sena Office
Nalasopara(E), Mumbai 401209
Email: operation@ukjas.com
www.ukjas.com
Tel: 8369083940/9322728183

i) **NOMINATIONS:**

You may send in your nominations to the course co-coordinator, UKJAS, on the Registration form at the following address along with the fees.

Ranjeet Prasad

8369083940

B-401, New Om Kaveri CHS Ltd, Nagindas Para, Next to Shiv Sena Office
Nalasopara(E), Mumbai 401209

Email: operation@ukjas.com

www.ukjas.com

Tel: 0250-2341170

Fees once paid will not be refunded, however it could be adjusted against the next course for the same financial year.

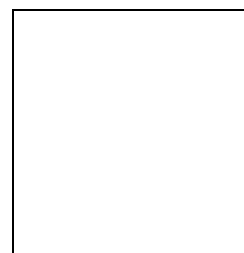
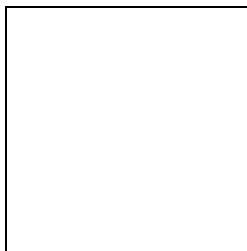
Please send your nomination of the delegated immediately as limited seats are available. Seats are filled on first cum first serve basis.

j) **TERMS & CONDITIONS:**

- I. UKJAS Accreditation Pvt Ltd general terms and conditions will be applicable for qualification of personnel.
- II. Minimum candidates per batch should be 04 Number and Maximum should be 25 per batch. **10% discount will be offered for** 04 Number and Maximum should be 25 per batch
- III. Delegate Fees shall be send in advance through cheque / DD in favor of **“UKJAS Accreditation Pvt Ltd”** payable at Mumbai.
- IV. UKJAS Accreditation Pvt Ltd will charge Service tax as applicable.
- V. Travel & Subsistence by 3rd AC train or economy class airfare will be charged for faculties on actual to be borne by client in case of course will be conducted in-house at client premises.



REGISTRATION FORM



PERSONAL DATA

Name in Full :
..... (In Capital Only)

Surname Name Father's/Spouse's Name

Name of the Firm & Address.....

.....

Phone No: (With STD Code) : Sex:

Mobile No: E-mail:

Date of Birth: Qualification:

Training Course:

Place: (Signature)

Date : Name:

PAYMENT MADE BY: Cheque No / Demand Draft No..... Date

Drawn on Bank:**Swift Code IOBAINBB089**

Cheque / Demand Draft Should be drawn in favors of **UKJAS Accreditation Pvt Ltd** payable at Mumbai, Maharashtra, India.

Note : Fees once paid will not be refunded, however this will be carried forward for the next course during the same financial year

UKJAS Accreditation Pvt Ltd, B-401, New om Kaveri CHS Ltd, Nagindas Para, Next to shiv sena Nalasopara (E) Mumbai 401209 Tel : 0250- 2341170 Fax : Extn. 206

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