|  |
| --- |
| This SOP Template (template) is being provided by Praxis Management International, LLC (Praxis) for the "fair use" by you, the User, as that term is defined under the U.S. Copyright Laws. All other use, reproduction or re-transmission in any form or by any means, electronic or mechanical, including photocopying and recording, or by any information storage or retrieval system, without prior written permission from Praxis is prohibited. ©2008-2015 Praxis Management International, LLC. All rights reserved.  Praxis makes no representations or warranties concerning the suitability or use of, or reliance on, the Template. Any actual or implied representation or warranty that the Template does not infringe the intellectual property rights of any third party is specifically hereby void. Any special, indirect or consequential damages or any damages whatsoever resulting from the use or misuse of the Template, the loss of use, data, or profits, whether in an action of contract, negligence, or other tortious action arising out of or in connection with the Template shall be born exclusively by the User. |

**Contents**

[Purpose: 3](#_Toc429124694)

[SOP Scope: 3](#_Toc429124695)

[Responsibilities 3](#_Toc429124696)

[Procedures: 3](#_Toc429124697)

[Application of Risk Assessment 3](#_Toc429124698)

[Training Materials 4](#_Toc429124699)

[Training Requirements 4](#_Toc429124700)

[Training Records 5](#_Toc429124701)

[System Changes 5](#_Toc429124702)

[Periodic Training Effectiveness Reviews 6](#_Toc429124703)

[ATTACHMENT A: System Training Matrices 8](#_Toc429124704)

[ATTACHMENT B: Instructor Led Training Record 9](#_Toc429124705)

[ATTACHMENT C: Self-study Training Record 10](#_Toc429124706)

[ATTACHMENT D: System Change Training Impact 11](#_Toc429124707)

[ATTACHMENT E: Training Effectiveness Review Log 12](#_Toc429124708)

# Purpose:

This SOP defines the procedures and controls necessary to ensure that employees have the training needed to effectively perform their assigned responsibilities regarding the Information Technology systems used in regulated activities.

# SOP Scope:

This SOP applies to all computer-based systems.

# Responsibilities

The IT Manager is responsible for

* Working with the Training Manager and Business Managers to establish the appropriate Training Matrix for each computerized system
* Providing system subject matter experts to participate in the development of training materials
* Notifying the Training Manager and Business Managers of new systems and upcoming changes to existing computerized systems
* Participating in periodic evaluation of training effectiveness.

The Business Managers are responsible for

* Working with the Training Manager and IT Manater to establish the appropriate Training Matrix for each computerized system
* Providing business subject matter experts to participate in the development of training materials
* Assuring that employees complete all training required per the system Training Matrix
* Participating in periodic evaluation of training effectiveness.

The Training Manager is responsible for

* Working with the Business Managers and IT Manater to establish the appropriate Training Matrix for each computerized system
* Developing, maintaining version control, and retaining training materials
* Scheduling and conducting training sessions
* Completing and retaining training records
* Participating in periodic evaluation of training effectiveness.

# Procedures:

## Application of Risk Assessment

1. For each computerized system function, the type of training needed is determined prior to implementation by applying a risk based approach. The complexity of the system function is also a factor.
   1. The criticality level associated with each system is determined using the process in *SOP System Risk Assessment.*
   2. The complexity levels are determined by the appropriate Business Manager using the following definitions:
      1. Low Complexity: System function is intuitive to use correctly
      2. High Complexity: System function is not intuitive to use correctly.
   3. The preferred format of training is determined according to the criticality and complexity of the associated system functions.

|  |  |  |
| --- | --- | --- |
| **Recommended Training Format** | | |
|  | **High Complexity** | **Low Complexity** |
| **High Criticality** | Instructor Led Class  Hands-on Exercises  Competency Exam | Self-study Materials  Hands-on Exercises  Competency Exam |
| **Medium Criticality** | Instructor Led Class  Hands-on Exercises | Self-study Materials |
| **Low Criticality** | Self-study Materials  Hands-on Exercises | Self-study Materials |

## Training Materials

1. The format of training material for each system function is determined using the chart above. Exceptions to the recommended training format must be approved by the IT Manager, Training Manager, and appropriate Business Manager.
2. Training materials are developed by certified training professionals with input from personnel with technical and business expertise.
3. Instructor led courses are delivered by personnel with experience in the system function that is the subject of the training.
4. Training materials are version controlled.
   1. Each new training material is assigned a unique identifier and version 1.0.
   2. Each time a training material is modified, a new version number is assigned.
5. A copy of each prior version of training material is retained for the duration of the associated training records.

## Training Requirements

1. Each computerized system has a System Training Matrix to identify the training requirements for each system access level. See System Training Matrices, Attachment A.
2. System Training Matrices will include:
   1. Training for the system function(s) that persons in each access level use to perform their assigned tasks
   2. Training on electronic records for systems that create electronic records under 21 CFR Part 11
   3. Training on electronic signatures for systems that create electronic signatures under 21 CFR Part 11
   4. Training on alternate record keeping methods for systems where alternate records are generated during times of system unavailability or failure.
3. Business Managers are responsible for verifying that each system user has completed the training associated with each requested access level prior to authorizing system access. See *SOP System Security* for forms and details.
   1. When training has an associated competency exam, the Business Manager is responsible for verifying that the system user obtained a score of 80% or higher prior to authorizing system access.

## Training Records

1. Training records are retained for all instructor led and self-study training. Records include:
   1. Training course name, unique ID, and version number
   2. Training date
   3. Trainee name, signature
   4. Competency exam score (for training with exams)
   5. Instructor name and signature (for instructor led courses)

See Instructor Led Training Record, Attachment B, and Self-study Training Record, Attachment C.

1. Completed competency exams are retained with the training records.
2. Training records and completed competency exams are retained for the same period of time as the electronic records generated by each trainee.

## System Changes

1. Changes to the functionality of computerized systems are evaluated for training impact prior to implementation of the change.
2. The IT Manager alerts the Training Manager and impacted Business Manager(s) that a change is being planned.
3. The IT Manager, Training Manager, and Business Manager(s) complete the System Change Training Impact form, Attachment D, to document:
   1. Complexity and criticality of the functionality being changed. Refer to the *Application of Risk Assessment section*, above.
   2. Modifications needed to align training materials with new system functionality
   3. Which system users are impacted by changes
   4. Method by which existing system users will be retrained on new functionality.
      1. Retraining requirements will vary based on criticality, complexity, and magnitude of functionality change. Retraining methods can vary from e-mail notification for minor, cosmetic changes to hand-on sessions for changes to complex, critical features.
4. Retraining activities are documented per the Training Records section, above. Documentation is retained by the Training Manager.

## Periodic Training Effectiveness Reviews

1. Each system’s training effectiveness is reviewed per this schedule:

|  |  |  |
| --- | --- | --- |
| **Training Effectiveness Review Schedule** | | |
|  | **First 3 Months** | **Life of System** |
| **High Criticality** | Monthly | Every 6 Months |
| **Medium Criticality** | Monthly | Annually |
| **Low Criticality** | Monthly | N/A |

1. IT Support personnel provide the Training Manager, Business Manager(s),and IT Manager with a list of all issues and questions reported to the Help Desk since the last training effectiveness review.
2. The Managers and Manager review the list of issues and questions to identify issues, such as:
   1. Specific users or groups of users requiring retraining
   2. Functionality that needs to be covered more thoroughly in training materials
   3. Training materials that need to be supplemented with hands-on exercises.
3. Results of the training effectiveness review are recorded in the Training Effectiveness Review Log, Attachment E.
4. Actions to correct or mitigate any negative findings are also recorded in the log.
5. The Training Manager indicates confirmation of all findings, corrections, and mitigations by signing the Training Effectiveness Review Log.

**References:**

21 CFR Part 11, Electronic Records; Electronic Signatures, March 20, 1997

Computerized Systems Used in Clinical Investigations, FDA, May, 2007

Eudralex Volume 4, Annex 11: Computerised Systems

GMP Guide for Blood Establishments, PIC/S, September 25, 2007

Good Practices for Computerised Systems in Regulated “GxP” Environments, PIC/S, September, 2007

# ATTACHMENT A: System Training Matrices

|  |  |  |  |
| --- | --- | --- | --- |
| **System Name** | **Access Level** | **Training Requirements** | |
| *Laboratory Information Management System* | *All Levels* | *P11-001*  *LIMS-001*  *LIMS-002* | *Electronic Records & Signatures*  *System Overview*  *LIMS Access and Navigation* |
| *Tester* | *LIMS-003*  *LIMS-999* | *Test Result Entry*  *Alternate Records* |
| *Manager* | *LIMS-004*  *LIMS-500* | *Test Result Approval*  *LIMS Reporting (CBT)* |
| *Viewer* | *LIMS-500* | *LIMS Reporting (CBT)* |
| *Tech Support* | *LIMS-700* | *Technical Support Procedures* |
|  |  |  |  |
| **System Name** | **Access Level** | **Training Requirements** | |
| *Complaints*  *Management System* | *All Levels* | *P11-001* | *Electronic Records & Signatures* |
| *Recorder* | *CMP-100* | *Complaint Initiation* |
| *Researcher* | *CMP-200* | *Complaint Investigation* |
| *Approver* | *CMP-200*  *CMP-300* | *Complaint Investigation*  *Complaint Approval* |
| *Manager* | *CMP-500* | *Browser (CBT)* |
| *Tech Support* | *CMP-500*  *CMP-800*  *CMP-900* | *Browser (CBT)*  *Query Tools*  *System Support Procedure* |
|  |  |  |  |
| **System Name** | **Access Level** | **Training Requirements** | |
| *etc.* |  |  |  |

# ATTACHMENT B: Instructor Led Training Record

Course Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Course ID & Version \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Instructor Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Instruction Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |
| --- | --- | --- |
| **Trainee Name** | **Trainee Signature** | **Competency Exam Score** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

The trainees have completed the training course and obtained the competency exam scores, as written on this form.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Instructor’s Signature

# ATTACHMENT C: Self-study Training Record

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Trainee Name** | **Trainee Signature** | **Course Name** | **Course ID** | **Course Version** | **Training Date** | **Competency Exam Score** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

Each signature is an attestation by the trainee that he/she has completed the training course and obtained the associated competency exam score, as written on the form.

# ATTACHMENT D: System Change Training Impact

**Summary of Changes:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Change #** | **Change Description** | **Functionality Criticality**  (H/M/L) | **Functionality Complexity**  (H//L) | **Access Levels Impacted** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**Training Material Impact Assessment:**

List all training material associated with the system and identify any impact of changes

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Training Material Name** | **ID** | **Version** | **Impact**  (Y/N) | **Description of Impact** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**Retraining Plan:**

Describe how impacted users will be retrained on changed functionality

|  |
| --- |
|  |
|  |
|  |

**Approvals:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Training Manager Business Manager IT Manager

# ATTACHMENT E: Training Effectiveness Review Log

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **System Name** | **Review Date** | **Review Findings** | **Correction or Mitigation** | **Confirmed by**  **Name/Signature/Date** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |