



BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Training and Qualification of Personnel in a cGMP Environment
SOP Number: 21600
Revision: 07

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1. PURPOSE

This document defines the process for training and qualification of personnel responsible for the manufacture and testing of Current Good Manufacturing Practice (cGMP) and Good Laboratory Practices (GLP) products in the Biopharmaceutical Development Program (BDP).

2. SCOPE

This SOP applies to personnel participating in or the support of the manufacture and testing of biopharmaceuticals following applicable regulations.

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3. OVERVIEW

Job-specific training is provided to employees upon entry into a job and continually throughout an employee's employment. A training plan is developed and maintained for each employee. The plan documents the general job responsibilities assigned to the employee and identifies the appropriate training necessary to develop and maintain competence in these job responsibilities. This training plan is implemented by the use of job codes. New or revised processes, new job responsibilities, etc., cause a change to the employee's training plan requiring action to maintain up-to-date training.

Training can consist of reading and understanding SOPs (or other written information), on-the-job training, training on skills using a "trainer," training courses provided internally, computer-assisted training courses, and courses/seminars offered off-site.

Competence is evaluated for critical job-specific skills, and competence must be demonstrated in these skills before an employee is considered to be "trained." Managers and Supervisors monitor the status of employee training against the employee's training plan. Quality Assurance has oversight of the process. The employee's training plan (curriculum or job code assignments), completed training, competency assessments are documented.

4. RESPONSIBILITIES

4.1 Trainees

- Ensures that they have received the necessary training prior to performing the associated task.
- Ensures there is a record of training within eDMS prior to performing the associated task.
- Attaches records of competency training, Form 21600-02, to a competency training task after successfully completing the necessary training required by the supervisor and/or the trainer.
- Attaches any record of external training to their trainee infocard (training folder) in eDMS.
- Completes required training in a timely manner.
- Completes re-training tasks in a timely manner.
- Signs training tasks as completed only after all questions have been answered.

4.2 Managers and Supervisors

- Ensures that employees are hired based on the proper combination of education and experience to adequately perform the duties as listed in the job description.

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- Develops and maintains a training plan for the employees reporting to them, including updating curricula when new processes or procedures are implemented.
- Establishes competency-based training requirements.
- Evaluates the competency of employees as required by the employee's training plan.
- Communicates the training plan to the employee.
- Selects qualified staff to serve as trainers for specific tasks/operations/equipment etc.
- Provides time for the trainee and trainer to complete training and for trainees to attend standardized training as required.
- Monitors the status of their staff's training to ensure that it is being accomplished in the manner and timeframes required.
- Reviews training requirements of their staff annually.
- Requests the addition of job codes when needed.
- Ensures that employees only independently perform tasks for which they have been trained, and that a record of that training exists
- Establishes training requirements for contract service providers based on the scope of their assignments.
- Serves as a point of contact for service providers or visiting scientists.
- Establishes training requirements for service providers or visiting scientists and copies of procedures and updates as required.
- Ensures service providers or visiting scientists are documenting training.
- Collects the completed forms and provides to BQAD for archival.

4.3 Trainers

- Provides the training coordinator with the training materials required to establish a course prior to the training.
- Provides the training coordinator with a group training form to import/grandfather the training.

4.4 Quality Assurance Management

- Develops a training policy to ensure regulatory compliance.
- Prepares cGMP training modules
- Conducts training, as needed.
- Assists Managers and Supervisors in the documentation and maintenance of a training plan for BDP employees.
- Ensures Managers and Supervisors update job codes when new processes or procedures are implemented.

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- Reviews and approves employee training plans and job codes.
- Facilitates the development of standardized training courses.
- Develops a schedule for presentation of standardized training courses.
- Monitors the effectiveness and compliance status of the training program.

4.5 Training Coordinator (QA)

- Creates Course infocards for new procedures.
- Associates course infocards to job codes and documents.
- Evaluates training needs during document review.
- Provides management with reports for annual review of training requirements

4.6 Biopharmaceutical Quality Assurance Documentation (BQAD)

- Maintains the Consultant Training File

4.7 Electronic Document Management System or Electronic Quality Management System (eDMS or eQMS)

- Notifies employees of training tasks of new or revised documents based on training requirements and system settings
- Prevents document access outside of the training task if training has not been completed.

5. DEFINITIONS

- **Competency:** The ability to do something well. Measured against a standard acquired through training or experience.
- **Course:** Anything identified as a trainable event.
- **Elective Course:** A course chosen by the trainee from a number of optional subjects or courses in a curriculum as opposed to a required course which the trainee must take.
- **Exams:** Tests used to check the effectiveness of the training.
- **Grandfathering:** Confirmation of completed paper-based training record that is imported into eDMS; performed by the training coordinator.
- **Group Training:** Documented on a Group Training Form 21600-04 to document training attendance in a classroom setting (in-person or virtual). This is only training provided by BDP Subject Matter Experts (SME) or someone contracted by BDP team to conduct training. This does not include any external training or training provided at a corporate level.

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- **InfoCard:** Detailed information about a document in eDMS. This includes but is not limited to Document Number, Title, Revision, Effective Date, and any defined custom fields.
- **Job Code:** Groups of people who have the same training requirement. The system uses job codes and roles to connect people to courses. A trainee can be in multiple job codes. Job codes define the curricula necessary for a trainee to perform a task or job.
- **On-the-Job Training (OJT):** The training of an operation or task by carrying it out step-by-step under the close supervision of the trainer.
- **Read and Understand:** The ability to perform an operation or task from only reading the standard operating procedure, form, or work instruction (batch production record).
- **Refresher Training:** Training that is required at regular intervals for some courses, even if the materials have not changed.
- **Retraining:** An individual or group may require retraining as a result of a corrective action.
- **Service Providers:** Contracted personnel that generate data and/or perform work that requires entering information on official records (e.g., validation contractors).
- **Trainee:** Any individual assigned a training task.
- **Trainer:** Trainers can include managers, supervisors, or other trained personnel, outside contractors or SMEs and/or the author of an approved procedure.
- **Training Coordinator:** Member of QA that is responsible for the quality training management system maintenance.
- **Training Requirements:** A list of core requirements that a trainee must be trained on to perform their assigned jobs.
- **Verifier:** Someone who confirms that the training requirements have been met, usually an SME, QA, or the trainee's management.

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6. OVERVIEW OF THE TRAINING PROCESS

Job-specific training is provided to employees upon entry into a job and continually throughout an employee's employment. A training plan is developed and maintained for each employee. The plan documents the general job responsibilities assigned to the employee and identifies the appropriate training necessary to develop and maintain competence in these job responsibilities. This training plan is implemented by the use of job codes. New or revised processes, new job responsibilities, etc., cause a change to the employee's training plan requiring action to maintain up-to-date training.

Training can consist of reading and understanding SOPs (or other written information), on-the-job training, training on skills using a "trainer," training courses provided internally, computer-assisted training courses, and courses/seminars offered off-site.

Competence is evaluated for critical job-specific skills, and competence must be demonstrated in these skills before an employee is considered to be "trained." For some specific analytical tests, analysts must complete a certification program before they may perform the test for GMP or GLP purposes. Managers and Supervisors monitor the status of employee training against the employee's training plan. Quality Assurance has oversight of the process. The employee's training plan (curriculum or job code assignments), completed training, competency assessments are documented.

7. EMPLOYEE TRAINING PLAN

The preparation and maintenance of an appropriate training plan for each employee is needed to ensure that the employee has the necessary training to adequately perform assigned job responsibilities. The implementation of appropriate training relies in large part on developing and maintaining an appropriate training plan. Status of training is monitored and evaluated based on the plan that has been developed for the employee.

7.1 Developing the Training Plan

7.1.1 The employee's training plan is developed by the QA Manager and the employee's Manager/Supervisor by selecting the appropriate job codes that reflect the major job responsibilities that will be assigned to the employee. Job codes are assigned and re-assigned at any time. Additional courses can be recommended to enhance an employee's understanding or to prepare an employee for assuming new responsibilities. If all the courses within a job code are not relevant for the trainee, courses can be taken as electives (manager approval is recommended).

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NOTE: The major activities of each department have been identified as various Job Codes. For example, aseptic filling is identified as a curriculum and include the required SOPs, training, and competencies to adequately perform the job responsibility of aseptic filling.

7.1.2 The plan is documented in the training module of eDMS.

7.2 Amending the Training Plan

7.2.1 An employee's training plan can be amended at any time to maintain a current status. Changes or additions to job responsibilities, reassignment to another department, etc., generally require an update to the employee's training plan. The Department Manager/Supervisor and QA work together to maintain the employee training plan.

7.2.2 New procedures are added to existing job codes or new job codes are established as needed.

7.3 Reviewing the Training Plan

Annually, the training coordinator will provide managers and supervisors with the training plan for each direct report. The manager or supervisor reviews the report, and evaluates the individuals' needs. The training plan can be amended to add additional training or to remove training no longer required.

8. INITIAL, NEW HIRE TRAINING

While training of new employees occurs over the course of several months, certain information must be understood by new hires immediately. This critical information includes:

- Review of the BDP document control and training system.
- HIPAA
- GMP Module Orientation
- SOP 21409 Good Documentation Practices
- SOP 21406 Personnel Signature and initial Verification System
- How laboratory notebooks are controlled and used. (if applicable)

Managers identify the new hire training that is appropriate for the new hire (for example, new hires that will not be using laboratory notebooks do not need to complete initial training for laboratory notebooks) and assist new hires to make appointments with the subject experts in these training areas. Subject experts present an overview of these topics, discuss any issues, and document the training provided. Completion of this initial training is targeted for two weeks from the date of hire.

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9. JOB-SPECIFIC TRAINING

9.1 General guidance for conducting job-specific training includes the following activities in the order presented.

- Reading and discussing (as necessary) the SOPs or applicable written documents with the trainer.
- Observing the trainer, or other person, perform the process.
- Performing the process with coaching by the trainer.
- Independent practice (as necessary).
- Competency Assessment (if required).

Individual job-specific training needs to be adapted by the trainer based on the employee's past experience, educational level, and general understanding of the process. Employees who have experience with the process (from a previous job, etc.) may be able to move through the training process quickly, perhaps not requiring any independent practice. The requirements for a competency assessment are at the discretion of the manager or supervisor and clearly documented on the competency training form.

Trainers should be aware of the different training needs and different learning styles of their trainees.

9.2 Required training is launched to the trainee when an applicable document is approved and an effective date set in eDMS.

9.3 Trainees are notified of a training requirement in the eDMS.

10. TRAINING – STANDARDIZED COURSES (INCLUDING GMP TRAINING)

10.1 Several job codes may include a requirement for the same knowledge or task. Standardized courses on this information may be developed and presented at appropriate intervals.

10.2 Standardized courses tend to be lecture-based but may also be offered as "computer-assisted training" or with a laboratory component. Often, a student's knowledge is assessed at the end of the course by an exam. A passing grade may be established for specific courses. Each exam is set up for a set number of retakes. Failing a course notifies the verifier. The verifier and/or the training coordinator works with the individual to determine the root cause of the failure. In the event the trainee requires a different method or manner of training, the training coordinator works with the SME to present the material in a way that the trainee can understand the material. The results of the exam and the training can be grandfathered into the system by the training coordinator.

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10.3 The Biopharmaceutical Development Program (BDP) conducts training on Good Manufacturing Practice (GMP) regulations (21 CFR 210, 211). The modules provide a complete set of training that fulfill cGMP training requirements for individuals involved in cGMP manufacturing, process analytics/quality control, and supporting operations. The training modules are provided over a 2.5-year span for new employees. Refresher courses are provided the following two years. The cycle then repeats. GMP training launches back to the users 5 years after the date of completion.

10.4 GMP Modules include:

- Orientation
- GMP Documentation
- Buildings and Facilities
- Equipment
- Control of Components (Raw Materials)
- Production and Process Controls
- Packaging and Labeling Control
- Laboratory Controls
- Regulatory Inspections and Audits
- Video “You’ll Soon Feel Better”
- Investigation of Non-Conformances
- Data Integrity
- HIPPA and PII Training
- Refresher Training 1
- Refresher Training 2

11. COMPETENCY ASSESSMENTS

11.1 Some specific skills within curricula are designated to require competency assessments to demonstrate acceptable competence in the skill. Evaluation of competency is documented on Form 21600-02, Competency Assessment and requires trainers or Managers/Supervisors to document their evaluation of individual competence in the specified task.

11.2 The trainer or the department Managers/Supervisors have the responsibility to assess competence and must select the method of assessment. Options include performing the process independently during a formal production, performing the process independently during a “mock” production, generating results consistent with a sample’s “standard value” or previous test results, passing an exam with minimum passing score of 80% or as defined for a specific exam, passing a gowning qualification without exceeding a maximum CFU count, etc.

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11.3 For each competency assessment, the Trainer or Managers/Supervisors must document how competency was assessed. All formal evaluations of competency are documented so that the employee and the department management can monitor the competency status of the employee.

11.4 Performance Competency is judged as either demonstrating basic competence or advanced competence. Trainees that do not demonstrate basic or advanced competence will be removed from the job code and will not be allowed to perform the activity.

11.4.1 Basic Competence

This level of competence certifies the individual as competent in the specified skill under routine conditions.

Employees who have been certified in Basic Competence may be re-evaluated to certify them to an Advanced Competence level.

11.4.2 Advanced Competence

This level of competence certifies the individual as competent in the specified skill in non-routine conditions. Individuals who serve as leads during productions or who perform advanced troubleshooting will be certified to advanced competence.

NOTE: Individuals assessed as being competent at an advanced level are also competent at a “basic” level. Competency assessment documentation should reflect this.

11.5 Periodic re-evaluation of competency for specific tasks is generally not required unless the process has changed significantly as to warrant another competency assessment or there is some indication (through trend analysis or employee observation) that competence in a specific task has been compromised or lost. Re-evaluation of a competency may be required in the event of quality events (e.g. deviations and or CAPAs).

11.6 Competency training records are not required for director level and above.

12. GROUP TRAINING / CLASSES

12.1 When multiple trainees attend a class or demonstration, a Group Training Form (21600-04) is used to capture the course information. These may or may not be listed as separate courses. If the training or demonstration is specific to a competency, the training should still be documented on the competency form.

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- 12.2 The BDP trainer or the BDP person responsible for coordinating the training for an external trainer signs the form attesting to the attendance.
- 12.3 In the event the training is held virtually, a screen shot / printout of the attendance list is included with the form. Signatures from those attending virtually is not required. Indicate the signature for virtual trainees by checking "N/A VIRTUAL" where a signature is required.
- 12.4 The form is submitted to the training coordinator to grandfather, enter or upload the training into the System.

13. EXTERNAL COURSES

- 13.1 Trainees that attend external courses may upload their certificates along with a course agenda into eDMS. This would include any certification held by the trainee (e.g. Lead Auditor, CQA, or other relevant certification).
- 13.2 These courses are not reportable by eDMS. These courses can be viewed / reviewed by Quality Assurance.
- 13.3 Training that is tracked through other corporate systems (e.g. EDGE, or NIH required training) are not required to be included in the System.

14. UPDATING JOB CODES

As processes are revised or developed, as SOPs are revised or generated, or as additional training becomes available, the training requirements for each job code may be amended.

15. MONITORING THE TRAINING PROCESS

- 15.1 Adequate training for a specific employee is judged against the current approved training plan. Information needed to make this assessment is available to the trainee, the employee's Supervisor/Manager, and BQA through reports in the System.
- 15.2 The adequacy of the training plan can be evaluated based on the employee's current job responsibilities.
- 15.3 A number of reports are available in the System that are used to monitor the training process.

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16. EFFECTIVENESS OF TRAINING / QUALITY OVERSIGHT

BQA reports to senior management any issues that demonstrate that employee training or the training plan is not being maintained. Effectiveness of training is measured by or with:

- Use of Exams
- Observations made during internal audits
- Lack of Quality Events (e.g., Deviations, CAPAs, investigations) created

17. SERVICE PROVIDERS OR VISITING SCIENTISTS

- 17.1 In the event a service provider or visiting scientist require training, all training requirements are managed by the BDP point of contact for the individual.
- 17.2 The point of contact is responsible for providing current copies of the procedures. In the event the procedure is updated, the point of contact is also responsible for providing an updated copy.
- 17.3 All requirements and record of training is completed on the Form 21600-05. For contractors or consultants, a copy of the scope of work, CV and description of the company is maintained in the Consultant file by BQAD.

18. DOCUMENTATION AND RECORDS

- 18.1 During the implementation of the Master Control System the most recent training dates were imported. All training after the implementation date are stored electronically within the system. Previous training is maintained in paper format in the BQAD archives. These records are maintained per **SOP 21407 Records Retention**.
- 18.2 Electronic Training Records are managed through the System. When an employee is terminated, the records are maintained by the system and retrievable by the System Administrator.

19. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
21 CFR 211.25	Personnel Qualifications
Form 21600-02	Personnel Competency Assessment



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Document Number	Title
Form 21600-04	Group Training Form
Form 21600-05	Service Providers or Visiting Scientist Training Form
21406	Personnel Signature and initial Verification System
21407	Records Retention
21409	Good Documentation Practices