ANALYST TRAINING AND CERTIFICATION PROGRAM

FDA/DIVISION OF DRUG ANALYSIS

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TRAINING AND CERTIFICATI0N OF ANALYSTS AT DIVISION OF DRUG ANALYSIS

> 21 CFR 211.25 (a) Each person engaged in the manufacture, processing, packing, testing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

In response to these requirements, a training and analyst certification program is being developed and implemented at the Division of Drug Analysis. The objectives for this plan are:

1. To provide a format for the required documentation of the training and qualifications of analysts in a pharmaceutical laboratory.
2. To demonstrate compliance with GMP regulations as they apply to certification of the competency of laboratory personnel.
3. To identify training needs for each analyst and develop plans for meeting those needs.

Documenting and certifying the qualifications of analysts at the Division of Drug Analysis (DDA), as in any laboratory, is a continuous process. For a newly hired analyst the process is relatively straightforward; training modules and practice samples are assigned, and completion is recorded. For an analyst with many years of FDA experience, the documentation of his/her expertise resides mainly in the records of completed samples and in reports and papers. For most analysts at DDA, this documentation already existed; it had only to be gathered and organized in a new way. A system was needed which would formalize and standardize those records which had formerly been kept individually by the first-line supervisors.

> "The means at a laboratory's disposal to demonstrate that their staff are technically competent and that adequate supervision is in place are limited within the time normally provided for either an assessment or surveillance visit. While proficiency testing programs have their place, an active in-house audit program and a formal training program for every member of staff are the proven basis of evidence for an assessor to review."
> Stanger, D.H., Evaluation of Accreditation Systems and Their Demands on the Independent Testing Laboratory, ASTM STP 1057, Harvey E. Schock, Jr., editor.

The DDA Training and Certification Plan has four elements:

STATEMENT OF ANALYST'S FUNCTIONS

This is a statement of the functions each analyst is expected to perform. It may be a general statement with additional functions added as the analyst gains experience. The statement should be agreed upon by supervisor and analyst. DDA's function statements assume the minimum education/training requirements of a GS-5 entry level chemist position.

QUALIFICATIONS OF ANALYSTS

Each analyst's qualifications to perform the stated functions are shown through records of training and completed work assignments, and where possible, through performance testing. For analysts who have completed at least the initial training period, the plan includes a yearly self-assessment of skills and training needs. Documentation is jointly maintained by analyst and supervisor.

According to their qualifications, chemists fit into three general categories: trainee/probationary (GS-5/7), permanent/experienced (GS-9/11), and senior (GS-12/13). There is of course a great deal of overlap between these groups, and a senior analyst may be a trainee in some particular new technique.

New analysts at all grade levels require extensive training in proper worksheet writing, and experienced analysts are still required to have yearly refresher training.

CERTIFICATION OF ANALYST

Certification of the analyst is done annually or more frequently by supervisory review of the documented qualifications.

REVIEW OF TRAINING AND CERTIFICATION

Documentation and certifications will be reviewed annually by the Quality Assurance Officer (QAO). File copies of 10% of all completed reports by DDA analysts will be audited at random by the QAO, assisted by a Quality Review Committee.

The plan is intended to be separate and distinct from the analyst's grade level and from the annual performance appraisal. The job of a newly hired chemist at any grade level is to be trained in the procedures in use at our laboratory. The amount of time spent on training will vary depending on the background and previous experience of the individual. As noted on the attached Functions/Skills Statements, the depth of supervisory review which an analyst's work receives is gradually reduced as experience is gained. Experienced analysts are still required to have annual updates on safety and GLPs, and the continual introduction of new instrumentation and techniques makes training essential for analysts at every level of experience. With the increasing complexity of analytical instrumentation, individual specialization is inevitable to some degree. Consequently, an analyst with years of experience and outstanding job performance may have no familiarity with a particular instrument, while a relatively new analyst with less overall experience may be the in-house expert on a certain technique or method.

Laboratory supervisors and analysts are jointly responsible for the planning and scheduling of training, selection of individuals, and documentation. A yearly review of the training/certification records for each analyst is done by the QAO.

Using information collected from the Analyst Skills Profile and from the Analyst Training Update, a data base could be created and used to identify those analysts who need or would benefit from training in a specific area, or conversely, to select those most qualified to perform a particular assignment.

Records Required for the Training and Certification Plan

Contents of Analyst Folders:

A. For new employees
   1. Statement of functions. (Attachments A-1 through A-5)
   2. Curriculum vitae. (Attachment A-6)
   3. Documentation of training assignments completed. (Attachment A-9) Checklist kept by supervisor showing date completed, name of senior analyst who supervised training (if applicable), result of analysis of test sample (if applicable). In addition, laboratory notebook to be kept by analyst.
   4. Certification by supervisor on completion of required training. (Attachment A-10)
   5. After completion of initial training/probationary period, updates, additional training, and self-assessment in same manner as long-term employees. (Refer to B. 3 and C. below)

B. For certification of long-term employees (Grandfathering)
   1. Statement of functions. (Attachments A-1 through A-5)
   2. Curriculum vitae. (Attachment A-6)
   3. Self-assessment forms: (Attachments A-7 & A-8)
      Analyst Training Update, Analyst Skills Profile
   4. Records (checklist) of annual updates for safety, GLPs.
   5. Documentation of work assignments.
   6. Certification by supervisor. (Attachment A-10)

C. Regular maintenance of folders after initial certification
   1. Additional training, courses, papers presented (update to CV).
   2. Assignments, projects, use of special equipment.
   3. Training given to other analysts, demonstrations for visitors.
   4. Write-up of SOP for calibration or use of special equipment.
   5. Annual review by QAO.

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LIST OF ATTACHMENTS

FUNCTIONS/SKILLS STATEMENT

GS-5 Chemist

Function: With guidance from supervisor or a senior analyst, analyzes samples of pharmaceuticals, both bulk drug materials and finished products, using established methods.

Completes training modules, check samples, Quality Assurance and safety training, and other training as assigned by supervisor.

Skill:

1. Knowledge of basic chemical principles, theories, and laboratory techniques, such as would be acquired through the successful completion of a four-year college program in chemistry.
2. Use of instrumentation required for official USP methods, in conformance with SOPs. (UV, IR, HPLC, GC, Automatic titrator, pH meter, Polarimeter, Melting point apparatus)
3. Application of required Quality Assurance procedures.
4. Adherence to established Laboratory Safety procedures.
5. Communication of results in written report.

Review level 1: Work is reviewed and discussed when assigned and while in progress. Report is reviewed, and revised as needed.

FUNCTIONS/SKILLS STATEMENT

GS-7 Chemist

Function: Analyzes samples of pharmaceuticals, both bulk drug materials and finished products, using established methods.

Skill:

1. Professional knowledge of chemical principles, theories, and practices.
2. Use of more advanced instrumentation, such as computer-controlled HPLC or GC systems, automated dissolution system.
3. Application of special techniques such as TLC, Thermal Analysis, Microscopy.
4. Application of required Quality Assurance procedures.
5. Adherence to established Laboratory Safety procedures.
6. Communication of results in written report.

Review level 1-2: Work is discussed when assigned and while in progress. Report is reviewed and revised as needed.

FUNCTIONS/SKILLS STATEMENT

GS-9 Chemist

Function: Selects the appropriate method and analyzes samples of pharmaceuticals, both bulk drug materials and finished products.

Skills:

1. Professional knowledge of chemical principles, theories, and practices.
2. Knowledge of Agency's regulatory programs and objectives.
3. Use of more advanced instrumentation, such as computer-controlled HPLC or GC systems, automated dissolution system.
4. Application of special techniques such as TLC, Thermal analysis, Microscopy.
5. Application of required Quality Assurance procedures.
6. Adherence to established Laboratory Safety procedures.
7. Communication of results in written report.

Function: Participates in collaborative studies with other chemists in FDA or outside laboratories.

Skill: Previous experience or hands-on training with the instrument or technique required by the method to be studied.

Function: Develops new methods or revises existing methods. Validates methods developed, conducts collaborative studies.

Skills:

1. Experience in sample analysis using compendial and manufacturer's methods.
2. Knowledge of validation techniques and criteria for method acceptance.

Review level 2: Work is discussed if needed, reports are reviewed.

FUNCTIONS/SKILLS STATEMENT

GS-11 Chemist

Function: Analyzes samples of pharmaceuticals, both bulk drug materials and finished products, including the very difficult, complex, or unusual samples. Does check analysis of samples found out-of-limits by original analysis.

Skills:

1. Professional knowledge of chemical principles, theories, and practices.
2. Knowledge of Agency's regulatory programs and objectives.
3. Use of most complex instruments, such as FTIR-TGA, GC-MS, Particle size testing, Ion Chromatography, Capillary Electrophoresis.
4. Application of special techniques such as TLC, Thermal analysis, Microscopy.
5. Application of required Quality Assurance procedures.
6. Adherence to established Laboratory Safety procedures.
7. Communication of results in written report.

Function: Evaluation of methods submitted with New Drug Applications or Abbreviated New Drug Applications.

Skill: Knowledge of method validation procedures.

Function: Participates in collaborative studies with other chemists in FDA or outside laboratories.

Skill: Previous experience or hands-on training with the instrument or technique required by the method to be studied.

Function: Develops new analytical methods or revises existing methods. Validates methods developed, conducts collaborative studies.

Skill:

1. Experience in sample analysis using compendial and manufacturer's methods.
2. Knowledge of validation techniques and criteria for method acceptance.

Function: May serve as a Team Leader for a project or study.

Skill:

1. Leadership of small group of analysts or technicians.
2. Planning of work for most efficient use of resources.
3. Knowledge of statistical methods for data evaluation.

Review level 3: Work is accepted as valid, report is reviewed.

FUNCTIONS/SKILLS STATEMENT

GS-12 Chemist

Function: Analyzes samples of pharmaceuticals, both bulk drug materials and finished products, including the most difficult, complex, or unusual samples. Does check analysis of samples found out-of limits by original analysis.

Skill:
1. Professional knowledge of chemical principles, theories, practices, nd established methodologies.
2. Knowledge of FDA law, regulations, agency programs, and industrial practices.
3. Use of new and complex computer-controlled instruments, such as FTIR-TGA, GS-MS, Particle size analysis, Ion Chromatography, Capillary Electrophoresis.
4. Application of special techniques such as TLC, Thermal analysis, Microscopy.
5. Application of required Quality Assurance procedures.
6. Adherence to established Laboratory Safety procedures.
7. Communication of results in written report.

Function: Evaluates methods submitted with New Drug Applications or Abbreviated New Drug Applications.

Skill: Knowledge of method validation procedures.

Function: Participates in collaborative studies with other chemists in FDA or outside laboratories.

Skill: Previous experience or hands-on training with the instrument or technique required by the method to be studied.

Function: Develops new analytical methods or revises existing methods. Validates methods developed, conducts collaborative studies.

Skill:
1. Experience in sample analysis using compendial and manufacturer's methods.
2. Knowledge of validation techniques and criteria for method acceptance.

Function: Acts as a Team Leader

Skill:
1. Leadership of small group of analysts or technicians.
2. Planning of work for most efficient use of resources.
3. Knowledge of statistical methods for data evaluation

Function: Evaluates new laboratory instruments.

Skill: Expertise in operation and calibration of instruments.

Review level 4: Work is accepted as authoritative. Report is accepted

with first level review.

FUNCTIONS/SKILLS STATEMENT

GS-13 Chemist

Function:

CURRICULUM VITAE

Educational Background: List for undergraduate and beyond, the name of each institution and the dates attended, majors and minors, and degrees awarded.

Additional Training: List all part-time or short-time training not included in Educational Background. Give dates and duration of course such as credit hours, etc.

Research and/or Scientific Experience: List professional jobs held in chronological order giving titles, grades, and dates.

Honors and Awards: List with dates and brief description.

Membership in Professional Societies: List

Participation in National Scientific Meeting, Technical Conferences, Workshops, etc.: List, give date, location, type of meeting, and title of talk, paper, or poster.

Special Assignments: List each one and briefly describe.

Publications: List in chronological order with names of all authors. Give full reference including journal, volume, and page number.

ANALYST TRAINING UPDATE

1. Please list the instruments/techniques you have used during this reporting period. Indicate the sample or project where the technique was used, name & model of instrument, if applicable.

2. Have you presented talks or poster sessions on a project you have worked on or are working on? Please list the name of the conference/meeting, the name of the paper/talk or project, and the date.

3. Have you conducted training or presented a demonstration on the use of a particular instrument or technique? List the type of training or demonstration, to whom it was presented, and the date(s).

4. List any new training or courses you have completed during this reporting period. Give name of person/company/institution who presented the training, number of hours, and dates.

5. Have you conducted or participated in a collaborative study during this reporting period? If so, give brief description of work.

6. What are your plans/needs for future training for yourself:
   Immediate - needed for current projects

   Long Range - needed for anticipated projects

7. List any areas where you are willing to offer training to others.

ANALYST SKILLS PROFILE

For each technique or instrument, write the number which best describes your level of experience (add to the list any instruments which are not listed):

1 - No experience
2 - Introductory - watched videotape or demo - no hands-on
3 - Beginning - some hands-on training, ran practice sample
4 - Familiar - run routine samples without assistance
5 - Familiar but not recently - need refresher to become current
6 - Advanced - give training to others, troubleshoot problems

HPLC

EC detector

RI detector

HPLC/PC Workstation

Capillary Electrophoresis

GLC

Capillary GC

GS-MS

FTIR

TGA

Titrator

Dissolution/HPLC

Dissolution-Automated UV

TLC

Densitometer

Particle size-Malvern

Particle size-Hyac/Royko

Polarizing microscope

Near-IR

Ion Chromatograph

Cascade Impactor

X-Ray Diffraction

Melting point apparatus (Mettler)

Polarimeter

PC - Windows Paradox

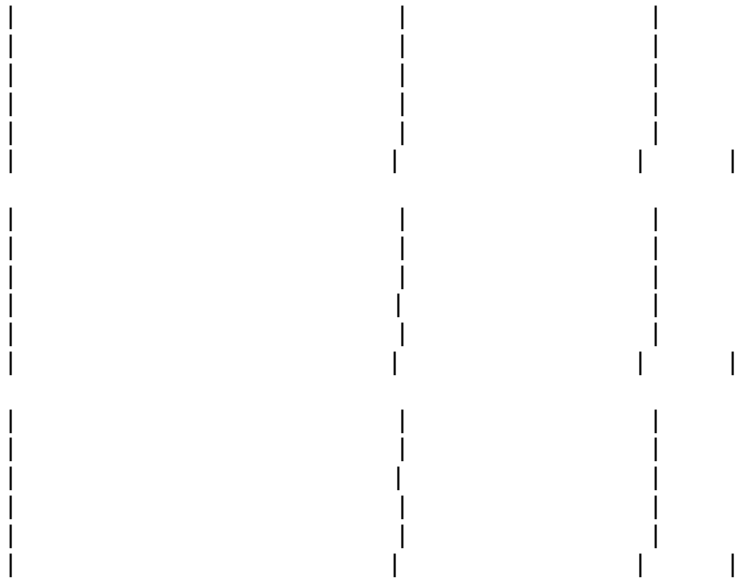
UV-Vis Spectrophotometer

TRAINING DOCUMENTATION CHECKLIST
Division of Drug Analysis
St. Louis, MO

Laboratory   Supervisor

Name   Quality Assurance Officer

Assignment/ Training Module REMARKS	Sample analyzed/ Method used	Instructor --------- Hours	Date Assigned/ Completed



STATEMENT OF ANALYST CERTIFICATION
Division of Drug Analysis
Drug Monitoring Branch

This certifies that Chemist
is qualified through documented experience and training to perform the functions required for this position in conformance with established DDA quality standards.

Laboratory Supervisor (Date)

Quality Assurance Officer (Date)