ESTABLISHING A CGMP LABORATORY AUDIT SYSTEM
A Practical Guide

David M. Bliesner
Delphi Analytical Services, Inc.
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10 9 8 7 6 5 4 3 2 1
To my wife Kathy, and my children Nick, Sam and Erin
for their love, support and patience.
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Delphi Analytical Services, Inc. has spent the last several years helping companies in the pharmaceutical industry improve their level of compliance with current good manufacturing practices (CGMPs). This involvement has included large and small companies who have already been subject to regulatory action from the U.S. Food and Drug Administration (FDA) as well as companies who are taking preventative measures to avoid regulatory action. As part of this effort, a significant amount of time has been spent reviewing the quality systems associated with analytical laboratories.

The FDA mandates that a drug firm and its laboratory be operated in a state of control by employing conditions and practices that assure compliance with the intent of the Federal Food, Drug, and Cosmetic Act and portions of the CGMP regulations that pertain to it. Specifically, a laboratory, which is in a state of control, provides services that confirm the company is producing finished drug products of sufficient quality, known strength, proper identity, and known purity.

In order to demonstrate that your firm is in control, data are needed to support your position. These data are obtained by executing a well organized and systematic laboratory audit.

In addition to demonstrating current control, you must show that you will be in control in the future. Therefore, you must also demonstrate you have a system in place to continually monitor the status of compliance within your laboratory and correct deficiencies if they are discovered.

*Establishing a CGMP Laboratory Audit System: A Practical Guide* is a systematic approach for auditing your laboratory to demonstrate to your
organization and, ultimately, to the FDA, that you are in control of your laboratory system. In addition, this guide helps you accomplish the goal of establishing sustainable compliance within your laboratory. This text is a “how to” book—how to establish a current good manufacturing practices (CGMP) laboratory audit system. The intended purpose of the book is to instruct through detailed flowcharts, checklists, and descriptions, the process of establishing a CGMP laboratory audit system from scratch or to upgrade existing systems to comply with current industry practices. Moreover, this process is an excellent means to teach or refresh laboratory personnel on the nuances of operating a modern pharmaceutical laboratory under CGMPs.

Specifically designed for laboratories regulated by the U.S. government, this guide is useful for:

- Facilities operating under current good manufacturing practices (CGMPs)
- Facilities operating under current good laboratory practices (CGLPs)
- Facilities operating under ISO standards.

However, any laboratory can benefit from the level of control obtained by the guide and the corresponding incremental gains in efficiency and productivity from implementing such a system.

This guide is not an academic treatise, but a collection of real-world tools, that can be applied immediately and directly to your laboratory. Some unique and special features presented include:

- Detailed audit checklists corresponding to the seven subelements which compose the laboratory control system
- A real-world audit summary report example template
- The current FDA guidance document on the subject of drug manufacturer inspections
- Audit tools and templates, such as suggested meeting agendas, audit routines, audit calendars, and data capture forms.

All of these tools and others are provided on a CD-ROM, which accompanies this book, for easy application by the end users in their own laboratories. Moreover, these tools and templates are provided in readily modifiable formats so that they maybe tailored to fit the needs of the individual organization. The inclusion of these practical tools makes this guide unique. It would require untold personnel hours to develop these checklists and example templates individually. In fact in smaller organizations, the time, talent, and experience to create such tools is most likely outside their capabilities.
To my knowledge no such detailed instructional text for implementing CGMP laboratory quality systems (including detailed example templates of critical end-user documents) exists in the marketplace. I hope you find Establishing a CGMP Laboratory Audit System: A Practical Guide useful and wish you the best in your continuing quest to attain compliance and improve quality.

DAVID M. BLIESNER

Indian Rocks Beach, Florida
February 2006
CHAPTER 1

INTRODUCTION TO THE QUALITY SYSTEMS APPROACH TO CGMP COMPLIANCE

1.1 OVERVIEW OF QUALITY SYSTEMS

The Food and Drug Administration (FDA) mandates that a drug firm, and therefore its laboratory, be operated in a state of control by employing conditions and practices that assure compliance with the intent of The Federal Food, Drug, and Cosmetic Act and portions of the Current Good Manufacturing Practice (CGMP) regulations (e.g., 21 CFR Parts 210 and 211) that pertain to it. Activities found in drug firms, including operation of the laboratory, can be organized into systems that are sets of operations and related activities. Control of all systems helps to ensure the firm produces drugs that are safe, have the proper identity and strength, and meet the quality and purity characteristics as intended.

For drug firms, the FDA has outlined the following general scheme of systems that impact the manufacture of drugs and drug products:

1. *Quality System.* This system assures overall compliance with CGMPs and internal procedures and specifications. The system includes the quality control unit and all of its review and approval duties (e.g., change control, reprocessing, batch release, annual record review, validation
protocols, and reports, etc.). It includes all product defect evaluations and evaluation of returned and salvaged drug products. (See CGMP regulation 21 CFR 211 Subparts B, E, F, G, I, J, and K.)

2. **Facilities and Equipment System.** This system includes measures and activities that provide an appropriate physical environment and resources used in the production of the drugs or drug products, including:
   (a) Buildings and facilities with maintenance;
   (b) Equipment qualifications (installation and operation), equipment calibration and preventative maintenance, and cleaning and validation of cleaning processes, as appropriate. Process performance qualifications are included as part of process validation done within the system where the process is employed and;
   (c) Utilities that are not intended to be incorporated into the product such as HVAC, compressed gases, steam, and water systems.
   (See CGMP regulation 21 CFR 211 Subparts B, C, D, and J.)

3. **Materials System.** This system includes measures and activities to control finished products and components including water or gases that are incorporated into the product, containers, and closures. It includes validation of computerized inventory control processes, drug storage, distribution controls, and records. (See CGMP regulation 21 CFR 211 Subparts B, E, H, and J.)

4. **Production System.** This system includes measures and activities to control the manufacture of drugs and drug products including batch compounding, dosage form production, in-process sampling and testing, and process validation. It also includes establishing, following, and documenting performance of approved manufacturing procedures. (See CGMP regulation 21 CFR 211 Subparts B, F, and J.)

5. **Packaging and Labeling System.** This system includes measures and activities that control the packaging and labeling of drugs and drug products. It includes written procedures, label examination and usage, label storage and issuance, packaging and labeling operations controls, and validation of these operations. (See CGMP regulation 21 CFR 211 Subparts B, G, and J.)

6. **Laboratory Control System.** This system includes measures and activities related to laboratory procedures, testing, analytical methodology development, validation or qualification/verification, and the stability program. (See CGMP regulation 21 CFR 211 Subparts B, I, J, and K.)

As stated in (6) above, FDA considers a firm’s laboratory control system to be a key element in CGMP compliance. Within the laboratory control
systems are at least seven additional subsystems or subelements which include:

- Laboratory managerial and administrative systems,
- Laboratory documentation practices and standard operating procedures,
- Laboratory equipment qualification and calibration,
- Laboratory facilities,
- Methods validation and technology transfer,
- Laboratory computer systems, and
- Laboratory investigations.

Establishing and maintaining quality systems and subsystems demonstrates control.

1.2 QUALITY SYSTEMS AND COMPLIANCE WITH CGMPs: REASONS FOR AUDITING YOUR LABORATORY

The purpose for auditing your laboratory is to demonstrate to your organization and ultimately to FDA that you are in control of your laboratory control system. In order to demonstrate control, data is needed to support your position. These data are obtained by executing a well-organized and systematic laboratory audit.

In addition to demonstrating current control, you must show future control. Therefore, you must also have in place a system that continually monitors the status of compliance within laboratory and corrects deficiencies if discovered.

1.3 GOALS OF AUDITING YOUR LABORATORY

In short, the goals of a laboratory audit are:

- Demonstrate control by conducting the audit and generating data to support your position.
- If not in control then:
  - Show that you know why you are not in control;
  - Show that you know which areas are out of compliance;
  - Show that you know which areas have the greatest impact;
  - Develop interim controls to mitigate the impact of the areas with the greatest risk;
  - Develop a plan to put you back in control;
Implement the plan; and
Generate a system to continually monitor your state of compliance so you stay in control in the future (e.g., sustainable compliance).

1.4 LABORATORY AUDIT PHASES

As stated in the preceding list, a well-organized and systematic laboratory audit must be executed in order to obtain data to prove control. To accomplish this, the audit may be organized into the following phases:

- Preparation phase,
- Audit and data capture phase,
- Reporting phase,
- Corrective action phase,
- Verification phase, and
- Monitoring phase.

Details of the design and implementation for each phase are described in the remaining chapters of this book. In addition, some of the tools, templates, and examples needed to complete such an audit are included in the Appendices.

1.5 INTEGRATION WITH EXISTING PROGRAMS

One of the strengths of the laboratory control system audit process described in this guide is that it allows for easy integration and linkage with existing audit programs and data. Specifically:

- Data collected from previous internal audits, 483 observations, external audits, and gap analyses are linked and compiled via use of the laboratory audit form (LAF) data capture instrument.
- Existing corrective action project plans become part of the corrective action phase of this process and are managed as one coherent effort.

1.6 MODIFIABLE AND SCALABLE APPROACH

In addition to the ability to integrate this approach into existing systems, the guide is also constructed with the following major characteristics:

- Scalable. The audit approach described here is useful regardless of the size of the facility. It works whether your organization has 10, 100, or
several hundred employees. Simply scale the magnitude of the audit based on the availability of resources at your facility and match those laboratories that constitute your quality operations.

• *Modifiable.* The tools and templates outlined in this book are designed not only to instruct but to be copied and modified. Take them and modify them a little or modify them a lot. They are meant to save time and prevent reinvention the wheel.

REFERENCE


BIBLIOGRAPHY

Food and Drug Administration, Code of Federal Regulations, Food and Drugs, Title 21 Parts 210 and 211 “Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs: General” and “Current Good Manufacturing Practice for Finished Pharmaceutical,” Revised April 1, 2005.


2.1 PROCEDURE

The key to executing a well-organized and systematic laboratory audit is taking the time to develop the proper audit team organizational structure, define work functions, assign roles and responsibilities, conduct audit familiarization and overview sessions, and perform audit team training. The steps in this process are shown in Figure 2.1 and described in Table 2.1. Some details for each step are summarized in Table 2.1.

2.2 AUDIT TOOLS AND TEMPLATES

As referenced in Step 7 of Table 2.1 (see p. 11), in order to efficiently and effectively prepare for the audit and properly train the audit team members, the audit team leader should create and prepare a series of audit tools and templates. Some example tools and templates are provided in the following text. These tool templates are included on CD-ROM, which accompanies this guide, for use and modification as needed. It should be noted that these are sample tools and templates and should be used as a starting point for developing your own project management and training tools. It must also be emphasized that efforts expended during the audit preparation phase will insure the effectiveness, efficiency, and therefore, overall quality of the audit.
**PREPARATION PHASE**

- **Management Commissions Audit in Writing**
  - Step 1: 0.25 Day

- **Audit Team Leader Assigned**
  - Step 2: 0.25 Day

- **Audit Team Leader Defines Functional Areas to be Audited**
  - Step 3: 1.0 Day

- **Audit Team Members Chosen**
  - Step 4: 3.0 Days

- **Audit Team Assembled and Briefed**
  - Step 5: 1.0 Day

- **Audit Team Leader Creates Audit Tools and Templates**
  - Step 6: 3.0 Days

- **Train Audit Team Members**
  - Step 7: 3.0 Days

- **Functional Area Managers Contacted to Participate in Familiarization and Overview Sessions**
  - Step 8: 1.0 Day

- **Audit Team Leader and Functional Area Managers Give Familiarization and Overview Presentations**
  - Step 9: 4.0 Days

- **Disclosure Sessions Scheduled for Functional Areas**
  - Step 10: 1.0 Day

- **Hold Disclosure Sessions**
  - Step 11: 2.0 Days

**FIGURE 2.1** Workflow diagram for the preparation phase.
### TABLE 2.1  Explanation of Preparation Phase Workflow Diagram Steps

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<th>Step</th>
<th>Description</th>
<th>Estimated Duration</th>
<th>Explanation</th>
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<tbody>
<tr>
<td>1</td>
<td>Management commissions audit in writing</td>
<td>0.25 day</td>
<td>The success of any audit depends on management commitment and involvement. In addition, the FDA is very clear in its expectations of management commitment with respect to compliance with CGMPs. Therefore, it is important that management, at some senior level within the organization, formally commissions the audit in writing. This commissioning document should include the following sections: (1) Purpose, (2) Start date, (3) End date, (4) Expected deliverables, (5) Designation of audit team leader, and (6) Definition of the team leader responsibilities, level of authority, and accountabilities. The commissioning document should be signed and formally issued to the audit team leader once that individual is selected. Moreover, copies of the document should be circulated to all impacted personnel within the organization. The audit should be a well-publicized event. The allocation of one-quarter day to complete the task is based on typical times required to generate an inter-office memorandum. (Note: Throughout this guide, the minimum amount of time allocated to any particular tasks is one-quarter day.)</td>
</tr>
<tr>
<td>2</td>
<td>Audit team leader assigned</td>
<td>0.25 day</td>
<td>As implied in Step 1, assignment of the audit team leader is part of the audit commissioning process and is performed by senior management. Selection of an audit team leader is critical. The audit team leader is accountable held for the successful completion of the audit within the expected time frame. An individual with good project management and organizational skills is required. The audit team leader need not possess an in-depth understanding of the organization and its operations but should have a good command of laboratory CGMPs and an understanding of the laboratory control system. Previous audit experience is also a plus. Although quality assurance (QA) personnel are often</td>
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<th>Step</th>
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| 3    | Audit team leader defines functional areas to be audited | 1.0 day           | The audit team leader works with senior management and department managers to identify those areas that need to be audited. For example, finished product testing laboratories, raw material testing laboratories, product stability testing laboratories, and method transfer laboratories should all be considered for auditing. In addition, any laboratories that may be involved in in-process testing should be included in the audit. Particular attention should be paid to those areas that have known, or are suspected to have, CGMP deficiencies. The selection of the different laboratories to be audited should be communicated to the entire organization in writing by senior management.

The allocation of 1 day to complete the task may be insufficient for larger facilities with a large number of testing laboratories. Adjust the estimated days required as appropriate. |

| 4    | Audit team members chosen                        | 3.0 days          | As discussed in Chapter 1, the laboratory control system consists of seven different subelements, namely: (1) laboratory managerial and administrative systems, (2) laboratory documentation practices and standard operating procedures, (3) laboratory equipment qualification and calibration, (4) laboratory facilities, (5) methods validation and technology transfer, (6) laboratory computer systems, and (7) laboratory investigations. Therefore, each of these subelements (as appropriate) needs to be included in the audit.

Since each of these subelements needs to be included, the ideal composition of the audit team should vary depending upon the subelement and/or the laboratory being considered for such roles, laboratory managers and supervisors should be considered as well. |
audited. For example, when the Laboratory Computer Systems subelement is audited, the ideal composition of the audit team would be: (1) A laboratory computer system subject matter expert (SME), (2) a representative from the quality assurance unit, and (3) an outside member (e.g., a consultant or someone from outside the laboratory being audited). However, for smaller organizations with limited resources, forming seven different teams may not be practical. Therefore, at the minimum, the team should include an SME and a representative from QA. The SME should function as the subelement leader who will receive direction from the audit team leader, during the subelement audit as necessary. Audit teams should not have fewer than two people, thus providing a data recorder and an interviewer. This minimum team number requirement insures data are appropriately captured and that the audit progresses in a timely fashion.

Since execution of CGMP laboratory audits can serve as excellent learning vehicles, consider involving as many personnel as possible. By participating in an audit, one often gains a much better understanding of CGMPs and the structuring and functions of the overall organization.

All personnel serving as audit team members should be assembled and briefed as to their individual responsibilities and the responsibilities of all involved parties. This briefing is conducted by the audit team leader. During this briefing the following topics should be covered: (1) Introductions of team members, (2) Review of the commissioning document, (3) Scheduling for training dates, and (4) Scheduled audit start date.

The allocation of one day to complete the task is given so that the audit team leader has sufficient time to prepare for the in briefing session. The actual session should only take about 1 hour.

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<th>Explanation</th>
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<tr>
<td>5</td>
<td>Audit team assembled and briefed</td>
<td>1.0 day</td>
<td>All personnel serving as audit team members should be assembled and briefed as to their individual responsibilities and the responsibilities of all involved parties. This briefing is conducted by the audit team leader. During this briefing the following topics should be covered: (1) Introductions of team members, (2) Review of the commissioning document, (3) Scheduling for training dates, and (4) Scheduled audit start date. The allocation of one day to complete the task is given so that the audit team leader has sufficient time to prepare for the in briefing session. The actual session should only take about 1 hour.</td>
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<tr>
<td>Step</td>
<td>Description</td>
<td>Estimated Duration</td>
<td>Explanation</td>
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</tr>
<tr>
<td>6</td>
<td>Audit team leader creates audit tools and templates</td>
<td>3.0 days</td>
<td>In order to efficiently and effectively prepare for the audit and train the audit team members, the audit team leader should create and prepare a series of audit tools and templates. Some of these tools and templates may include: (1) A detailed audit workflow diagram, (2) A weekly audit routine template, (3) A monthly audit schedule template, (4) An audit participant roles and responsibilities matrix, and (5) A detailed audit team member training agenda. These types of tools and templates allow for the most efficient use of managers and audit team members’ times. Moreover, once they are developed they can be modified at-will (as appropriate) and promulgated during the audit to all of the participants. In short, they can be used as project management tools. In addition, they can also be used for repeat audits executed during the verification and monitoring phases. Some example tools and templates are shown in Figures 2.2–2.4 (see pp. 14, 15, and 24) and Tables 2.2 and 2.3 (see pp. 17 and 21).</td>
</tr>
<tr>
<td>7</td>
<td>Train audit team members</td>
<td>3.0 days</td>
<td>Training of audit team members is critical. The better understanding of the audit process all team members possess, the more successful the audit will be. Training is usually conducted by the audit team leader, but may include QA personnel, consultants, personnel from other departments and divisions who have already been through an audit, or any other individuals who may improve the effectiveness of the training. At a minimum, training should include: (1) Review of the goals of the audit, (2) An in-depth review of the audit process, (3) Review of roles and responsibilities, (4) Discussion of the working calendar and audit routine, (5) Instruction on data capture and CGMP deficiency documentation, and (Continued)</td>
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TABLE 2.1  \textit{(Continued)}

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<th>Step</th>
<th>Description</th>
<th>Estimated Duration</th>
<th>Explanation</th>
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<tr>
<td>(6)</td>
<td>Audit strategy development including team member roles and responsibilities, sampling plans, etc. The working calendar is preliminary at this stage and will be finalized following discussions with the functional area managers. The allocation of three days to complete the task may be insufficient for larger facilities with a large number of testing laboratories. Adjust the estimated days required as appropriate.</td>
<td></td>
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<tr>
<td>8</td>
<td>Functional area managers contacted to participate in familiarization and overview sessions</td>
<td>1.0 days</td>
<td>These sessions are designed to introduce functional area managers to the audit process. Moreover, it is an opportunity for the audit team leader to get a general understanding of where and how each functional area manager fits into the organization.</td>
</tr>
<tr>
<td>9</td>
<td>Audit team leader and functional area managers give familiarization and overview presentations</td>
<td>4.0 days</td>
<td>The audit team leader gives an audit familiarization and overview presentation to all the functional area managers. The presentation should cover: (1) Review of the commissioning document, (2) Overview of the audit process, (3) Data capture procedures, (3) Procedures for reporting findings, and (4) Overview of the corrective and preventive action process. The managers should also be provided with guidelines and/or templates for disclosure session presentations from the audit team leader. This assists them in preparation and execution of disclosure session presentations, which they will be required to give in the future. Following the audit team leaders overview presentation, the functional area managers give a very brief description (high level) of who they are, what they do, and what testing their departments or sections are responsible for executing. Managers should provide organizational charts to the audit team leader at this point. Disclosure sessions are used to provide more detail about each</td>
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