

GMP Training Systems, Inc.

Creators of the GMP Ready-to-Use Training System™

Outsourcing Boot Camp *Qualifying, Working with, and Maintaining your Supplier/Vendor Relationship*

Learning Objectives

Upon completion of this workshop, participants will be able to:

- Understand the benefits and pitfalls of outsourcing.
- Develop effective User Requirements Specifications.
- Conduct effective supplier audits.
- Successfully award a project and engage your supplier.
- Develop a successful technology transfer plan.
- Successfully manage your supplier relationships.

Who should attend

This workshop is designed for anyone working in the FDA regulated industries who has responsibilities for working with outside suppliers. This typically includes Quality Assurance, Manufacturing, GMP Auditors, Purchasing, and Regulatory personnel.

Workshop instructors

Our instructors all have management experience in the FDA regulated industries. They have first-hand experience dealing with the day-to-day challenges of maintaining a compliant workplace. Our instructors work hard to keep each participant engaged in active learning throughout the entire workshop. Gamal Amer, Ph.D. is the instructor for this course.

Our approach

Our workshops are hands-on and practical, not theoretical. We use proven adult learning techniques, which includes a diverse array of group discussion, lecture, demonstrations, and small group interactive activities.

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Workshop description

Outsourcing has become a bigger part of our industry. This workshop will define what it means to use third party vendors and the reasons to use them. We will review the types of vendors or suppliers that may be needed, the reasons for outsourcing certain functions within the biopharmaceutical or medical device industry to such suppliers, and the regulatory imperatives associated with using outside vendors as defined in the Code of Federal Regulations (CFR), International Conference on Harmonization (ICH) Guidance and ASTM International E-2500.

You will learn a formalized approach to identify the need for outside service providers, how to qualify third party vendors, getting the process outsourced to the selected supplier, and engaging as well as managing your supplier. We will review some of the advantages of outsourcing as well as the perils and pitfalls to avoid.

We will discuss make-buy analysis, Request for Proposals (RFP) and their content, the need to conduct supplier audits, and eventual benchmarking of services' quality and cost. The workshop will look at all aspects of identifying, qualifying, engaging and managing third party suppliers in the Food and Drug Administration (FDA) regulated industries. We will also discuss some of the contractual issues and ending the relationship between you and your supplier.

DAY ONE

8:30 – 9:00

- 1. Introductions, initial questionnaire and identify attendees objectives**

9:00 – 10:00

- 2. Overview of the Supplier and Customer Issues and Making the Decision to Outsource**

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We will review what is meant by outsourcing and the issues associated with outsourcing. We will review the types of outsourced activities and suppliers available. We will also review the regulatory requirements associated with outsourcing drug product manufacturing related activities. During this presentation we will answer the following questions:

- a. What is outsourcing?
- b. Why outsource?
- c. What to outsource?
- d. How to use outsourcing to mitigate risks in your operation?
- e. How to define your needs and develop a User Requirements Specification (URS)?
- f. Make versus buy decision, what does it entail?
- g. What are some of the pitfalls associated with outsourcing and how to avoid them?
- h. What are the regulatory imperatives associated with outsourcing the drug industry?

10:00 – 10:30

3. **Exercise 1:** Develop a URS for a specific problem; Namely contract Packaging of a solid oral dosage product. Develop a list of supplier requirements.

10:30 -11:00 Refreshments Break

11:00-12:00

4. Identifying the Right Supplier for your Particular Need

We will discuss the steps and the proper approach to identify the correct supplier for your particular need.

We will explore:

- a. Developing a Request for Proposal (RFP).
- b. RFP content
- c. Developing the initial list of suppliers.
- d. How to qualify your supplier and select the right one.

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- e. Auditing your suppliers; why, when, who, how, and what?
- f. Approved, preferred, and qualified suppliers
- g. Award project to the chosen supplier.

12:00 – 1:30 Lunch

1:30 – 2:30

5. Supplier Audits and How to Conduct Them

We will outline the why, when, who, how, and of conducting a supplier audit to ensure that you select the correct supplier to meet your outsourcing needs.

During the presentation you will learn:

- a. Why audit your supplier.
- b. Who will audit your supplier.
- c. When will you audit your supplier.
- d. What will you audit.
- e. How will you conduct the audit;
 - i. Pre-audit questionnaire
 - ii. Areas to be audit and using check lists
 - iii. Close out meeting
 - iv. The advantages and disadvantages of using numerical audit scores.
 - v. Issuing observation reports and recommendations to your management and to your potential supplier.

2:30 – 3:00 Refreshments break

3:00 –4:00

6. Awarding the Project and Engaging your Supplier

In this presentation we will discuss the steps you must take in order to award the project to a certain contractor and how to work towards a successful relationship.

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This session will discuss the following:

- a. Issuing RFP to potential suppliers.
- b. Analyzing received proposals.
- c. Negotiating the Contract.
- d. Awarding the project.
- e. Transferring the technology.
- f. Managing the relationship.
- g. Terminating the relationship.

4:00 – 5:00

7. **Exercise 2:** Prepare a Supplier Audit Checklist for the example based on information developed in exercise 1.

END OF DAY ONE

DAY TWO

8:30 – 9:00

8. **Recap of Day One**

9:30-10:30

9. **Technology Transfer: Basis for Successful Outsourcing**

Having a plan to transfer the technology to your new contractor is very important. Properly transferring the technology you have to your contractor and ensuring that they can assimilate it quickly and effectively is a recipe for success. You must define what you all be transferring a-priori and have a well defined team and plan of action to do it once the contract is signed and the project is set in motion.

In this session you will learn:

- a. What is technology transfer
- b. What should be transferred
 - i. Process technology
 - ii. Facility and utility requirements
 - iii. Testing methods and laboratory techniques
 - iv. Safety and environmental issues/precautions

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- c. System to Facilitate Technology Transfer
 - i. Tech Transfer team
 - ii. Tech transfer procedures
 - iii. Tech transfer documentation
 - iv. Training procedures, schedules, and plans
- d. Timing for Conducting the Transfer
- e. Assisting your supplier with assimilating the new technology
 - i. Training Personnel
 - ii. Technical Support for Start-up
- f. System Validation
- g. Technical Support as Needed

10:30 – 11:00 Refreshments Break

11:00 – 12:00

10. Exercise 3:

Develop a request for proposal (RFP) based on information for the project in exercise 1. Outline a bid tab or check list to analyze various proposals.

12:00 – 1:30 Lunch

1:30 – 2:30

Continue exercise 3.

2:30 – 3:00 Refreshments Break

3:00 – 4:00

11. Managing The Relationship: How to Succeed and Get What you Want

This presentation will focus on the ongoing relationship between you and the contractor and how to ensure that the proper relationship is developed. Assuming the relationship will be a long one, you must learn how to deal with your contractor in such a manner that you meet your objectives and ensure that they remain profitable and a viable business.

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In this session you will learn:

- a. The role of the project manager.
- b. Key issues for success such as good communications, measuring performance, assisting with issues and conducting regular and issue related audits.
- c. Bench marking your contractor's performance and how to define the proper metrics.
- d. Oversight.
- e. Required management systems.

4:00 END OF DAY TWO