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PharmaED's

OUTSOURCING

Qualifying, Working, and Maintaining your Supplier/Vendor Relationship

JANUARY 25-26, 2010, RADISSON-PLAZA WARWICK, PHILADELPHIA, PA

Key Learning Objectives:

- Understand Supplier and Customer Issues in Outsourcing Relationships
- Learn Strategies for Making the Decision to Outsource
- Know How to Identify the Right Supplier for your Particular Outsourcing Need
- Understand How to Conduct Supplier Audits
- Learn Strategies for Awarding Projects and Engaging your Suppliers
- Understanding Technology Transfer Considerations for Successful Outsourcing
- Learn Strategies for Managing the Outsourcing Relationship

About Your Trainer:

Instructor:

Gamal Amer, Ph.D.

- *Experience includes over 25 years experience in the pharmaceutical and related industries*
- *Has held senior management positions with leading pharmaceutical and consumer products companies*
- *Comprehensive process design experience in bulk pharmaceutical chemicals manufacturing, biotechnology manufacturing, pharmaceutical solid dosage manufacturing, and containment of potent and radioactive therapeutics*
- *A recognized expert in Risk Management Planning (RMP), Risk Based GMP Compliance, and validation.*
- *Has lectured and published extensively, including in peer reviewed publication on Risk, Validation and GMP compliance.*

Bring this workshop to your location:

For more information, contact PharmaEd Resources at (217) 721-5774.

PharmaED RESOURCES, Inc.

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WORKSHOP AGENDA

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 CFR, ICH Guidance and ASTM 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 FDA regulated industries. We will also discuss some of the contractual issues and ending the relationship between you and your supplier.

Who Should Attend:

1. QA personnel
2. Manufacturing Personnel
3. GMP auditors
4. :Purchasing Personnel
5. Regulatory Personnel

Day One

8:30 ### Introductions, initial questionnaire and identify attendees objectives

9:00 ### Overview of the Supplier and Customer Issues and Making the Decision to Outsource

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 URS?
f. Make verses 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 ### 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 *Refreshment break*

11:00 ### 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.
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 *Lunch*

1:30 **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 *Refreshment break*

3:00 **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.
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 **Exercise 2**

Prepare a Supplier Audit Checklist for the example based on information developed in exercise 1.

5:00 *End of Day One*

Day Two

8:30 **Recap of Day One**

9:00 **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
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 *Refreshment Break*

11:00 **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 *Lunch*

1:30 **Continue exercise 3**

2:30 *Refreshment Break*

3:00 **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.

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 *Close of Workshop*

About The Instructor

Dr. Amer has over 25 years experience in the pharmaceutical and related industries. He has held senior management positions with leading pharmaceutical and consumer products companies. His experience includes comprehensive process design in bulk pharmaceutical chemicals manufacturing, biotechnology manufacturing, pharmaceutical solid dosage manufacturing, and containment of potent and radioactive therapeutics. He is also experienced with facility development for therapeutic products operations. Dr. Amer is a recognized expert in Risk Management Planning (RMP), Risk Based GMP Compliance, and validation. He has lectured extensively in the US, Europe, Asia, and the Middle East and taught many courses on subjects such as controlled release technology, GMP trend, Validation and Change Control, and implication of GMP compliance on process and facility design in the biotechnology industry. He has also published extensively in peer reviewed publication on Risk, Validation and GMP compliance.

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About your conference destination:

The Radisson-Plaza Warwick is located in the heart of downtown Philadelphia, and adjacent to beautiful Rittenhouse Square. From the conference venue, you can access many points of interest in Philadelphia including Independence Hall, the Kimmel Center and the Avenue of the Arts and numerous shops, hotels and excellent restaurants!

REGISTRATION INFORMATION

Register for the conference using one of four options:

Online: www.pharmaedresources.com **Phone:** (217) 355-7322 **Fax:** (847) 589-0708

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VENUE INFORMATION:

Dates:	January 25-26, 2010
Hotel:	Radisson Warwick Plaza Hotel
Hotel Address:	1701 Locust Street Philadelphia, PA 19103
Reservations:	(888) 201-1718 US
Hotel Telephone:	(215) 735-6000
Fax:	(215) 789-6105
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