

*Design of Experiments: SHORT COURSE*  
**REGISTRATION FORM (Please print or type)**  
**Registration Deadline is 2 weeks before the course.**

**Date: July 21 or July 28, 2016**

**Location: HTD Biosystems**

Name: \_\_\_\_\_

Company: \_\_\_\_\_

Mailing Address: \_\_\_\_\_  
\_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_

Postal/ZipCode: \_\_\_\_\_ Country: \_\_\_\_\_

Telephone Number: \_\_\_\_\_

FAX Number: \_\_\_\_\_

Email: \_\_\_\_\_

**Please send registration to:**  
HTD Biosystems  
1061 Serpentine Lane, Suite E  
Pleasanton, CA 94547

Tel: 510-367-0528  
Fax: 509-267-1491  
htd@htdcorp.com

**Cancellations:** Only requests for cancellation received prior to 1 week of the course will receive a full refund.

**SHORT COURSE REGISTRATION**

A registration form is included in this brochure. The registration fee of \$ 849 USD includes printed materials as well as refreshments and lunch on the day of the short course. All registration forms must be accompanied by a check made payable to: HTD Biosystems Inc. An acknowledgment of registration and a receipt will be emailed to you.

You can also register online at:

[Online Registration](#)

Please register early as the course is limited to only 10 registrants.

Contact HTD Biosystems for in-house training courses.

***HTD Biosystems***

HTD Biosystems provides assistance to companies faced with rapid development of pharmaceuticals. Our mission is to help these companies develop pharmaceutically acceptable, high quality formulations and drug delivery systems more efficiently. We also have experience with other aspects of processing sciences. HTD Biosystems uses unique and novel strategies in drug development that are much more effective than traditional approaches. Our approaches include:

- Implementing a coherent formulation/drug delivery strategy for efficient process development. We provide detailed preformulation and formulation services, lyophilization development, and development of critical stability-indicating assays.
- Comprehensive analytical methodology for characterization of pharmaceuticals using biochemical and biophysical analytics.
- Multivariate Statistical Methods for analyzing complex data sets and use of Design of Experiments (DOE) approaches that maximizes information from experimental trials. Dr. Nayar is a certified trainer for ECHIP DOE software

**Please visit us at [www.htdcorp.com](http://www.htdcorp.com)**

# Design of Experiments for Pharmaceutical Scientists

**Presented by**

**HTD Biosystems Inc.**

**BENEFITS OF ATTENDING**

This course will provide

- a detailed overview of the concepts of DOE and how to use DOE efficiently.
- emphasis will be placed on a mechanistic, rather than a phenomenological approach, toward rational and practical use of DOE in pharmaceutical development.
- the concept of Experiments by Design (EbD) and how it relates to Quality by Design (QbD) in pharmaceutical development is stressed.
- Using DOE in Real World Problems (with active class participation)

**Registration is \$**

## COURSE INSTRUCTOR

### *Rajiv Nayar, Ph.D.*

He received his B.Sc. and Ph.D. in Biochemistry from University of British Columbia, BC. After postdoctoral work at MD Anderson Tumor Institute, he joined the Canadian Liposome Company in Vancouver, B.C. In 1991, he joined Bayer Corp. Biotechnology Division in Berkeley, CA, where he was head of the Formulation and Drug Delivery Unit until 2000. He is presently President of HTD Biosystems Inc. He has published over 60 scientific articles and received eight U.S. patents. His research interests include protein formulation, drug delivery systems, and multivariate statistical methodology to product development. Rajiv Nayar is a certified course instructor in DOE.



### COURSE BACKGROUND AND OBJECTIVES

To provide attendees with: (1) the concept of Experiments by Design (EbD) and how it relates to QbD, (2) a solid understanding of Design of Experiments (DOE) methodology; and when and when **not** to use DOE; (3) detailed, rational strategies for using DOE efficiently

### WHO SHOULD ATTEND?

Anyone involved in development of pharmaceuticals as commercial therapeutic agents, whether for human or veterinary use. This would include those involved in production, purification, formulation, and manufacturing of small molecules, peptides, proteins, and vaccines. Managers responsible for oversight of these operations would benefit as well as researchers working in the laboratory.

## SHORT COURSE OUTLINE

- I. Basics of DOE
- II. Experiments by Design (Building Quality into DOE)
- III. Deming's Wheel: Quality by Design and how to effectively use EbD using efficient DOE methodology
- IV. The EbD and DOE processes: Plan, Do, Check, Act, and Report.
- V. Screening verses Response Surface Designs
- VI. DOE concepts: (Data error, Model error, resolution, least important difference, # of trials, # of replicates)
- VII. DOE in Pharmaceutical Development.
- VIII. Real World Problems



### *Testimonials*

*"This course gave me a clear understanding of how to best use DOE in my projects. A great course for scientists in pharndeuv."*

*"The concept of EbD was the most interesting thing I learned in this course. Using DOE by using the principals of EbD is the only way to go!"*

*"The instructor taught the course very clearly without getting us lost in statistical jargon".*