Biological Assays Course

REGIONAL BIOASSAY COURSES

OTHER FASTRAIN

COURSES IN THE FOLLOWING LOCATIONS

Seattle, WA	**June 4-5**
San Diego, CA	**July 19-20**
San Francisco, CA	**August 25-26**

FasTrain

- **High Quality**
- **Up-to-Date**
- **No Hidden Agendas!**
- **Practical**

4 Ways to Sign Up:

Phone:
916-729-0109

Fax in the Form:
916-729-2602

Web:
Www.bioquality.biz

Email:
Bq_editor@surewest.net

Back by Popular Demand!

Tired of paying for a technical course only to find out the "instructors" have a not-so-hidden agenda of getting you to use their CRO or buy their instrument? Come to this course and learn about the new trends and approaches to developing and validating biological assays. No hidden agendas—just pure technical savvy.

This 2-day intensive training course will ensure that you understand the basics of biological assays, including modern approaches to streamlining assay development., global regulatory requirements and various approaches to validation

About Your Instructor

Dr. Laureen Little, PhD
Back after a Three Year Hiatus from Teaching Public Courses!

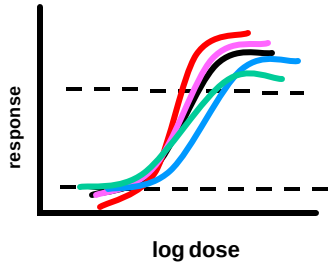
Dr. Laureen Little has worked for more than 20 years in biotechnology with an emphasis on the development and validation of biological assays for supporting commercial biopharmaceutical assays. She has worked with cell-based assays, animal assays, and binding assays for a variety of different products including; antibodies, vaccines, cell-based therapies, gene therapies, rDNA proteins, peptide hormones. She is a leading expert in the field of biological assays.,

What You Will Learn at This Course

- Regulatory requirements for potency assays during clinical studies
- Formatting your assay for reliability and efficient testing
- Selecting the right biological reagents to jumpstart your assay development
- Best practices for establishing dose-response curves and selecting appropriate models
- Approaches for establishing curve similarity (parallelism) between test and reference samples
- Appropriate calculation of potency values from relative potency assays
- Using Design of Experiment (DOE) approaches for streamlining development and robustness studies
- ICH and non-ICH approaches to assay validation
- New technical and regulatory trends—including inspection results for potency assays

Course Objective

How Parallel is Parallel?



Biological potency assays are considered a key quality assay for the development and commercialization of biopharmaceuticals. Despite this there are few published guidelines or journal publications about the expectations for these assays.

This course starts with development of biological assays with an emphasis on best practices, regulatory requirements and streamlined approaches to shorten your development times. The course then moves on to discuss the use of potency assay during clinical development and the approaches to establishing specifications and releasing clinical material.

The course then moves onto assay validation and preparation of data for BLA . Topics will include ICH approaches vs. non-ICH approaches and the use of DOE to shorten and improve robustness studies.

The course ends with a summary of recent inspection findings.

Upon completion of this course you will be posed to accelerate your assay development and be assured that you are meeting the most up-to-date regulatory expectations

Register Today

Four ways to register:

Phone:
(916) 729-0109

Fax:
(916) 729-2602

Email:
bq_editor@surewest.net

Web:

Who Should Attend? When Should we Show Up?

This course is designed to meet the requirements of professionals from biopharmaceutical companies who have been tasked with developing, submitting and running biological potency assays. The course is designed with the needs of novices and seasoned-bioassay specialists alike. Directors, heads of departments, managers, section heads, scientists and analysts from the following departments will be interested in attending:

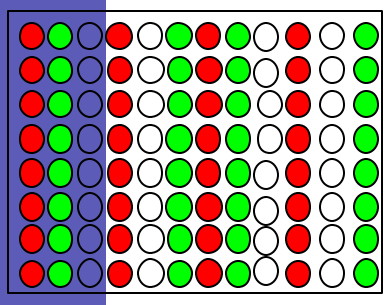
- Analytical Development
- Biologcial Assay Development
- Research and Development
- Quality Control
- Quality Assurance
- Regulatory Affairs

Although the course is designed with the practicing bioassay scientists in mind it is a great course for regulatory and statistical professionals.

A course receptionist and continental breakfast is onsite starting at 7:30 AM. Course instruction begins at 8:30 AM and will conclude at 4:30 PM. Lunch will be served at all courses.

"An appropriate assay format is a key to improving assay robustness. A poor format also keys in regulators whether you know what you are doing or not."
Laureen Little, PhD

Non-Cluster (non-random) Format



Reference Test #1 Test #2

Practical and Easy to Implement

This course is guaranteed to provide numerous hints—which are easy to understand and even easier to implement. No need to hire a consultant, statistical or otherwise to understand the concepts post-course!

Go back to your lab and reformat non-clustered format, know the number of replicates you need to run, have a rationale approach to choosing dose-response curve models and various approaches to determining parallelism.

Find out the top 10 errors and smart moves that your colleagues have made. (Hint: Always pay attention to your cells or watch animal husbandry!)

Course Agenda

Day 1

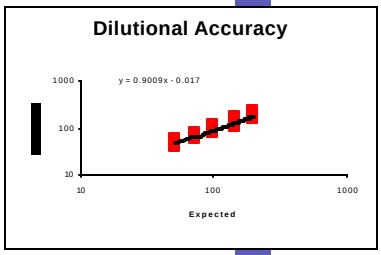
- Regulatory Framework:
  - Available Guidances (or lack thereof) and other publications
  - Pharmacopeial Chapters,: Final and Draft
  - FDA, EMEA, and WHO Expectations
  - Potency Requirements During PI/II/III Clinical Trials
- Assay Development
  - Selection and Handling of Critical Rare Reagents
  - The Reference Material: What is it? How do you treat it? And why you have to have it!
  - Establishing Dose-Response Curves: Model Selection, Doses, Number of Replicates
  - Determination of Curve Similarity Between Reference and Test Samples
  - Robust Plate Designs
  - The Pitfalls of Pseudo-Replicates
- Calculation Potency

Day 2

- Characterizing the Biological Assay
  - Determining Precisions and relative Accuracy: Statistically vs. ICH Practical Approaches
  - Specificity Issues: Common Pitfalls and Solutions
  - Establishing System Suitability: Using Initial Characterization Data and SPCC Approaches
  - Using DOE; Streamline Approaches to Robustness Studies
- Validation
  - ICH Approaches vs. VCA Approaches: How much? When? Balancing Resources and Analytical Requirements
  - Pre-Validation SOP Recommendations, including analyst training, calibration requirements, reagent and instrument qualification
- Valuable Case Studies
  - Binding Assay Validation and Animal Assay Validation
  - Cell-Based Assay Validation
- Dotting the I's and crossing the T's
  - Setting Specifications for Product Release
  - Stability Indication Properties of the Biological Assay
  - Comparability Studies for Replacing and Upgrading Existing Assays

"The Best Course and Instructor I have ever had for Bioassays! I will be sending all my analysts as soon as I can!"

Previous Course Attendee



Why a Log vs. Log Graph? This allows us a constant distribution of the variances.

BioQuality

WWW. bioquality.biz

Other FasTrain Courses Include:

- **Development and Validation of Immunogenicity Assays**
- **Three-Day GMP Training**
- **Stability Programs for Biotechnology and Biologic Products**

PO Box 7087
Citrus Heights, CA 95621
Phone: (916) 729-0109
Fax: (916) 729-2602
E-mail: bq_editor@surewest.net

BioQuality is dedicated to the dissemination of critical information in a easy-to-understand format. To this end we publish a monthly newsletter and provide high quality training courses. All of our courses can be customized and brought in-house to your company. In-house courses are provided at flat fees, starting at $8500.00 for US two-day courses.

For More Information contact:
Cori Schrader (916)729-0109

RESERVE YOUR PLACE TODAY!

Sign up Now.

Bring a Colleague and get a Group Discount!

Preferred Course:

☐ Seattle Bioassay Course	1 x 1590.00	or	_____ x 1390.00 =	_____
☐ San Francisco Bioassay Course	1 x 1590.00	or	_____ x 1390.00 =	_____
☐ San Diego Bioassay Course	1 x 1590.00	or	_____ x 1390.00 =	_____

Total _____

Student Name _____

Company _____

Address _____

_____

Additional Student Name _____

Additional Student Name _____

Additional Student Name _____

Additional Student Name _____

Method of Payment

- ☐ Check
- ☐ Bill Me
- ☐ Visa
- ☐ MasterCard

Credit Card # _____

Signature _____