

# Immunogenicity Assay Development and Validation

A FASTRAIN REGIONAL TRAINING COURSE

THIS FASTRAIN COURSE:

OFFERED IN THE  
FOLLOWING  
LOCATIONS

Seattle, WA June 9-10

San Diego, CA July 15-16

San Francisco, CA August 27-28

## FasTrain

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

## 4 Ways to Sign Up:

Phone:  
916-729-0109

Fax in the Form:  
916-726-1302

Web:  
[www.bioquality.biz](http://www.bioquality.biz)

Email:  
[bq\\_editor@surewest.net](mailto: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 approaches to developing and validating biological assays. No hidden agendas—just pure technical savvy.

This 2-day course will ensure that you understand the basics of immunogenicity assays, including modern regulatory expectations, increasing sensitivity, approaches to the drug-on-board issues and validating the assay. The course will cover screening assays, verification assays and neutralizing antibodies assays.

## About Your Instructor



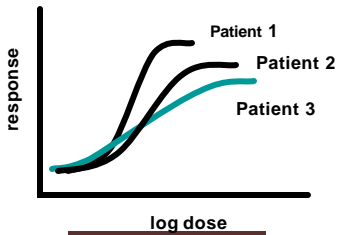
**Dr. Lauren Little, PhD**  
**Back after a Three Year**  
**Hiatus from Teaching Public**  
**Courses!**

Dr. Lauren 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, including assays to detect anti-drug immune response. Her expertise encompasses assay development, regulatory submission and expectations and establishing compliant laboratories for supporting immunogenicity studies. She is a leading expert in this field and an excellent instructor.

## What You Will Learn at This Course

- Establishing the correct biological reagents from the beginning
- Three-tier testing strategies and their use to decrease and improve sensitivity.
- Cut point determinations: current trends and common pitfalls.
- Improving assay sensitivity and reporting it appropriately
- Assay Sensitivity in the presence of circulating drug: improving and determining reportable values
- Regulatory requirements for immunogenicity assays during preclinical and clinical studies.
- Standard assay formats for screening immunogenicity assays.
- How to set up and run neutralizing immunogenicity assays.
- Design of Experiment (DOE) to streamline development and shortening robustness studies
- Practical validation approaches for serum-based assays.

Problem is actually even more complicated



# Course Objective and Outline

The course starts with a review of the requirements of an immunogenicity program, including the establishment a three-tier testing approach for screening, positive confirmation assay analysis and neutralizing capability determinations. The course then covers basic development of these assays, highlighting how to develop critical rare reagents. Different assay formats, including an analysis of strengths and weak-

nesses of each, is reviewed. This is followed by a review of how to establish positive/negative cut-offs, and improve sensitivity while maintaining throughput. The sensitivity of various assays to circulating drug will be discussed and an overview of available technologies and sample treatment approaches will be discussed. The course then moves into validation of the assays to support phase I, II and III clinical

studies. The course will end with preparation of the assay for use in a clinical screening laboratory. This includes an in-depth look at how the assay needs to be run, the writing of the clinical report, which of the GXP's are applicable in each of the ICH regions and a technical assessment of how to keep the assay running and how to verify that answers from one study to another are comparable.

"I gained more from this 2-day course than any other conference or course I have ever attended."  
Previous Course Attendee

COMPLETE COURSE AGENDA AVAILABLE AT [WWW.BIOQUALITY.BIZ](http://WWW.BIOQUALITY.BIZ)

## RESERVE YOUR PLACE TODAY!

Preferred Course:

- Seattle Immunogenicity Course
- San Francisco Immunogenicity Course
- San Diego Immunogenicity Course

Bring a Colleague and get a Group Discount!

- One attendee    1 x 1390.00 = \_\_\_\_\_
- Two attendees    2 x 1290.00 = \_\_\_\_\_
- Three or More    \_\_\_\_\_ x 1190.00 = \_\_\_\_\_

Total \_\_\_\_\_

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Student Name

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Fax: 916-726-1302 Call: 916-729-0109 or sign up on the web: [www.bioquality.biz](http://www.bioquality.biz)