

**BEBPAs first
white papers**



Biological Assays Conference

**Join us for these
free discussions.**

Round Table Discussions

Roundtable Discussions Added to the 2010 BEBPA Bioassay Conference

Two Evening Roundtable Discussion Groups

Setting and Using Assay Acceptance Criteria in Bioassays

Interactive roundtable discussion will be captured and will be put into BEBPA's first white paper. If you have thoughts or approaches you would like the industry to consider, this is the place.

Generating new topics for White Papers and Workshops

The scientific committees are being formed right now for future white papers. Come be part of the process and propose tough technical issues for future white papers.

MEETING UPDATE

BEBPA To Launch First White Paper Main Topic: Assay Acceptance Criteria

One of BEBPA's stated purposes is to produce non-consensus white papers to help industry achieve technical solutions more efficiently. BEBPA announces first white paper is now in progress. Come join us for the first white paper discussion groups.

Last year, in Rome, workshop attendees learned about various problems associated with maintaining cell-based potency assays for routine use. This year ideas from this workshop and any others you bring to the table will be included in BEBPA's first non-consensus white paper.

Several topics have already been proposed, including:

- Plate Specific Control Samples
- Technical Definitions of Terms Specifically for Bioassays
- Source of Assay Control Material
- Approaches to establishing acceptance measurements

Also be sure to join us on Thursday evening for a one hour discussion to gather new White Paper topics. Be an active participant in aiding BEBPA in gathering information for new Workshops. Here is how you can help:

- Propose new topics for White Papers
- Help define procedure for capturing information
- Sign up, volunteer, vote on Workshop themes

Not-for-Profit Meeting:

Practical and Scientific: Developed by Scientist for Scientists

Contact us at: www.BEBPA.org Phone: +1-916-729-0109 Fax: 1-916-729-2602

BEBPA's 3rd Annual Biological Assay Conference

Roundtable Discussion: Assay Acceptance Criteria

Wednesday, September 29, 2010

Setting and Using Assay Acceptance Criteria in Bioassays

The Topic:

Assay Monitoring for cell-based assays is a critical activity for maintaining and using assays for routine product release. Currently there are no standardized terminology or practices. Regulatory guidance is non-existent and industry standards are vague and highly variable. This round table will focus on proposing terminology and various parameters for monitoring as well as explore statistical approaches for setting action limits.

The Approach:

Dr. Michael Sadick will facilitate the discussion while a note taker records suggestions and comments. All suggestions will be compiled into a publicly available white paper to be posted on the BEBPA web page. Attendees are encouraged to bring ideas, slides, handouts or any other form of notes they are interested in having included in the white paper. No companies or individuals will be identified with specific recommendations unless they specifically request recognition.

- Criteria used are Assay Acceptance, rather than System Suitability, as the latter imply acceptance measurements taken, via 'system control' samples, prior to using the system to assay the test samples.
- Assay Acceptance Criteria samples need to be run on every assay plate; i.e., each plate must be tested independently of other plates (exceptions will be discussed).
- Assay Acceptance Criteria need to be based, primarily, upon an Assay Control, run along with the test (unknown) samples on every plate.
- The Assay Control sample needs to be treated, prepared and tested in the exact same fashion as the reference standard and test/unknown sample(s).
- Example: if the reference standard and test samples are run as an 8-point serial dilution curve in triplicate, then the Assay Control sample must be run as an 8-point serial dilution curve in triplicate
- Assay Control sample must be able to be evaluated and compared to reference curve both in terms of curve shape/fit as well as potency.
- Source of Assay Control material ought to be different than source for reference standard (e.g., different lot, etc).
- Two independent dilutions of the reference standard material, one as reference and one as Assay Control are not sufficient. Only testing ability to pipette accurately, not controlling the assay.

Thursday, September 30, 2010

Organizational meeting for future white papers

- Propose New Topics
- Discuss Writing Process
- Solicit volunteers for writing white papers

Roundtable leaders will be Doctors Stanley Deming and Michael Sadick.

Three Ways to Register

www.BEBPA.org Telephone: +1-916-729-0109 Fax: 1-916-729-2602