

Bioassay Design, Development, and Validation (3 Day) (Classroom and Laboratory)

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| Art. ID | USP-BIO-1030-02 |
| Unit | Each |
| Deliverydetails | No Dangerous Good |

Description

This three-day bioassay course consists of a two-day lecture presentation and a one-day hands-on laboratory experience. It will focus on the essential factors to be considered in the design, development and validation of bioassays. The course introduces related USP general chapters, terminology, bioassay life cycle, important statistical tools and best practices, followed by a detailed discussion on the topics of design and development, robustness, validation and post-validation, with examples of USP pharmacopeial bioassay. The course reflects statistical tools in USP General Chapters <111>, <1030>, <1032>, <1033> and <1034>. The lab portion of the course introduces attendees to best practices and techniques for successful bioassay development and validation. (Classroom 24 hours)