

SAFEBRIDGE[®] BOOT CAMP II: ADVANCED CONCEPTS TO SUPPORT DRUG DEVELOPMENT OF POTENT COMPOUNDS FROM R&D THROUGH MANUFACTURING

This advanced 1-day course builds on the concepts covered in the 2-day Potent Compound Safety Boot Camp, with a focus on case studies and problem solving to address potent compound safety issues in discovery, development, contract manufacturing, and commercialization. It leverages a systematic approach to successfully support drug R&D and manufacturing operations. Integrated case studies illustrate the elements involved in an effective safety management approach including:

- Data availability throughout drug development
- Containment and control, and handling guidelines at each scale of operation
- Managing potent compound safety in an outsourcing paradigm

COURSE FEE: \$1,225; includes a comprehensive resource manual, refreshments, breakfast, and lunch.

AGENDA: Registration and Breakfast start at 7:45 a.m.
Course Adjourns: 5:00 p.m.

COURSE TOPICS:

- **Drug Discovery**
 - Evaluation of compounds based on the literature, experience, computer modeling, and early testing
 - Identification of the unique risks of the research laboratory
 - Selection and verification of effective control strategies
- **Drug Development – Early Stages**
 - Evaluation of toxicity and clinical data
 - Evaluation of worker exposure at increasing scales of operation
 - Enhanced controls
 - Development of effective use of IH data
- **Drug Development – Late States**
 - Evaluation of more complex data
 - Application to quantitative risk assessment
 - Implementation, testing, and statistical demonstration of effective controls at larger scales
- **Commercial Scale Operations**
 - Application of defensible limits
 - Evaluation of CMOs
 - The concept of product safe handling guidelines

About SafeBridge Consultants

SafeBridge Consultants, Inc., a Trinity Consultants company, is the premier resource for high-level safety, health, and environmental support to the pharmaceutical, fine chemical, and biotechnology industries. Experts in the area of potent compound safety, the SafeBridge team combines industry veterans and board-certified health and safety professionals, toxicologists capable of determining safe workplace exposure levels for new chemicals and pharmaceuticals, industrial (occupational) hygienists who assess worker exposure and recommend controls for the manufacturing environment, and chemists knowledgeable in analytical techniques capable of detecting these materials at extremely low levels.

***For additional information, call Kent Rader at (650) 961-4820 x238
or register online at safebridge.com***