

## セミナー開催のご案内：

著名な産業衛生コンサルティング会社・SafeBridge 社による

高活性化化合物の安全な取り扱いに関するセミナー

“BOOT CAMP”<sup>®</sup> I が日本で開催されます。

2 日間にわたりおこなわれる高活性化化合物の安全な取り扱いに関する訓練コースです。高活性化化合物の安全性で業界をリードする専門家が講師となり、医薬品化合物の評価と安全な取り扱いに関する重要な概念を理解頂くもので、EHS やそれに関連する専門家向けに組まれたものです。

この集中カリキュラムは、化合物の活性と毒性の評価、サンプリングとモニタリングのプロトコル、制御技術、効果的な調査とそのコミュニケーション手法などに焦点を当てています。

参加者は以下を習得できます。

- ・化合物の活性や毒性の評価法
- ・モニタリング手法とその管理目標の設定やモニタリング結果の評価方法
- ・研究段階や毒性が知られていない化合物の安全な取り扱いに対する体系的なアプローチ
- ・高活性医薬品の安全な取り扱いのための包括的な健康/安全プログラムの要点
- ・欧米製薬会社での産業衛生の取り組み

### 日程：

7 月 12 日 (火) 9:00～18:00 (昼食：12:00～13:00)

7 月 13 日 (水) 9:00～18:00 (昼食：12:00～13:00)

### セミナーの内容

- 計画と要領 (組織的措置)
  - 実験室や製造現場での職業曝露に関するケーススタディ
  - プロジェクトチームへの化合物安全性要素の取り込み
  - 定性的/定量的ハザード評価
    - ✓ 職業曝露区分 (OEB)
    - ✓ 職業曝露限度 (OEL)
    - ✓ 許容一日曝露量 (ADEs/PDEs)
    - ✓ Acceptable Surface Limits (ASLs) など

- 定性的/定量的な産業衛生曝露評価（演習を含む）
- 封じ込めと制御（技術的措置）
  - 施設的设计とコントロール
  - プロセス設計とコントロール
  - 従来のコントロールと高度なコントロール
  - 実験室規模と製造規模のコントロール
  - 利用可能な暴露データ
    - ✓ 柔軟な封じ込め装置
    - ✓ 換気により封じ込め装置
    - ✓ アイソレータ
  - OEBs/OELs と封じ込めとそのコントロールの関連付け（演習を含む）

#### ✚ SafeBridge Consultants について

SafeBridge Consultants, Inc.（Trinity Consultants グループ）は、製薬、ファインケミカル、バイオテクノロジー業界に対して、安全、衛生、環境に関する高度なサポートを提供する世界的に著名なコンサルタント会社です。高活性化合物に対する安全な取り扱いに関する専門家集団である SafeBridge は、豊富な実績と資格を持った安全衛生の専門家、新しい化学物質や医薬品の安全な職場暴露レベルを決定できる毒物学者、作業員の暴露を評価し製造環境の管理を推奨する産業（職業）衛生士、これらの物質を極めて低いレベルで検出できる分析技術に精通した化学者などから構成される専門家集団です。

<https://www.trinityconsultants.com/safebridge-regulatory-life-sciences-group>

#### ✚ 協賛（同時通訳/会場の提供）；

ファルマ・ソリューションズ（株）

<http://www.ph-s.com/>

### 会 場

[TKP 日本橋カンファレンスセンター](#)

### 参 加 費

**参加料： ¥170,000/名**

【注記】参加料には、リソースマニュアル（英語版）、昼食が含まれています。

【注記】募集人数：最大 40 名

【注記】同時通訳があり。

### 申込み方法

弊社からのご案内の E メールに、「参加」とご記入の上、ご返信願います。受付後、弊社から受講票、並びに参加費のお振込み口座番号を連絡致しますので、受信後、お振込み願います。なお、お振込み手数料はご負担願います。

### 申込締切

2022年7月1日(金)

【注記】募集定員に達した時は、申込締切日前であっても、お申し込みを締め切らせて頂く場合がございますのでご了承ください。

【注記】参加者が 20 名以下の場合は、開催を断念させて頂く場合があります。

### キャンセル

2022年7月5日(火)以降のキャンセルにつきましては、申し訳ありませんが返金致しませんので、ご了承ください。申し込み者が出席できない場合は、代理出席が可能です。

### 服装

本セミナーの服装は、出席者にお任せ致します。気楽なビジネスカジュアルでご参加ください。

### 連絡先

ファルマ・ソリューションズ株式会社 PS セミナー事務局 松本/竹田

TEL : 045-489-3891

E-mail : [information@ph-s.com](mailto:information@ph-s.com)

【注記】セミナー開催日緊急連絡先 : 090-8876-8628 (竹田携帯)

🌟 講師略歴 :

● **Robert Sussman, Ph.D., DABT, (米国毒性学会認定毒性学者)**  
**Managing Director, SafeBridge Consultants, Inc.**

Dr. Sussman is currently Managing Director of SafeBridge Consultants, Inc., a Trinity Consultants company that provides environmental health and safety services to pharmaceutical, chemical, biotechnology and other industries. With more than 30 years of experience, he is a recognized expert in the evaluation of occupational hazards of potent pharmaceutical compounds and has delivered numerous papers and lectures on the subject. Dr. Sussman has extensive experience in: (1) performing risk assessments

including evaluating toxicological and exposure information to determine potential health effects of chemicals, (2) presenting toxicological data to regulatory agencies and assessing the potential impact of environmental, health and safety regulations on chemical and pharmaceutical companies, (3) evaluating safe levels for product cross-contamination by drug substances or other chemicals, and (4) the testing of chemicals for their toxic effects and the interpretation of data from these tests. Dr. Sussman has provided clients with the practical aspects of applying toxicological data to worker and consumer exposure situations for potent and toxic compounds handled in the workplace. He has provided training and technical support to diverse audiences to meet regulatory requirements and to provide solutions to their environmental health and safety challenges.

He has worked in various capacities in corporate occupational toxicology groups culminating as a Director of Occupational Toxicology in Pfizer's Corporate Environmental Health and Safety Department. His group was responsible for evaluating the toxicity of pharmaceutical products, their intermediates and other chemicals handled in research facilities and providing hazard communication information to all research facilities worldwide.

Bob has an Sc.B. in Bioenvironmental Engineering from Brown University and a Ph.D. in Environmental Health Science from New York University. He is a Diplomate of the American Board of Toxicology, a past member and chair of the AIHA's WEEL Committee, and a founding member of the Occupational Toxicology Roundtable and serves on that organization's steering committee. Bob is also a member of the Society of Toxicology, American Industrial Hygiene Association, and the International Society of Pharmaceutical Engineers. He has had an adjunct appointment at the NYU Medical Center where he gives several lectures each year on regulatory toxicology, risk assessment, and industrial hygiene aspects of the pharmaceutical industry.

● **Ryan Graff, MS, CIH (米国産業衛生協会認定産業衛生士)**

**Principal Industrial Hygienist, SafeBridge Consultants, Inc.**

**Principal Industrial Hygienist – Trinity Consultants, SafeBridge Regulatory & Life Sciences Group (2022-present)**

- Lead the SafeBridge industrial hygiene program. Our experts work with life sciences clients to deliver qualitative and quantitative exposure assessments, containment performance assessments, potent compound handling guidance, engineering project reviews, and provide technical support.

**Associate Director of Industrial Hygiene – Merck & Co Inc (2011-2022)**

- SARS-CoV-2: Provided structured, reliable, and timely guidance during unprecedented time of uncertainty. Collaborated with cross functional company team to develop and communicate global facility response and management policies, ensured availability of critical PPE and materials to keep on-site essential workers safe and achieved zero process interruption and continuous global supply of medicine to patients throughout the pandemic. Developed company specifications and designed/selected reusable cloth masks which were distributed to 95000 workers and their families globally. Collaborated with CDC/NIOSH, trade organizations, private industry and laboratories to develop and publish global mask performance and design specifications in ASTM F3502-21 Standard Specification for Barrier Face Coverings.
- Site Support: Reduced worker health risk and company liability through coaching and management of IH programs across 35 manufacturing and research facilities in north and south America. Provided technical support for IH hazard identification, evaluation, risk management, control solutions, and capital projects. Improved implementation and integration of industrial hygiene objectives through global or site-specific training programs with site IH leads, EHS managers and non-EHS business partners.
- Program Management: Standardized the practice of industrial hygiene by creating and managing global IH standards based on industry practice, international regulations, and varying country norms. Prioritized \$120MM capital investment and risk reduction

for thousands of operations globally through management of a global portfolio of IH improvement and compliance projects. Strengthened site EHS programs and proactively identified improvement opportunities through more than 20 international EHS audits with focus on health and high-risk work. Prioritize and influenced the development of internal exposure limits through active participation on Merck Industrial Toxicology Advisory Committee.

**Interim EHS Manager Boston-Cambridge, MA – Merck & Co Inc (6 months - 2017)**

- Led Boston-MRL through GSE standards implementation, audit response and site GSE team development while establishing MRL Cambridge through concept, construction, and occupancy.
- Served as active member of the Boston site leadership team. Provided business and EHS input to site management decisions.
- Managed site EHS staff and consultants, as well as onboarding of new site EHS manager.

**Senior Specialist – Safety, Industrial Hygiene, Ergonomics West Point, PA – Merck & Co Inc (1999-2011)**

- Standardized EHS Work: Standardized the practice of environmental health and safety across the West Point EHS team by writing, implementing, and providing training on internal EHS department general operating procedures. Wrote and implemented site safety procedures based on national regulations and company standards (e.g., powered industrial trucks, machine guarding, respiratory protection, hearing conservation, ventilation and testing, asbestos, EHS training, medical surveillance, injury and illness investigation).
- People: Influenced EHS program strength and perceptions. Delivered Safety Can Be Managed monthly in-person 8-hour course to more than 1000 new safety representatives, supervisors, and managers over 5 years. Influenced differentiation of early-mid career business partners through their active membership on top performing divisional safety committees.
- Site Support: Provided primary safety and industrial hygiene services to research, pilot plant, manufacturing departments.

Reduced workplace health risks through leadership of the site industrial hygiene team. Built and implemented tools used to prioritize and manage 7000+ IH and ergonomic risk assessments annually. Ensured that equipment and people were work ready. Built systems to track more than 90 IH instruments and more than 2000 respirator fit tests annually. Managed EHS master data for site implementation of SAP to track more than 18,000 hazardous materials.

**Off-shift Supervisor, Graphic Services West Point, PA – Merck & Co Inc West Point, PA (2000-2002)**

- While working in WP Safety & IH department on day shift, managed a union workforce of approximately 50 employees in a paper printing and folding facility during off-shift and weekends. Industrial Hygiene Technician Merck West Point, PA – Kelly Scientific (1998-1999)

- Provided industrial hygiene services to Merck West Point Asbestos Abatement and Safety & IH departments.

Radon Public Health Specialist – IUP Healthy Homes Project, Indiana, PA (1995-1997)

- Built a grant-based business with PA Department of Health and Indiana University of Pennsylvania to distribute free radon testing kits to low-income families.

- Managed a student team that responded to a radon hotline and processed distribution and tracking of radon testing kits.

- Delivered in-person or televised radon awareness training through local news media, social clubs, and school organizations.

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以上