

Product Safety and Recall Seminar

Providing manufacturers of unregulated products and manufacturers regulated by the Food & Drug Administration (FDA) with current information regarding their duties and responsibilities after sale of their products.

Thursday, August 12, 2010

**San Diego Marriott Hotel and Marina
333 West Harbor Drive
San Diego, CA 92101**

Schedule-at-a-Glance


Product Safety and Recall Seminar

The seminar will provide manufacturers of unregulated products and those regulated by the Food & Drug Administration (FDA) with current information regarding their duties and responsibilities after sale of their products. Attendees will learn about the best practices associated with protecting their companies and themselves from the legal and economic risks associated with product safety, product liability and recall matters.

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| 9:00 – 9:30 | Registration |
| 9:30 – 10:45 | The Legal and Regulatory Perspective – Kenneth Ross – Bowman and Brooke LLP
Post-sale risk assessment and post-sale responsibilities under the common law and FDA requirements for post-sale monitoring, reporting, and recalls. |
| 10:45 – 11:00 | Break |
| 11:00 – 12:00 | Recall Preparedness and Execution – Steve Edwards – ExpertRECALL |
| 12:00 – 1:00 | Lunch – Q&A with Willie Bryant – Former FDA Senior Recall Coordinator |
| 1:00 – 2:00 | Recall Case Study – Steve Edwards – ExpertRECALL |
| 2:00 – 2:15 | Break |
| 2:15 – 3:15 | Defending Litigation Involving Recalls – Kim M. Schmid – Managing Partner, Bowman and Brooke LLP |
| 3:15 – 3:30 | Q&A |

General Information

Fee covers: All seminar literature, continental breakfast and lunch will be provided.
Location: San Diego Marriott Hotel and Marina, 333 West Harbor Drive, San Diego, CA 92101



Speaker Bios

Kenneth Ross – Of Counsel – Bowman and Brooke LLP

Kenneth Ross is one of the world's most experienced and well-known lawyers practicing in the areas of product safety, product liability prevention, and regulatory compliance. One area where Mr. Ross concentrates his practice is post-sale issues such as recalls and retrofits. He helps companies organize themselves to deal with post-sale issues, evaluate post-sale issues, and decide how to respond such as reporting to an applicable government agency and undertaking a recall. He has worked with the U.S. Consumer Product Safety Commission since the late 1970's and more recently with the FDA and the NHTSA.

Steve Edwards – Recall Consultant – ExpertRECALL

Steve Edwards is a Recall Consultant for ExpertRECALL. Mr. Edwards is responsible for ExpertRECALL's Recall service offering including working with prospective clients to ensure flawless customer integration and satisfaction. Steve assists in the recall scoping, execution and plan development for pharmaceutical and medical device manufacturers, including execution of one of the largest reported medical device recall events in 2007-08. Prior to joining ExpertRECALL, Mr. Edwards worked for Sony as an Outsourcing/Planning Specialist for their Americas Optical Disc manufacturing division. Steve is a graduate of Purdue University and holds a bachelor's degree in Organizational Leadership.

Willie R. Bryant, Jr. – Former FDA Senior Recall Coordinator

Willie R. Bryant, Jr. is a thought-leader in the world of recalls, as a result of his extensive experience. During his 41 year tenure at the U.S Food and Drug Administration (FDA), Mr. Bryant served in the Emergency Operations Branch providing guidance, policy, and coordination of all recall functions to the FDA district and center recall staffs. Mr. Bryant also worked as the coordination point between drug and device firms, the center recall staffs, FDA's Office of Criminal Investigation, and other district offices who were involved with the management of recall activities. Additionally, Mr. Bryant led the development of the FDA's newest technology for recalls, the Recall Enterprise System (RES), which creates seamless and immediate information exchange between district recall coordinators, center recall staffs, the Office of Public Affairs, and contractors. For the past several years, Mr. Bryant has shared his expertise with business leaders and clients as a distinguished fellow at ExpertRECALL™. Mr. Bryant graduated from Frederick College in 1963.



Kim M. Schmid – Managing Partner – Bowman and Brooke LLP

Kim Schmid focuses her litigation practice on defending companies in drug and medical device cases in courts across the country. She is currently serving as National Coordinating Counsel in mass tort medical device litigation. In addition to her defense litigation practice, she advises clients on FDA regulatory compliance and reporting requirements.

In courts, Kim has successfully tried cases and defended medical device products including latex gloves, breast implants, hip stem implants, infusion pumps, orthopedic devices, implantable cardiac care devices, suction devices, surgical instruments, device monitors and blood warming units. She has also defended IDE products utilized in clinical trials as well as Class I, II and III FDA cleared devices and defended pharmaceutical cases involving generics, branded, OTC and Rx medications.

Kim was recently named as Medmarc’s Attorney of the Year for 2010; Medmarc is the nation’s largest insurer of medical device companies.



Product Safety and Recall Seminar

Space is limited. Register early to assure your place at the August 12th Conference!

Registration fee: Early Bird Special \$149 if you register before July 20th
 \$199 if you register after July 20th

Name: _____

Title: _____

Company: _____

Address: _____

City/State/Zip: _____

Phone: () _____ Fax: () _____

Email: _____ Nickname (name tag) _____

Billing Information _____

Company Name: _____

Card Holder Name: _____

Billing Address: _____

Type of Credit Card (circle one): MasterCard Visa Discover AMEX

Credit Card Account Number: _____

Expiration Date: _____

How to Register _____

Fax: Fax completed form to 866.875.0545

Call: 317.275.7537 with questions.

Email: Email to ksutton@stericycle.com

Substitution Policy

Please send any substitution information to the fax, phone or e-mail listed above. No cancellations accepted.