



BIO SOTERIATM

DRUG SAFETY & RISK MANAGEMENT SPECIALISTS



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DRUG SAFETY IS OUR FOCUS

BioSoteria, a drug safety consulting company with offices in California and North Carolina, provides high quality, innovative drug safety consultant services and educational programs to the biopharmaceutical and healthcare community.

BioSoteria offers **a wide range of pharmacovigilance consultative services throughout the product life cycle**, including clinical safety surveillance, postmarketing pharmacovigilance, and therapeutic risk management programs.

The field of drug safety is complex and dynamic. Maintaining corporate compliance in medical product safety surveillance requires continuous updates and training to keep up with rapidly changing regulations and practices. As such, BioSoteria provides **engaging, up-to-date multimedia educational opportunities and training programs** on multiple topics in drug safety and pharmacovigilance, as well as customized training solutions to meet the unique needs of your company.





FROM THE PRESIDENT & CEO

Thank you for your interest in **BioSoteria**.

I founded BioSoteria in 2007 with a strong vision of a progressive drug safety and pharmacovigilance consulting and education company that would serve the needs of the biopharmaceutical and medical device industry today, and tomorrow.

Our team of dedicated drug safety and educational professionals offer our clients superior service and programs. We are:

- **Experienced** in safety surveillance and therapeutic risk management throughout the product life cycle
- **Dedicated** to patient safety
- **Committed** to excellence
- **Devoted** to building and sustaining partnerships with the pharmaceutical, biotechnology, and healthcare communities
- **Leaders** in drug safety training and innovative educational programs

We look forward to partnering with you and your company.

Sally Van Doren, PharmD
President & CEO, BioSoteria

WHAT'S IN A NAME AND LOGO? **OUR CORE VALUES.**



From the beginning, we set out to build a company based on our sincere commitment to public health and patient safety. We wanted a name that reflected who we are and what we do, every day and in every way. The result: BioSoteria, derived from the union of Bio, the Latin root for Life, and Soteria, the Greek goddess of safety and of deliverance and preservation from harm. Our logo represents a cradling protective hand of individual people and diverse populations, and exemplifies BioSoteria's commitment to patient safety.



CONSULTING SERVICES

BIOSOTERIA'S EXPERIENCED DRUG SAFETY SPECIALISTS INTEGRATE SEAMLESSLY WITH YOUR TEAM TO PROVIDE A FULL RANGE OF SERVICES, INCLUDING:

- Premarketing safety surveillance
- Postmarketing pharmacovigilance
- Therapeutic risk management
- Regulatory compliance assessment and regulator inspection preparedness
- Safety department infrastructure and SOP development
- Selection and implementation of hosted safety database solutions
- Multimedia eLearning courses and customized, on-site training programs

SAFETY SERVICES

THROUGHOUT THE
PRODUCT LIFE CYCLE

PREMARKETING SAFETY SURVEILLANCE

- Serious adverse event case management, medical evaluation, and reporting
- Annual safety reporting
- Premarketing safety signal detection and assessment
- Development of Safety SOPs and Safety Monitoring Plans
- MedDRA coding and review
- Developmental Core Safety Information (DCSI)
- Data Monitoring and Event Review Committee preparation
- NDA, BLA, 505(b)2, 510(k) submission safety analyses and report writing
- FDA advisory committee safety advisement and preparations
- Responses to safety inquiries from regulatory agencies



POSTMARKETING PHARMACOVIGILANCE AND RISK MANAGEMENT

- Spontaneous ADR report management, medical evaluation, and reporting
- Literature review for ADR reports
- Safety compliance audits
- US Periodic and Periodic Safety Update Reports
- Company Core Data Sheet (CCDS) and Product Labeling updates
- Therapeutic risk management (RMPs, RiskMAPs, REMS)



Clinical Safety
Surveillance

NDA/BLA
Submissions

Hosted Safety
Database Solutions

Postmarketing
Pharmacovigilance

Safety Signal
Detection, Risk
Management

Educational
Programs

EDUCATION AND TRAINING

TODAY'S RAPIDLY CHANGING GLOBAL REGULATORY ENVIRONMENT

requires safety professionals to possess a strong foundation in safety surveillance and pharmacovigilance, which requires ongoing, comprehensive, and up-to-date education and training. **BioSoteria is your best source for pharmaceutical, biologic, and medical device safety training programs.**



BIOSOTERIA'S EDUCATION AND TRAINING TEAM OFFER:

- **The innovative eLadder Safety™ eLearning Program**, developed by drug safety experts for drug safety practitioners, and for those who wish to prepare themselves to enter the field



- **Relevant news and information** via *DSI: Drug Safety Intelligence*, BioSoteria's weekly drug safety newsletter

- **Customized, targeted, in-house training programs** designed to meet your needs with an optimal blend of print, eLearning, live workshops, job aids, and coaching/mentor programs

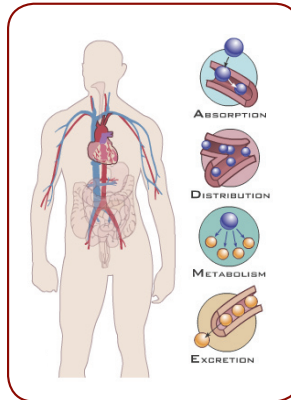
- **Cutting-edge webinars, live webcasts, and virtual conferences** that leverage the latest Web 2.0 technology to deliver you the latest information on drug safety and pharmacovigilance from international key opinion leaders and working professionals in the field today



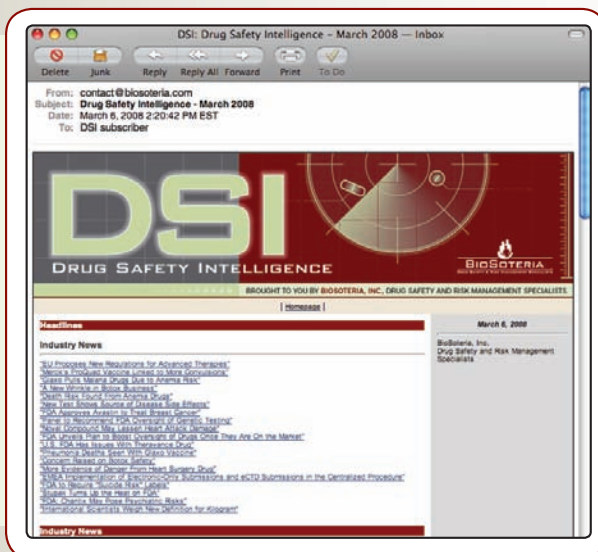
NEED TO TRAIN YOUR IN-HOUSE DRUG SAFETY AND PHARMACOVIGILANCE STAFF?

Courses in BioSoteria's engaging, innovative, online eLadder Safety eLearning Program are:

- **Available off-the-shelf** for rapid deployment drug safety training—no travel or customized development fees required
- **AICC/SCORM-compliant** and ready to run on your Learning Management System (LMS). No LMS? No problem. We offer a hosted LMS solution to deliver training to your employees or contractors.
- **Content-rich and truly multimedia**, with engaging graphics, animations, audio, video, and immersive application exercises
- **Developed by a multi-disciplinary team**, including:
 - A faculty of subject-matter experts and drug safety practitioners
 - Instructional designers and medical writers who specialize in eLearning
 - Graphic designers, animators, and certified medical illustrators
 - eLearning programmers and Learning Management System (LMS) specialists



VISIT WWW.BIOSOTERIA.COM FOR A DEMO TODAY.



UPDATES AND ANNOUNCEMENTS

about our training and educational programs, including our eLearning courses and drug safety conferences, can be found weekly in **DSI**, BioSoteria's free weekly newsletter. Sign-up today by emailing subscribe@biosoteria.com.

CONTACT US TODAY to learn more
about BioSoteria's drug safety and
pharmacovigilance consulting and training
solutions for you and your company.



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