ADVERSE EVENT SURVEILLANCE

24/7 MEDICAL CONTACT CENTER

- Phone, email and chat support
- Human and animal expertise
- Management of inquiries, ADEs and product quality complaints
- After hours support, night, weekends, holidays
- Seasonal volume overflow

Our Medical Team

Our medical contact center is staffed with licensed or certified professionals in both human and veterinary medicine, all with strong clinical backgrounds. Our human medical team is comprised of paramedics, nurses, pharmacy technicians, pharmacists (PharmD), and physicians with board-certifications in toxicology and occupational medicine. Our veterinary team is comprised of veterinarians, including board- certified veterinary toxicologists, internists, and criticalists, along with certified veterinary technicians, all of whom receive extensive training in toxicology and pharmacovigilance.

CREDENTIALED EXPERTS

SafetyCall is staffed with credentialed experts including physicians, pharmacists, veterinarians (board-certified in toxicology, internal medicine, emergency and critical care) and professionals in the basic sciences.

OUR MISSION

To make the world a safer place.
We do this by reassuring and providing quality care for our clients, their customers, animals and pets by delivering immediate. 24/7 access to clear and trusted health, safety and medical information, and by enhancing and promoting product safety

Regulatory Services Overview

- Adverse Event Management & Documentation
- Incident Analysis & Classification for Regulatory Reporting
- Regulatory Report Generation & e-Submission Support
- Scientific Literature Review
- Trending Analysis & Benchmarking Review

VALUE PROPOSITION:

SafetyCall is a nationally recognized triple licensed health care practice providing unmatched professional leadership and expertise in delivering total solutions for human and animal adverse event management, regulatory compliance and post-market surveillance. SafetyCall partners with consumer and commercial product manufacturers and distributors to help them define and enhance the safety of their products.

We make our clients better!

Regulatory Compliance Services

Under federal law distributors, manufacturers and packers of Drugs and Dietary Supplements in the United States must report medical problems that are associated with their products. Firms are required to document and assess adverse events based on "reasonable medical judgment." Adverse events meeting the FDA defined criteria for serious must be reported to the FDA within 15 days.

Serious Adverse Events may include but are not limited to the following: "death," "a life-threatening experience," "inpatient hospitalization," "a persistent or significant disability or incapacity" or "a congenial anomaly or birth defect."

The health care professionals at SafetyCall have over 30 years of experience responding to issues related to Drug and Dietary Supplement products. All adverse events are documented and stored in our case management software application. Clients have access to their incident data 24/7 utilizing a secured password protected web-based search engine.

Important Considerations

Causality is not a prerequisite for tracking and reporting adverse events associated with the use of drugs or dietary supplements.

Understand that consumers will most likely report adverse events directly to the manufacturer. This means that manufacturers need to implement additional processes for differentiating between those adverse effects which may represent a potential safety concern from those having nothing to do with the use of the product.

For information, please contact:
Kathy Wahlers
Sr. Director of Sales & Marketing
Direct phone 952-852-9503
Kwahlers@safetycall.com

Industries We Serve:

- Drugs: Prescription/OTC
- Dietary Supplements
- Medical Devices
- AgChem Products & Pesticides
- Animal Health & Veterinary Products
- Consumer Products
- Industrial Chemicals
- Institutional Products