REME*TREX*®
I N C O R P O R A T E D

Solutions a step ahead. Service by your side.

Safety System Software - AE

REMETREX® Safety AE is a web-based, enterprise level adverse event management system, designed for seamless data integration and linking with REMETREX® PQ (complaint handling) and all other REMETREX® solutions.

AE Features

— Design consists of multiple layers of access control and multi-location event numbering schemes

— Dynamic synchronizing processes between Safety AE and Product Quality issues

— 21 CFR Part 11 and 21 CFR Part 820.100 compliant

— Unique criticality assessment to determine issue cycle time

— Complete metrics assessments and reviews

— Designed for full circle event management, processing and reporting

— Provides complete audit trail & activity history

— Events are tracked utilizing MedDRA coding

— Provides multiple methods of communication, including assigning file responsibilities and progress monitoring

— Develop custom workflows

— Email notifications can be generated by issue requirements, workflow assignments or custom data driven events

— Designed for customization to an individual company's requirements, such as contact demographic information, product specific information, reports and additional options required by each company

— Provides ability for attaching and modifying photos, documents, Emails, PDFs etc. to complaints. These files are securely stored in the system database and may be downloaded by system users. Attachments are complete with audit trail

Event Reporting Module

— Generate reports based on a variety of event file information

— User defined report parameters can be saved and reused, saving time and providing reporting consistency

— Reports can be generated in PDF, Excel and other popular formats

— Reports can be run in real time, or submitted to batch and Emailed back to you upon completion

— You can also schedule your reports once and have them run daily, weekly, monthly etc. and receive them via Email

— Report titles are customizable and can be saved with report parameters

— Selection criteria chosen can be appended to the report, to provide further parameter clarification

— Adhoc reporting component allows you to select the data you want, in the sequence you want with the criteria you want, all within an easy and intuitive interface

AE
Safety System Hardware

REMETREX SOLUTION FEATURES

— Easy collection, quantification and identification trends

— Configurable to address present and future needs

— Compatible, seamless integration of all components

— 100% web-developed, accessible through internet connection

— Centralized single database

— Highly scalable for future requirements

— Secure environment, individualized access

— Flexible reporting

Advanced Quality solutions with personal service dedicated to *you*.
Serving the pharmaceutical, biotechnology, and medical device industries.