

CONSULTARE INC. GROUP A Compliance Co.



OTC Local Anesthetic Cream - Adverse Event Reporting Compliance Services Action Items

- Establish a standard operating procedure (SOP) for adverse event reporting.
- Set up a reporting system that allows for easy capture of adverse events.
- Train staff on recognizing and reporting adverse events.
- Develop a database for tracking and managing reported adverse events.
- Monitor reported adverse events regularly for trends or signals.
- Ensure timely submission of reports to regulatory agencies as required.
- Create a process for investigating reported adverse events.
- Implement a communication strategy for informing stakeholders of significant adverse events.
- Document all adverse event reports and follow-up actions taken.
- Review and update the adverse event reporting system regularly for effectiveness.

To avail of our professional services kindly contact hello@consultareinc.com or call 1-202-982-3002