

You can guard against catastrophic events with superior risk control practices & disaster recovery insurance protection. Area's that pose the greatest threat include:

- Supply Chain process
- Facility Management & Maintenance
- Workforce safety & clean environment hygiene
- Information security & software defect
- Intellectual property

Lack of risk control is the leading contributor to increased litigation & insurance claims. Areas of inadequate risk management practices include:

- Insufficient quality control practice of 3rd party supply chain partners
- Failure to maintain building systems, equipment, and instruments
- Improper use or lack of use of protective and sterilization equipment & tools
- Lack of technological security software & protocol exposing theft of personal identifiable information
- Improper Intellectual Property monitoring

Our SFG Risk Protection Solution process is designed to evaluate risk awareness, assess risk tolerance, and create a specialized risk management & insurance coverage solution tailor designed to protect your corporate assets and enhance unique growth opportunities. Our SFG Risk Protection Solution and resources include:

- Enterprise wide Comprehensive Insurance Protection Portfolio
- Supply Chain Risk Analysis
- Risk Transfer Practices
- Quality Control/Compliance Program Assistance
- Business Continuity Planning
- Product Recall Program Management
- Intellectual Property & Brand Protection

*For 60 years, the name Scirocco has been synonymous with quality, service and innovation in the insurance industry.*

**SCIROCCO GROUP**  
INSURANCE

What is your plan to control risks and avoid disaster?

Call **Anthony Nigro** to schedule your diagnostic appointment

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**Life Science...  
Risks & Solutions**



Over the last ten years drug recalls have increased by **638%**. 2013 shattered previous records and 2014 is expected to be even higher.

Year	Total Recalls	Class I	Class II	Class III
2014*	836*	101	640	95
2013	1,225	59	1,031	135
2012	499	29	381	89
2011	444	66	236	142
2010	246	35	135	76
2009	164	23	85	56
2008	203	18	128	57
2007	126	11	56	59
2006	116	1	109	6
2005	253	8	140	105
2004	166	11	68	87

\* As of August 11

Over the last ten years medical device recalls have increased **97%** and are expected to further increase over the next few years.

Year	Total Recalls	Class I	Class II	Class III
2012	1,190	57	1,043	90
2011	1,271	50	1,152	69
2010	876	49	753	74
2009	776	32	677	67
2008	832	14	710	108
2007	662	26	540	96
2006	659	22	505	132
2005	572	26	422	124
2004	631	24	467	140
2003	604	7	460	137

**Class I Recall** - a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

**Class II Recall** - a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

**Class III Recall** - a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

The Life Science industry is global, highly dynamic and characterized by cutting-edge technology used in the design and manufacturer of a broad range of drugs, supplements, products & devices. By its very nature, Life Science companies face emerging risks typically emanating from:

**Research & Development operations and Manufacturing** - processes within the Life Science industry require strict regulatory compliance and a high degree of attention to safety. The complexity of these processes requires unique risk control solutions.

**Technology Solutions** - software has become more involved in a medical device, as a medical device itself, used in the manufacturing of a medical device. Failure to implement software design controls and/or testing procedures can often lead into medical device recalls.

**Product Liability** - is one of the most significant exposures facing all of those participating in the product or service supply chain. Product failure and Product recall can damage a company's reputation and financial well-being.

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**Property protection** - is paramount with modern day high value, state-of-the-art technology and equipment paired with facility & process compliance standards. Our SFG Risk Protection Solution can help control and protect you from exposures to potential losses from:

- Fire and smoke Contamination
- Power failure
- Change in environment/temperature - spoilage
- Clean room contamination

**Workforce compliance & safety** - is a major concern for businesses because skilled & experienced employees are a company's greatest asset. Priority dollars in invested keeping employees current with changing regulations to ensure cGMP standards and safe from the variety of occupational accident hazards they are exposure to daily.

**Disaster Recovery Preparedness** - is mistakenly under prioritized for many life science companies. Product recall and business continuity programs are critical to this industry. Without a recovery plan designed to resume operations as quickly and seamlessly as possible, valuable time, assets, customer and investor goodwill are at risk.

