



Your partner:



Dr. Alexander Jaecklin

With 20 years experience of risk management and underwriting for a global industrial insurer, Dr. Jaecklin is specialized in product liability assessments, casualty loss adjustments and product recall in the sectors of pharmaceuticals, medical devices, food & feed, as well in machinery and chemical technical products. Languages DE, EN, FR

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Product- and Recall- Risk Management

*Have you control of your activities, products
and services?*

Product safety Product liability

Are your products complying with the EC Product safety directive 2001/95/EEC? Do your products comply with the EC Product liability directive 85/34/EEC?



Product safety

Products must be safe and meet the expectations of the user. They have to comply with the EC Product safety directive 2001/95/EEC and the related national regulations. Manufacturers and distributors may be liable for defective products (EC Product liability directive 85/34/EEC). A product is defective if it is

- Incorrectly manufactured
- Improperly designed or
- Accompanied by inadequate warnings or instructions

Requirements of the EC product safety directive 2001/95/EEC:

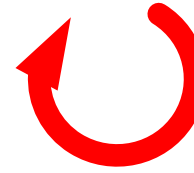
- Prerequisites to bring products to the market:
 - Essential requirements for health and safety
 - Applied harmonized standards
 - Technical documentation
 - Instructions for use
 - CE conformity assessment
- Duties for bringing products to the market:
 - Hazard analysis
 - Prevention plan
 - Traceability
 - Post market surveillance
 - Registration, certification and cooperation with competent authorities and notified bodies
- Rights of the competent authorities:
 - Investigational procedures
 - Decree of recalling products
 - Public warning and communication to member states
 - Recall of products, confiscation, destroy

Companies must have a product risk management in place to assure product safety and control over the entire life cycle.

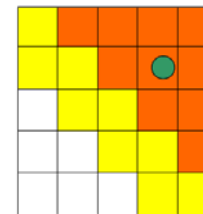
Companies rely on an independent product risk assessments!



Product Risk Management



Product life cycle



The product risk management must include all activities, products and services of a company. Control is required over the entire product life cycle:

- Management system, Corporate Governance
- Innovation and quality planning
- Hazardous properties such as physical, chemical, biological, electrical or other health & safety hazards
- Manufacturing and quality controls
- Product marketing and contracts
- Product surveillance including complaint management, ongoing regulatory compliance, warnings & recalls

Make profit of the long-lasting experience to prevent product liability, claims and litigations:

- **Risk assessments** of products, systems and services
- **Instruction for use:** Review and assessment of the technical documentation, warnings and instructions
- **Regulatory compliance** assessment for products intended to be brought to the market
- **Post market surveillance** and ongoing safety risk evaluation
- **Claims and loss adjustment** management
- **Recall management** to minimize losses and prevention of reputational losses

Risk assessments are performed in accordance to the international recognized standard ISO 31000:2009 Risk management or the guideline ONR 49000:2010:

Risk identification → Risk analysis → Risk evaluation

Industrial casualty and speciality insurers rely on independent risk assessments and loss adjustment to safeguard their loss ratio!