Quality Management / Quality Control

The purpose of this Risk Factor is to assess the quality management system in place, and the quality controls / quality assurance applied to the product(s) under review. Quality Controls are related to the output (product / service) quality and cover the whole product testing in manufacturing cycle from component to final product. This Risk Factor does not cover control of raw materials and supplied goods (see Risk Factor 8 “Management of Procurement and Outsourcing”).

What do we look for?

**Exposures**
- High level of industry-specific quality management requirements
- Complex analytical or technical sampling and testing required
- Long life products or finished goods, requiring full life cycle testing and analysis to predict lifespan and failure effects
- Highly technical quality control equipment or highly skilled technical operators required for quality control processes
- Many new products introduced annually

**Controls**
- Comprehensive quality planning and control and Standard Operating Procedures (SOPs) for all significant processes, fully documented; take into account that the bare existence of a certified quality management system is of only limited conclusiveness
- Effective employee training programs and suitably skilled employees
- Full familiarity of employees with quality management procedures
- Audit programs and follow-up of findings
- Regular review and updating of procedures and processes
- State of the art equipment, personnel, methods, processes and documentation of results for quality control and/or outsourcing strategy in place

**Risk Improvement Ideas**
- Regular review of compliance with legal provisions on inspection and testing
- Quality control strategy and related controls shall heavily be product safety oriented, i.e. quality control for products posing higher hazards to users shall not be the same as for products free from hazards
- Review and audit activities and corrective actions for on-going monitoring of quality
- Implementation of a system for continuous improvement

**Resources**

**External Standards**
- Applicable international product safety directives (e.g. European Directive 2001/95/EC on general product safety, U.S. Consumer Product Safety Act) and related industry standards (e.g. ISO, EN ISO, ISO/TS, ANSI, OHSAS, AS/EN, SCC/SCP, EMAS etc.)
- Industry publications on best practices, taking into consideration latest developments (state of science and technology) in the area of quality management and quality control
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