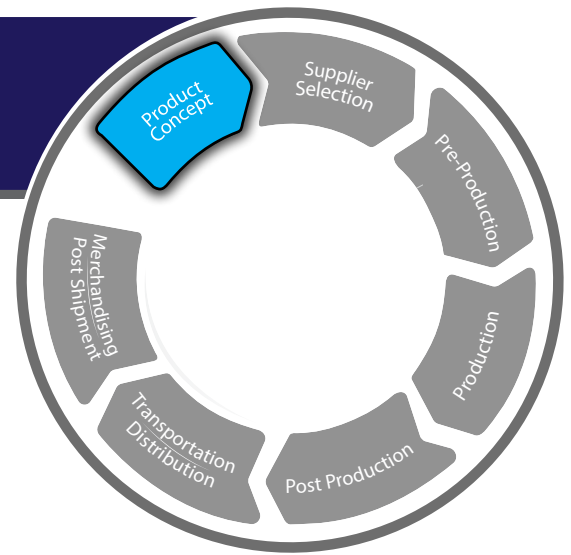


# Product Concept: Product Quality Considerations

Intended for intermediate compliance programs

Key activity: Risk and hazard assessment

Step-by-step approach to consider risk related to product quality during the product concept stage.



Establish a quality assurance procedure

- Discuss client expectations
- Define acceptable quality standards
- Identify areas of risk and hazard
- Determine testing and labeling requirements
- Determine mechanical and performance requirements

Establish a design evaluation risk assessment

- Conduct risk and hazard assessment to design out potential hazards
  - Mechanical
  - Chemical
  - Toxicological
  - Microbial
  - Electrical
  - Flammable
- Design the product with performance expectations in mind
- Evaluate materials, assembly and production methods; packaging and labeling; prepare specs and bills of material
- Will the material shrink, fade or tear?
- Could some parts be hazardous?
- Can any hazards be “designed-out” of the product or concept?
- What other potential “points of failure” can be eliminated or reduced?

Consult with a test lab for product and labeling reviews

Communicate your expectations and testing requirements with potential vendors during this stage

- Performance requirements
- Physical, mechanical and materials specifications; describe tolerances
- Compliance specifications; applicable regulations and standards
- Testing requirements for compliance, safety and quality