

Guarantee product safety R 1

type	realization process
purpose	<ul style="list-style-type: none"> • guarantee product safety throughout the supply chain • include safety critical items in the processes
owner	production manager / safety manager / project leader
risks	<ul style="list-style-type: none"> • not identifying all hazards • not evaluating all risks • not identifying statutory and regulatory safety requirements • not notifying the customer on statutory and regulatory safety requirements • not including the special approval of process and product FMEA and control plans • not training staff on safety aspects • not approving changes with safety impacts • not taking into account all safety critical items • not implementing appropriate control means • not initiating reaction plans
upstream processes	<ul style="list-style-type: none"> • manage changes • control processes • audit • address risks • manage operational risks • carry out FMEA
downstream processes	<ul style="list-style-type: none"> • implement traceability • implement control plan • communicate • meet statutory and regulatory requirements • provide training
inputs	<ul style="list-style-type: none"> • statutory and regulatory requirements • results of the inventory of safety critical items • incident reports • criteria for risk evaluation
activities (sub-processes)	<ul style="list-style-type: none"> • identify hazards and evaluate risks • manage operational risks • identify safety statutory and regulatory requirements • include special approvals in process and product FMEA and control plans • train the staff on safety aspects • approve changes with safety impacts • manage safety critical items • implement appropriate control means • initiate reaction plans • investigate and communicate on safety incidents • standardize lessons learned
outputs	<ul style="list-style-type: none"> • list of safety risks • action plan • staff awareness
resources	production, quality and safety departments, process owners
indicators	<ul style="list-style-type: none"> • identified risks • risks processed • safety incidents • implemented actions • days without incident
procedures / documents	safety, FMEA, audit, risks, communication, identification and traceability, training, operational control / list of risks, action plan, quality plan, process and product FMEA, control plans
customers	all the staff, all processes, all products

Glossary:

- FMEA - Failure Mode and Effects Analysis

