

## Guarantee product safety R 1

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

