Manage risks

|  |  |
| --- | --- |
| type | realization process |
| purpose | * reduce the risks * achieve objectives |
| owner | production manager / quality and safety manager |
| risks | * not taking into account the context of the company * not understanding the requirements of interested parties * not identifying all operational risks * not providing the necessary resources * not defining risk assessment criteria * not assigning responsibilities * not implementing the actions to address identified risks * no follow-up on the implemented actions * not communicating implemented actions to staff or customer |
| upstream processes | * plan the QMS * carry out FMEAs * analyze data |
| downstream processes | * design and develop new products * establish process ownership * produce * inspect * communicate * sell products |
| inputs | * context of the organization * regulatory and operational requirements * new technology * conditions (normal and abnormal) * identified operational risks |
| activities  (sub-processes) | * assign responsibilities * define risk assessment criteria * identify operational hazards * analyze operational risks * assess operational risks * choose treatment (avoid, reduce) * accept a level of remaining risk * monitor actions implemented * standardize lessons learned * communicate |
| outputs | * action plan (control measures) * new technology control * monitoring of the actions * remaining risks * staff awareness |
| resources | production manager, process owners, project leaders |
| indicators | * KPI – key performance indicators * identified risks * risks processed * actions implemented |
| procedures / documents | customer satisfaction, process control, analysis of data, monitoring and measure, FMEA, continual improvement, communication, training, planning, change control, design and development, / business plan, quality policy, objectives, indicators, list of risks, action plans, quality plan, list of processes, process sheets, customer satisfaction survey, change requests, reports |
| customers | production, realization processes, customers |

Glossary:*FMEA (Failure Mode and Effects Analysis)*

title / codification

owner

purpose

* reduce the risks
* achieve objectives

manage risks / R 13’

production manager / quality and safety manager

upstream process amont

* plan the QMS
* carry out FMEA’s
* analyse data

downstream processes

risks

* not taking into account the context of the company
* not understanding the requirements of interested parties
* not identifying all operational risks
* not providing the necessary resources
* not defining risk assessment criteria
* not assigning responsibilities
* not implementing the actions to address identified risks
* no follow-up on the implemented actions
* not communicating implemented actions to staff or customer
* design and develop new products
* establish process ownership
* produce
* communicate
* sell products

outputs

activities

imputs

* action plan (control measures)
* new technology control
* monitoring of the actions
* remaining risks
* staff awareness
* context of the organization
* regulatory and operational requirements
* new technology
* conditions (normal and abnormal)
* identified operational risks
* assign responsibilities
* define risk assessment criteria
* identify operational hazards
* analyse operational risks
* assess operational risks
* choose treatment (avoid, reduce)
* accept a level of remaining risk
* monitor actions implemented
* standardize lessons learned
* communicate

procedures / documents

customers

indicateurs

resources

customer satisfaction, process control,analysis of data, monitoring and measure**,**  FMEA**,** continual improvement, communication, training, planning, change control, design and development, / business plan, quality policy, objectives, indicators, list of risks, action plans, quality plan, list of processes, process sheets, customer satisfaction survey, change requests, reports

production, realization processes, customers

KPI – key performance indicators, identified risks, risks processed, actions implemented

production manager, process owners ; project leaders