Meet statutory and regulatory requirements R 27

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| --- | --- |
| type | realization process |
| purpose | ensure compliance of purchased products, processes and services with statutory and regulatory requirements within the designated country in terms of:   * receipt * shipment and * destination |
| owner | purchase manager / quality manager |
| risks | * not taking into account statutory and regulatory requirements * not taking into account all risks identified * raw material poorly specified * unsigned confidentiality agreement * reliability and performance of external provider not evaluated * no traceability of raw material * special controls not applied on the external provider * special controls not applied internally |
| upstream processes | * address risks * negotiate the contract * implement preventive actions * purchase components * control outsourced processes * manage external providers |
| downstream processes | * conduct second-party audit * receive, store and deliver * approve product * solve problems * manage changes * inspect * sell |
| inputs | * list of risks * list of external providers * statutory and regulatory requirements * certifications by accreditation bodies * external provider evaluation questionnaire |
| activities  (sub-processes) | * establish multidisciplinary team * evaluate risks * evaluate statutory and regulatory requirements compliance * ensure implementation of special controls internally and externally * audit the external provider * monitor the performance of the external provider * monitor the documented information used by external providers * carry out actions following the external provider's failure to comply with statutory and regulatory requirements * updating the status of external providers |
| outputs | * results of second-party audits * annual performance * updated risks identified * updated list of external providers * evaluation results |
| resources | documented information from purchase, reception and quality departments |
| indicators | * nonconformities’ rate at reception * approved external providers * statutory and regulatory nonconformities * special controls implemented |
| procedures / documents | risks, documented information, external providers, purchase, reception and storage, contract review, changes, audit, identification and traceability / list of risks, list of external providers, annual performance, audit results, evaluation results |
| customers | external providers, purchase, reception and quality departments, customers |

purpose

owner

title / codification

ensure compliance of purchased products, processes and services with statutory and regulatory requirements within the designated country in terms of:

* receipt
* shipment and
* destination

purchase manager / uality manager

meet statutory and regulatory requirements / R 27

risks

upstream processes

downstream processes

* conduct second-party audit
* receive, store and deliver
* approve product
* solve problems
* manage changes
* inspect
* sell
* address risks
* negotiate the contract
* implement preventive actions
* purchase components
* control outsourced processes
* manage external providers
* not taking into account statutory and regulatory requirements
* not taking into account all risks identified
* raw material poorly specified
* unsigned confidentiality agreement
* reliability and performance of external provider not evaluated
* no traceability of raw material
* special controls not applied on the external provider
* special controls not applied internally

activities

inputs

outputs

* results of second-party audits
* annual performance
* updated risks identified
* updated list of external providers
* evaluation results
* establish multidisciplinary team
* evaluate risks
* evaluate statutory and regulatory requirements compliance
* ensure implementation of special controls internally and externally
* audit the external provider
* monitor the performance of the external provider
* monitor the documented information used by external providers
* carry out actions following the external provider's failure to comply with statutory and regulatory requirements
* updating the status of external providers
* list of risks
* list of external providers
* statutory and regulatory requirements
* certifications by accreditation bodies
* external provider evaluation questionnaire

indicators

resources

customers

procedures / documents

risks, documented information, external providers, purchase, reception and storage, contract review, changes, audit, identification and traceability / list of risks, list of external providers, annual performance, audit results, evaluation results

documented information from purchase, reception and quality departments

external providers, purchase, reception and quality departments, customers

nonconformities’ rate at reception, approved external providers,

statutory and regulatory nonconformities

special controls implemented