

7 Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

- *quality objectives and requirements for the product;*
- *the need to establish processes and documents, and to provide resources specific to the product;*
- *required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;*
- *records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).*

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

Nos projets se découpent en plusieurs étapes ; tout d'abord nous approchons le client avec une proposition qui répond à son appel d'offre. Selon ses retours, nous nous engageons avec lui pour le projet. S'en suit la réalisation de celui-ci, puis une fois terminé nous passons par une phase de clôture du projet qui nous permet d'améliorer nos processus.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

- A. *requirements specified by the customer, including the requirements for delivery and post-delivery activities,*
- B. *requirements not stated by the customer but necessary for specified or intended use, where known,*
- C. *statutory and regulatory requirements applicable to the product, and*
- D. *any additional requirements considered necessary by the organization.*

NOTE Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

Réunion avec client pour déterminer les besoins et arriver à une proposition

b) Processus SCRUM : de nouvelles choses peuvent apparaître au cours du projet, au fur et à mesure que le client prend conscience des possibilités qui lui sont offertes.

Les fonctionnalités non explicitement demandées par le client mais essentielles pour le fonctionnement du produit seront ajoutées à la proposition par l'équipe. Les fonctionnalités supplémentaires demandées au cours du développement par le client feront l'objet d'une extension de contrat.

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

- a) product requirements are defined,*
- b) contract or order requirements differing from those previously expressed are resolved, and*
- c) the organization has the ability to meet the defined requirements.*

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

Nous nous assurons avec le client que les spécifications du produit à livrer sont complètes et validées avant signature du contrat, et que nous sommes capables de livrer un produit répondant aux exigences ainsi définies.

En cas de modification des spécifications produit au cours du développement, l'organisation notifie les équipes concernées et adapte le contrat en conséquence.

7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to

- a) product information,*
- b) enquiries, contracts or order handling, including amendments, and*
- c) customer feedback, including customer complaints.*

Nous nous assurons de la conformité du produit livré par l'implication du client tout au long du processus de développement. Nous sommes à l'écoute de ses retours, et nous faisons évoluer le produit en conséquence. Nous mettons en valeur le rôle du propriétaire du produit pour que le client soit toujours au courant des dernières avancées du projet, et puisse donc prendre des décisions concernant la suite du développement.

7.3 Design and development

7.3.1 Design and development planning

The organization shall plan and control the design and development of product.

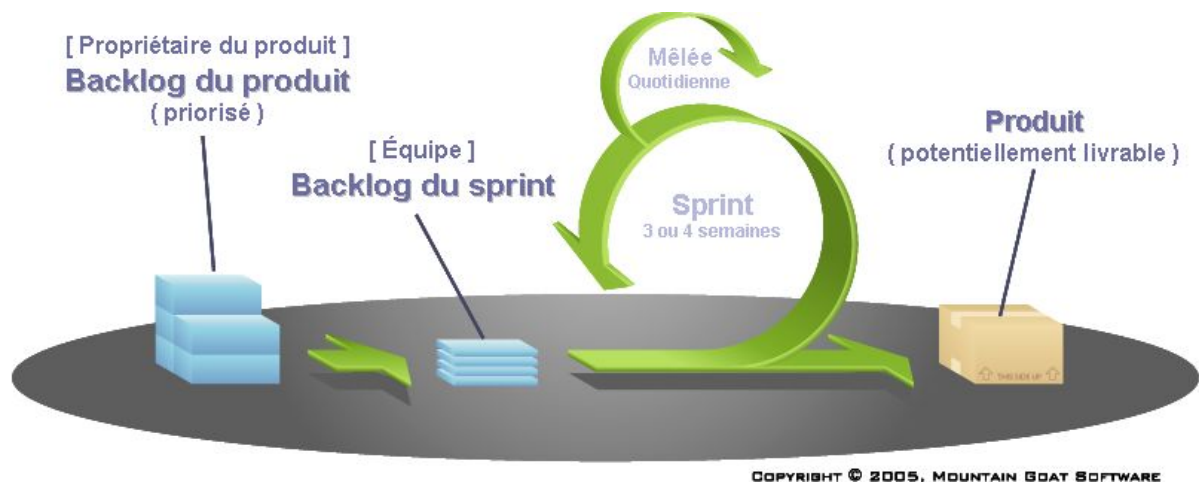
During the design and development planning, the organization shall determine

- a) the design and development stages,*
- b) the review, verification and validation that are appropriate to each design and development stage, and*
- c) the responsibilities and authorities for design and development.*

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

NOTE Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.



Nous respectons la méthodologie SCRUM pour tenir les délais fixés au préalable avec notre client. Le propriétaire du produit, le SCRUM Master et l'équipe de développement se réunissent à chaque début de Sprint pour le planifier. Elle permet de déterminer les objectifs à atteindre durant le sprint, et comment le travail sera effectué, c'est-à-dire comment il sera décomposé et organisé tout au long du Sprint.

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4).

These inputs shall include

- a) functional and performance requirements,*
- b) applicable statutory and regulatory requirements,*
- c) where applicable, information derived from previous similar designs, and*
- d) other requirements essential for design and development.*

The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and development outputs

The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

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Design and development outputs shall

- a) meet the input requirements for design and development,*

0) provide appropriate information for purchasing, production and service provision,

a) contain or reference product acceptance criteria, and

b) specify the characteristics of the product that are essential for its safe and proper use.

NOTE Information for production and service provision can include details for the preservation of product.

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

a) to evaluate the ability of the results of design and development to meet requirements, and

b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements.

Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

7.4 Purchasing

7.4.1 Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements.

The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including, where appropriate,

a) requirements for approval of product, procedures, processes and equipment,

b) requirements for qualification of personnel, and

c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and service provision

7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable,

- a) the availability of information that describes the characteristics of the product,*
- b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring equipment, e) the implementation of monitoring and measurement, and f) the implementation of product release, delivery and post-delivery activities.*

7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable,

- a) defined criteria for review and approval of the processes,*
- b) approval of equipment and qualification of personnel,*
- c) use of specific methods and procedures,*

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- d) requirements for records (see 4.2.4), and*
- e) revalidation.*

7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.

Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4).

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4).

NOTE Customer property can include intellectual property and personal data.

7.5.5 Preservation of product

The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.6 Control of monitoring and measuring equipment

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4); b) be adjusted or re-adjusted as necessary;

0) have identification in order to determine its calibration status;

c) be safeguarded from adjustments that would invalidate the measurement result;

e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected.

Records of the results of calibration and verification shall be maintained (see 4.2.4).

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When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.