

			Process Design and Development
QMS PQ11	Rev A	Date 09-01-17	Procedure Authority: Quality Assurance Manager

Purpose: The purpose of this procedure is to describe and direct our activities associated with process design and development (D&D).

Scope: This procedure will address process design planning, design inputs, controls, outputs, and design changes.

Responsibility: The Department Manager most closely related to the resulting product is responsible for administering this procedure.

Definitions: NA

Reference Documents: NA

Procedure:

1. Upon realization of a new program and the need for process design, a project manager (usually the department manager), will be assigned and a multidisciplinary team will be chosen.
2. During the planning stage the department manager will consider the following:
 - a) The nature, duration and complexity of the design and development (D&D) activities;
 - b) The required process stages, including applicable D&D reviews;
 - c) The required D&D verification and validation activities;
 - d) The responsibilities and authorities involved in the D&D process;
 - e) The internal and external resource needs for the D&D of products and services;
 - f) The need to control interfaces between persons involved in the D&D of products and services;
 - g) The need to control interfaces between persons involved in the D&D process;
 - h) The need for involvement of customers and users in the D&D process;
 - i) The requirements for subsequent provision of products and services;
 - j) The level of control expected for the D&D process by customers and other relevant interested parties;
 - k) The documented information needed to demonstrate that D&D requirements have been met.
3. Regarding D&D inputs, the project team will consider the following:
 - a) Customer requirements;
 - b) Functional and performance requirements;
 - c) Experience from previous process designs;
 - d) Statutory and regulatory requirements
 - e) Standards or codes of practice that we've committed to implement;
 - f) Potential consequences of failure due to the nature of the products and services;
 - g) Product design output data including special characteristics;
 - h) Targets for productivity, process capability, timing, and cost;

Procedure Continued:

- i) Manufacturing technology alternatives;
 - j) New materials;
 - k) Product handling and ergonomic requirements; and
 - l) Error proofing methods as appropriate.
4. Regarding D&D Controls the project team will ensure the following:
- a) The results to be achieved are defined;
 - b) Reviews are conducted to evaluate the ability of the results of D&D to meet requirements;
 - c) Verification activities are conducted to ensure that the D&D outputs meet the input requirements;
 - d) Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
 - e) Any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
 - f) Documented information of these activities is retained.
5. Regarding D&D Outputs the project team will ensure that:
- a) The process results meet the input requirements
 - b) Results are adequate for any subsequent processes;
 - c) Measurements and monitoring results are appropriate and include acceptance criteria;
 - d) Specifications exist on the characteristics of the resulting product that are essential for its intended purpose and safe function.
6. Regarding D&D Changes, we will review and control changes made to our processes, to the extent necessary, to ensure that there is no adverse impact to requirements.

AMENDMENT RECORD

Revision	Date	Details	Authority
A	09-01-17	Originated	E. Ide