

	Company name: "ABCD Ltd."	XX/XX/XXXX
	R&D Procedure	Page: 1 of 9
	COMPETENCE AND TRAINING MANAGEMENT COMPETENCE AND TRAINING MANAGEMENT COMPETENCE AND TRAINING	

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	Company name: "ABCD Ltd."	XX/XX/XXXX
	R&D Procedure	Page: 2 of 9
	COMPETENCE AND TRAINING MANAGEMENT COMPETENCE AND TRAINING MANAGEMENT COMPETENCE AND TRAINING	

INSERT COMPANY LOGO

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	Company name: "ABCD Ltd."	XX/XX/XXXX
	R&D Procedure	Page: 3 of 9
	COMPETENCE AND TRAINING MANAGEMENT COMPETENCE AND TRAINING MANAGEMENT COMPETENCE AND TRAINING	

INSERT COMPANY LOGO

INDICE

1.0	Purpose	3
2.0	Scope	3
3.0	Terms and definitions	3
4.0	Process	3
4.1	Design Request	3
4.2	Design Planning	3
4.3	Gathering Premises	3
4.4	Pre-Design	3
4.5	Cost Estimation	4
4.6	Design Review	4
4.7	Prototype Development	4
4.8	Test Protocol Definition	4
4.9	Prototype Realization	4
4.10	Prototype Validation	4
4.11	Industrialization	5
4.12	Design Verification	5
4.13	Creation of a Sample Batch	5
4.14	Testing	5
4.15	Design Validation	5
5.0	Records	5

	Company name: "ABCD Ltd."		XX/XX/XXXX
	R&D Procedure		Page: 4 of 9
	COMPETENCE AND TRAINING MANAGEMENT COMPETENCE AND TRAINING MANAGEMENT COMPETENCE AND TRAINING		

INSERT COMPANY LOGO

	Company name: "ABCD Ltd."	XX/XX/XXXX
	R&D Procedure	Page: 5 of 9
	COMPETENCE AND TRAINING MANAGEMENT COMPETENCE AND TRAINING MANAGEMENT COMPETENCE AND TRAINING	

INSERT COMPANY LOGO

1.0 Purpose

The purpose of this procedure is to define the methods and responsibilities for managing research and development activities for the products and services of the Organization.

This process aligns with the requirements outlined in Clause 8.3 of ISO 9001:2015: "Design and Development of Products and Services."

2.0 Scope

The activities described in this procedure apply to the phases of research, development, and industrialization of new products and services of the organization.

Please note that for minor changes to existing products or services, this procedure does not apply.

3.0 Terms and definitions

- Research
Research refers to a deliberate and organized process that involves collecting, analyzing, and interpreting information or data in a methodical manner. The primary goal of research is to generate fresh insights, knowledge, or understanding on a particular subject or issue
- Development
Development is a structured process that follows the research phase and is focused on converting the outcomes of research, such as ideas, concepts, or prototypes, into practical and real-world applications, products, or services. This phase involves the design, testing, refinement, and construction of tangible solutions.

4.0 Process

4.1 Design Request

The Head of Commercial contacts the R&D director and transmits all available documentation (e.g., customer drawings, specifications, commercial offers, etc).

	Company name: "ABCD Ltd."	XX/XX/XXXX
	R&D Procedure	Page: 6 of 9
	COMPETENCE AND TRAINING MANAGEMENT COMPETENCE AND TRAINING MANAGEMENT COMPETENCE AND TRAINING	

INSERT COMPANY LOGO

4.2 Design Planning

The R&D director creates a dedicated project folder on the company server for the specific project and sets up the corresponding 'Technical File'.

Additionally, the R&D director compiles a 'Design Planning' file, outlining the timelines and responsibilities for each phase of project development.

4.3 Gathering Premises

R&D director analyzes the information and documentation provided by COM, and if necessary, request additional information while storing all of it in the dedicated folder. Based on the insights from this analysis, compiles the 'R&D File - 01. Premises.'

4.4 Pre-Design

R&D director proceeds with the partial development of the project, integrating technical materials and specific descriptions of various possible technical solutions. The activities performed and the insights gained are recorded in the 'R&D File - 02. Pre-Design.'

4.5 Cost Estimation

The R&D director writes the economic evaluations in the 'R&D File - 03. Cost Estimation,' specifically regarding design and implementation costs, while integrating them with any external documents.

4.6 Design Review

The economic feasibility of the project and its compliance with the input requirements ('R&D File - 01. Premises') are assessed, evaluating any necessary variations and alternatives.

If the outcome is positive, the project proceeds to the next phase.

Otherwise, the possibility of abandoning the project or returning to one of the previous steps is considered. All considerations arising during this evaluation, including any agreed-upon

	Company name: "ABCD Ltd."	XX/XX/XXXX
	R&D Procedure	Page: 7 of 9
		

INSERT COMPANY LOGO

modifications to the previously planned work, are documented in a meeting summary and incorporated into the project documentation. Additionally, the review outcome is formally recorded by the R&D director at the end of the documents:

'R&D File - 02. Pre-Design'

'R&D File - 03. Cost Estimation'

4.7 Prototype Development

The R&D director compiles the document 'R&D File – 04. Prototyping,' outlining the overall guidelines for the prototype development process and its objectives.

Furthermore, it proceeds to develop detailed technical documentation, including construction drawings, assemblies, and other necessary elements for the prototype's realization."

4.8 Test Protocol Definition

R&D director compiles 'R&D File - 05 Testing,' defining a testing protocol that establishes, for each function to be tested:

1. The type of test to be conducted
2. The necessary instrumentation
3. Acceptance criteria.

During this phase, R&D director also prepares the necessary forms for recording the tests that will be conducted.

4.9 Prototype Realization

R&D prepares a prototype for validation, and if necessary, the production facility is responsible for its production.

The R&D director and the head of production jointly ensure that any adjustments to settings and layout made to create the prototype do not adversely affect the production plant's efficiency in manufacturing the standard product.

	Company name: "ABCD Ltd."	XX/XX/XXXX
	R&D Procedure	Page: 8 of 9
		

INSERT COMPANY LOGO

4.10 Prototype Validation

R&D conducts and maintains a record of all the tests listed in the testing protocol outlined in 'R&D File - 05 Testing.'

If the tests yield positive results, the process continues.

If the tests yield negative results, the R&D team, along with the CEO and potentially the customer, will assess whether to abandon the project or revise parts of it. In such a case, decisions made will be documented in a dedicated meeting summary.

4.11 Industrialization

R&D compiles 'R&D File - 06. Industrialization,' providing a detailed description of production-related critical aspects and practical considerations.

This includes special procedures, required equipment, external management, timelines, and more. R&D also proceeds with the detailed development of the technical documentation necessary for project closure and production.

4.12 Design Verification

R&D Director and the CEO verify that the results of detailed design (industrialization) are adequate and suitable to ensure compliance with the technical input requirements and to enable the release of the bill of materials in SAP.

A dedicated meeting summary must be prepared, in order to keep track of the topics.

4.13 Creation of a Sample Batch

Following all the information collected/prepared in the previous steps, a first Sample batch is prepared.

	Company name: "ABCD Ltd."	XX/XX/XXXX
	R&D Procedure	Page: 9 of 9
	COMPETENCE AND TRAINING MANAGEMENT COMPETENCE AND TRAINING MANAGEMENT COMPETENCE AND TRAINING	

INSERT COMPANY LOGO

4.14 Testing

The quality department carries out, under the supervision of R&D, the tests specified in the testing protocol on 100% of the manufactured pieces.

The results of the tests conducted will be analyzed during the production validation meeting, with the presence of the CEO.

4.15 Design Validation

The test results are discussed with the management to authorize the project's closure and the product's commercialization. A meeting summary of this meeting must be kept for record.

5.0 Records

All R&D projects are tracked using the form "11 - FRM - R&D Planner Form"