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Quality Manual SMQ2020

Based on the SMQ2020, this Quality Manual is registered and updated in the Quality Management IT directory. A copy of this manual is available on our website. In case of divergence between the different translations, the French version shall prevail. Its contents cannot be copied or reproduced without the authorisation of Management.

Summary

1. Introduction

This Quality manual SMQ2020 describes the general provisions implemented in the company.

It defines the principles of the system. It introduces the approach of each process

Process management is done through the SMQ2020 application. This was put in place with the goal to make the entire system available to all collaborators in real time.

Hybrid SA is certified according to standards ISO 9001: 2015 and ISO 13485: 2016.

The company does not cover the full scope of ISO 13485: 2016, exclusions are listed in Appendix A of this manual.

This manual has been written and approved collectively by Management and members of the Executive Committee.

2. Presentation of the company

Hybrid SA is ideally situated on the shores of Lake Neuchâtel, the birthplace of microtechnology and microelectronics. Founded in 1989 by Mr. Claude Gaille, the company was acquired in 2004 by employees under an MBO.

In pursuing activities related to the development of complex microelectronic circuit assembly, Hybrid SA has committed itself to serving its customers efficiently by capitalising on the expertise of each employee.

2.1. Applications

- Industrial (sensors, actuators, drivers, …)
- Medical
- Scientific (institutions and schools)
- Aeronautics and aerospace

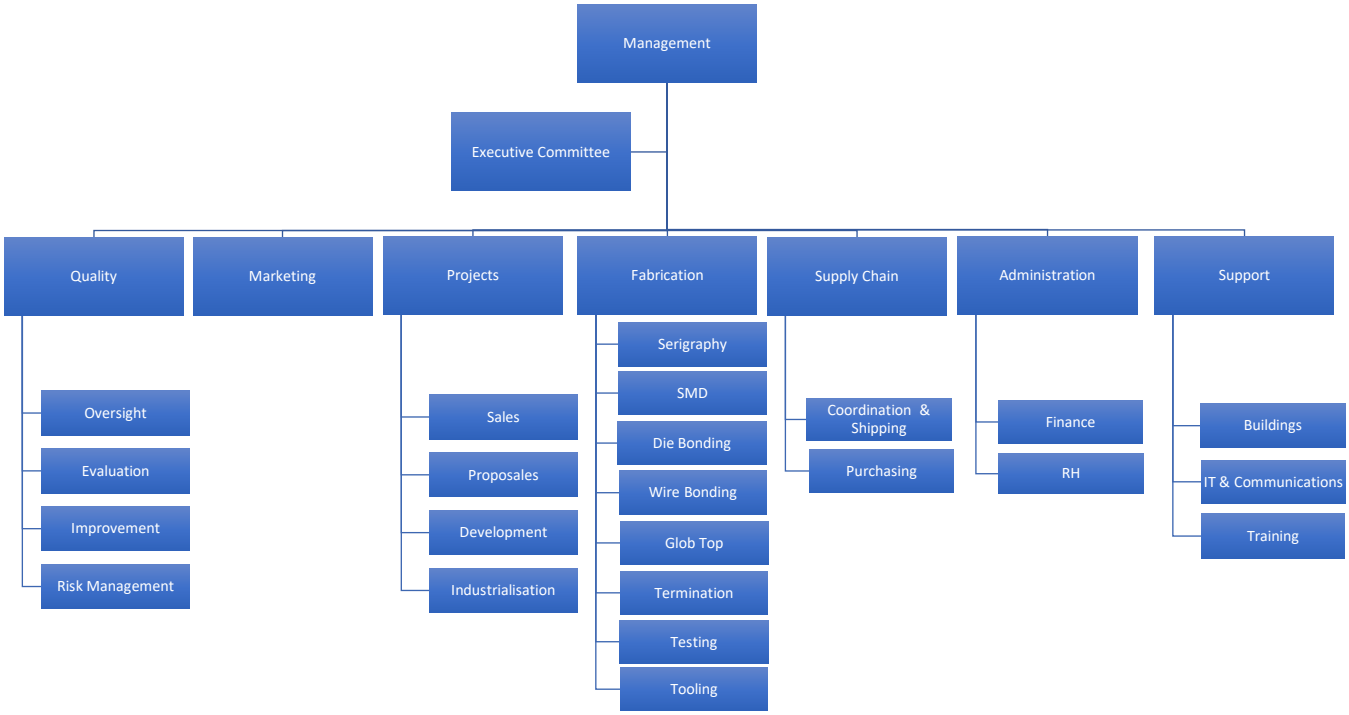
2.2. Primary technologies

- Screen printing of thick film circuits (Al2O3 ceramic)
- Assembly of surface mount components (SMD)
- Chip on board (die bonding / wire bonding / encapsulation)
- Flip chip (bumping and assembly)
- Termination work (mounting connectors, cables, through mounts, ...)
- Electrical function test (developed in collaboration with the customer)

3. Organisation structure

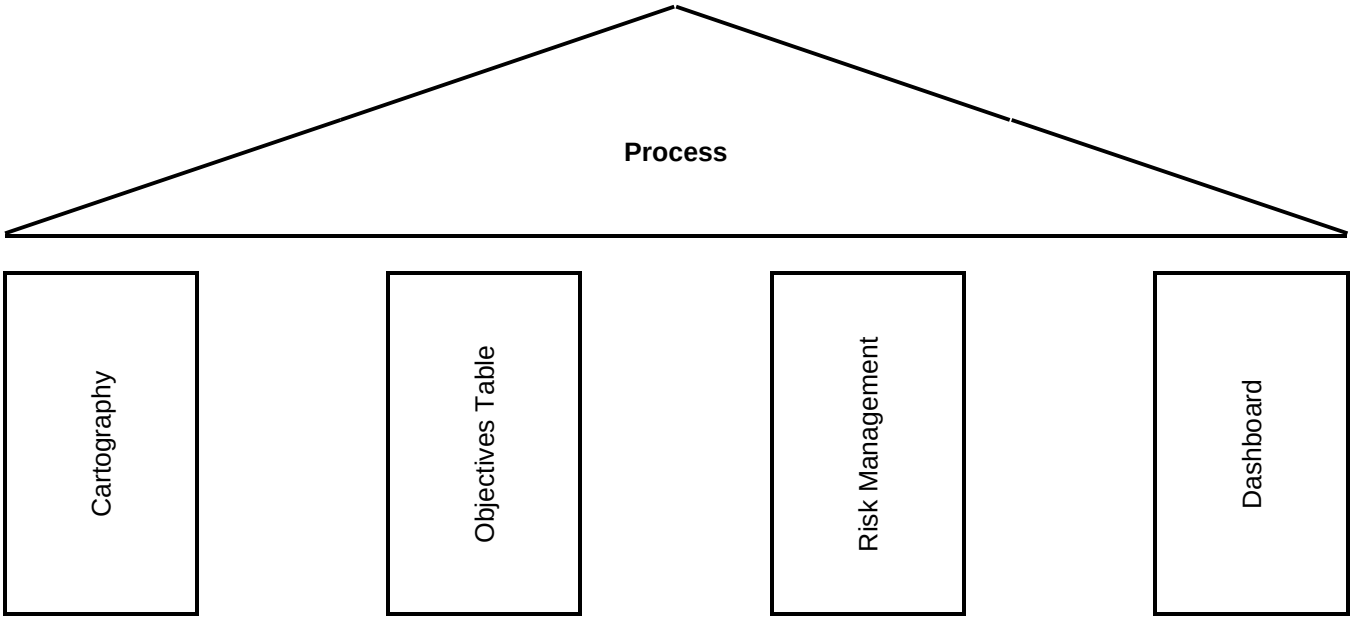
The company is structured by processes.

All activity is linked to a process reflected in the chart below.



3.1. Processes

All processes and subprocesses have the same management structure. This structure is based on four pillars: cartography, the objectives table, risk management and the dashboard. Each of these pillars has a very specific function described below.



3.2. Cartography

Cartography is a visualisation tool. It is composed of several elements.

- Description of the process and its objectives
- Identification of risks
- Input elements (materials, resources, requirements)
- Output elements (product, service, decision)

It is a useful prerequisite for risk management.

3.3. Objectives Table

The objectives table is a planning tool. Initially it describes the overall objectives of the process to achieve long-term results. Secondly, it leads to more precise objectives and the identification of needed resources along with their scheduling. These objectives are established to meet customer requirements and to bring improvements to the process in accordance with company policies.

3.4. Risk Management

Risk management is a living tool to aid decision-making.

It consists of continuously analysing and evaluating events that would prevent the achievement of objectives. The risks are then treated according to one of the following 4 strategies:

- Removal
- Reduction
- Transfer
- Acceptance

3.5. Dashboard

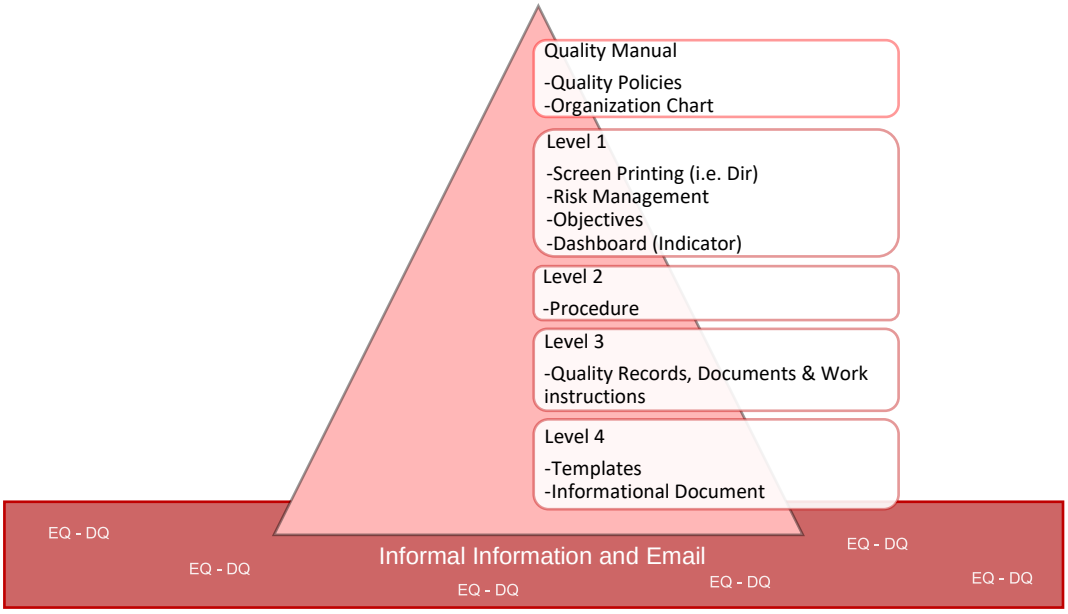
The dashboard is an evaluation tool.

Its function is to enable monitoring and easy exploitation of relevant data concerning a process. This data, also called performance indicators, provides information as to how the process is working in order to predict, decide and act.

4. Document Management

Document management is organised in a hierarchical manner.

The QMS2020 Manual is, along with the Quality Policy and Process Flowchart, at the top of this hierarchy.



Even informal information is considered a faint signal that should not be overlooked. This draws attention to potential events that are evaluated on a case-by-case basis.

All documents are accessible from the SMQ2020 application.

Process owners are responsible for documenting them. They continually oversee their updates.

5. Management

Management defines strategic choices in accordance with guidelines set by the Board of Directors. It drives the company, establishes or sees that structures and methods are established to achieve set objectives. Furthermore, it gathers, manages and allocates resources necessary for the realisation of company projects.

5.1. Management Commitment

Management is committed to ensuring that customer requirements along with legal requirements are identified, understood and met.

It is committed to ensuring that the quality management system is effective and in line with the company's Quality Policy (vision, mission, values). It ensures that the requirements of the Quality Management System are integrated into all company processes.

For each process, Management works to ensure that resources are available and encourages the development of risk management and continuous improvement.

5.2. Executive committee

The Executive Committee is a platform for communication and decisions.

It meets monthly to consider the areas of finance, operations, resources and quality.

It consists of process managers chosen for their seniority and their strategic level in the process. Other participants may be called upon to participate from time to time according to the subjects to be addressed.

5.3. Quality

On behalf of the Management, the Quality process ensures the rational and functional implementation of a Quality Management System appropriate to the company.

It monitors and verifies its integration and application in all processes.
To do so, it regularly conducts internal audits, processes feedback from external audits, from customer feedback along with internal and external non-compliance reports.

Quality process employees direct the system by working closely with process owners at all levels of the organisation.

It challenges Management in its strategic and systemic commitments. It oversees planning and conformity of the quality of the content of the annual management review.

6. Interaction between processes

In order to respond effectively to customer demand, the valorisation of their products is done through the coordinated implementation of processes:

- The "Projects" process develops the specifications of the product.
- The "Purchasing" process ensures the availability and supply of components.
- The "Manufacturing" process implements technical operations required to produce the product.
- The "Quality" process ensures that the realisation of the product evolves in a controlled environment.
- The "Coordination and Shipping" process manages the entry and administration of orders as well as logistics related to shipping.

7. Postscript

Control over advanced processes and technologies combined with an attentive approach leads to success in our quest for customer satisfaction.

A culture of continuous improvement engages the company on a path of excellence. To do this, Hybrid SA takes care to involve each team member by supporting and empowering them in the tasks entrusted to them.

Hybrid SA is founded on discipline, efficiency and integrity. These immutable values assure long lasting benefits to customers, suppliers and employees alike.

Chez-le-Bart, June 2018

The Management

Annexe A Exclusions to ISO standard 13485 : 2016

Hybrid SA does not market or manufacture products on its behalf.

Hybrid SA provides subcontracting services for assembling electronic subassemblies. It does not do product design and development.

The following chapters of ISO 13485 : 2016 are excluded:

- 4.2.3 Medical device file
- 6.4.2 Contamination control
- 7.3 Design and development
- 7.5.2 Cleanliness of product
- 7.5.3 Installation activities
- 7.5.4 Servicing activities
- 7.5.5 Particular requirements for sterile medical devices
- 7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems
- 7.5.9.2 Special requirements for implantable medical devices
- 8.2.3 Reporting to regulatory authorities