# Quality Control and Assurance Procedure

Revision 0 – January 2022

synapt.ec

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## 1. Quality, Health, Safety, and Environmental (QHSE) Policy

Synaptec is committed to the wellbeing of its employees, contractors, and those impacted by its operations, and to safeguarding the environment. Synaptec believes that:

- All accidents are avoidable;
- Its activities should have the minimum practical impact on the environment.
- Its processes should result in a clear understanding of its customers‘ requirements and that the Company should consistantly deliver products and services to the standards and commitments agreed with its customers.
- A commitment to quality and continuous improvement must be at the core of Synaptec’s business, culture, and operations.
- It should develop solutions, products, and systems that create value for our customers.

To ensure that we meet our obligations to our customers, staff, partners, and shareholders, we adopt a procedure-driven approach to our work, embedded in our Integrated Management System, aimed at ensuring we safely deliver high-quality products and service. The management system:

- Identifies work related threats and hazards and put in place appropriate safeguards and controls.
- Requires performance that meets or exceeds the industry benchmark standards and best practices applicable to each operation.
- Ensures that employees are trained to conduct their duties in an effective, safe, efficient and environmentally sensitive manner.
- Requires the measurement, and regular review, of QHSE performance against a number of key performance indicators and customer stasfaction.
- Drives continual improvement and innovation based upon efficient business processes, well-defined measurements, regular audits, best practices, and customer feedback
- Develops staff competencies, creativity, empowerment and accountability
- Requires us to work with suppliers and partners who share or exceed our quality standards and expectations.

Synaptec requires that its employees:

- Accept responsibility for protecting themselves, the environment, and those impacted by their activities.
- Comply with the Company’s policies and procedures.
- Participate in developing and using safe working and quality assurance procedures.
- Report all hazards, near misses, incidents, accidents, and non conformances and participate as required in further investigation.
- Conduct themselves in a manner which has the minimum impact on the environment.

In line with this QHSE Policy, Synaptec maintains an Integrated Management System (IMS) that is fully compliant with ISO 9001:2015, as certified and audited annually by Lloyd’s Register QA (LRQA).

Synaptec recognises the importance of environmental protection and will comply with all relevant environmental legislation, regulations and appropriate codes of practice relating to the processes and activities of the company. It is the company's objective to co-operate and maintain good relations with all regulatory authorities and to operate in full compliance with ISO 14001:2015.

Synaptec will carry out all reasonably practicable measures to continually improve its environmental performance. Wherever possible, the company aims to:

- assess the environmental impacts of the company's activities during the manufacture of its products, namely instrumentation hardware, sensors, and software systems;
- reduce the amount of $CO_2$ and particulate emissions produced by company travel by promoting active travel options, the use of public transport, by minimising air travel, and through use of teleconferencing technologies;
- reduce the amount of waste produced;
- reduce the consumption of raw materials, water and fuels;
- reduce and/or limit the discharge of pollutants to water, land and air;
- use recyclable and renewable materials in place of virgin products where possible.

The company will foster environmental awareness and understanding in all employees, suppliers, customers, subcontractors and other stakeholders. Where practicable, the company will provide information and assistance to customers on environmental issues arising from its products and services.

Synaptec requires its staff comply with a number of health-related policies, including drug and alcohol, smoking in the workplace, and workplace ergonomic policies.

We believe that no business objective is more important than these QHSE goals.

Further information relating to Synaptec's QHSE policies and procedures may be obtained by visiting https://synapt.ec/company/quality/.

## 2. Objective of this procedure

Each year, Synaptec's Management defines QHSE metrics and objectives for the year to monitor QHSE performance in line with its QSHE Policy. This procedure:

- Determines the processes needed for its operation and their application throughout all activities;
- Determines the sequence and the interaction of these processes;
- Determines the criteria and methods needed to ensure that both the operation and control of these processes are effective;
- Ensures that these processes are monitored, measured, and analysed;
- Ensures that processes are according to applicable regulatory standards;
- Ensures that necessary actions are implemented to achieve planned results and continual improvement of these processes.

At the beginning of each year, an internal audit of the Integrated Management System (IMS) is conducted by Management, led by the Chairman of the Board of Directors, which is then reviewed by the Board. The internal audit of the IMS considers the overall performance of the system and the level of fulfilment of the previous year's objectives. As a result of this revision, actions are taken to improve the system which may include the definition of the new objectives and/or indicators. The new objectives/indicators are then presented by the Managing Director at the first company-wide general meeting of the year.

QHSE metrics are reported on by Management to the Board at Board meetings, which are held every two months throughout the year.

## 3. Suppliers

3.1 Purchasing process

Synaptec ensures that the products purchased conform to the specified purchase requirements. To achieve this, Synaptec assesses supplier performance by sampling of purchasing orders, assessing criteria such as delivery delay, product non-conformity, and package condition.

Synaptec evaluates and selects key suppliers based on their ability to supply products in accordance with the following specified requirements:

- Compliance with technical requirements;
- Price;
- Associated logistics;
- Compliance with the supplier's financial situation;
- RoHS Compliance;
- Compliance with "Conflict Minerals" restrictions;
- Applicable certification;
- Risk assessment;
- Carbon emission standards.

Suppliers not used for a period exceeding one year shall be re-evaluated by Synaptec prior to the placing of the order. The ongoing ability of the supplier to provide conforming product or service shall be reviewed at periods not exceeding two years.

While the test and final inspection of certain components may be sub-contracted, the responsibility for ensuring compliance with customer specifications will be Synaptec's. Suppliers providing a product or service that can affect the product's compliance with specifications will only be selected after an evaluation by Synaptec that the supplier has demonstrated they can ensure compliance with all specified requirements.

Suppliers providing calibration services (including verification of measuring devices by comparison with calibrated equipment) are evaluated on their ability to meet stated requirements.

Documented objective evidence that a supplier can provide a product or service that is fit for its purpose can be made by one of the following methods:

- the supplier has an acceptable quality management system;
- the supplier has a quality system certificate in accordance with the appropriate standard and with an acceptable scope;
- a site assessment to ensure that all relevant controls are available, documented, understood and effective.

Synaptec maintains records of the results of the evaluations and of any necessary actions in compliance with records control definition.

3.2 Verification of purchased products

Synaptec performs incoming inspection of goods to ensure that purchased products meet the specified purchase requirements.

Where a key supplier has been assessed by Synaptec and documented objective evidence exists to demonstrate that the supplier is fully capable of producing and verifying the product or service, and declaration of conformity is supplied with each batch or product, then verification of the product or service on receipt is not required routinely.

Where verification of purchased goods cannot be carried out after manufacture then the product shall only be accepted if supplied with a declaration of conformity. This shall specifically state compliance with the purchase documents, listing the factors that together demonstrate full conformity of the product.

When sample inspections or tests are permitted, they shall be conducted in a manner which demonstrates conformity of the entire batch.

## 4. Production

4.1 Verification of products

Synaptec plans and develops processes required for high-quality, repeatable and traceable product manufacture. This planning of product manufacturing is consistent with the requirements of the other processes within the IMS. Synaptec determines, as appropriate, during the planning phase of the product manufacturing:

- the quality objectives and requirements for the product;
- the need to establish processes, documents, and provision of resources specific to the product;
- activities required by the specifics of the product and the criteria for product acceptance: verification, validation, calibration, and test;
- the records necessary to provide evidence that both the production process and the resulting product meet requirements.

4.2 Determining product requirements

Synaptec determines the following requirements that are related to our product:

- requirements that have been specified by the customer, including any such requirements for delivery and post-delivery activities;
- requirements that have not explicitly stated by the customer but that are necessary for the specified or intended use of the product (where the use is known);
- statutory and regulatory requirements applicable to the products;
- any additional requirements that Synaptec considers necessary.

4.3 Reviewing product requirements

Synaptec reviews the requirements related to products prior to commitment to supply a product to the customer (e.g., prior to the submission of proposals, prior to the acceptance of contracts or customer orders, or prior to the acceptance of changes to contracts or orders). This review is designed to ensure that:

- product requirements are clearly defined;
- any changes to previously expressed or agreed contract or order requirements are resolved and agreed;
- Synaptec has the ability to meet the defined requirements.

4.4 Identification and control of products

All individual products or modules (interrogation systems, sensors, servers, etc.) are identified by unique serial numbers. Typically, product identification is achieved by a print label stating the name, serial number, product number, and applicable legal or regulatory marks, disposal notices, manufacturing notices, and bar codes. Alternatively, laser-engraving marking may be utilised for identification if requested by and agreed with the customer.

4.5 Relevant manufacturing documents

The information for manufacture of the products is described by the Engineering Specific Procedures within the IMS, prefixed SP-EN. The SP-EN document for each product contains all production details with acceptance criteria to ensure high quality standards, typically including:

- Assembly processes
- Inspection points
- Tests
- Labelling and marking

The Specific Procedure describes the methods to be used to monitor and control processes, including instructions to safely use the equipment or tools, and the techniques and methods to manufacture, test, and control the processes. The EN-SP document also describes the responsibilities during the process for testing, checking, and sign-off.

4.6 Inspection and test equipment

Inspection and test procedures are divided into three categories:

Stock & warehouse:

Upon receipt of goods/materials/parts to be used and/or assembled in products, the stock manager must test, verify, and check them according to the notes, drawings, and measurements documented in the purchase order and other documentation associated with the goods. It is the responsibility of the product development team to produce, generate, and deliver this technical file with all relevant verification points that should be tested and verified on goods receipt, as well as the acceptance criteria and tolerances. Technical files and drawings are revision controlled and maintained as part of the IMS. Compliance certificates are checked and stored with the purchase documentation. Inspected products that do not fulfil the specifications or conformities are labelled and stored separately from accepted stock while remedial action is taken.

Intermediate tests and verifications:

Quality control is applied throughout the phases of assembly and manufacture to guarantee a high quality of products. For example, electrical sensor modules undergo a preliminary sensitivity test to that the response to applied voltage is within the defined tolerance, and electronic sub-assemblies of the interrogation systems are subject to intermediate tests and calibration processes before they are approved for assembly into the interrogation system chassis.

Final tests and verifications:

The products have a Final Quality Validation (FQV) step that includes final inspections, verifications, and tests. For interrogation systems, the FQV ensures a full acceptance test using all components and accessories to be supplied and all software functional modules that are deployed.

4.7 Handling, storage, packing, release, and shipping

Handling & Storage:

All employees ensure that documents, records, and products are carefully handled to prevent damage and or deterioration of the goods. All items are handled and stored in designated storage and packaging areas, being dry and cool spaces. The storage area respects:

- The ESD protection for the electronic components;
- The safety of the employees;
- The dirt protection for the optical components;
- The proper handling for the optical components.

Packing:

Each product is packaged according to its requirements. Typically, interrogators and sensor components are protected by cut foam enclosures and packed in cardboard boxes.

Packaging includes the associated documentation calibration certificate sheets, user manuals, and material disposal/end-of-life instructions. On agreement with the customer, certain documents may be provided in digital format for convenience.

Each package is labelled externally with the serial number of the products for reference.

Release:

Prior to shipping, a final review is conducted of the products that were ordered by the customer.

Shipping & delivery:

Shipping is performed using either the client's preferred courier company or by a freight forwarder registered as a key supplier to Synaptec.

4.8 Production records

Product traceability is ensured by SP-EN procedures which instruct the recording of data resulting from the manufacture and calibration of the products (e.g. sensor raw calibration data, derived coefficients, etc.). All records related to production are retained within the IMS.

The control and management of the IMS and its records are the responsibility of the IT Manager and Managing Director. The hard disk drives of the local servers are periodically backed up in both online (cloud) and offline (local air-gapped) format.

## 5. Production Development

5.1 General

Product development activities are of utmost importance in the life cycle of Synaptec's products. Synaptec provides planning, control, and design input for the development of products and services based on its technologies.

5.2 Planning

The product design and development procedures are documented in the IMS by Engineering Specific Procedures (SP-EN). It is the responsibility of the product development team to:

- ensure that the product specification requirements are clear;
- the necessary planning tools are utilised;
- all necessary resources are identified;
- to oversee design, implementation and testing activities;
- to coordinates all activities relating to the design of products, features, software, and associated tests.

The design plan for a new or revised product, feature, or software module includes:

- Overall project management;
- Design and development stages;
- Required design reviews;
- Customer reviews and feedback;
- Test and validation;

- Production of documentation, its transfer to Production, and the delivery of associated training.

5.3 Inputs

Inputs relating to product requirements are defined and documented according to SP-EN-003 Design Procedure. All inputs are reviewed for adequacy and completeness and are approved to resolve any ambiguity. Inputs include:

- Functional, performance, and safety requirements according to intended use;
- Applicable regulatory requirements;
- Customer requirements.

5.4 Outputs

Outputs of concepts and/or detailed designs and development activities are documented according to SP-EN-003. Outputs include:

- Metrics to determine fulfilment of input requirements;
- Appropriate information for production, stock, engineering, and service provision;
- Specification of the characteristics of the product that are essential for its safe and proper use;
- Design and validation reports for review by delivery team.

5.5 Review

The design plan specifies stages of product development activities and respective product development reviews. Reviews take place according to SP-EN-003 at regular product development meetings attended by Lead Engineers. Results of design reviews are recorded within the IMS.

Design reviews include:

- Evaluation of the results of the product development activities;
- Identification of problems and definition of necessary actions to resolve.

Reviews must include representatives of functions concerned with the design and development stage being reviewed, as well as other personnel as determined by the relevant Lead Engineer acting as the Design Authority.

5.6 Test and validation

Design test and validation is planned and performed to ensure that the development outputs have satisfied the development input requirements and the specified or known intended use or application. All relevant test and manufacturing setups are reviewed and approved at this point. Records of the results of the test and validation, and definition of necessary actions are maintained within the IMS.

5.7 Control of changes

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The product development process defines the identification, recording, verification, validation and approving of design changes. The review of design changes includes an evaluation of the effect of the proposed changes on the constituent parts and the complete delivered product. Records are maintained to show the results of the review and any necessary actions identified during the review.