



Cooptech Kft.'s Integrated Management System

Our company is committed to providing high-quality products and services. Accordingly, Cooptech Kft. has established a Quality Management/Validation Group to support the required level of quality throughout every stage of the manufacturing and construction processes. Where applicable, this is implemented through validation process steps in which documented test results demonstrate compliance with customer requirements. Our company primarily supplies the aseptic pharmaceutical and medical-device manufacturing sectors; therefore, maintaining a strong focus on customer needs and keeping our knowledge of the relevant guidelines, standards and legislation up to date are particularly important to us.

For this reason, **Cooptech Kft.** maintains an integrated management system certified by *e.com-CERT Kft.*, incorporating the requirements of the following international standards:

- ISO 9001
- ISO 14001
- ISO 45001
- ISO 27001

When developing our integrated management system and carrying out project validations, we take into account the requirements of Good Engineering Practice (GEP), Good Manufacturing Practice (GMP) and Good Automated Manufacturing Practice (GAMP) guidelines (cGxP, ISPE). Cooptech Kft. designs, manufactures and inspects its equipment in accordance with MSZ EN ISO 3834-2, MSZ EN 1090-1 and MSZ EN 1090-2.

Our company performs the design, manufacture and inspection of pressure equipment, as well as the preparation of technical documentation, using personnel qualified in accordance with the following legislation:

- Government Decree 216/2019 (IX. 5.)
- Decree 8/2018 (VIII. 17.) of the Ministry for Innovation and Technology
- Pressure Equipment Directive 2014/68/EU (PED)

Where necessary, we engage and supervise highly qualified subcontractors holding welding qualifications in accordance with ISO 9606, welding operators qualified in accordance with ISO 14732, and personnel performing non-destructive testing in accordance with ISO 9712.

Our electrical design, electrical installation and electrical cabinet manufacturing processes have been developed with due consideration for the requirements of MSZ EN IEC 61439-1, MSZ EN IEC 61439-2 and MSZ EN 60529.

The Process Automation Group consists of IT engineers with several years of process-management experience who are also familiar with the relevant regulations, recommendations and standards, including GAMP 5 and 21 CFR Part 11.



Main objectives and activities of the Quality Management/Validation Group:

- Preparation of documentation in accordance with customer, standard and legal requirements. Based on the URS (User Requirements Specification), we prepare the following project documents together with the relevant departments:
 - Project documentation list
 - Detailed design documentation
 - As-built documentation
 - Validation-plan documentation, which may include the following documents:
 - Validation Plan
 - TRMX (Traceability Matrix)
 - FAT (Factory Acceptance Test)
 - SAT (Site Acceptance Test)
 - IQ (Installation Qualification)
 - OQ (Operational Qualification) documents
- Promoting continual improvement in quality-assurance systems and procedures by conducting internal audits.
- Identifying, correcting and preventing defects during manufacturing and construction activities, including installation and commissioning.
- Supervision, inspection and calibration of measuring equipment used during manufacturing and construction.
- Regular training of employees, assessment of training needs and preparation of a corresponding training plan.
- Supplier control: We carefully evaluate our suppliers to ensure the quality of supplied materials and components.
- Management of customer feedback: We monitor customer feedback and use it to improve our products and services.

Our Team:

Our Quality Management/Validation Group consists of experienced professionals committed to excellence. Its members continuously develop their knowledge and skills so that they can provide appropriate support in meeting customer, quality and legal requirements applicable to the various disciplines.

- **Director of Quality and Pharmaceutical Technology:** Responsible for the overall operation and strategy of the Quality Assurance Department.
- **Validation Manager:** Responsible for the overall quality assurance of projects, proper project documentation and fulfilment of URS requirements.



- **Validation Engineer:** Supports the Validation Manager and is responsible for project quality assurance, proper project documentation and fulfilment of URS requirements.
- **ÜGYE Manager:** Responsible for the final inspection of manufactured products and for conducting FATs.
- **Quality Assurance Documentation Specialist:** Verifies and documents compliance with design documentation during projects. Supports the Validation Manager and compiles project documentation. Implements and complies with the quality-assurance procedures and ensures that they remain up to date.

Further Information:

If you have any questions about our Quality Assurance Department or our quality-assurance procedures, please feel free to contact us at [contact details].