







We have worked for more than two decades with both international and domestic companies within the pharmaceutical and biotech industry. In the past ten years a great number of our assignments have been in the area of biopharmaceuticals.

In industrial biotech our know-how covers all process phases from upstream processing to cultivation and downstream purification with a variety of strategies for purification processes. We also have experience of engineering work for BSL3 (biosafety level 3) facilities.

#### **Our customers**

Our customers include both big international companies and smaller local companies in Europe, India, Asia, The Middle East and Africa. We can offer our customers assignments of any size from consulting and conceptual design up to EPCM and turnkey solutions.

# Good Engineering Practices – our promise to you

Elomatic's way of working complies with Good Engineering Practises that ensure time and cost savings in design, commissioning, qualification and validation of completely new or modified facilities. We are able to establish and maintain project documentation that is both technically of a high standard and that is valid throughout the whole project. This project documentation forms the backbone of the successful life cycle management of the process plant and has an effect beyond the time when the project is completed. The proof of our know-how and experience in biotech and pharma are the numerous facilities we have worked on that have passed inspections by EMEA or FDA.

#### Deep domain knowledge

- Biotechnical manufacturing processes
- Biopharmaceuticals
- All pharmaceutical dosage forms



- Highly potent compounds in manufacturing
- Diagnostics production
- Clean utility systems
- Clean rooms
- Automation (according to GAMP)
- Commissioning, qualifications and validation
- Regulatory and quality issues



# **Broad in-house engineering scope**

- Process engineering
- Plant engineering
- Mechanical engineering
- Construction engineering
- HVAC engineering
- Electrical engineering and instrumentation
- Automation system engineering
- Information system engineering

## **Related Elomatic services**

- Electrical, Instrumentation, Automation & IT
- Machine Safety and CE Marking
- Plant and Process Engineering
- ► Validations Services







# Sterile Liquid Plants

Elomatic offers customers in the Bio & Pharmaceutical industry turnkey deliveries of sterile liquid plants (SVP, LVP). Our extensive experience in the biotech sector is complemented by our strong know-how in EIA&IT, clean rooms and clean utility equipment.

We comply with good engineering practices. Our goal is to create added value for our customers: time and cost savings in design, commissioning, qualification and validation. The proof of our know-how and experience are the numerous facilities we have worked on that have passed inspections by the EMEA or FDA.

Our mission is to place our more than two decades of experience in the pharmaceutical and biotech industry at your disposal to ensure that your sterile liquid plant not only complies with all the necessary regulations, but also provides the continued desired ROI over the entire life cycle of the plant.

#### **Example delivery**

Elomatic conducted a turnkey delivery of a new infusion solution factory for the Ministry of Health and Medical Industry of Turkmenistan in 2013. The demanding delivery included 400 m<sup>2</sup> of clean room spaces and extensive logistical coordination. The project was started in June 2012 and the factory started up without incident in July 2013.

The factory's capacity is 10 million infusion solution bottles a year, which is ample to meet Turkmenistan domestic demand.

Elomatic's scope included:

- Design
- Process equipment
- Laboratory equipment and furniture
- Clean utility equipment
- Clean rooms and clean room HVAC
- Piping and electrical installations
- Automation
- Commissioning, start-up and qualifications





## **Formulation processes**

## Turnkey delivery

- Design Specification's (FS, FDS, HDS, SDS)
- Design of the unit
- Including equipment, piping, electricity, and instrumentation
- Built in workshop, then shipped to site
- CFR 21 Part 11 compliant automation
- Commissioning, start-up and qualifications

#### **Active Waste Decontamination**

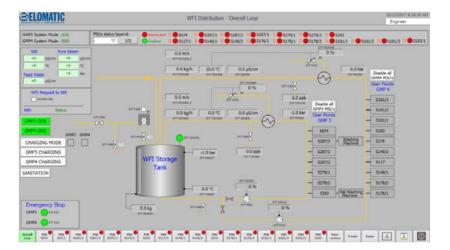
## Turnkey delivery

- Design of the unit
- 2 decontamination vessel
- Steam both in jacket and direct injection
- Process piping
- Instrumentation and electricity
- Magnetic agitators
- Automation documented according to GAMP
- Built in workshop, then shipped to site
- FAT and SAT protocols and Execution

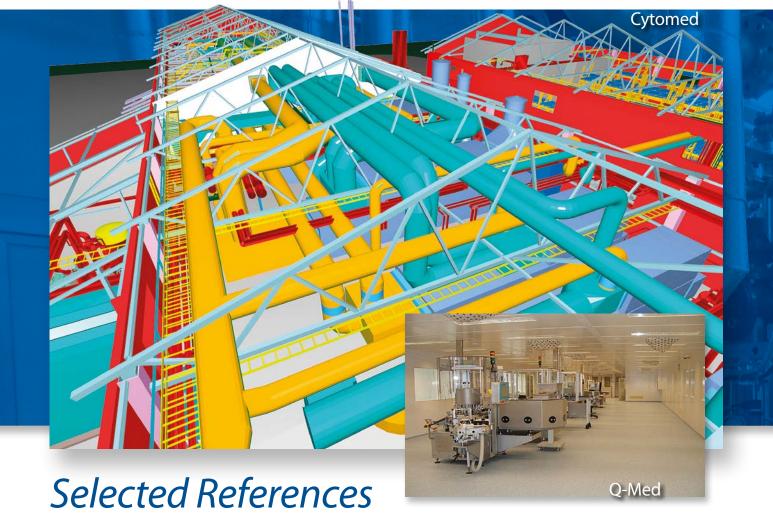
## **Clean Utility Scada Automation**

## Turnkey delivery

- Design Specification's (FS, FDS, HDS, SDS)
- System Hardware and Software
- Tested and documented delivery according to GAMP
- Control cabinets, distribution boxes etc.
- Instrumentation and electrical installation
- Quality control instrumentation
- CFR 21 Part 11 compliant automation
- Commissioning, start-up and qualifications







# Ministry of Health and Medical Industry of Turkmenistan

Turnkey delivery of a new infusion solution factory

- Process equipment
- Laboratory equipment and furniture
- Clean utility equipment
- Clean rooms and clean room HVAC
- Piping and electrical installations
- Automation
- Commissioning, start-up and validations

## Cytomed Oy

Rebuilding of existing workshop

- In the first phase 440 m<sup>2</sup> clean room area, grade
   D areas (EU GMP) for capsules, dry syrups, creams, ointments and suppositories
- Space for future expansion for sterile ampoule filling facility
- Basic and detail design, all official applications, equipment specifications, construction supervision and validation of process, HVAC and clean rooms

#### O-Med

A new, complete production facility for aesthetics injections

- All utilities produced in-house
- 624 m<sup>2</sup> clean room area, class 7 and 8 areas (ISO 14644-1)
- Conceptual, basic and detail design, project coordination, specifications, construction supervision, commissioning and validation
- European authorities approved factory for production and FDA

#### Pfizer Health

Production Facility for Tumor Therapeutic Antibodies (TTMA)

- All utilities produced in-house
- 260 m<sup>2</sup> clean room area, grade C and D areas (EU GMP)
- Basic and detail design, project coordination, specifications, construction supervision, commissioning and validation







#### **Contact Information**



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#### Hetero Drugs Limited, Hyderabad, India

Concept, Basic and Detailed engineering for greenfield vaccine facility

#### Biovitrum Ab, Stockholm

Biotech pilot plant including cell culture fermentation, purification, clean utility and other utility systems

- All utilities produced in-house
- 380 m<sup>2</sup> clean room area, class 7 and 8 (ISO 14644-1)
- Basic and detail design, process and clean room design

## Orion Oyj

A new building expansion connected to existing hormone gel department.

#### Final result

- $\bullet$  6,000 m<sup>2</sup> on four floors
- 1,300 m<sup>2</sup> Clean rooms class 8 (ISO 14644)
- Warehouse and loading bays
- Stability study chambers

- New tank farm outside for storage of flammable clean utilities (ATEX)
- Manufacturing equipment: isolator, washing machines, holding tank (ATEX), filling & packaging line
- Clean utility piping

## Elomatic scope

- Project coordination for all disciplines and project phases
- Production ongoing during building, short stops for connecting new and old areas
- Process, plant, HVAC design for conceptual, basic and detail design including 3D modelling (CADMATIC and other software)
- Documentation for procurement, construction supervision, commissioning & validation supervision

#### Fit Biotech

Conceptual design for a vaccine plant, from fermentation to fill & finish





Elomatic is a leading European consulting and engineering company. Our close to 900 professionals work in machinery and equipment manufacturing, pharmaceutical, process, energy, offshore and marine industry projects.

We offer consulting, engineering, product development and project management services as well as products and turnkey solutions to industrial and public sector customers.

The cornerstones of our success are customers that are leaders in their respective fields and professional, customer-oriented and motivated personnel.

- Technical Consulting
- Engineering
- Project Management
- Product and Service Development
- Products & Turnkey Solutions
- Software Development
- Design Software Solutions

## **Key customer segments**

- Pharmaceuticals
- Process Industries
- Energy
- Foodstuffs industry
- Starch and Potato Processing
- Machinery and Equipment Manufacturing
- Marine & Offshore
- Oil & Gas

#### **Contact information**

We operate globally and have clients in over 80 countries. Our offices are located in Finland, China, India, Italy, the Netherlands, Poland, Serbia, Russia and the UAE.

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