

## PHARMA HEALTHCARE MICROELECTRONICS

Design&Build Turn-key projects in cleanroom environment

## Seeing what doesn't exist yet



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Technology has always been at the heart of our company. Ever since the beginning in 1975, we are creating technology that impacts people's lives and makes their working and living environment healthier and safer, and the future stronger.

Today Amelicor Group is one of the global leaders in HVAC, Cleanroom Solutions, and CAPEX engineering in Pharma, Healthcare and Microelectronics, operating in more than 50 countries worldwide.

## About us

One group, 4 companies, 47 years of history Know-how | Experience | Agility

*(klimaoprema* 

Cleanroom and HVAC production, R&D, logistics Cleanroom engineering, design, planning, execution, assembly, construction

**MCRT** Flexible cleanroom solutions for microelectronics Li KOEC Energy management, virtual power plant



#### **OUR EXPERTISE**

- Design and manufacture high-quality Cleanroom/HVAC equipment
- Cleanroom technology and engineering
- Providing fast-track projects for pharmaceutical, microelectronics, health and automotive industry
- Logistics, installation and maintenance
- Validation/Qualification services
- Training and after-sales support services



We understand that every cleanroom is unique. Our experienced engineers create cleanrooms based on specific needs.

#### **STRENGTHS**

- Turn-key solutions tailored to customer needs
- Flexibility and attentiveness to details
- One stop-shop approach to optimize time, energy and financial resources
- Innovation and sustainability

### PHILOSOPHY

- Passion driven
- Commitment to work
- Courage to go forward
- Desire to take care of our employees
- Developing and producing high-tech solutions
- Providing comprehensive engineering services

#### **Our values**

- Constant learning and evolvement •
- Foreseeing changes, adjusting our business strategy accordingly
- Focus on the development based on professional knowledge
- Active cooperation with the center of ۲ excellence
- Applying the latest technologies •
- Financial stability & risk control .
- Recognizing challenges, providing solutions .
- Innovations, product competitiveness .
- Expansion into new markets .
- Desirable and competitive employer able to • retain and transfer knowledge
- Healthy work atmosphere • & work-life balance



#### **Our story**

#### 1975 1982 ----2005-2012

Klimaoprema was founded 12 empl.	w	We started orking in tl proom indu	he S	First factory amobor and extension 6 000 m <sup>2</sup> 220 empl.	its
2015-2019		2021		2022	)

Aqusition

600 empl.

**First factory in** N.Gradiška and its of MCRT GmbH extension 31 000 m<sup>2</sup> 470 empl.

Amelicor Group was founded. **Expansion to new** markets 850 empl.

#### WHAT MAKES **US DIFFERENT**

#### **FASTER EXECUTION**

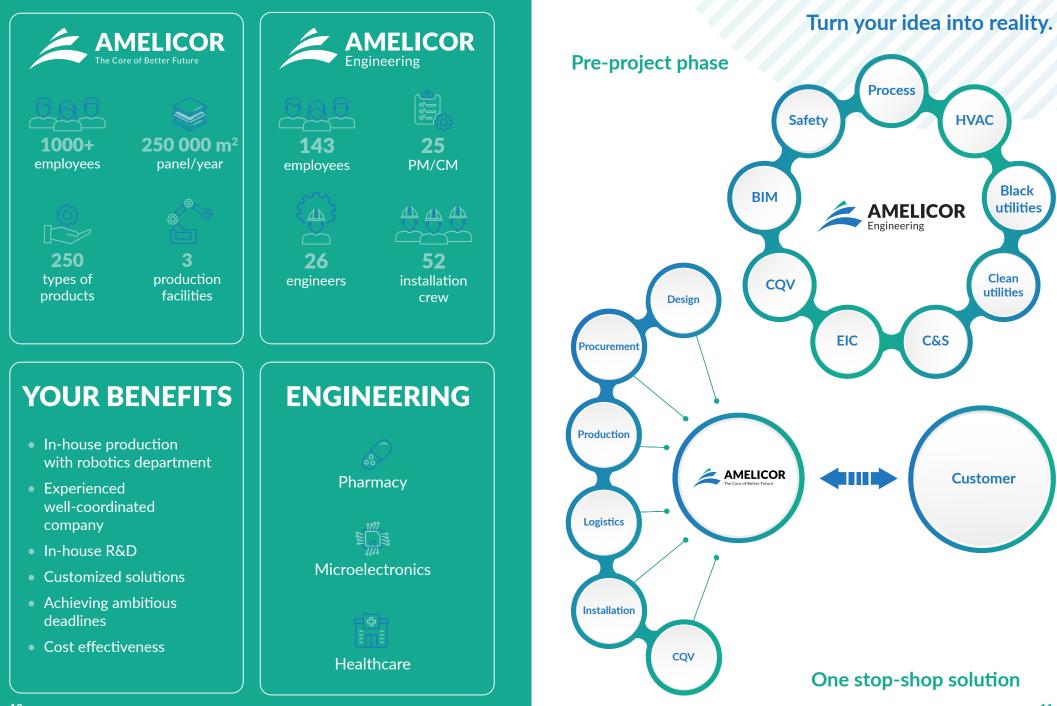
- Turn-key projects from the earliest phase
- Design, production, construction and CQV with one partner

#### **COST-EFFECTIVE PROJECTS**

- The result exceeds expectations
- One stop-shop
- Fast-track projects
- Responsibility for the final result

#### **PEOPLE RELATIONS**

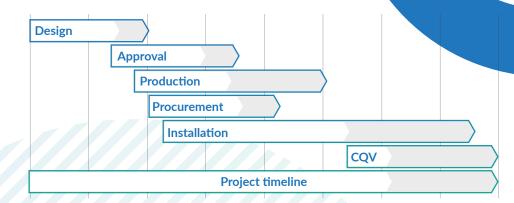
- Close cooperation with the project management
- Prevention of poor communication



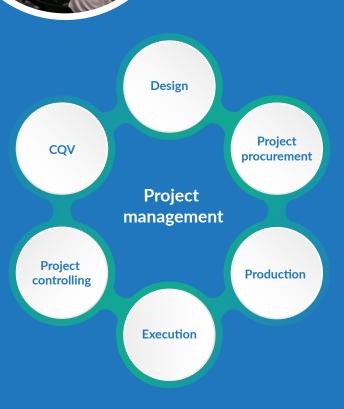
#### **Project management**

- Clear, organized plans
- Managing budgets and timelines
- Documentation control
- Well defined goals
- Team accountability
- Interdependencies across teams
- Early risks identifying
- Visibility to project progress and status
- Balance between the time, cost and quality

One stop-shop approach results in fast and cost-effective projects.



Teamwork. Incredible power to achieve anything.



#### Design

- Evaluating the personnel and material workflow
- Defining the cleanliness classes
- Defining the pressures and air-flow
- Defining all relevant parameters
- Mechanical installations layout
- Heating/Cooling calculations

#### **BIM modeling**

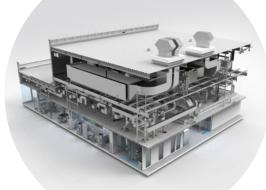
- Information for multiple disciplines, companies and project phases
- Managing design information across life-cycle of entire project
- Shared file of design components, tools, workflows, and production standards
- Efficient coordination of building system
- Creation of simulation scenarios by defining areas, activities and operational information
- Establishing customizable requirements



## Excellence and innovation built into every design.

#### Visualization

- Enabling virtual design reviews
- Enabling setting-up a digital twin of the facility
- Ensuring crystal clear communication and direction for flawless project execution, time and cost savings
- Enabling customer to have accurate building plans and 360° image
- Minimisation of re-planning efforts
- Remote and effective communication with team members





#### **Project procurement**

- Planning of internal/external items
- Vendor evaluation
- Vendor coordination
- Fully transparent procurement process
- Creating and controlling procurement documentation
- Minimizing the risks
- Ensuring compliance with the specifications
- Maintaining high ethics codes

We adhere to strict codes of conduct and make sure our process meets the customer's needs.

#### Production

- 3 production facilities (approx. 40 000 m<sup>2</sup>)
- High-rack storage warehouse
- Robotized and automated production lines
- CNC machines
- Monitoring by MES software
- Incoming and outgoing quality control
- Waste management



#### **Production capacity**

# **100** m<sup>2</sup> / 1h cleanroom panels

- Automated and robotized Cleanroom production lines
- Production based on innovative and sustainable solutions
- No impact on the environment
- Focus on a safe and healthy working environment
- Focus on the behavior and business model of material suppliers

## We create cleanrooms, respect details, and solve problems.

#### Execution

Execution is a structured database for Good Engineering. Practices fully integrated within our Quality Management System (QMS).

Based on Amelicor's guidelines for Project Execution Model and external standards, it includes all elements of a project life-cycle from the Front End (Conceptual Design), Engineering (Basic&Detail Design) to Construction, Commissioning&Qualification and Handover.

#### **Construction management**

Amelicor's construction management approach aims to increase productivity and construction quality from constructability reviews to the completion of the building.

#### HSE Health, Safety&Environment

Millions of hours are spent working across our international operations every year. Our number one priority is to ensure everyone's safety each day. Amelicor Group approach ensures safety as an integral part of design processes. The result is a safe project and facility to use after the handover.

#### CQV Commissioning, Qualification, Validation

Amelicor Group offers complete turn-key services such as the design, manufacture, construction of cleanrooms, as well as servicing, regular preventive maintenance, and validation.

Regular servicing, maintenance and validation of equipment or facilities ensure safety during the use and longer life. Our modern approach to running a system requires continuous maintenance and documentation traceability throughout the exploitation.

#### **SERVICES**

- HVAC commissioning and balancing
- Cleanroom and device qualification
- Integrity testing of HEPA filters
- Particle counting
- Cleanroom recovery test
- Smoke test
- Temperature mapping/monitoring

#### DOCUMENTATION

- URS User Requirement Specification
- GMP RA Risk Assessment
- RDS Room Data Sheet
- FS Functional Specification
- TS Technical Specification
- DQ Design Specification
- MC Mechanical Completion

- FAT Factory Acceptance Test
- SAT Site Acceptance Test
- IQ Installation Qualification
- OQ Operation Qualification
- TEMPERATURE MAPPING cold or hot rooms, chambers, warehouse
- Calibration certificates

#### QMS Quality Management System

Amelicor Group QMS is a process-oriented, integrated management system that ensures requirements specified in ISO 9001.

Through the implementation and compliance with the QMS requirements, we make sure our services are in line with customer expectations, regulatory requirements and the company's own requirements at all times.

Amelicor Group QMS is certified in accordance with an internationally approved and accredited certifying body.

> ISO 17025

Our certificates

ISO 14001

EC Certificate of

Conformity

ISO 50001

ISO

9001

Fire resistance

certificate

ISO

9001, 13465

13001, 45001

50001, 17025

ISO 14971

ISO

45001

Various certificates

of product

testing

**Technical** 

standards

Q

**Regular audits** 

from customers

### SELECTED REFERENCES



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