The Essential
is Inside

Company profile

01 I 2023

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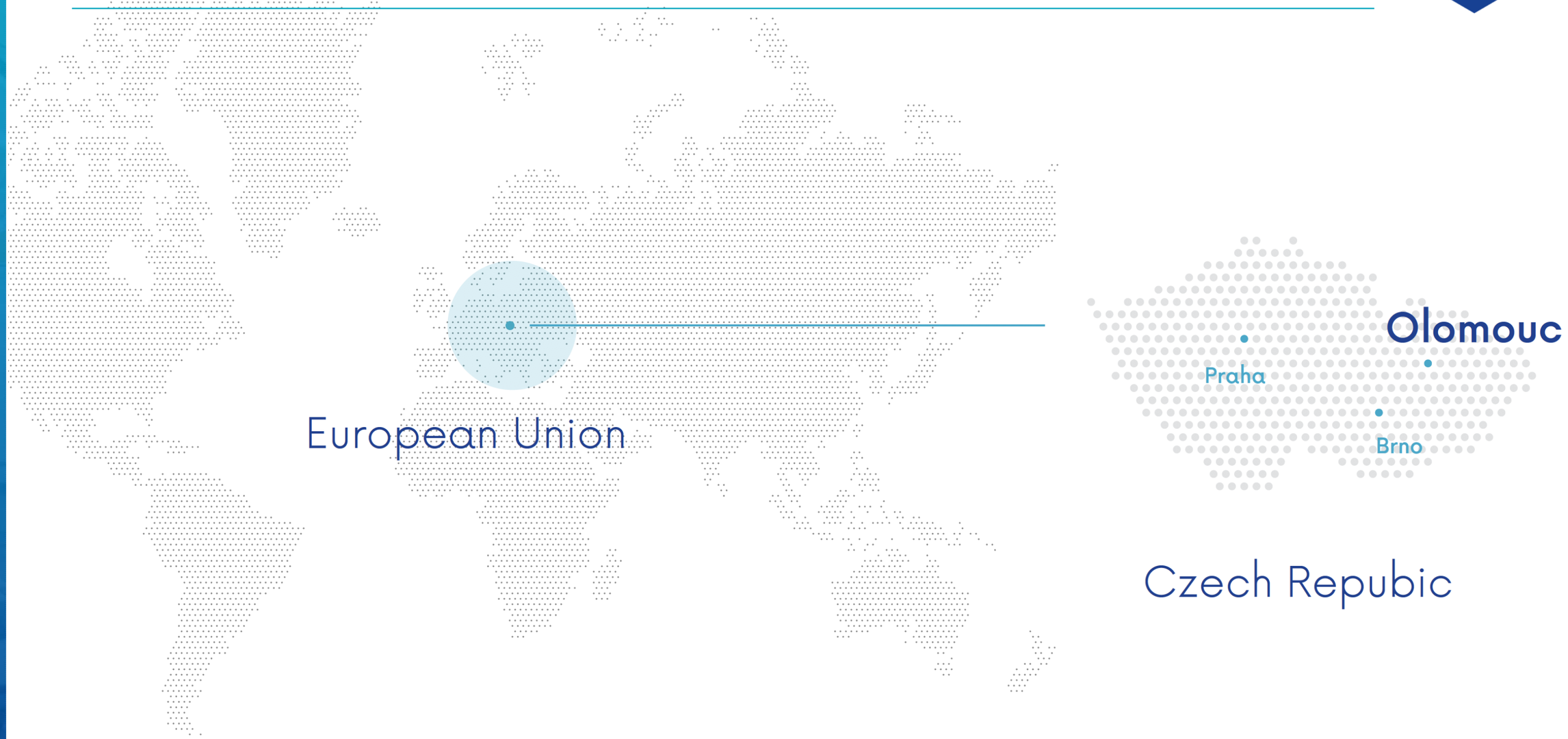
INTRODUCTION

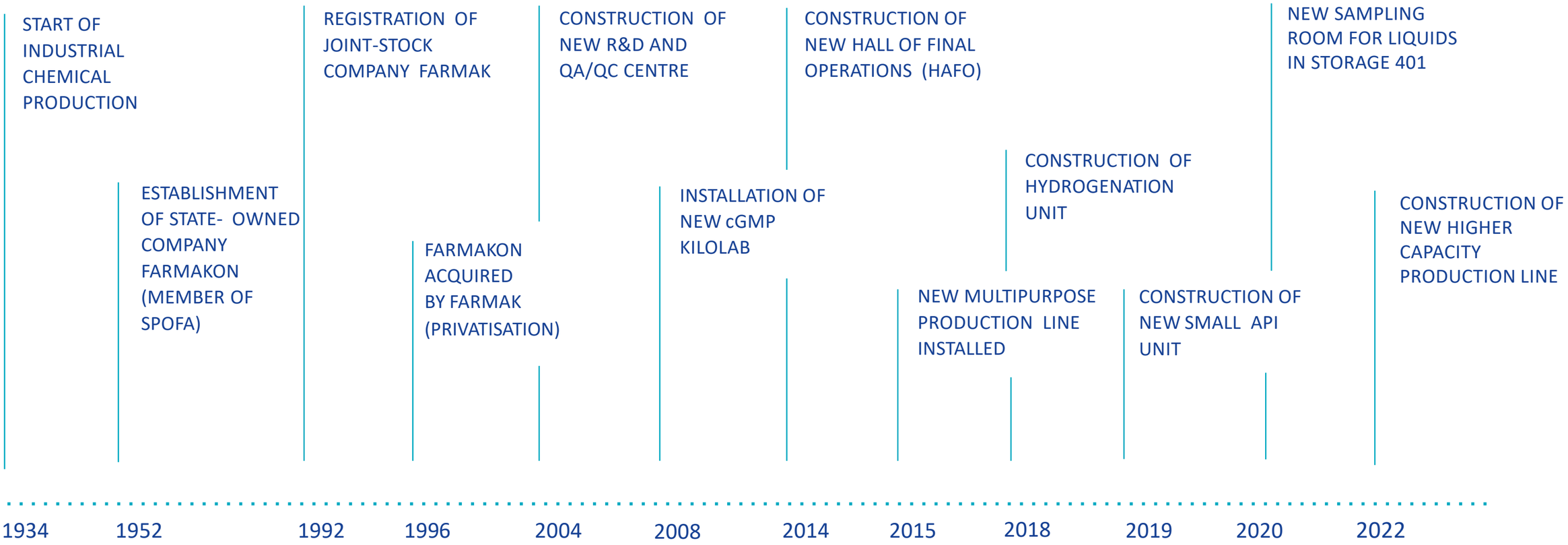
- Czech, privately owned company with tradition of industrial chemical production dating back to 1934
- Globally active and strongly export oriented
- Focused on R&D, manufacturing and marketing of:
  - Generic API´s
  - Advanced intermediates
  - Chemical specialities
- Open to Contract Manufacturing and Custom Synthesis
- Flexible, reliable and customer oriented partner

Company profile

LOCATION



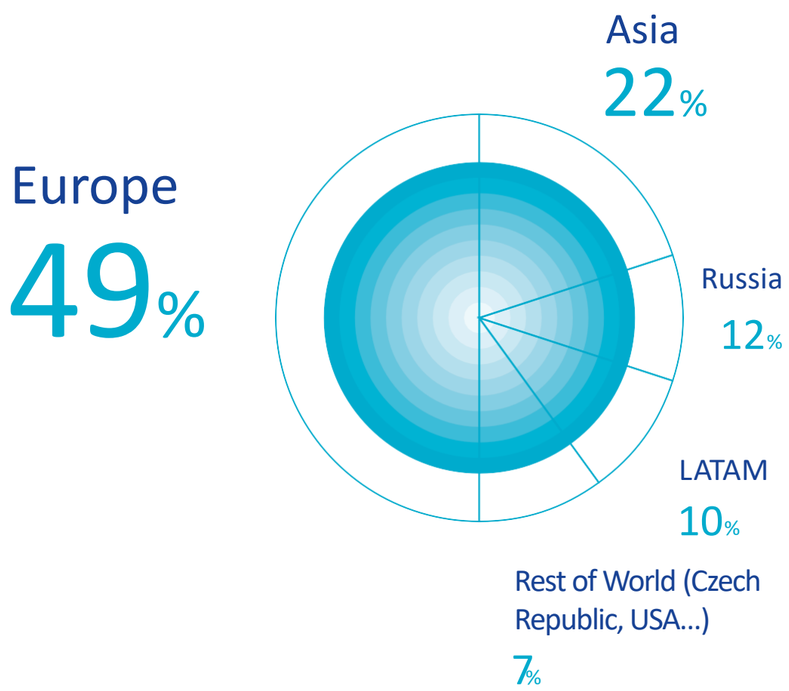
HISTORY

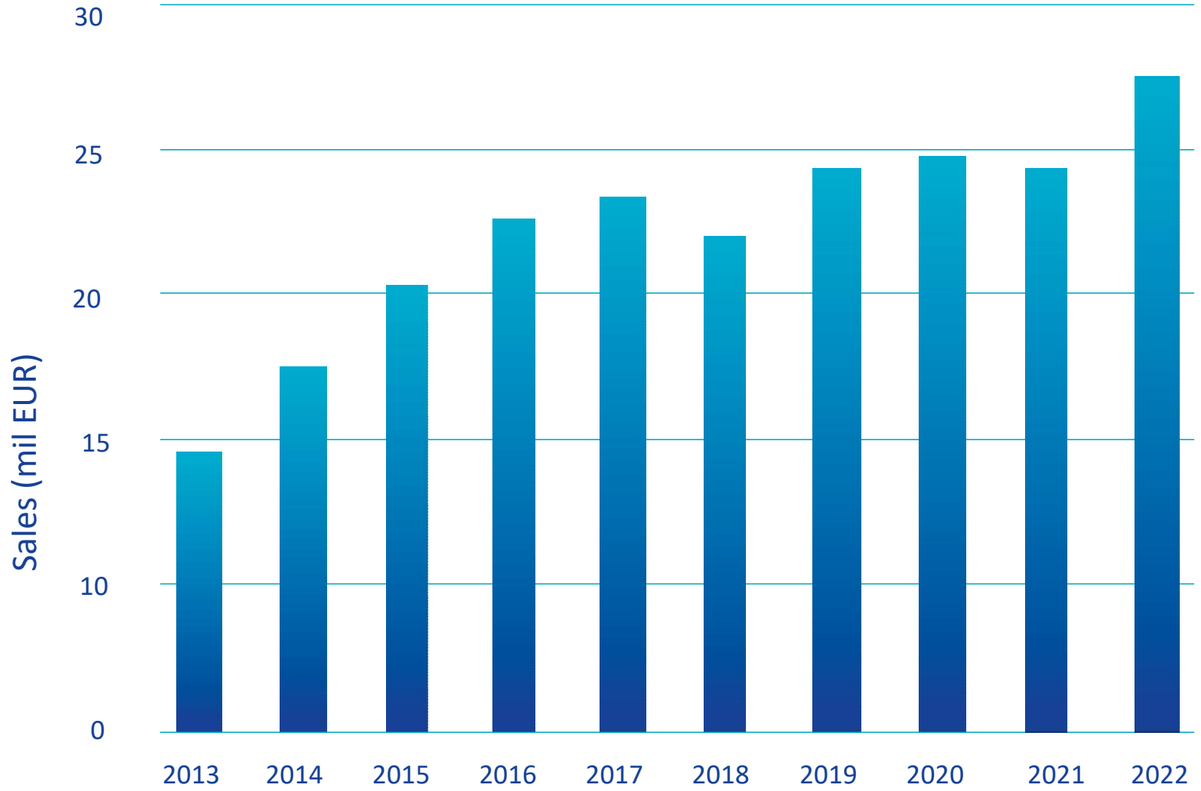

START OF INDUSTRIAL CHEMICAL PRODUCTION
1934
ESTABLISHMENT OF STATE- OWNED COMPANY FARMAKON (MEMBER OF SPOFA)
1952
REGISTRATION OF JOINT-STOCK COMPANY FARMAK
1992
FARMAKON ACQUIRED BY FARMAK (PRIVATISATION)
1996
CONSTRUCTION OF NEW R&D AND QA/QC CENTRE
2004
INSTALLATION OF NEW cGMP KILOLAB
2008
CONSTRUCTION OF NEW HALL OF FINAL OPERATIONS (HAFO)
2014
NEW MULTIPURPOSE PRODUCTION LINE INSTALLED
2015
CONSTRUCTION OF HYDROGENATION UNIT
2018
CONSTRUCTION OF NEW SMALL API UNIT
2019
NEW SAMPLING ROOM FOR LIQUIDS IN STORAGE 401
2020
CONSTRUCTION OF NEW HIGHER CAPACITY PRODUCTION LINE
2022

SALES AND MARKETS

- More than 180 business partners across the world
- Export level in sales approx. 94%

TERRITORIES

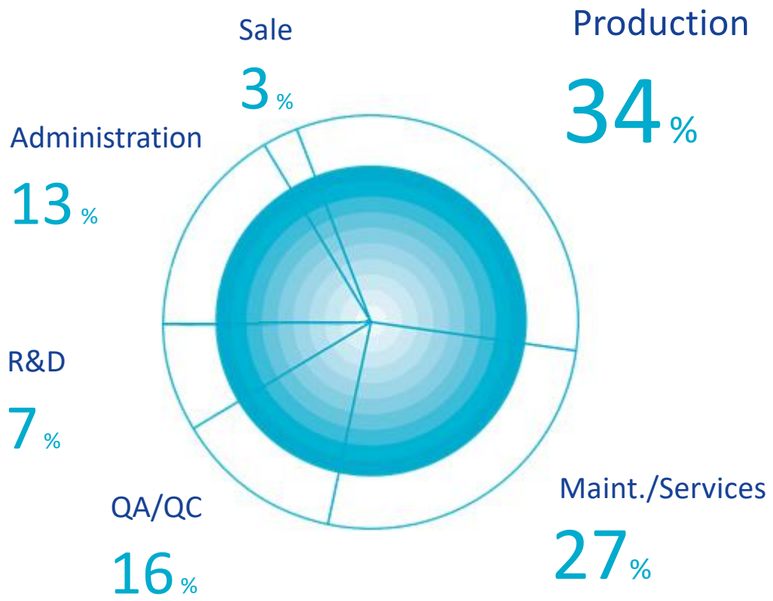




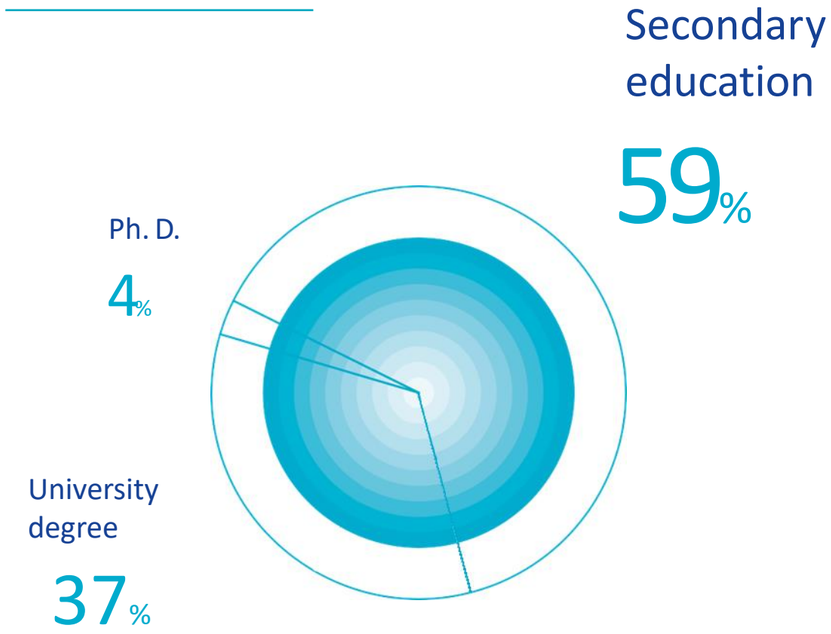
HUMAN RESOURCES

- **Approx. 281 employees**

STRUCTURE



EDUCATION



QUALITY MANAGEMENT SYSTEM

- Compliance with international **cGMP** standards:
  - **EU GMP** Eudralex Volume 4, Part 2
  - **ICH Q7**
  - **US FDA CFR's**
- Customer's Quality Assurance Agreements
- **ISO 9001** & **ISO 14001** International Standards
- Certified Integrated System of QC and Environmental Protection
- **DMF** & **CEP** Regulatory Documentation available

QUALITY MANAGEMENT SYSTEM

› Inspected by authorities on regular basis:

- Czech State Institute for Drug Control
- US Food and Drug Administration
- Russian State Institute of Drugs and Good Practices
- Institute for State Control of Veterinany Biologicals and Medicines

› Approved by:

Pharmacautical and Medical Devices Agency (JAP)

INSPECTIONS & CERTIFICATES HISTORY

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
FDA	x		x				x		x				
SUKL[1]			x		x	x	x	x	x	x		x	
KFDA			x										
RESPONSIBLE CARE	x			x			x				x		x
SID & GP[2]									x		x		
PMDA							x					x	
USKVBL[3]									x			x	
PSCI										x			x
ISO 9001 and 14001	x	x	x[4]	x	x	x[4]	x	x	x[4]	x	x	x[4]	x

[1] State Institute for Drug Control (Czech authority)
[2] State Institute of Drugs and Good Practices (Russian authority)
[3] Institute for State Control of Veterinary Biologicals and Medicines (Czech authority)
[4] Re-certification ISO audits

	2015	2016	2017	2018	2019	2020	2021	2022
CORPORATES	2	4	3	3	6	4	6	2
EU CUSTOMERS	17	13	14	20	13	17	21	15
US CUSTOMERS	1	2	2	1	3	1	2	1
ASIA CUSTOMERS	1	7	6	6	2	4	7	14
RoW CUSTOMERS	2	0	0	4	4	0	0	0

PRODUCTION FACILITIES

- Facilities area: approx. 36,000 m^2
- 2 GMP production halls (one is FDA approved)

- **Hall of Final Operations:**
  - Milling
  - Micronization
  - Sieving
  - Packaging

- **Supporting facilities:**
  - Warehousing
  - Wastewater treatment
  - Water purification
  - Service and maintenance

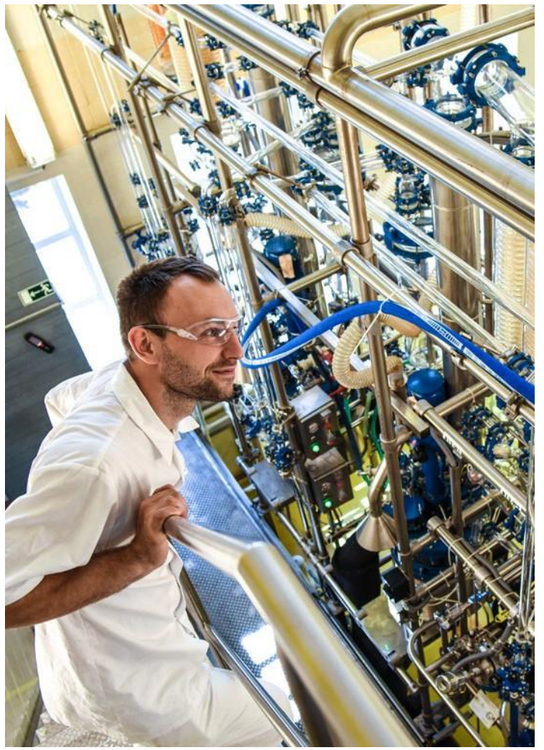
PRODUCTION HALLS

- Glass-lined, stainless steel jacketed reactors (typical volume is 1,600 litres)
- Total reactor capacity: 100 m^3
- Batch size 5 - 250 kg
- Reaction temperatures between -20 and +300 °C

- Reaction pressure between -80 and +300 kPa
- Product separation - centrifuges, filters, filter/dryers (some of them of Hastelloy C22)
- Drying equipment (some of them of Hastelloy C22)

KILOLAB + Small API Unit

- Büchi ChemReactor CR: 2 x 60 L, 1 x 15 L , 3 x 400 L
- Cryogenic technology (temperature -90 – 175°C)
- Glove box
- Mobile Pressure Filter
- Hastelloy C22 Process Filter
- HVAC system
- Protected area for raw material dispensing
- Isolation of material in clean rooms class D
- 0.2 – 5 kg batches (KILOLAB) and 5 – 20 kg (Small API Unit)



HALL OF FINAL OPERATIONS

- Milling/micronization
- Sieving
- Custom packaging
- Two independent finalization rooms class D with separate HVAC

R&D AND QA/QC CENTRE

Analytical Centre – QC Department

- Production sample service – raw materials, intermediates, final samples
- Documentation – SOP’s, analytical instructions, CoA’s
- Standards, stability studies, validation of methods, chemical monitoring of water

Instrumentation

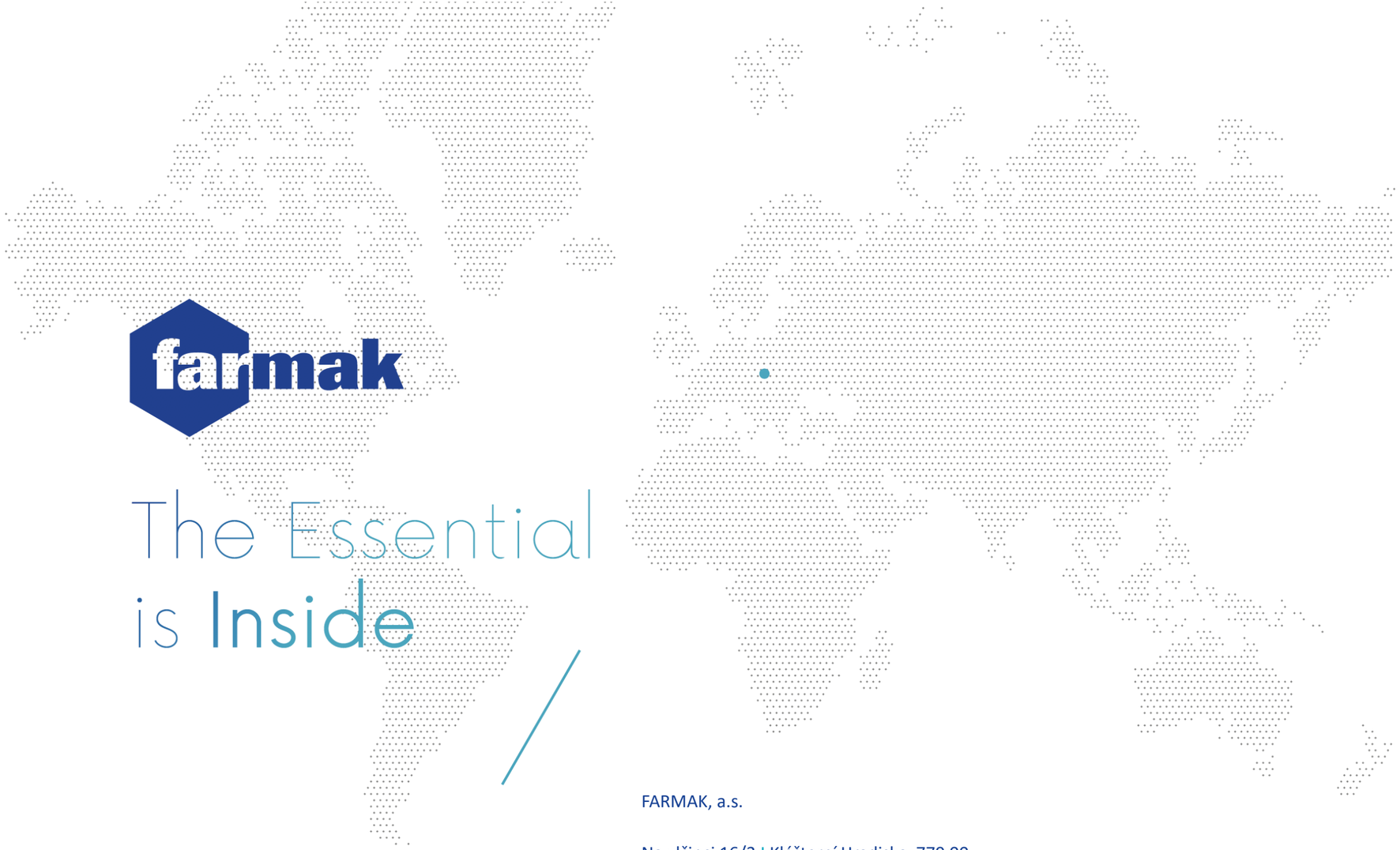
- LCMS, GCMS, GC, HPLC/TLC
- Capillary Electrophoresis
- NMR, UV/VIS, IR and XRPD
- Spectrometry and DSC
- Laser Particle Size Analyzer (Cilas+Malvern)

R&D Analytical Department

- Structural analyses
- Purity / impurity profile analyses
- Development of analytical methods

ECOLOGY AND SAFETY

- Environmental policy in line with FARMAK’s strategy
- Certified integrated system **ISO 9001** and **ISO 14001**
- Own wastewater treatment plant
- **Responsible Care** certificate holder for more than 20 years
- Approved by **SEDEX** – Ethical and Responsible Supply Chain since 2015, site reference ZS1073996
- Involvement in the national System of Assistance in Accidents Related to Transportation of Dangerous Materials
- Own fire department
- Gold EcoVadis Medal for Sustainability



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