



The Essential  
is Inside

# Company profile

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01 | 2023

[WWW.FARMAK.CZ](http://WWW.FARMAK.CZ)





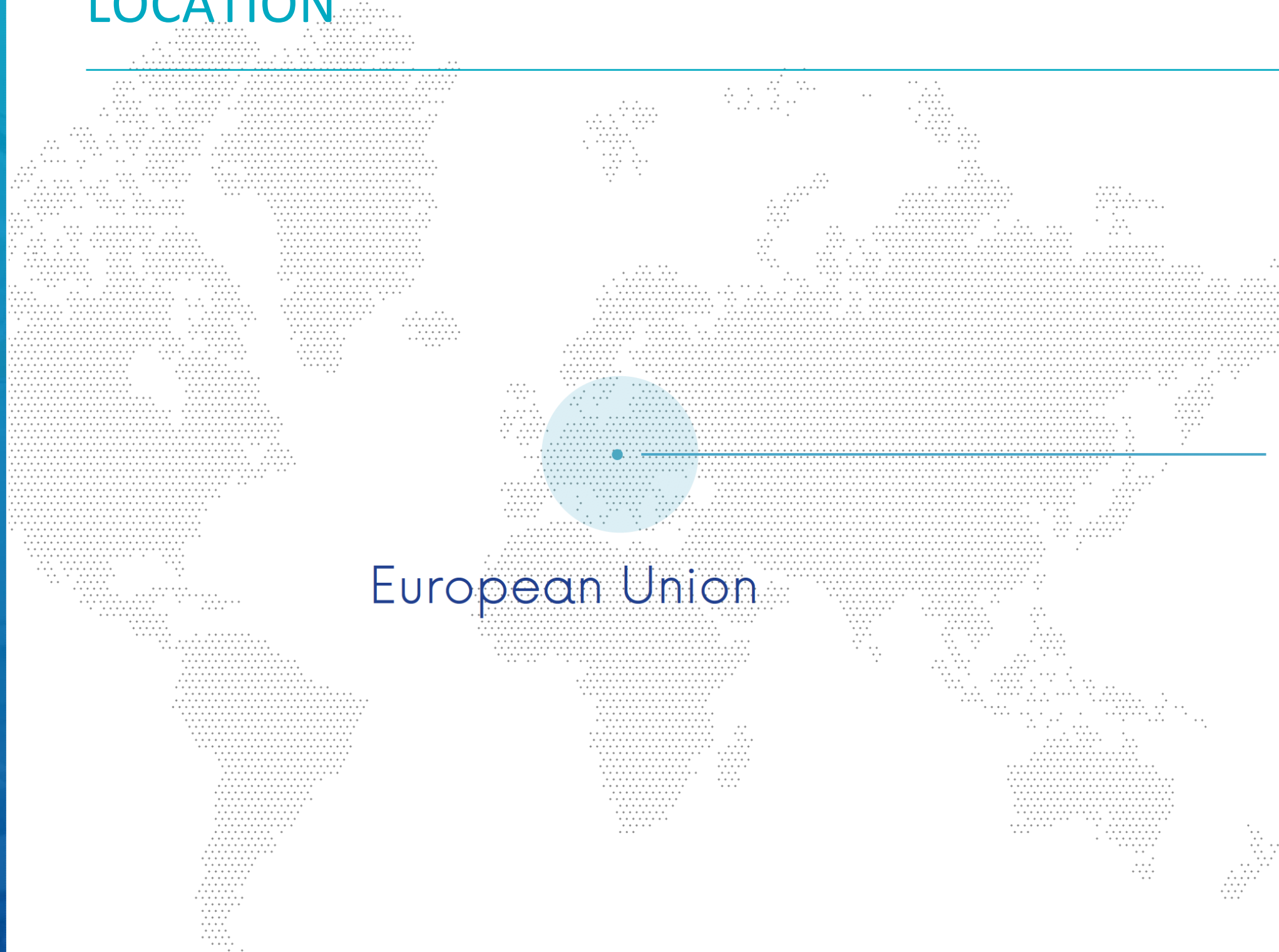
# INTRODUCTION

- › 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



# LOCATION

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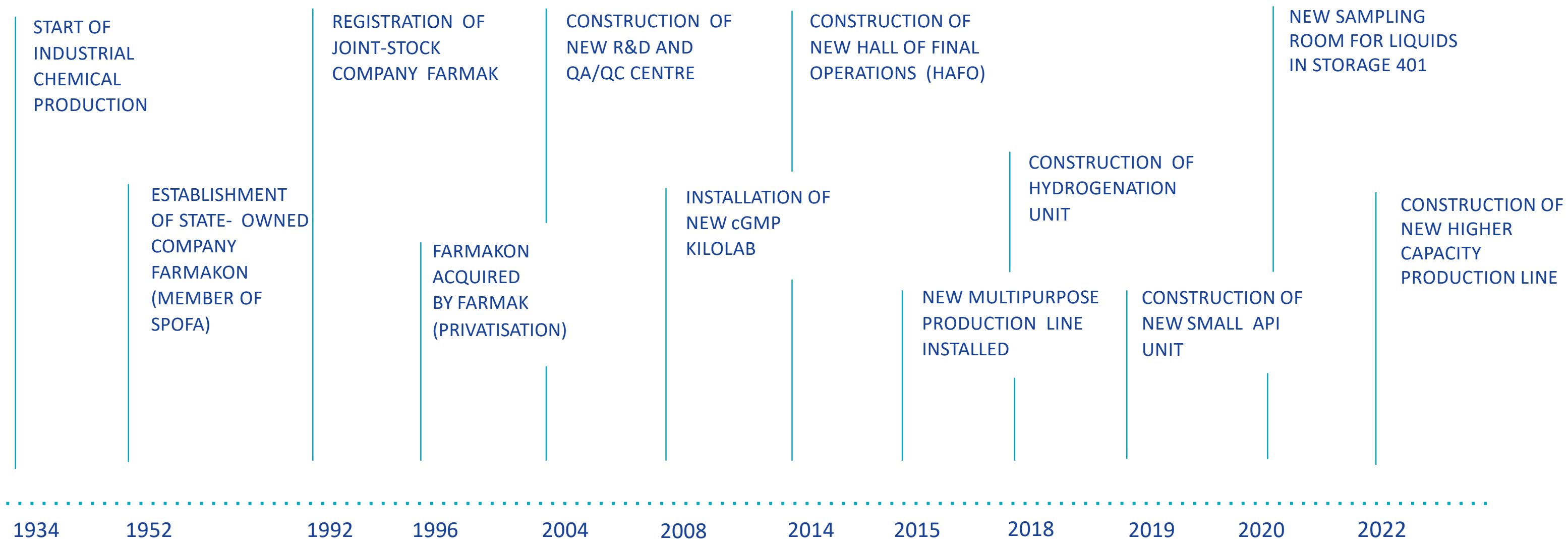


European Union



Czech Republic

# HISTORY

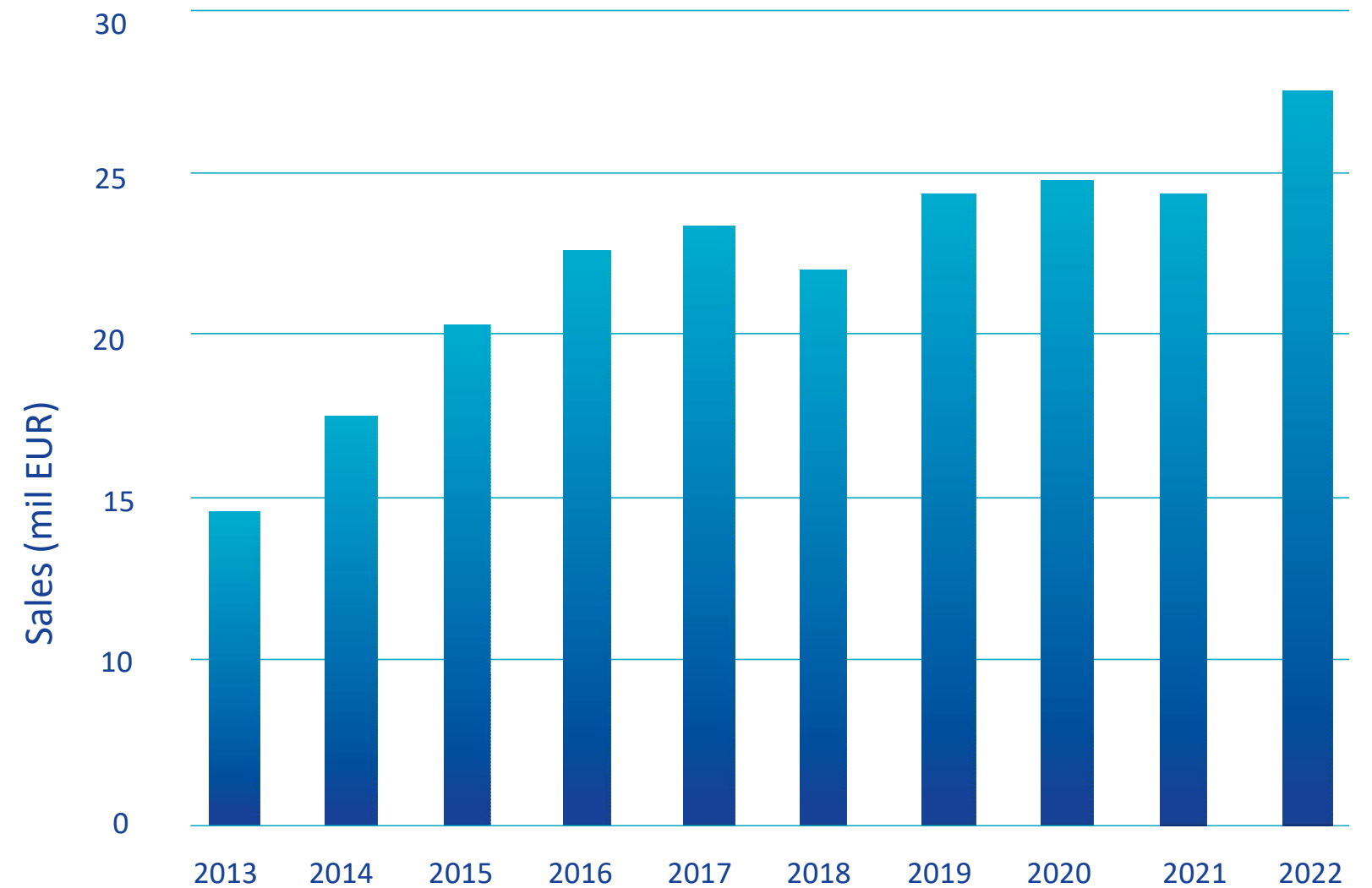
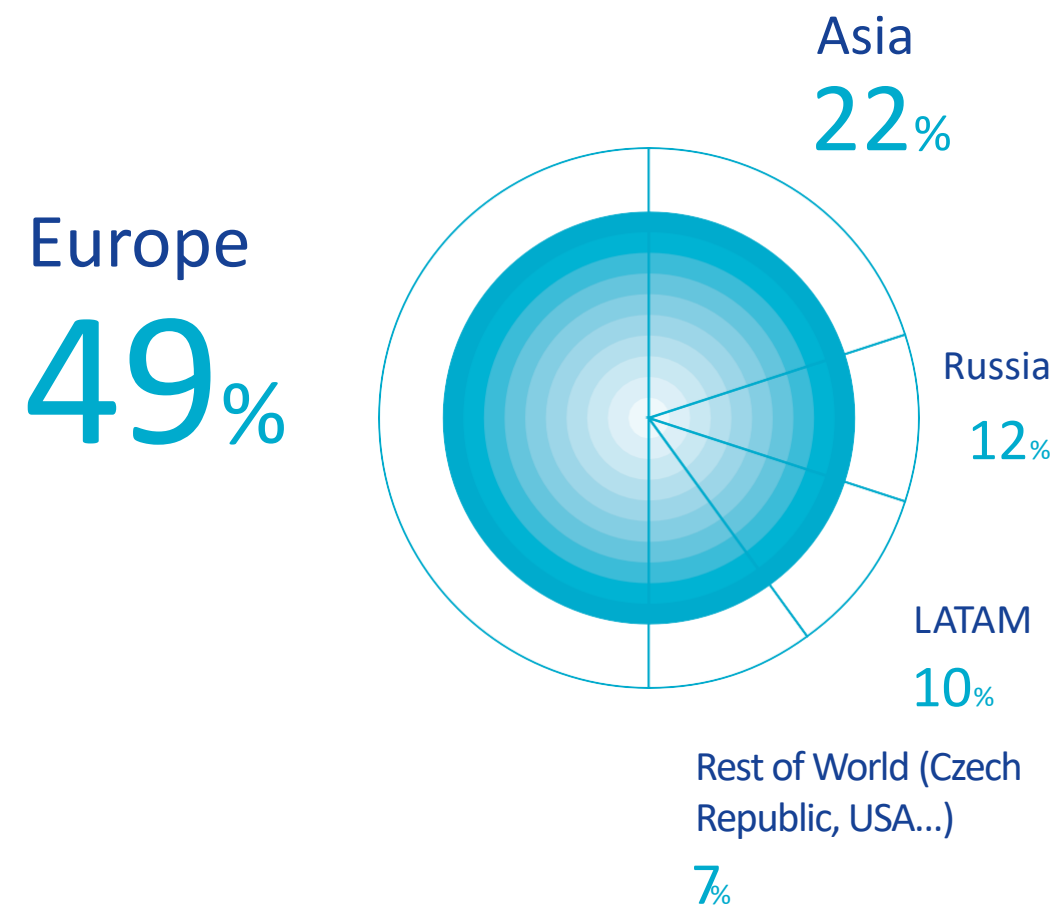


# SALES AND MARKETS



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

## TERRITORIES

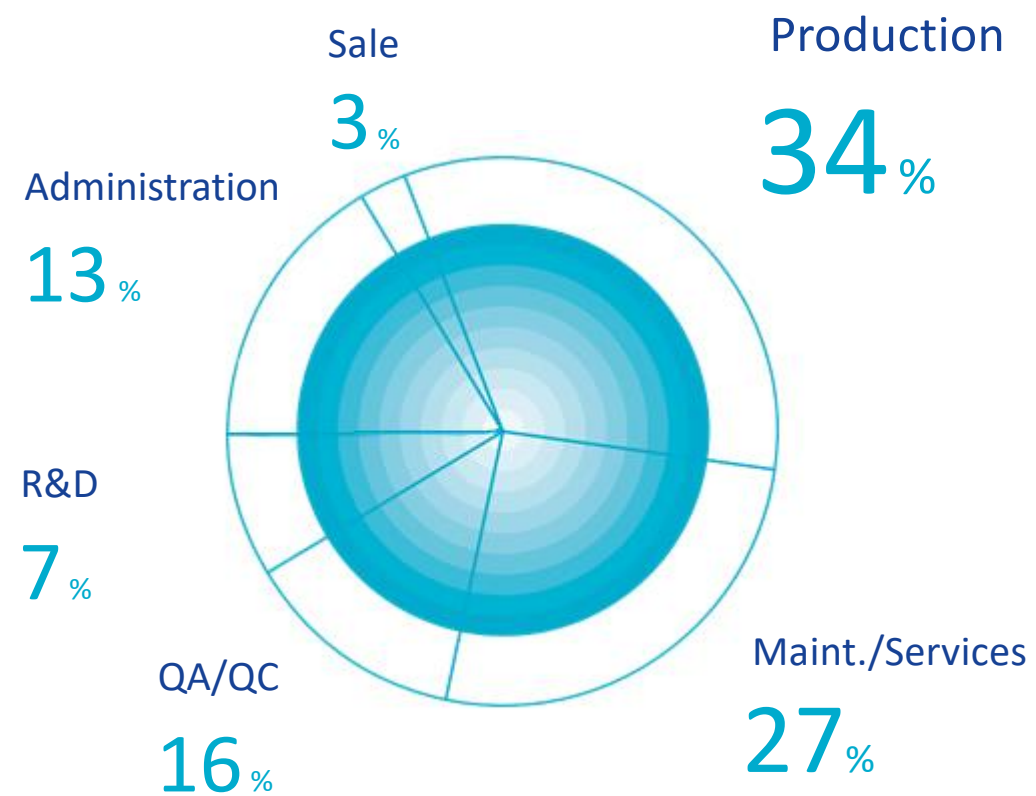


# HUMAN RESOURCES

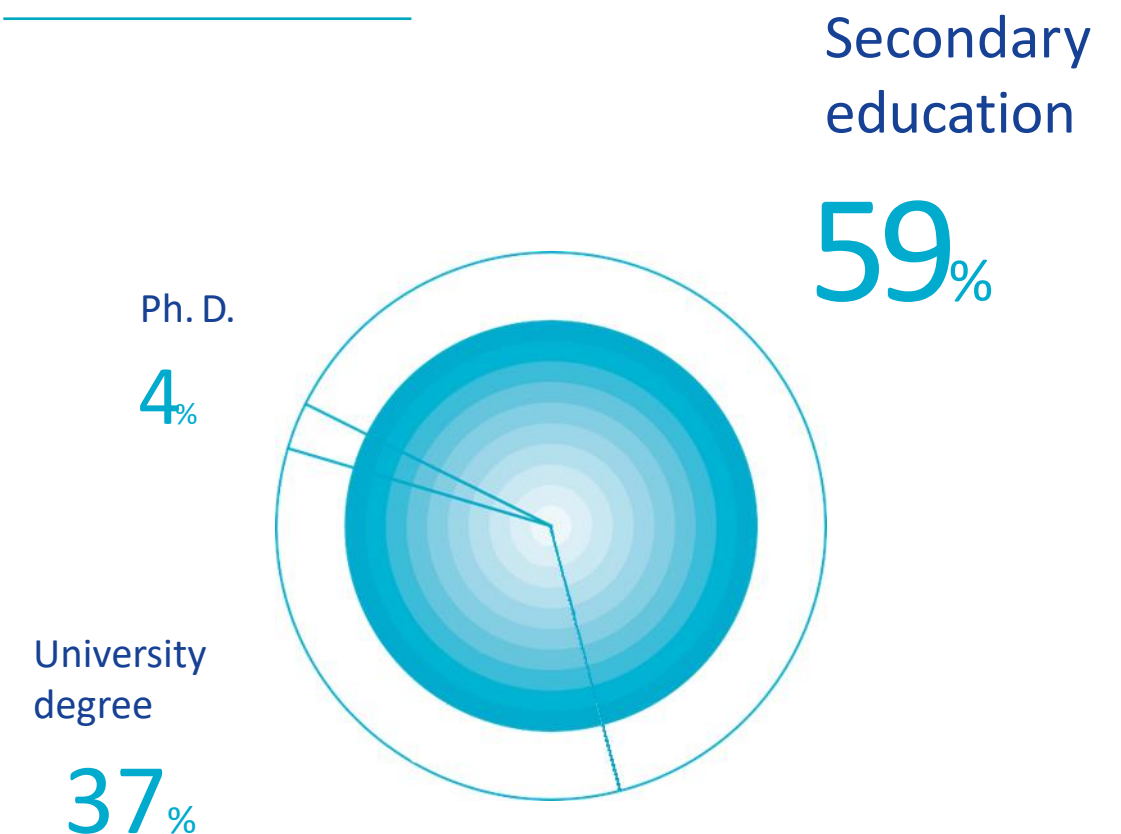


> **Approx. 281 employees**

## STRUCTURE



## EDUCATION



- › 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 Veterinary Biologicals and Medicines



State Institute  
of Drugs  
and Good Practices



## › Approved by:



Korean Food and Drug Administration



Pharmaceutical 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 <sup>1</sup>			x		x	x	x	x	x	x		x	
KFDA			x								x		
RESPONSIBLE CARE	x			x			x				x		x
SID & GP <sup>2</sup>									x		x		
PMDA							x					x	
USKVBL <sup>3</sup>									x			x	
PSCI										x			x
ISO 9001 and 14001	x	x	xx	x	x	xx	x	x	xx	x	x	xx	x

<sup>1</sup> State Institute for Drug Control (Czech authority)

<sup>2</sup> State Institute of Drugs and Good Practices (Russian authority)

<sup>3</sup> Institute for State Control of Veterinary Biologicals and Medicines (Czech authority)

xx 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<sup>2</sup>
- › 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<sup>3</sup>
- › 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



## 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

- › 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





The Essential  
is Inside

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