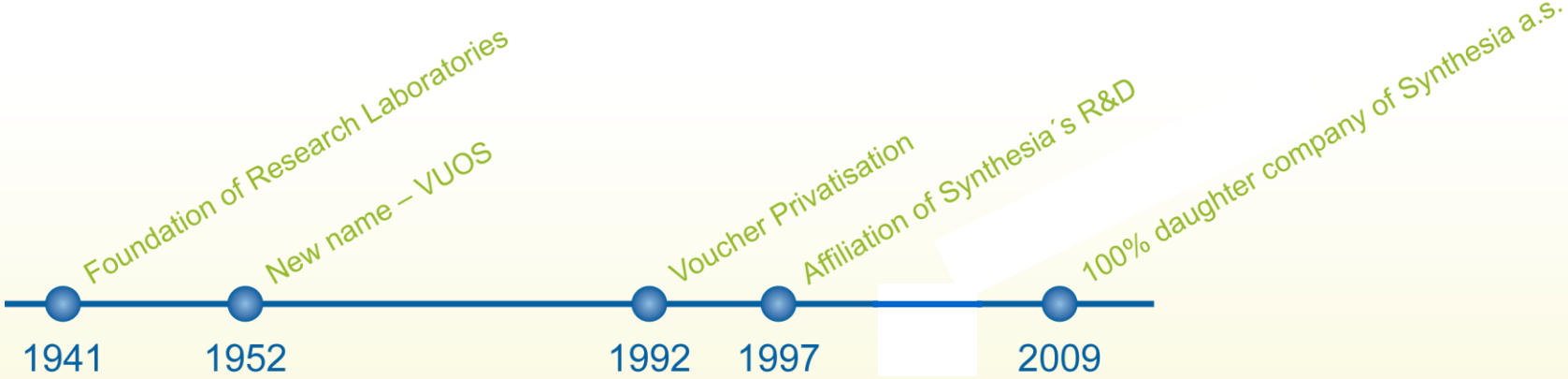
VUOS

Cooperation in the field of toxicology, analytics, R&D and production

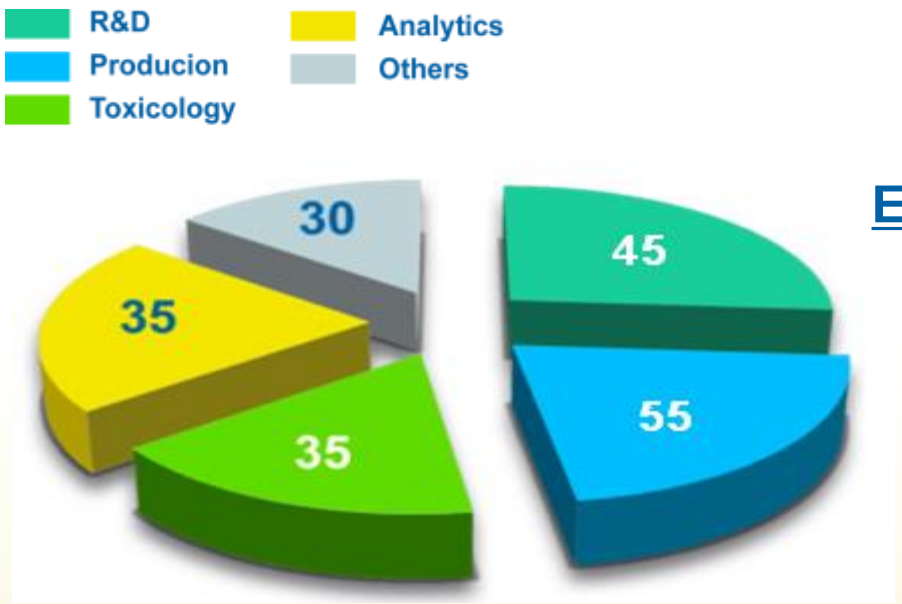
Where you can find us

History


Foundation of Research Laboratories
New name – VUOS
Voucher Privatisation
Affiliation of Synthesia´s R&D
100% daughter company of Synthesia a.s.
1941
1952
1992
1997
2009

Organizational structure

1. R&D and Production of Fine Chemicals
2. Toxicology and Analytics

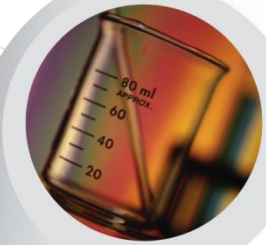


Number of Employees

Education structure of employees

Skilled – 25 %
Secondary – 30%
University degree – 36%
Ph.D. degree – 9%

What can VUOS offer



- Research
- Development
- Scaling up
- Production from gram to MT
- Analytics
- Testing of new chemicals
- Registration according to REACH legislative
- State-of-the-art equipment
- Experienced staff

R&D

- Pharmaceutical intermediates
- Intermediates for microelectronics
- Custom syntheses of chemical specialities
- Dyes and pigments for special application
- Activity in the field of heterocycles and API Building Blocks
- And many other areas

Selection of technologies (I)

Organometallic and Cryogenic Chemistry

- Organolithium Chemistry
- Organozinc Chemistry
- Grignards
- Sodium Hydride Reactions

Transition-Metal Catalysis

- Homogeneous and Heterogeneous Transition-Metal Catalysis
- Cross Couplings (Suzuki, Kumada, Heck, etc.)

Selection of technologies (II)

Hazardous and Unpleasant Chemistry

- Phosgenation
- Halogenation (PCl3, POCl3, SOCl2, BCl3, BBr3, etc.)
- Rections with Nitroalkanes
- Nitration
- Sulfonation

Reduction and High-Pressure Hydrogenations

- Reduction with Sodium borohydride, Red-Al, Superhydride, etc.
- Reductive Alkylation
- Reductive Amination
- Hydrogenolysis
- Dehalogenation

And many other areas

R&D, upscaling

Wide range of quantities

Grams – in laboratory

Kilograms – in kilolab unit

Metric tons – in VUOS production plant

Hundreds of MT – Synthesia, a.s.

Kilolab and Semi-Pilot Unit

Phosgenation

Reactors up to 1 600 l

Hydrogenation

Autoclaves up to 1 000 l
Temperature max. 200°C
Pressure max.130 bar

Low temperature, RLi, RMgX, NaH

Reactors 650 l, 400 l and 60 l
cooled down to - 80°C

Multipurpose chemistry

20x glass reactors, 100 l each
6x glass lined reactors up to 1 500 l
2x evaporators 50 l/H
4x stainless steel reactors up to 1500 l
Sufficient filtration and distillation capacity

Production Unit

Production Equipment

- 45 x glass lined reactors, total vol. 85 000 l (500–6 000 l)
- 16 x stainless steel reactors, total vol. 29 000 l (1 000–6 000 l)
- 8 x High performance rectification columns
- sufficient filtration capacity (nutsches, centrifuges)
- computer controlled

Toxicology, Ecology and Analytics

Spheres of Activities:

- Industrial Chemicals (REACH)
- Pesticides and Biocides
- Pharmaceuticals
- Medical Devices
- Cosmetics
- Quality Control

Toxicology, Ecology and Analytics

Industrial Chemicals (REACH)

Toxicological testing

In vivo and *in vitro* tests according to the OECD or EU methods

- Acute toxicity
- Skin and Eye irritation
- Skin sensitisation
- Repeated dose toxicity
- Reproductive toxicity
- Carcinogenicity
- Mutagenicity
- *In vitro* tests
- others…

Toxicology, Ecology and Analytics

Industrial Chemicals (REACH)

Ecotoxicological testing

- Aquatic toxicity
- Biotic degradation
- Abiotic degradation
- Adsorption/desorption

Physico-chemical testing

- Information on physico-chemical properties of substance

Toxicology, Ecology and Analytics

Industrial Chemicals (REACH)

REACH and CLP Services

- Literature search
- Preparation of dossiers in IUCLID 5
- Chemical Safety Assessment
- Non-testing approaches
  - (Q)SAR
  - Grouping/Read-across
- Preparation of eSDS
- Classification and Labelling

Experience from registration 2010 and 2013

- 15 Lead registrant´s dossiers for substance on its own
- More than 50 dossiers of Member of Joint submission

Toxicology, Ecology and Analytics

Pesticides and Biocides

- Toxicology and toxicokinetics
- Characterization of pesticides
- Field trials and efficacy testing (partner facility)
- Anti-counterfeit effort analyses
- Physico-chemical tests
- 5-batch analysis
- Stability studies
- Trace and ultra-trace analysis
- Structure identification
- Method development and validation

Toxicology, Ecology and Analytics

Pharmaceuticals

Non-clinical safety testing

- Reproductive and Developmental Toxicity
- Single-Dose Toxicity
- Repeated-Dose Toxicity
- Genotoxicity
- Carcinogenicity
- Local Tolerance
- Bioanalytics (partner facility)
- *In vitro* models

Toxicology, Ecology and Analytics

Medical Devices

Biocompatibility testing according to EN ISO 10993 guidelines in conformity with EN ISO/IEC 17025:2005

- Tests for genotoxicity, carcinogenicity and reproductive toxicity
- Tests for local effects after implantation
- Tests for irritation and delayed-type hypersensitivity
- Tests for systemic toxicity

Cosmetics

- In vitro tests for skin and eye irritation
- Genotoxicity
- Cytotoxicity

Toxicology, Ecology and Analytics

Quality Control

Analytical Services

- NMR Spectrometry
- Mass Spectrometry (LC/GC-MS)
- ICP-AES
- IR Spectrometry
- Chromatography (HPLC, GC)
- UV-VIS
- Method development and validation

USP & Ph. Eur. Methods

The Certificates of VUOS

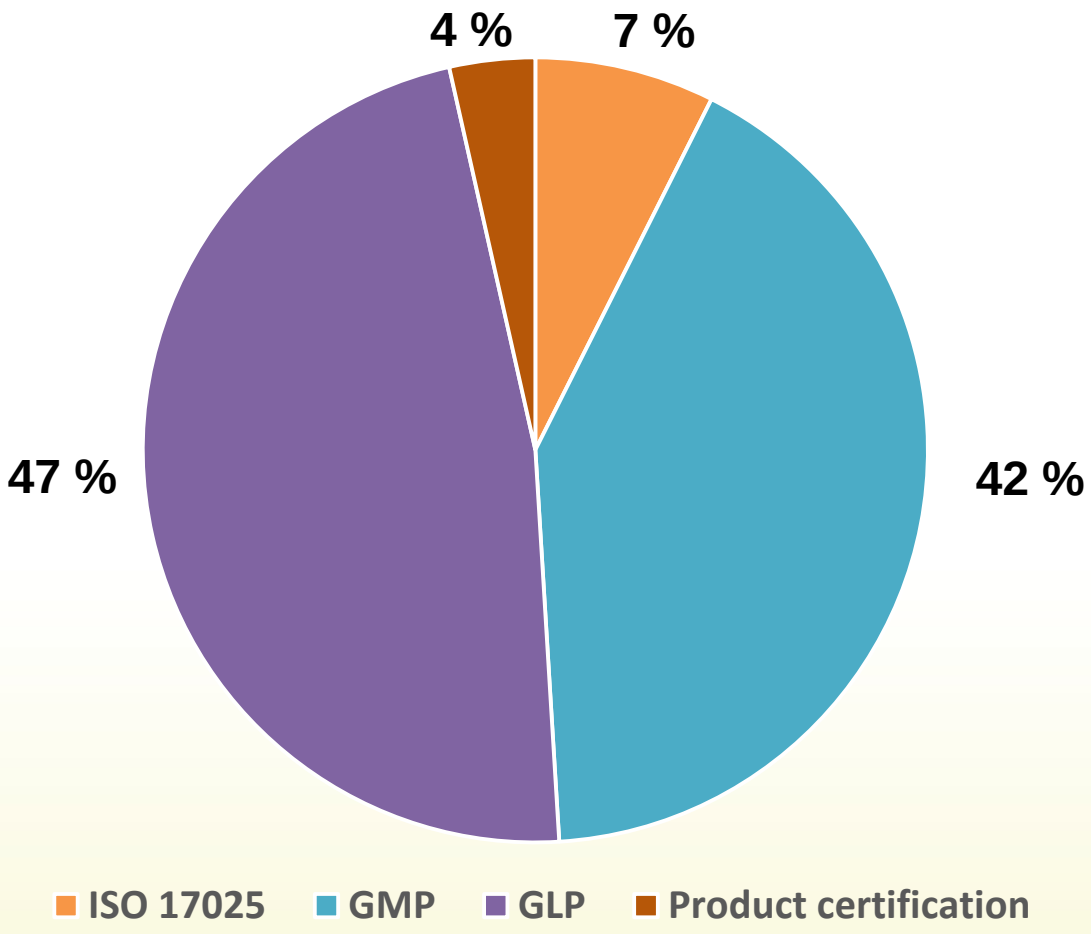
Certificates of Good Laboratory Practice (GLP)

Certificate on Compliance with Principles of Good Manufacturing Practice in laboratory (GMP)

Certificate of Accreditation No. 230/2002 Testing Laboratory No. 1057 (EN ISO/IEC 17025:2005)

ISO 9001:2008

Certificates issued by CETA (September 2014 - March 2015)



What´s new in VUOS (I)

Amendment of REACH annexes VIII, IX and X by ECHA (13 March 2015)

two-generation reproductive toxicity study (EU B.35, OECD TG 416)

replaced by

Extended one-generation reproductive toxicity study (EOGRTS, EU B.56, OECD TG 443)

What´s new in VUOS (II)

Q Exactive Focus
Single Stage Quadrupole-Orbitrap Mass Spectrometer

- HPLC – MS
- Identification and determination of unknown substances (*non- target analysis*)
- Information: exact molecular weight →
  prediction of elemental composition
  of unknown molecules

VUOS – Germany cooperation

REACH services:

- Toxicology
- Ecotoxicology
- Substance identification

Biocompatibility testing of medical devices under ISO 17025:

- Hemostatic wound dressing for topical application

Qualification of our staff

- National Coordinator of the OECD Test Guidelines Programme
- Representative of the Ministry of Environment of the Czech Republic in OECD Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology
- Committee member at the Ministry of Health of the Czech Republic for the protection of animals used for scientific purposes
- Members of the Federation of Laboratory Animal Science Associations (FELASA)

Why to choose VUOS?

- Responsive and efficient
- High quality service
- Experienced staff
- Flexibility and adaptability
- Full service for REACH registration
- R&D services
- GLP, GMP, ISO 17025, ISO 9001 compliant

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