



**OUR  
SCIENCE,  
YOUR  
PRODUCT**

**VIO** CHEMICALS

**From chemical process design  
to high value products**

*11/2019*

# Who we are

We are a Swiss chemical company with global outreach.

Driven by technological innovation and our passion for chemistry, **every day we push our boundaries to create better products** that enhance people's lives, now and in the future.

Our mission is to provide you with **the best chemistry** and services **at the best rates** for safer, sustainable and competitive products.



# What we do

We apply inspired science to **create complete solutions for leading industries.**

We deliver **innovative chemical solutions, from idea to market**, that help you respond to constantly evolving challenges in process development and keep up with the biggest trends in the market.



# Our approach

We apply cost-performance benchmarks on a project-by-project basis to find **the best solution for your product development.**

We use all our resources to design and implement innovative processes to produce your product sustainably and **ensure uninterrupted supply for your business.**

We are proactive and anticipate any regulatory bottlenecks with **a view to mitigate business risks and reduce time-to-market.**



# Global presence

## Switzerland

 VIO Chemicals AG, HQ

## Greece

 R&D Centre

 VIO AG Pharmaceuticals SA

## China

 Representative Office

## India

 Representative Office

## North America

 VIO Chemicals US

## Sales Offices & Agents

**Japan**, MK Chemical Co., Ltd

**France**, CHEMGO SARL



# Our services

## Research & Development

Our R&D solutions are made to further stimulate your product development. We help you produce safer, sustainable and high performance products that meet the needs of your customers and can hold enduring leading positions in high-growth markets.

## Manufacturing

With our vast network of partners in China and India, we offer access to a broad range of technologies, as well as reliable, sustainable and flexible manufacturing solutions at any production scale.

## Strategic Sourcing

With our long-term collaborations and extensive networks in China and India, we offer a broad range of procurement and supply chain solutions for your catalogue, custom-manufactured and proprietary products.



## Integrated support & Consultancy

We offer comprehensive intelligence and support in quality assurance, intellectual property and regulatory affairs at all stages of product development to achieve dynamic compliance in highly regulated markets.

# Research & development services

*High-value, cost-competitive and non-infringing solutions*

## **Process R&D**

We optimise or re-design the chemical process to arrive at your exact product. Our goal is to improve yields and the overall quality of your product and minimise production costs.

## **Analytical research, development and validation**

We undertake full characterisation analysis to ensure the highest quality for the properties of your product.

## **Technology transfer and production**

We develop chemical transformations to safe, robust, scalable and exactly repeatable manufacturing processes.



# The R&D centre

*A powerhouse of science at highly competitive rates*

- A team of 35 highly experienced scientists and professionals with extensive experience in process R&D and thorough understanding of compliance requirements in highly regulated markets.
- Primary focus on innovative, non patent-infringing, safe and robust processes
- Over 150 publications in prime journals with average impact factor >4
- More than 30 patent filings
- ISO 9001 & ISO 14001 certification for research and development of Active Pharmaceutical Ingredients (APIs).

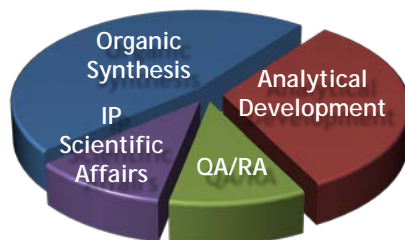
■ OS: 7 PhD, 6 MSc

■ AD: 3 PhD, 5 MSc, 1 BSc

■ QA/RA: 1 PhD, 2 MSc

■ IP/ScA: 2 PhD, 1 MSc

+ Management: 1 PhD / 1 MSc





# Organic synthesis lab



- 8x Fume Hoods
- 1x Dry Anaerobic SS Glovebox
- 4x Rotary evaporators
- Modular flow chemistry system with gas/solid reaction modules and Zaiput continuous membrane separator
- 1x Gas reaction module
- Ozonolysis equipment
- Laminar Air Flow (LAF) bench
- 3x Preparative HPLCs (Shimadzu)

# Kilo lab (1)



- 2x 50L Reactors (-45 to 150°C)
- 1x 30L Reactor (-35 to 150°C)
- 1x 20L Reactor (-40 to 150°C)
- 1x 5L Reactor (-30 to 150°C)
- 1, 2 and 5L High Pressure Reactors
- Nutsch filter 50L (Buchi GlassUster)
- Centrifuge 10000rpm (Hermle Sieva 2)
- 20L Rotary Evaporator
- Thin Film Evaporator



# Kilo lab (2)



- 15kg Freeze dryer (Labogene Coolsafe)
- 25kg Freeze dryer (Lyoepic85)
- 2 vacuum tray dryers, Memmert (max capacity ~500g each)
- 1 vacuum air dryer, Raypa (max capacity ~500g)

# Analytical development lab



- 12x HPLCs (Shimadzu) with UV, PDA, RI, ELS, FR detectors
- 1x UPLC MS (Shimadzu)
- 4x GC headspace/liquid (Shimadzu) with FID, MS, ECD detectors
- 2x FTIR (Perkin Elmer, Shimadzu)
- 2x Digital Polarimeter (Perkin Elmer, Shimadzu)
- Stability Chambers (short/long term)
- Photostability Chamber



# Manufacturing services



**Planning through to commercial production**  
We develop safe, robust, scalable and exactly reproducible processes, we can manufacture your product products with consistency and confidence.

**Flexibility through trusted partnerships**  
We have a broad network of reliable manufacturing partners in India and China and we will select the appropriate partner depending on your product requirements.



# Manufacturing services

We provide access to a broad range of capabilities, technologies and chemical reactions, including:

- Carbohydrates transformation
- Condensation
- Addition & cycloaddition
- Reduction & oxidation
- Nitration
- Acylation
- Methylation ( $\text{Me}_2\text{SO}_4$ )
- Cyanation ( $\text{NaCN}$ )
- Esterification
- Carbonylation
- Friedel-Crafts reaction
- Diazotization
- Chlorination ( $\text{Cl}_2$ ,  $\text{POCl}_3$ ,  $\text{SOCl}_2$ )
- Bromination & fluorination
- Grignard reaction
- Reactions from  $-78^\circ\text{C}$  to  $300^\circ\text{C}$
- High pressure hydrogenation
- Reactions in liquid  $\text{NH}_3$
- Enzymatic processes for chiral products
- Thin film distillation
- High vacuum distillation



# R&D and manufacturing

*Our approach for high-value products*

From Europe



to China or India

**Inquiry**

**Evaluation &  
Design**

**Research &  
Development**

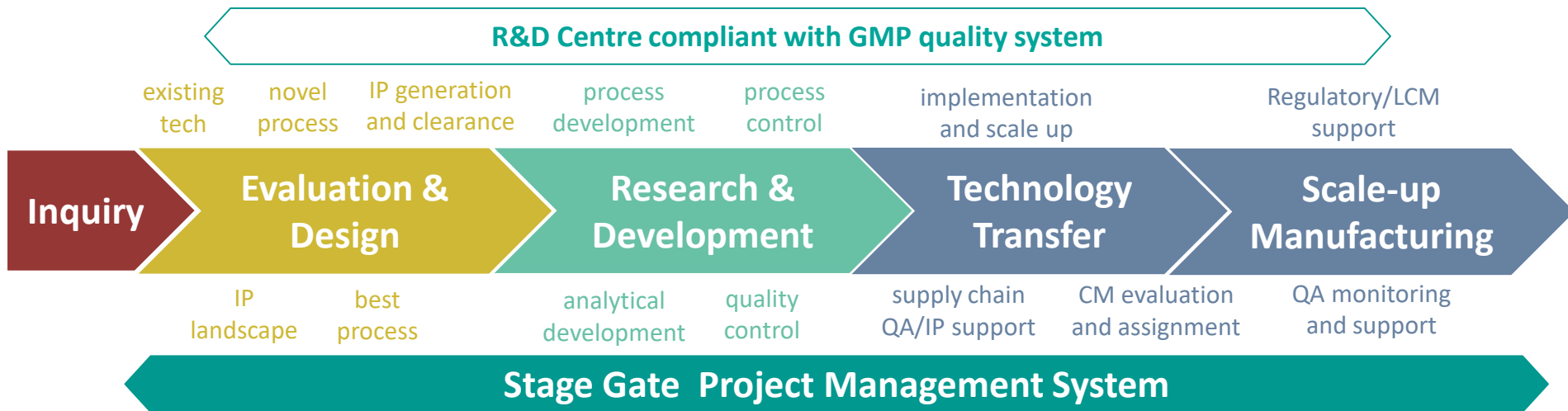
**Technology  
Transfer**

**Scale-up  
Manufacturing**

- Identify and overcome key constraints
- Innovative and efficient processes
- Non-infringing IP solutions

- Wide range of technologies
- Cost-effective solutions
- Sustainable processes

# How we do it



We have developed an integral Stage-Gate (SG) Project Management System, which implements and updates an established Quality Management System, with written Standard Operating Procedures. That way we can ensure traceability throughout the developing process by following basic GMP documentation requirements.



# Stages-Gates Workflow

R&D Centre compliant with GMP quality system

Customer involvement throughout the whole process

Quality System - Project Management System

## Evaluation & Design

### SG1: Project framing

- Inquiry elucidation/ Market intelligence
- Goal framing and project outlook
- Target selection/acknowledgment
- Prior art, IP landscape and existing technology evaluation
- Identification and evaluation of constraints
- Potential involvement strategies

### SG2: Project evaluation and design

- Novel approach ideation vs prior art
- New technologies potential
- Shadow cost benchmarking and competition evaluation
- Targeted properties and specifications
- Targeted quantities and timelines

Best Approach Proposals

## Research & Development

### SG3: Feasibility

- Proof-of-Concept and Feasibility studies
- IP generation and Optimal ROS selection

### SG4: Optimization

- Assessment/preparation of impurities Lab samples and Reference Standards
- Analytical method development
- Intermediates and product specifications
- Pre-stability/ holding time studies

### SG5: Lab Validation

- Analytical Method validation/protocols
- Raw Material Cost calculation
- Technology Transfer Document
- Full Technical Package

R&D Process for Scale-up

## Tech-transfer & Scale-up

### SG6: Technology Transfer

- Key Raw Material suppliers' approval
- Manufacturer quality status and technical evaluation and assignment
- Manufacturing technology transfer
- Analytical method transfer
- Lab familiarization and process implementation troubleshooting

### SG7: Scale-up manufacturing

- Process scale-up/ piloting and commercial production
- Commercial production troubleshooting
- Commercial cost calculation
- QA and RA support for registration and lifecycle management

Scale-up material

# Our products

*Made for leading companies worldwide*

- APIs\*
- Intermediates for API synthesis
- Steroid & other intermediates
- Drug formulation excipients
- High-quality amino acid derivatives
- Bicyclo[1.1.1]pentanes
- Specialty chemicals and reagents
- Organophosphorous products
- Plant ingredients as nutritional supplements

- All APIs are offered through our wholly-owned subsidiary in Greece, VIO AG Pharmaceuticals S.A.
- For APIs visit [www.viopharmaceuticals.com](http://www.viopharmaceuticals.com)



# Products

*Our approach for high value products*

**Step 1:** Conduct market evaluation



**Step 2:** Define product specifications



**Step 3:** Select the appropriate production partner



**Step 4:** Consult improvements with partner on how to meet specifications



# Strategic sourcing services

*Securing an uninterrupted supply for your business*

- Over 15 years of presence in the Chinese market with an ISO 9001-certified office in Nanjing and a strong procurement team of 8 people
- New sourcing office in Vadodara, India, with a strong team of 7
- Market knowledge and price benchmark
- Excellent knowledge of local regulations
- Supplier screening, evaluation and risk assessment
- HSE evaluation, GMP and QA monitoring
- Complete logistics services
- High quality, reliable supply, competitive pricing, regulatory compliance and fast delivery of your product
- Complementary consulting and regulatory services



# Integrated support and consultancy services

*Comprehensive intelligence and support to achieve dynamic compliance*

## **Quality assurance**

We perform all stages of synthesis, analysis, setting of specifications and monitoring of results in compliance with ICH guidelines, while providing full traceability during the process development, analysis and stability studies.

## **Intellectual property**

Integrated or independent technical and legal IP support to ensure non-infringing processes and mitigate business risks.

## **Regulatory affairs**

Proactive strategic RA insight and scientific advice from the early stages of development and assessment period up to the final approval of the DMF and product lifecycle management.



# Why choose us

## **High quality vs. Low costs**

We combine high-quality European R&D expertise with low development and production costs.

## **Total traceability**

All processing steps are traceable and monitored in a Quality-by-Design approach, ensuring exact reproducibility of the process and consistent product quality and delivery timelines.

## **Solid scientific skills for highly demanding products**

Our extensive experience in process development and excellent knowledge of the individual patent systems, regulations and industry standards, enable us to apply our science for a broad range of products, from specialty chemicals to APIs.

## **Complete integrated support, from idea to market**

We offer comprehensive intelligence and support to help you achieve dynamic compliance so that you legitimately sell your product in any regulated market.

## **Swiss excellence at every step**

We develop our chemistry and handle your needs with the highest level of quality, precision and transparency.

# VIO CHEMICALS

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