



Flexible  
Cost-efficient  
EU-based  
Strategic CDMO Partner

## **CONTRACT DEVELOPMENT & MANUFACTURING SERVICES**

HELP SA group of companies

## We focus on



**Cost-efficient EU manufacturing**



**Mature and generic products**



**Small and mid-size volumes**



**Fast and flexible project management**



**Long-term relationships**



**Customer-centric solutions**



**Supply security**



## Our Services

### Contract Development & Manufacturing

Tailored expertise for specific projects.

IP evaluation

Formulation development

Analytical development & validation

Lab-scale, scale-up & registration batches

ICH stability studies

Regulatory support & registration

Post-approval support

Supply of finished product

### Own developments / Co-developments

Alongside our own product developments, we work with partners on joint development projects. Products may be developed with one or more partners, or exclusively for an individual partner.

### Out-licensing

Contact us to receive our portfolio.



**More than a supplier.  
A strategic partner.**

**Supporting small and medium-sized  
pharmaceutical companies.**

# Technologies

## Product categories

**Pharmaceuticals**

**Nutraceuticals**

**Medical devices**

**Cosmeceuticals**

## DOSAGE FORMS



**NON-STERILE**

### **Liquid dosage forms**

**Oral solutions**

**Oral suspensions**

**External use solutions**

**Nasal sprays**



**NON-STERILE**

### **Semisolid dosage forms**

**Gels / Creams / Ointments**

**Suppositories**



**NON-STERILE**

### **Solid dosage forms**

**Tablets**

**Hard capsules**

**Pellets**

**External use powders**



**STERILE**

### **Liquid dosage forms**

**Glass vials**

**Glass ampoules**

# Development Capabilities



## Preformulation

- Crystallinity & polymorphism
- Powder characterization
- Powder flow properties
- Solubility studies
- Dissolution
- API-excipient and excipient-excipient compatibility



## Formulation Development

- Compatibility studies
- Formulation studies
- Lab-scale trials
- Scale-up feasibility studies
- Pre-stability studies
- Stability studies



## Process Development

- Design space (QbD)
- In-process controls (IPCs)
- Process validation
- Production transferability
- Production scale-up
- Technology transfer



## Analytical Development

- Analytical method development
- Analytical method validation
- Multimedia dissolution studies
- Method transferability



## Development Capabilities

We utilize a range of innovative formulation technologies to enhance solubility, stability, taste, and release profiles. These include microencapsulation, solid dispersion systems, taste and odor masking techniques, and modified release systems such as SMEDDS/SEDDS. Each technology is applied strategically to deliver therapeutic and commercial value.



### Expert Services

- Formulation support
- Process support
- Production efficiency
- Scale-up efficiency
- Cost efficiency
- Time efficiency



### Other Studies

- Sterilization validation
- Media fill studies
- Hold-time studies
- Filter validation
- Extractables & leachables
- Nitrosamine impurities
- Elemental impurities
- Genotoxic impurities



### Technology Platforms

- Microencapsulation
- Taste masking
- Odor masking
- SMEDDS / SEDDS
- Solid solutions
- Modified drug-release kinetics



**100+**  
Customers

Single partner  
for all your  
CDMO needs



## Manufacturing Capabilities

### Sterile products

Aseptically prepared and terminally sterilized products, with flexible batch sizes and competitive pricing.



#### Ampoules

UP TO

**100.000**

ampoules / batch

CONTAINER SIZE

**2-10 ml**

CONTAINER TYPE

**Closed ampoules, type D or E**



#### Vials

UP TO

**16.000**

vials / batch

CONTAINER SIZE

**2-4 ml**

CONTAINER TYPE

**Neutral glass, type 1**

### Contamination Control Strategy

**According to EudraLex GMP Annex 1**

# Manufacturing Capabilities

## Non-sterile products

Established manufacturing expertise across liquid and semisolid dosage forms, with flexible batch sizes and competitive pricing.



### Oral liquids

Syrups, suspensions, oral drops

Container: 5-500 ml

Up to 800 L



### External-use solutions

Container: 5-500 ml

Up to 180 L



### Nasal / ear liquids

Solutions, suspensions and sprays

Container: 10-11 ml

Up to 110 L



### Creams / Ointments / Gels

Laminate or aluminum tubes

Container: 2-150 g

Up to 300 kg



### Suppositories

Vaginal / rectal

Container: 1.000-2.500 mg

Up to 200 kg

# Manufacturing Capabilities

## Solids



### Granulation

- Fluid bed spray granulation
- Wet granulation
- Aqueous & organic granulation
- Dry granulation

**Up to 300 kg**



### Tablets

- Uncoated
- Film-coated
- Modified release
- Chewable

**Up to 500.000**

tablets / batch, depending on tablet size



### Capsules

Hard gelatin capsules  
Sizes 0-3

**Up to 80 kg**



### Pellets

Pellet coating

**Up to 80 kg**

### Solids' Packaging

#### Primary

Blister PVC / PVDC / PCTFE  
Plastic bottles: HDPE or PP

#### Secondary

Standard packs with 2D barcode  
EU serialization and tamper evident label

**12 million**

packs / year



On time  
in full



Reduced  
lead time



Right first  
time

## Analytical & Regulatory Services

### QC Services

- Quality control testing & release
- Analytical validation / method development
- Stability programs
- Photostability studies
- Antimicrobial efficacy testing
- EU batch release



**500 m<sup>2</sup>**

**New EU-GMP laboratory**

### Stability conditions

| Temperature | Relative humidity | Climatic zone |
|-------------|-------------------|---------------|
| 5°C ± 3°C   | N/A               | -             |
| 25°C ± 2°C  | 60% ± 5%          | II            |
| 30°C ± 2°C  | 65% ± 5%          | IVa           |
| 30°C ± 2°C  | 75% ± 5%          | IVb           |
| 40°C ± 2°C  | 75% ± 5%          | -             |

### Regulatory Affairs Services

- Development, update and conversion of product dossiers to electronic CTD or country-specific formats.
- Registration of pharmaceuticals, medical devices, cosmeceuticals and nutraceuticals with health authorities.
- Post-authorization license management, including renewals, variations and notifications.

## Key Benefits



**Wide range of dosage forms**

CDMO consolidation



**EU-GMP standards**

Easier access to markets



**Cost-efficient European base**

Sustainable profitability



**Flexibility & adaptability**

Effective changes in a fast-moving environment



**Strategic location**

Convenient access to Europe,  
North Africa, the Middle East and  
CIS



**Reliable lead times**

Successful business planning

**Science. Quality. Partnership.**

# Technical Transfer

## A streamlined approach

01

### Coordinated, experienced transfer team



Less time to commercial production launch.

02

### Clear and open transfer operations



Doing it right the first time.

03

### Regulatory CMC support during transfers



Integrated, cost-effective services.



**From technical transfer  
to commercial supply**

**One coordinated partnership.**

## Global Reach

**Built on experience. Connected globally.**

**50+**  
**Years of experience**

**50+**  
**Years of experience**

180

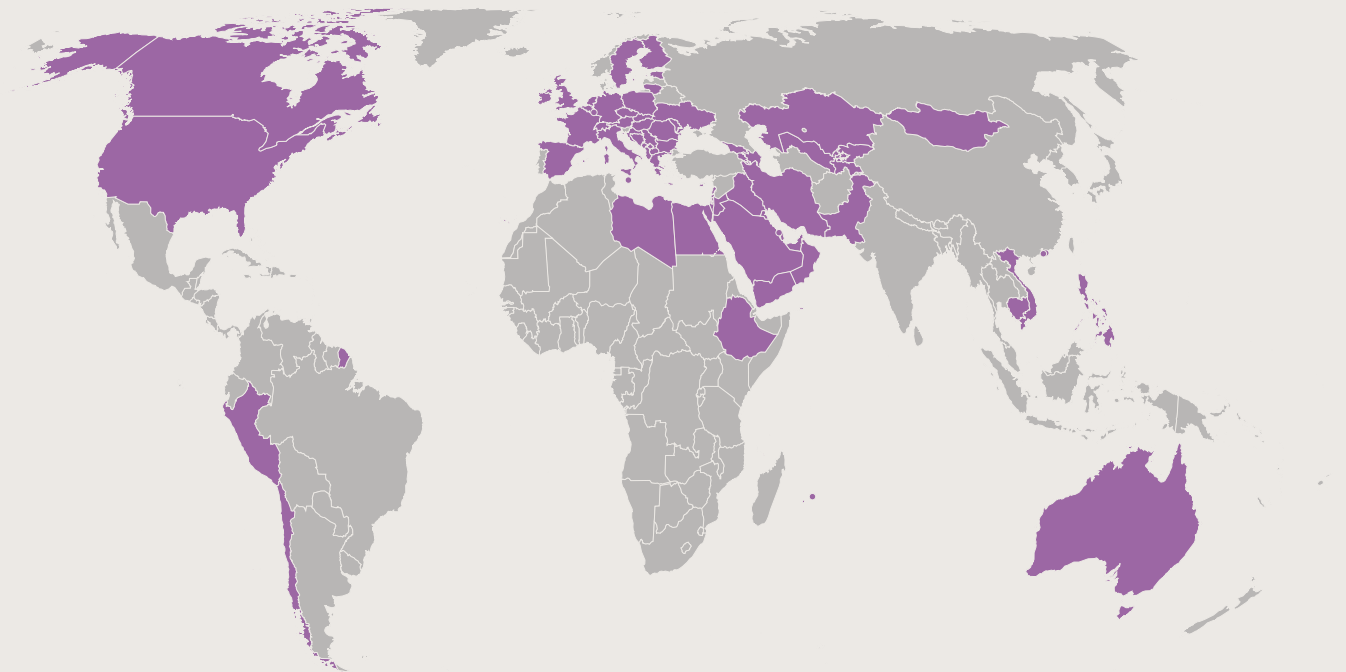
**Specialized professionals**

180

**Specialized professionals**

**50+**  
**Export countries**

**50+**  
**Export countries**



## ■ Export markets

**Exports and regulatory expertise in more than 50 countries.**



**EU-GMP certified manufacturing**

**alongside with ISO 13485:2016 certification for medical services and global GMP approvals including EAEU, Canada and Australia.**



**Let's explore  
partnership opportunities.**



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