



PRODUCTS
FROM PEOPLE
WHO CARE

It's all a matter of care

ALFASIGMA 
Contract Manufacturing

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Your Partner of Choice

1

ALFASIGMA CMO



Alfasigma CMO is your ideal partner in Contract Manufacturing, capable of offering **a complete and integrated service in pharmaceutical outsourcing activities**.

Top-level quality is guaranteed by the specific **know-how acquired in more than 60 years**, staying true to our company values (innovation, perfection, diversity and focus on results) and using innovative technologies.

We continue to pursue **continuous improvement in order to always guarantee the latest generation technologies and products of the highest quality**.

Production lines in Pomezia (Rome), Alanno (Pescara) and Trezzano Rosa (Milan) enable Alfasigma Contract Manufacturing to meet the requests of an increasingly demanding market.

2

DEVELOPMENT AND MANUFACTURING SERVICES



Formulation and Process Development

Alfasigma Contract Manufacturing Business Unit is structured to provide its customers with all **services** for the development, manufacturing and quality control of their products. Thanks to a dedicated structure, Alfasigma CMO is able to support the customers from formulation development to production of commercial batches, for almost all pharmaceutical forms.

Analysis and Formulation Development:

- Optimization of manufacturing processes of pharmaceutical formulation
- Physical and chemical test definition
- Lab-scale batches
- Scale-up batches for IPC definition
- Manufacturing of technical test definition
- Engineering batches for IPC testing
- Quality by Design (QbD) process development

Analytical and Stability Services

Thanks to the efficiency and capabilities of our laboratory equipped with the highest quality analytical instruments, the **Analytical Development Unit** is able to develop and validate analytical methods, and carry out stability studies, offering constant and efficient support during the formulation development stages to guarantee product reliability and safety.

Analytical services and methods development:

- Development of chemical and biological analytical methods for small and large molecules
- Validation and transfer of analytical methods
- HT studies
- ICH stability studies (for all the climate zones)
- Photostability and in-use stability studies



3

PHARMACEUTICAL FORMS



We have a **large production capacity**, and we offer a remarkable versatility and diversification of products through a wide range of forms. These include **liquid injectables** (terminally sterilized & aseptic ampoules and vials, pre-filled syringes and cartridges), **lyophilized products in vials and ampoules**, and **sterile powders**.

We also supply **vaccines and sterile hormonal products** to meet specific customer needs. Our sterile departments in the Alanno plant and our extraordinary know-how in the field of sterile filling make Alfasigma the ideal partner for any pharmaceutical and biotechnology company.

Our pharmaceutical capabilities also include **semi-solids, non-sterile liquids, pressurized foams and oral solids**.

ALANNO

LYOPHILIZED PRODUCTS*



Ampoules Manufacturing and Packaging



Vials Manufacturing and Packaging

STERILE POWDERS



Sterile Powder Vials filling and packaging

STERILE LIQUIDS*



Small Volume Liquids Ampoules Manufacturing and Packaging (Terminally Sterilized & Aseptic Process)



Small Volume Liquids Vials Manufacturing and Packaging (Terminally Sterilized & Aseptic Process)



Prefilled Syringes and Cartridges** (Terminally Sterilized & Aseptic Process)

*Including Corticosteroids & Sexual Hormones

**Including Vaccines

POMEZIA

ORAL SOLIDS



Tablets and Capsules



Hormonal Tablets



Probiotic Sachets



Sachets

SEMI-SOLID DOSAGES AND NON-STERILE LIQUIDS



Soft Gels



Suppositories



Syrups

TREZZANO ROSA

ORAL SOLIDS



Tablets



Film-Coated Tablets



Granules in Sachets

SEMI-SOLID DOSAGES AND NON-STERILE LIQUIDS



Creams



Gels



Emulsions



Suspensions



Phosphate Enemas



Hormonal Suspensions

PRESSURIZED



Foams



Hormonal Foams

ALFASIGMA

Contract Manufacturing



Alfasigma S.p.A.

Alanno (PE) | Via Enrico Fermi, 1

Pomezia (RM) | Via Pontina, 30

Trezzano Rosa (MI) | Via Firenze, 40

alfasigma.com/contract-manufacturing