

API CONTRACT MANUFACTURING  
原料药委托加工

QUALITY ASSURANCE & REGULATORY AFFAIRS  
品质保证与药品注册

CUSTOM SYNTHESIS  
定制合成

ACTIVE PHARMACEUTICAL  
INGREDIENTS  
原料药

OUR MANUFACTURING OFFER  
我们的制造业务



**YOUR INDUSTRIAL PARTNER**  
EUROPEAN API MANUFACTURER

**您的工业合作伙伴**  
欧洲原料药生产商

# CEPIA

Within the industrial Affairs of Sanofi, CEPIA (Commercial & External Partnership, Industrial Affairs) is an organization fully dedicated to third party activities.

## ONE OF THE KEY ACTIVITIES OF CEPIA IS TO OFFER A BROAD RANGE OF INNOVATIVE SOLUTIONS INCLUDING:

- Intermediates and Active Pharmaceutical Ingredients (APIs) supply
- Custom Synthesis & API Contract Manufacturing

CEPIA sales is a Sanofi activity dedicated to manufacturing and supply a broad range of APIs available on catalogue basis.

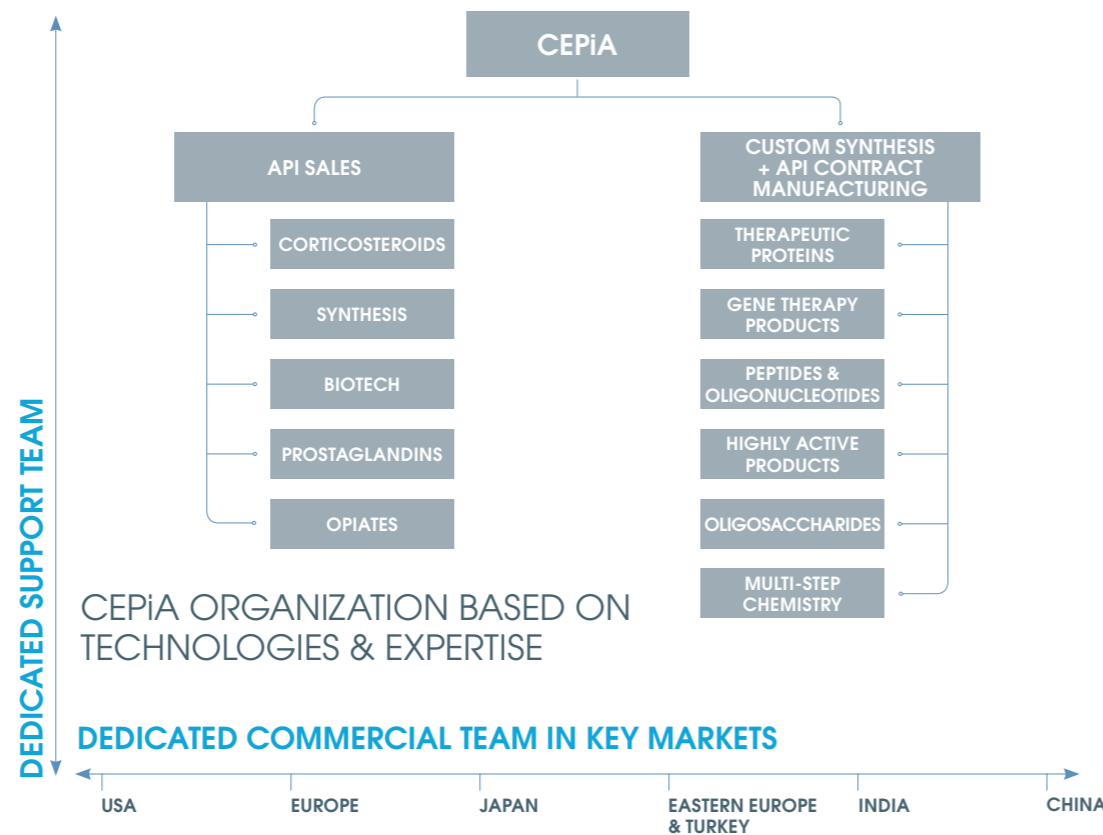
We offer API contract manufacturing services and custom synthesis expertise from small molecules to biologics, from lab scale to commercial quantities, etc...

By employing its exhaustive industrial capabilities and other resources expected of a big pharma, CEPIA provides its clients with "fast to the market" solutions.

## CEPIA STRUCTURE IS A MATRIX ORGANIZATION BASED ON:

- Chemistry
- Biotechnology
- Geographical dedicated teams to be close to customers' needs
- Dedicated support functions such as Customer Service, Quality & Regulatory, etc ...

- Around **200** APIs on catalogue ...
- ... sold in more than **80** countries
- API **CMO Services**
- **Dedicated teams for:**
  - **Quality Assurance**
  - **Regulatory Affairs to support worldwide market**
  - **Customer Service**



# CEPIA

隶属于赛诺菲工业事务部，CEPIA (工业事务对外合作部) 专门致力于第三方合作。

## CEPIA的主要业务之一是提供最大可能的创新解决方案，包括：

药物中间体与原料药 (API) 供应  
定制合成与原料药委托加工

CEPIA销致力于药品的生产以及各类原料药的供应

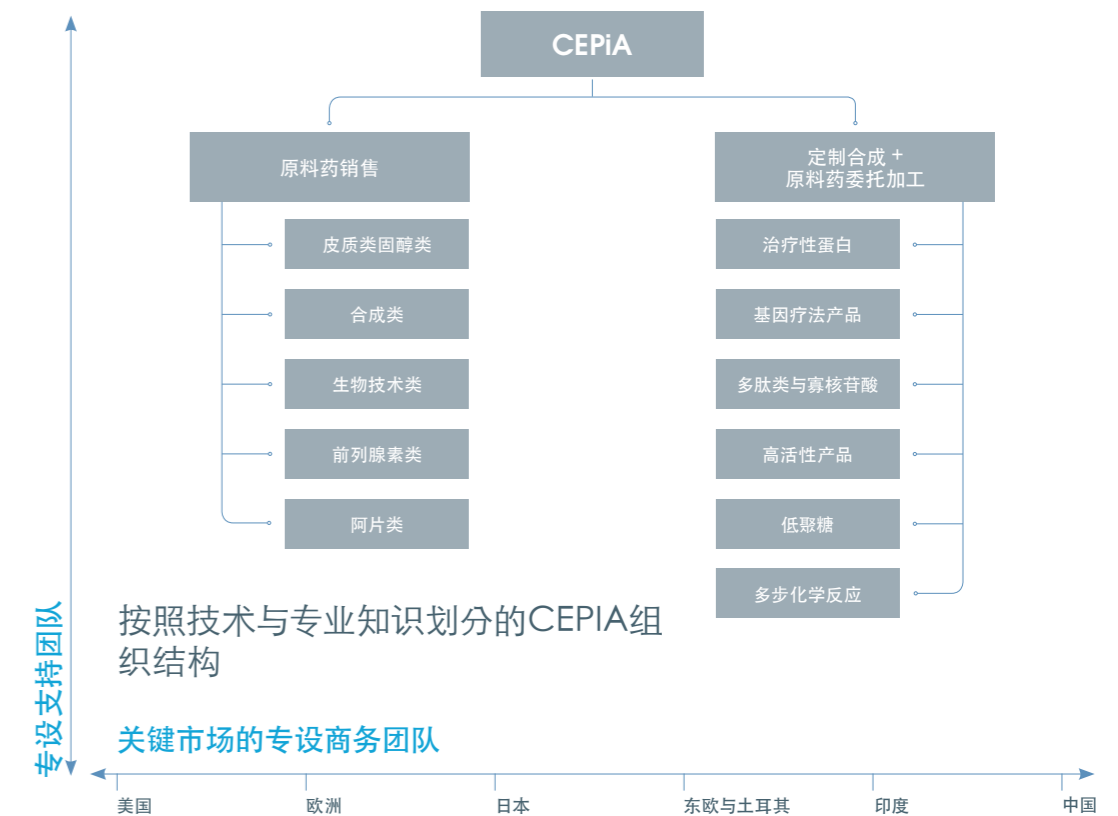
我们提供原料药委托加工服务和定制合成专业技术。服务范围广泛，包括从小分子到生物制剂，从实验室规模到商业规模等。

利用一家大型制药企业所具备的行业实力和其他资源，CEPIA可为客户提供“迅速进入市场”的解决方案。

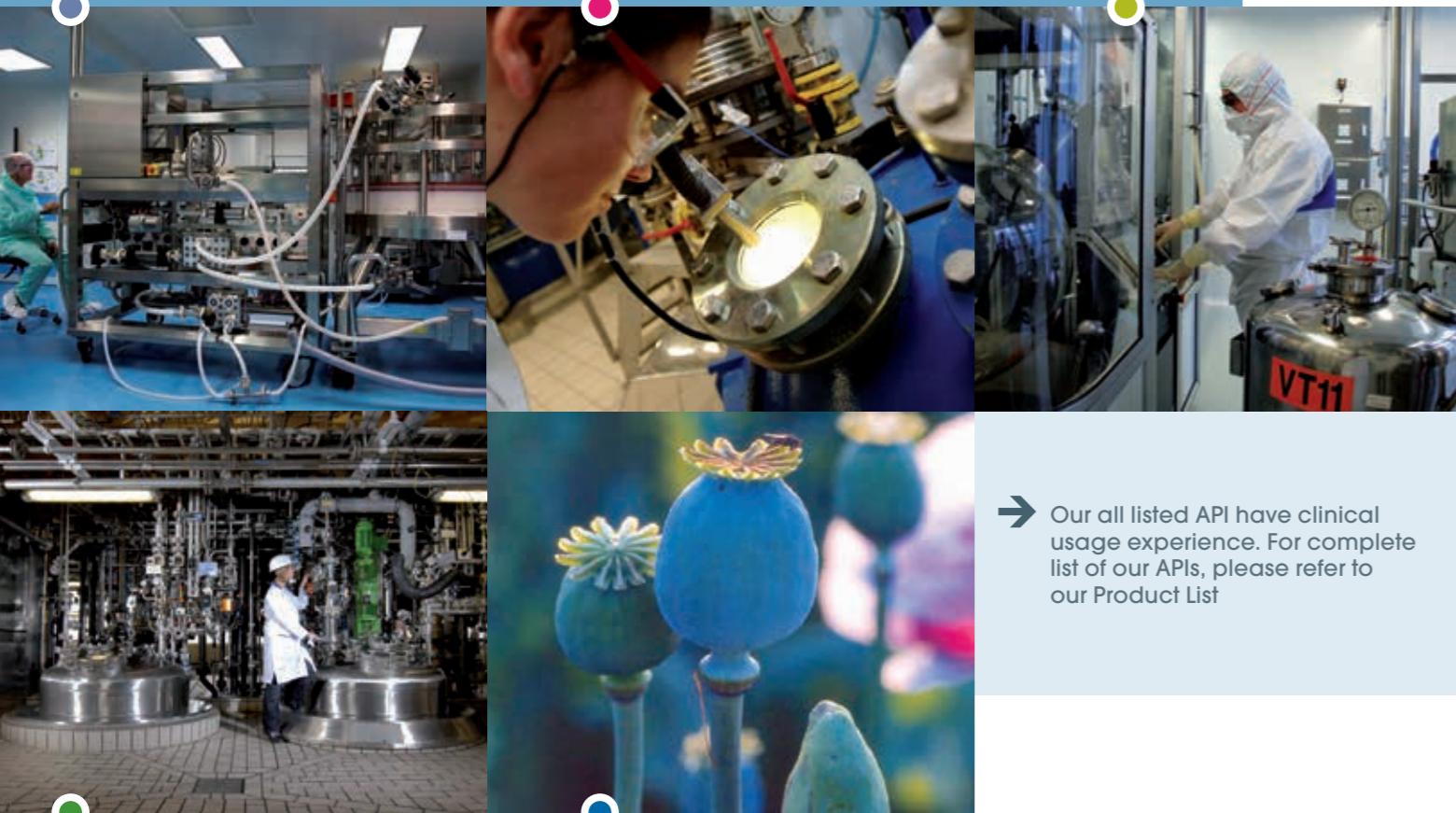
## CEPIA 的结构是一种矩阵式结构，结构基于：

- 化学
- 生物技术
- 近距离满足客户需求分布于世界各地的专设团队
- 专设支持职能部门，如客户服务、质量保证与药品注册等部门

- 约**200**种原料药
- 行销 **80** 多个国家
- 原料药**CMO**服务
- **专设团队：**
  - **质量保证团队**
  - **支持全球市场的药品注册团队**
  - **客户服务团队**



# API OFFER



→ Our all listed API have clinical usage experience. For complete list of our APIs, please refer to our Product List

## FERMENTATION & BIOTECHNOLOGY

- Vitamin B12 & derivatives
- Antibiotics & Antituberculosis
- Packaging customization
- Customized product grade

## SYNTHESIS

- A portfolio of more than 60 APIs covering various therapeutic areas
- 12 Sanofi manufacturing sites involved to support this broad offer
- From mass production (Metamizole, Ketoprofen) to medium and small scale production

## CORTICOSTEROIDS & HORMONES

- 30 corticosteroids manufactured on a ton scale
- Sustainable process for a long term presence
- Fully back integrated manufacturing
- Jet milling expertise

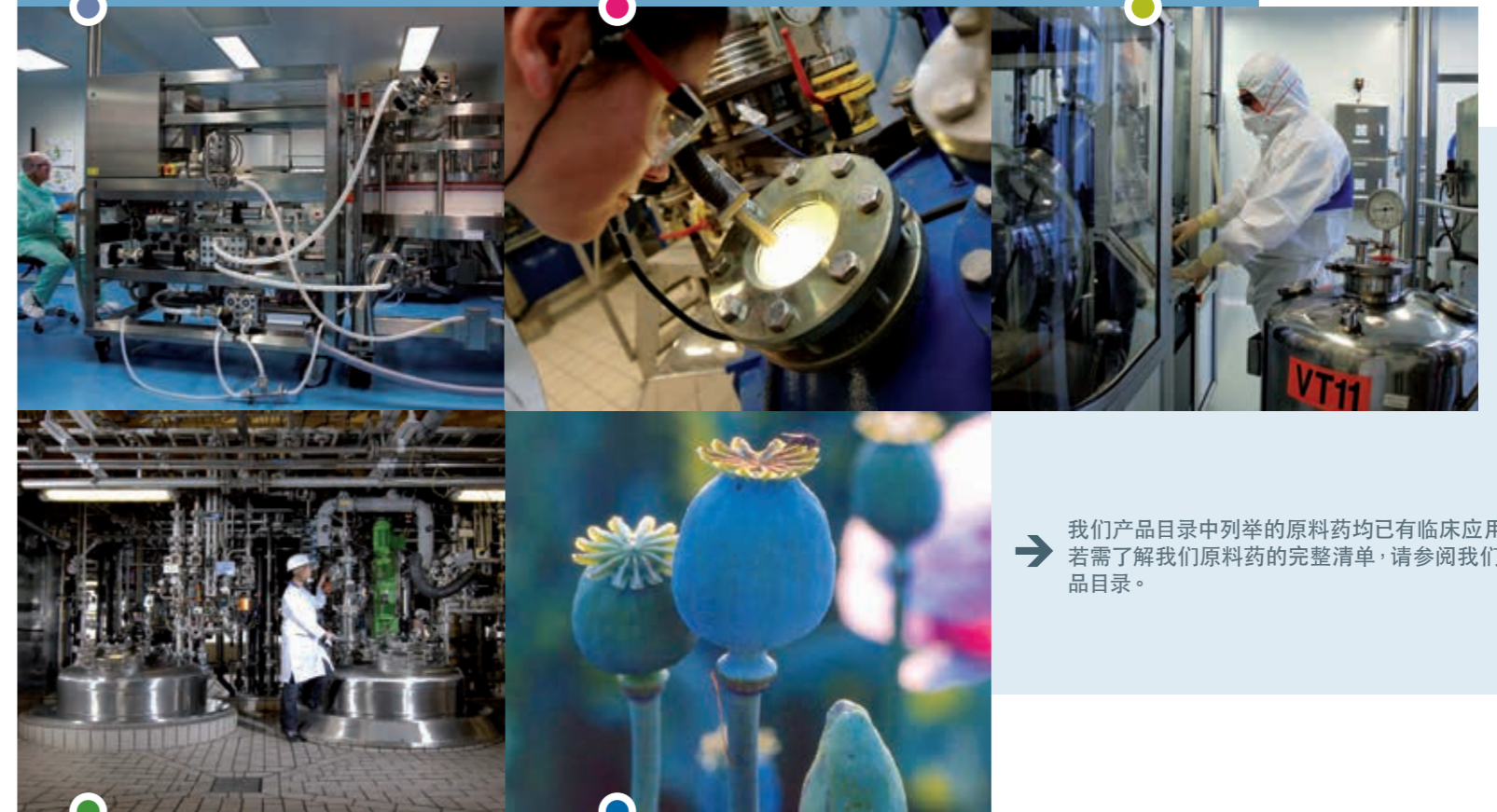
## OPIATES & OPIOIDS (FRANCOPIA)

- From poppy seeds to APIs
- World number 1 Codeine producer & exporter
- 20 Narcotics & Antagonists in portfolio
- 80 years experience in Alkaloid extraction

## PROSTAGLANDINS

- Supply of natural & modified Prostaglandins APIs
- Continuous evolution of product portfolio
- Process development and scale-up of new chemical entities
- Multipurpose production lines, batch sizes up to 10 Kg API
- cGMP compliance for all operations, with proven record of seamless regular FDA inspections and customer audits

# 原料药产品



→ 我们产品目录中列举的原料药均已具有临床应用。若需了解我们原料药的完整清单，请参阅我们的产品目录。

## 发酵与生物技术类

- 维生素 B12 及其衍生物
- 抗生素与抗结核药物
- 包装定制
- 按产品级别定制

## 合成类

- 涵盖不同治疗领域的 60 多种活性药物成分
- 12 个赛诺菲生产基地为该业务提供支持
- 从批量生产 (安乃近、酮洛芬) 到中等规模与小规模生产

## 皮质类固醇与激素类

- 吨级规模生产的 30 种皮质类固醇
- 长期稳健的生产工艺
- 全面整合的一体化生产
- 气流粉碎专业技术

## 阿片类 (FRANCOPIA)

- 从罂粟籽到原料药
- 排在世界首位的可待因生产商与出口商
- 共有 20 种麻醉剂与拮抗药
- 生物碱提取领域 80 年的经验

## 前列腺素类

- 提供天然的与改良的前列腺素活性药物成分
- 产品线持续扩大
- 工艺开发与新化学单体规模化生产
- 多用途生产线，批量生产规模最高可达 每批次 10 公斤原料药
- 所有业务均符合动态药品生产管理规范，在 FDA 定期检查与客户审核方面有良好的记录

# CUSTOM SYNTHESIS & API CMO

We are a Contract Manufacturing Organization (CMO) in chemistry and Biotechnology to offer both toll-manufacturing and exclusive synthesis of Active Pharmaceutical Ingredients of multi-step synthetic intermediates under cGMP conditions.

We offer:

- development from lab to industrial scale
- exclusive manufacturing of API and/or intermediates
- full regulatory support during development and launch (US, EU, Japan, emerging countries...)



## OUR EXPERTISE FIELDS COVER

### CHEMISTRY

- Oligosaccharides
- Peptides
- Oligonucleotides
- Corticosteroids and Hormones
- Prostaglandins
- Opiates and opioids
- Highly active products (HAP)
- Multi-step heterocyclic chemistry

### BIOTECHNOLOGY

- Therapeutic proteins (Production / Extraction / Purification)
  - Extractive proteins
  - Recombinant proteins
  - Viral vectors

## CORE TECHNOLOGIES & EXPERTISE

- Asymmetric synthesis
- Chloromethylation
- Enantiomeric / racemic separation
- Enzymatic conversion
- Epoxidation
- Friedel-Crafts acylation and alkylation
- Grignard and organometallic reactions
- Glycosylation
- Heterocycle ring formation
- Hydrogenation
- Lithiation
- Metal catalyzed coupling reaction (Pd, Pt, Ru...)
- Photobromination
- Reductions (NaBH<sub>4</sub>, LiAlH<sub>4</sub>)
- Reductive amination
- Wittig reactions
- Azidation
- Cyanides handling (NaCN, KCN)
- Methylation under high pressure (CH<sub>3</sub>CL)



# 定制合成 与原料药CMO

我们是一家化学与生物技术领域的委托加工企业 (CMO)，符合动态药品生产管理规范 (cGMP) 要求，提供原料药或多步合成中间体的付费生产和独家合成。

我们可提供：

- 从实验室规模到大规模生产的药品研发服务
- 原料药/或中间体的独家生产
- 药品研发与上市期间提供全方位的注册支持 (美国、欧洲、日本、新兴市场……)



## 我们的专业领域涵盖

### 化学

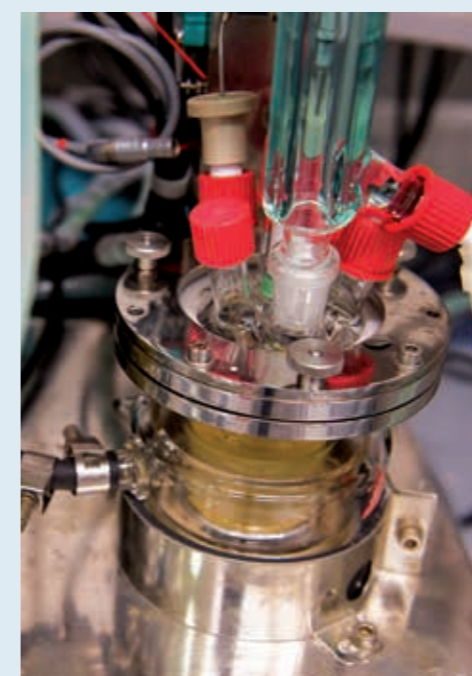
- 低聚糖
- 多肽类
- 寡核苷酸
- 皮质类固醇与激素
- 前列腺素
- 阿片类
- 高活性产品 (HAP)
- 多步杂环化学

### 生物技术

- 治疗性蛋白 (生产/萃取/纯化)
  - 可萃取蛋白
  - 重组蛋白
  - 颗粒剂、散剂

## 核心技术与专业知识

- 不对称合成
- 氯甲基化
- 对映体/外消旋分离
- 酶法转化
- 环氧化反应
- 傅-克酰基化反应与烷基化反应
- 格氏反应与有机金属反应
- 糖基化反应
- 杂环成环反应
- 氢化反应
- 锂化
- 金属催化偶联反应 (Pd、Pt、Ru等)
- 光溴化反应
- 还原反应 (NaBH<sub>4</sub>, LiAlH<sub>4</sub>)
- 还原胺化反应
- 维蒂希反应
- 叠氮化反应
- 氯化物处理 (NaCN, KCN)
- 高压下的甲基化反应



# CEPIA A WORLDWIDE NETWORK

## CEPIA 全球网络

### EUROPE FOCUS



**FRANKFURT**  
 API Sales: ■ ■  
 Custom Synthesis: ● ● ● ● ●

**BRINDISI**  
 API Sales: ■  
 Custom Synthesis: ●

**FRAMINGHAM**  
 API Sales: ■  
 Custom Synthesis:

**JURONG**  
 API Sales: ■  
 Custom Synthesis: ●

**PLOËRMEL**  
 API Sales:  
 Custom Synthesis: ●

**ELBEUF**  
 API Sales: ■  
 Custom Synthesis: ●

**VERTOLAYE**  
 API Sales: ■ ■ ■  
 Custom Synthesis: ●

**VITRY**  
 API Sales:  
 Custom Synthesis: ● ●

**MOURENX**  
 API Sales: ■  
 Custom Synthesis: ●

**ARAMON**  
 API Sales: ■ ■  
 Custom Synthesis: ● ● ●

**SISTERON**  
 API Sales: ■  
 Custom Synthesis: ● ●

**API Sales :** ■ Corticosteroids ■ Synthesis  
■ Biotech ■ Prostaglandins ■ Opiates

**Custom Synthesis:** ● Monoclonal Antibodies  
● Therapeutic Proteins ● Gene Therapy Products  
● Tides ● Highly Active Products ● Biotech  
● Oligosaccharides ● Multi-step Chemistry  
● Biochemistry

**API 销售 :** ■ 皮质类固醇 ■ 合成  
■ 生物技术 ■ 前列腺素 ■ 阿片剂

**定制合成 :** ● 单克隆抗体  
● 治疗性蛋白 ● 基因疗法产品  
● 多肽类 ● 高效产品 ● 生物技术  
● 低聚糖 ● 多步化学反应  
● 生物化学

# QUALITY ASSURANCE & REGULATORY COMPLIANCE



Quality & Regulatory is the core value of Sanofi, implemented at all levels, from the manufacturing to the delivery of our products.

All our manufacturing plants are regularly inspected by the Health Authorities (ANSM, USFDA, PMDA, KFDA, ANVISA...) and all our products are manufactured under cGMP and in accordance with the unique Sanofi Quality Policy.

For each product, a dedicated Quality & Regulatory team is in charge of any of your requests from your day-to-day business to long-term projects.

**Our objective is customer satisfaction by:**

- ensuring that all your enquiries find a suitable solution
- working together for the success of your project.



# 质量保证和药品注册



质量与注册是赛诺菲的核心价值观。从产品生产到产品交付，质量与注册贯穿于赛诺菲业务的始终。

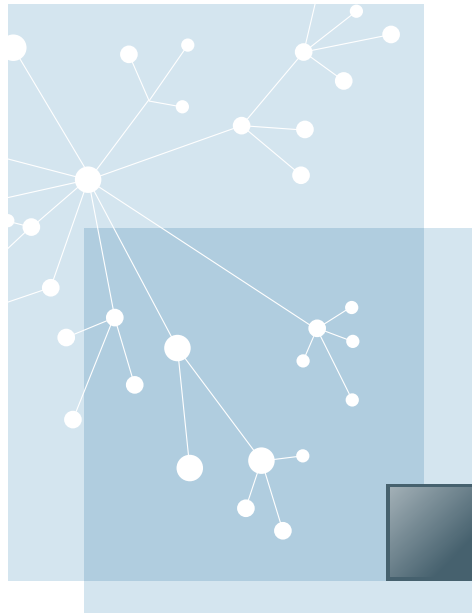
我们所有的生产基地都接受权威卫生部门的定期检查 (ANSM, FDA, PMDA, KFDA和ANVISA等)，而我们所有的产品都是严格遵守国际GMP规范和赛诺菲特有的高标准质量方针进行制造生产的。

对于每一个产品，我们都有专职的质量和注册团队，来回答您提出的各类关于日常业务或长期项目的问题。

您的满意是我们工作的目标：

- 确保您的需求都能获得一个合适的解决方案
- 通过我们的协助获取最终项目的成功





#### **CONTACT US**

##### **CEPIA China Zone**

19F Tower III, Kerry Center  
1228 Middle Yan'an Road  
Jing An District, Shanghai, 200040, China  
Tel: +86 21 2226 6032  
Mobile: +86 186 2186 5966  
E-mail: Jolie.Zhu@sanofi.com

#### **联系我们**

##### **CEPIA 中国区**

中国上海市延安中路 1228 号  
静安嘉里中心 3 座 19 楼，邮编 200040  
电话：+86 21 2226 6032  
电子邮件: Jolie.Zhu@sanofi.com

**CEPIA**  
SANOFI 

[www.cepia-sanofi.com](http://www.cepia-sanofi.com)

