

---

# API Manufacturing: Excellence in Every Molecule

---

## Why Choose Evotec?

▶ **Expert Teams:**

Over 80 chemists and analysts across two sites (Abingdon and Verona)

▶ **Advanced Facilities:**

cGMP Kilolab and 3 GMP pilot plants (18 reactors, 100–1,600L, total 7 m<sup>3</sup>) supporting research (Phases 1–3) and low-volume commercial API manufacturing

▶ **Specialized Capabilities:**

- Handling highly potent compounds (down to 0.1 µg/m<sup>3</sup>) on a large scale (up to 1,600L)
- Operating in cryogenic conditions at plant scale (up to -80°C on 400L scale)

▶ **Flexible Product Lifecycle Management:**

Tailored strategies, especially for APIs in rare diseases





---

## **Our Expertise and Capabilities**

### **Process Validation**

Our chemical development and plant chemistry teams excel in validating chemical processes for commercial API manufacturing. Utilizing QbD, DoE, and PAT methodologies, they design and execute process performance qualification (PPQ) and ongoing process verification (OGPV) protocols

### **API Manufacturing**

Our FDA, MHRA, and AIFA-approved GMP labs and pilot plants offer flexibility in manufacturing a wide range of APIs, including potent and controlled substances, at various scales (20L to 1,600L). Our production teams have extensive experience in delivering pre-clinical, clinical, and commercial stage API manufacturing projects

### **QC/Analytics**

We provide comprehensive analytical services, including ICH method validation, cleaning verification, ICH stability, and forced degradation studies. Our modern analytical techniques include instrumentation for non-chromophoric species analysis (CAD, ELSD, MS detection)

### **Supply Chain/Logistics**

Our strong relationships with raw material suppliers and custom manufacturers ensure reliable supply chains. Our logistics team, experienced in handling controlled substances globally, uses audited QA-approved couriers and IATA-qualified experts to ensure safe and diligent delivery of our products

**Ready to Elevate  
Your Drug  
Development?**  
Contact us now:

