OFICHEM

Pharmaceutical Development Services

Process Development & GMP Manufacture

From early development through clinical and commercial supply, we deliver integrated process development and GMP manufacture designed around regulatory strategy, robustness and lifecycle scalability. Our approach and business model ensures development decisions translate directly into compliant, reproducible API manufacture.

Integrated Cross Disciplinary Process Development

Driven by close collaboration between chemistry, analytics, quality and regulatory, so each route is designed with the product in mind.

- Route evaluation focused on scalability, robustness and campaign suitability in line with **QbD** principles *via* **DoE** studies**.**
- Early identification of **critical process parameters (CPPs)**, impurity drivers and HAZOP to support control strategies
- Integrated analytical support for in-process controls, impurity identification**,** method development and verification, potential genotoxic impurity (PGI) & nitrosamine limit testing.
- Starting material sourcing & qualification, patent aware route selection, and clinical phase appropriate studies to enable efficient filing strategies

Quality Driven GMP Manufacture

Development and manufacturing (D&M) are executed by the same technical teams, for dependable GMP production.

- Removal of **tech-transfer risk** with Ofichem & secure the supply of API with European operations
- Retention of operational insight: reaction behaviour, visual cues, machine settings and response strategies
- Flexible infrastructure with **14 GMP** manufacturing **suites** and scalable reactor volumes, providing redundancy and rapid capacity response
- Capability across **pilot**, clinical and **commercial** manufacture, with new investments driven for our customers
- GMP & FDA-approved facility with over 50 years of API production with proven history of regulatory inspections and continuous quality improvements.

Regulatory Excellence Built In

With extensive global filing experience, regulatory strategy is embedded from the earliest stages of development.

- 50+ **successful submissions**: US DMF, ASMFs, CEP and IMPDs
- Regulatory strategy developed in parallel with chemistry, guiding route selection, control strategy and documentation
- **Phase-appropriate** data generation enabling speed without re-work and efficient clinical progression
- Comprehensive regulatory documentation prepared in a **submission-ready** format (e.g. CTD), enabling efficient integration into customer dossiers.
- Clear **alignment** between drug substance and downstream drug product dossiers

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