

# Process Research and Development

**At Onyx Scientific, we deliver process research and development services (PR&D) for your small molecule API to meet specific requirements.** Our chemists develop your small molecule API to the highest standards, ensuring progress through the development process is as swift as possible. We aim to provide a safe and scalable route whilst generating reproducible quality material.

## Chemistry is at the core of everything we do

At Onyx, we deliver phase-appropriate studies tailored to a project's needs, with our early-phase work incorporating the production of process outlines, stress testing, impurity tracking (including PMI control) and specification setting. This creates a sound basis for later phase development where we look at more detailed specifications and impurity synthesis that will ultimately lead to process validation.

We offer our customers defined work programs with a fixed budget and timeline along with milestone targets and costed assumptions that allow for transparency in scale-up estimations. The development is supported by expert analytical development and process chemistry for complete understanding of your compound and GMP manufacture in our custom-built laboratories.



## Development Laboratory Capabilities

Our team of highly skilled chemists take a responsive and flexible approach in collaborating with customers to ensure development of the most effective chemical synthesis of the target API. Depending on the phase of development, this will include the following capabilities:

- Multi route scouting
- Complex synthesis and route design
- Route efficiency evaluation
  - Development/scale up of selected route
  - Optimisation of conditions through variation of process changes: stoichiometry, temperature, reagents etc
  - Work-up improvements including avoiding chromatography
- Solubility investigations
- Crystallisation/slurry development
- In silico process modelling (Dysochem Scale-up systems)
- Heavy metal scavenging
- Cryogenic techniques down to -70oC
- Pyrophoric handling
- Fate and purge investigation of impurities/solvents
- PMI identification
- Stressing and hold point assessment
- Design of Experiments (DoE) investigations
- Failure Mode and Effects Analysis (FMEA) investigations

Your molecule, our people - it's good chemistry

## Equipment

A range of development equipment is available ensuring progress through the development process, including scale up assessment and the production of a process typical batch is as swift as possible.

- Reaction carousels for fast parallel screening
- MYA parallel platform
- Range of Huber controlled jacketed vessels from 250mL up to 10L
- Range of heating/mixing options - hot plates, overheads, mantles
- Controlled dosing (syringe pumps, peristaltic pumps, HPLC pumps)
- Scavenger, catch & release columns
- Pressure vessels – from 300mL (with insert for parallel screening) up to 20L
- Chromatography
- Microwave reactor
- Flow equipment
- Spray drier
- Lyophilisation
- Distillation – range of columns, packing and heads
- Wiped Film Evaporator
- Milling (Ball, Jet, Co and Fitz mill)
- 2 x 400MHz NMR
- Range of HPLCs in development labs



## Development Output

As part of Onyx's development campaigns, we offer an array of deliverables as appropriate for the phase of development:

- Process descriptions
- Weekly development reports
- Final development report
- Process typical development batch with detailed Certificate of Analysis
- Specification setting – RSM, IPC, INT and API as per ICH guidance
- Data interpretation: NMR, HPLC-MS, GC
- PMI control strategies
- Cleaning methods between stages and API
- Impurity identification and purge information per stage
- DoE analysis and interpretation using MODDE Pro – including Normal Operating Range (NOR) and Proven Acceptable Range (PAR) values
- Critical process parameter assessment
- Failure Mode and Effects Analysis (FMEA)
- Structure elucidation using NMR – 1H, 13C, HSQC, HMBC
- CMC writing and support

## Contact us

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