PRAGUE SCIENTIFIC

API Development Services

Route Scouting

- Literature search to establish current state of the art routes, as well as to identify synthetic routes options including designing novel routes
- Laboratory assessment and optimization in a small scale to select the most promising synthetic route including preparation of standards of impurities
- Synthesis of oligonucleotides

Process Development and GMP Operations

- Optimization of chemical reactions parameters utilizing Design of Experiments (DoE) and Quality by Design (QbD) principles (e.g. Cost of goods manufactured, yield, cycle time, quality etc.)
- Process safety data measurement
- Designing scale-up and scale-down models
- Process validation of Development APIs for clinical trials and commercial supply
- Manufacturing of commercial APIs in the Prague kilolab, Ankleshwar (India) Pilot plant

Solid Form Screening and Analytical Development

- Screening and process development of crystalline forms (polymorphs, hydrates, solvates, salts, cocrystals)
- Screening and process development of amorphous forms (amorphous APIs, co-amorphs and solid solutions by precipitation, hot melt extrusion (HME) or spray-drying)
- Particle size modification, API solubility increase systems
- Analytical method development, Validation and transfer
- Specification setting, Stability and Stress testing
- Preparation of CMC part of ASM

Nitrosamine Impurities

- Preparation of nitrosamine risk assessment reports
- Synthesis and analytical characterization of nitrosamine standards
- Confirmatory nitrosamine testing on the ppb/ppm level (analytical methods development and validation)
- Coordination and evaluation of additional toxicological tests such as AMES
- Nitrosamine free drug product reformulation and development