



Norac Pharma is your optimal choice for confident delivery of pharmaceutical process technology and API supply. We offer decades of experience in process R&D, analytical method development, regulatory compliance and manufacture of APIs, whether for preclinical or clinical studies. Our goal is to provide complete confidence in delivery of process technology, analytical methods, regulatory support and supply of drug substance, achieved through innovative research, flexible tailoring of process and analytical R&D to suit drug development phase, close partnership with our clients and deployment of the best technology to ensure timely supply of product with consistent product quality through each scale of manufacture.

### Mission

We firmly believe that our customers deserve no less than what they would expect from their own staff – a strong, professional work ethic, strict attention to detail, and adherence to the highest scientific, quality, and ethical standards. Norac Pharma is committed to earning and maintaining a first-rate reputation, both in the scientific business community, and in the local communities where our employees work and live.

### Services

Our talented staff and state-of-the-art process R&D laboratories make the difference in the development and optimization of your synthetic process, creating a seamless supply of API from pre-clinical, through clinical supply to commercial quantities.



#### Process Research and Development

- > Route Discovery
- > Route Optimization

#### Small- and Large-Scale API Production

- > Toxicology and Pre-Clinical Quantities
- > Clinical Trial Supplies (Phase I-III)
- > Full Breadth of Scale from gm to 100's kgs

#### Advanced Technologies

- > Potent Compounds
- > Controlled Substances
- > Enzymatic Transformations
- > Photochemical Processes
- > Peroxide Reactions
- > Process-Scale Chromatography
- > Air- and Moisture-Sensitive Compounds
- > Asymmetric Synthesis

#### Analytical Services and Instrumentation

- > Method Development and Validation
- > Stability and Photostability Testing
- > Impurity Identification, Synthesis, and Characterization
- > Reference Standard Synthesis and Qualification
- > 400 MHz NMR
- > LC-MS/MS, GC-MS
- > Prep-Chromatography for Reference Standards
- > Ion Chromatography
- > ReactIR™
- > Lasentec FBRM™

#### Regulatory Support

- > FDA
  - > Regulatory Submissions
  - > DMF Preparation and Maintenance
- > DEA
  - > Schedule I, II, and III Registration

### Client Partnership

At the start of each project, Norac Pharma establishes a multi-functional project team that operates in close partnership with our client organizations to negotiate the challenges of drug development and thereby facilitate efficient and flexible delivery of optimal process technology, tailored to client needs and drug development phase.

### Cost Effective Solutions for Your Process

- > Innovative and Robustly Scaleable Process Design
- > Reduced Raw Material Costs
- > Enhanced Volume Productivity
- > Increased Yield and Fewer/Telescoped Manufacturing Steps
- > Simplified Purifications
- > Enzymatic Transformations
- > Continuous Reactor Technology
- > Environmentally Sound and Safe
- > Foresight for Long-Term Production

### Management Team

- > **Danny Levin, PhD**  
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