

PharmaZell

PharmaZell, Inc.
Custom Pharmaceutical Services
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Vital Statistics

Year Founded: 2006 (former Noveon Pharma, GEA Pharma)

Number of Employees: 470

Key Personnel: Dr. Wolfgang Burger, Managing Director; Dr. Oliver Bolzern, Managing Director; Dr. Clemens Katschthaler, Director of Business Development, Europe; Dr. Del Alley, Head, Business Development, N.A.; George Hlass, MBA, Business Development Manager.

Who We Are

DRAWING UPON DECADES OF EXPERIENCE in development and commercial manufacture of API's, amino acids and advanced intermediates, PharmaZell offers drug substance and drug product development and manufacturing services to pharmaceutical innovators. Three R&D sites and four plant sites in Germany, Denmark and India offer a comprehensive package of assets, technologies, project management skill and regulatory services, all geared to provide rapid, cost-effective execution of API and dosage form projects. With extensive experience with global regulatory agencies in DMF filings and site inspections, PharmaZell provides innovators with support in preparation of CMC and IND packages as well as DMF filing.



Services Offered

Custom Synthesis of API's

- Chemical route development
- Analytical method development
- Stability testing
- Three R&D sites

API Manufacture

- cGMP pilot scale-up
- Process validation
- cGMP commercial production
- Four manufacturing sites
- FDA inspected facilities

Advanced Intermediate Development & Mfg

- cGMP, non-cGMP
- Diazotization
- Epichlorohydrin
- Electrochemistry
- Pyrimidines, amino acids

Formulation Development

- Solid oral dosage forms
- Controlled release
- Coatings and Tablets
- Clinical trial batches (cGMP)

Project Management

- Dedicated teams
- Schedule-driven

Regulatory Services

- CMC and IND support
- DMF preparation and filing (U.S.,EU)
- Consultancy & strategy

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