

Multiplicity
Flexibility
Partnership
Trust
Service
Speed

# PharmaZell

**Your Sources for High Quality Products & Services** 

#### PharmaZell offers

- Active Pharmaceutical Ingredients (API)
- Advanced Intermediates
- Custom Synthesis (Development & Manufacturing)
- Analytical and Regulatory Services
- Pharmaceutical Development new !

from laboratory scale to commercialization

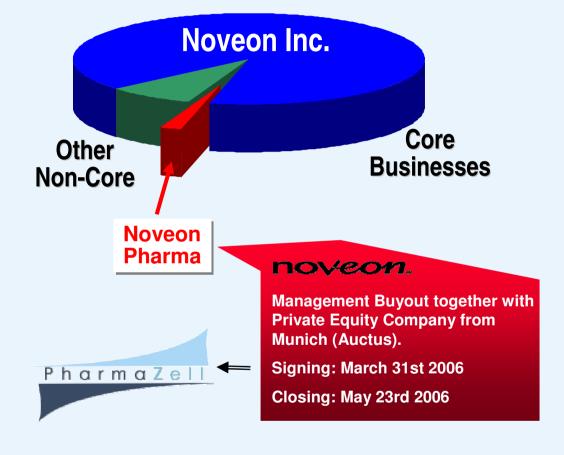
www.pharmazell.com

PharmaZell





#### Where we come from:



In June 2007 GEA Pharmaceuticals A/S in Copenhagen, Denmark was acquired.



# 6 Key Characteristics of PharmaZell

Mission: provide sustainable quality ingredients & services

at competitive prices

Service: competent and fast solutions on standard APIs,

intermediates, custom synthesis & pharmaceutical

development

Structure: separate manufacturing sites in Germany, Denmark

and India

Certification: all sites are cGMP certified by European authority,

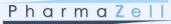
proven long track record with the US-FDA

Flexibility: cost structure and capacity through European and

**Indian manufacturing sites** 

Commitment: state of the art quality products & services; specialized

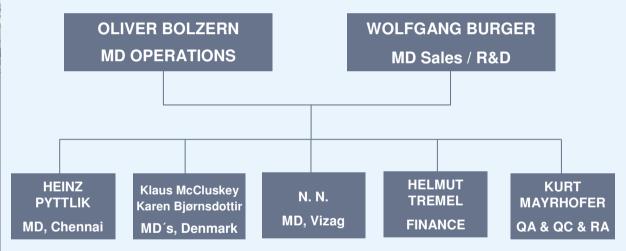
to meet specific customer formulation requirements







# PharmaZell Organization









## PharmaZell is now active on four sites

	Raubling, Germany	Copenhagen, Denmark	Chennai, India	Vizag, India
Site founded	1947	1927	1996	2007
Production scale	Pilot & commercial	Pilot & commercial	kg-Lab & commercial	commercial
Employees*	119	83	181	85
Compliance	cGMP	cGMP	cGMP	cGMP
Total reactor volume (m³)	> 100	29	65	expandable
Key characteristics	Group Head Office	Production of Controlled Substances Drug Product Development	Attractive labor & raw material cost structures	Gradually expandable  R&D center to start-up in Q.1. 2008

<sup>\*</sup> Number of employees as per 31st of December 2007

P h a r m a Z e l l



Site Raubling



# PharmaZell Site Raubling, Germany (close to Munich)

**API Production since 1947 Fully Integrated Site:** 

- R&D, Pilot Plant, Commercial Production
- QA/QC/RA, Sales & Marketing
- Project Assessment & Management

cGMP compliant (incl. product specific certificates)
last FDA Inspection Nov. 2007

#### **Activities:**

- Process Development
- Custom Manufacturing
  - of new APIs
  - of advanced Intermediates
- Analytical Method Development





Site Copenhagen



### **GEA Pharmaceuticals A/S**

a PharmaZell Company

## Copenhagen, Denmark

**API Production since 1927 Fully Integrated Site:** 

- R&D, Pilot Plant, Commercial Production
- QA/QC/RA, Project Management
- Pharmaceutical Development

**cGMP compliant** (incl. product specific certificates)

#### **Activities:**

- Process Development
- Custom Manufacturing
  - of new APIs
  - of Advanced Intermediates
  - including **controlled substances** (e.g. Amphetamines, Opioids)
- Analytical Method Development
- Complete Dossier Development for Finished Dosage Forms
- Manufacture of Clinical Trial Batches

P h a r m a Z e l



**Site Chennai** 



# PharmaZell Site Chennai, India

Inauguration in 1996 German Management Fully Integrated Site

- R&D, Kilo-Lab, Production, QA/QC/RA **cGMP compliant** (incl. product specific certificates)

#### **Activities:**

- Process Development
- Custom Manufacturing
  - of mature APIs
  - and Intermediates
- Analytical Method Development





# PharmaZell Site Vizag - Pharma City, India

#### "Bhoomi Puja" (Groundbreaking Ceremony) 06/2007

- R&D Center (Dezember 2007: fully operational)
- Production Units (Summer 2008: Start up of Mesalazine production)











## **Technical and Chemical Capabilities**

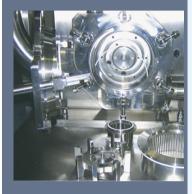
- Large "Toolbox" of Chemical Reactions suitable for Multi Step Synthesis
- Multi Purpose Batch Production with Reactor Sizes from 200 – 14000l
- Drying and Product Handling in Controlled Areas
- Milling and Micronization in Controlled Areas

#### **Specially Equipped Units exist for:**

- Electrochemical Reductions
- Halogenation
- Nitration 100% Nitric Acid
- Diazotation
- Epichlorohydrine Chemistry
- Catalytic Hydrogenation
- Acylation and Alkylation
- Synthesis and Handling of Synthetic and Opiod Controlled Substances



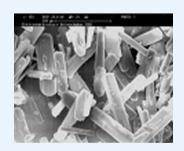


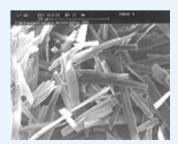


We put particular emphasis on custom made particle forms to meet formulation needs of our customers by:

- Designing Crystallization Processes
- Drying Technology
- Milling and Micronization
- Micronization with Ball Mill e.g. for Inhaler Products

# Challenge us to convert your product to the right form!













# **Pharmaceutical Development**

- Formulation and Process Development
- Manufacture of Clinical Trial Batches
- Scale up/Tech. Transfer to Costumer Sites
- Development and Production Support
- -> Excellences:
- Functional Coatings
- Pellets

## **Clinical Support**

- Bioequivalence Studies
- Bioanalytics, Method Development/Validation
- Biometry







# ... we are your partner for

- ✓ API's and Advanced Intermediates
  - Tailor Made Physical Characteristics of API's
- √ Custom Synthesis
  - Projects in Clinical Phases
  - Outsourcing Requirements
- √ Pharmaceutical Development
  - Formulation and Process Development
  - Projects in Clinical Phases
- ✓ Product Volume from few kg to multi ton Scale



# PharmaZell www.pharmazell.com