

# **Company Profile**



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Dr. Oliver Bolzern Managing Partner

Dr. Wolfgang Burger Managing Partner

#### **Editorial**

#### Dear Reader,

As a partner of pharmaceutical companies Pharma-Zell operates in an industry of the future characterized by rapid change and highly complex structures. An enterprise that wants to rank among the top ten in its segment, such as PharmaZell, faces requirements that are correspondingly tough. We will leverage a comprehensive portfolio of services, our presence in the world's most important regions, and a business strategy that relies on intelligent growth to attain this objective.

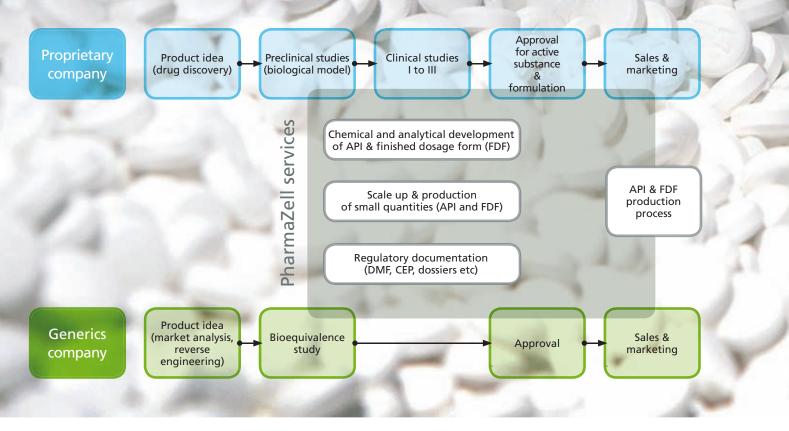
There are many terms that reflect PharmaZell's corporate philosophy: service orientation, a culture of innovation, responsible corporate citizenship, and flexibility. However, one of the most important terms is partnering. When we partner with pharmaceutical companies (for both proprietary products and generic drugs), it is a partnership among equals that enables PharmaZell to provide its customers with offerings that are tailored precisely to their needs. Partnering means: Much more so than a supplier or outsourcing contractor, "real" partners must understand the core of their customers' needs, know the bigger picture and be aware of manufacturers' typical problems and difficulties. Only if this understanding exists will "real" partners know how and where to optimally support their customers. Only if they are intimately familiar with their customers' structures and processes will they understand what offerings stand to really help their customers – and may even support them in gaining a competitive advantage. Only if all of these prerequisites are met, can there be real sustainability.

On the following pages, we would like to present to you in detail PharmaZell as a partner of the pharmaceutical industry. The range of topics covered will span the company's history, its product portfolio, and its presence in the world's major economic regions.

Get an idea of who we are. We hope you will enjoy reading about us.

Sincerely, Dr. Oliver Bolzern and Dr. Wolfgang Burger

### PharmaZell Services – Development and Production



## Who We Are

## A Thorough Understanding of Our Clients Needs:

PharmaZell develops and produces active pharmaceutical ingredients, formulations, and the respective registration documents for originator and generic pharmaceutical companies. The Company thinks of itself as providing services to and partnering with its customers and relies on customized and yet competitive solutions. Customers have a choice: Depending on their requirements, PharmaZell will supply individual components or provide complete solution packages.

### The Best of Both Worlds:

A technology platform that is as extensive as it is flexible is complemented by intensive and trustbased collaboration with customers that comprises countries and continents.

At 4 locations in Germany, Denmark, and India, the Company employs some 500 professionals. Corporate headquarters are located in Raubling, Bavaria, with a sales branch situated in Cleveland, Ohio.

05

"Many exciting projects with new challenges."

### Adding to Our Competitive Edge:

PharmaZell places particular emphasis on continuously optimizing its development and production processes. A culture of innovation is as much one of the Company's core values as is acting according to ethical principles with respect to staff, partners, and the environment. R&D departments develop production processes and formulations that are turned into commercial products at high speed and in accordance with market and cost requirements. A continuously adapted supply chain ensures optimal quality and reliable product supply.

#### Seizing Opportunities:

With its eyes firmly set on the future, PharmaZell relies on growth. Precisely targeted and continuous investment as well as a permanent optimization process ensures that the company will continuously enhance existing offerings. In addition, staff works at the highest level to develop new, seminal technologies.

## PharmaZell in the Course of Time

A Young Company with a Tradition





1960

1947: The name PharmaZell appears: PharmaZell is newly established in Raubling as a subsidiary of Aschaffenburger Zellstoffwerke AG paper mill near Munich and begins producing active pharmaceutical ingredients.

1940

1969: More or less 20 years after the company's foundation, PharmaZell gets acquired – the first of several acquisitions to follow. Diamalt AG buys PharmaZell and expands the site's chemical operations. 1979: Schering AG, a pharmaceutical company, acquires a majority of Diamalt shares and begins actively investing into Raubling. The company is steadily growing.

1970



"I love my job although it is quite turbulent sometimes."



### 1990

### 2000

1994: Diamalt is acquired by Freedom Chemical Company and continues to be run under its old name of Diamalt GmbH.

1995: Diamalt builds its first production site in Chennai (the former Madras) in India to produce Cysteine products.

**1998**: BF Goodrich acquires the Freedom Chemical Company.

2001: The performance material segment is spun off from BF Goodrich under the name of Noveon, with the active pharmaceutical ingredients business now being managed as Noveon GmbH & Co. KG.

2006: Today's PharmaZell is created through a management buyout of the Noveon pharmaceutical business with the help of private equity investor Auctus. The Raubling headquarters near Munich become the Company's registered office.

2007: PharmaZell acquires a significant share in GEA Pharmaceutical Copenhagen from Sandoz.

2008: PharmaZell builds a new production plant in Vizag (India) and the production of Mesalamine starts. PharmaZell opens a new R&D center in Vizag as well.

## **Worldwide Operations**

3 Countries and 4 Locations



"Pharmazell provides a fundamental and comprehensive training that very well prepares for the future career." PharmaZell is a globally operating company with a tradition: Its 4 production plants are located in Raubling (Germany), Copenhagen (Denmark), and in the industrial centers of Chennai and Vizag, India. Currently a total of 493 employees work for the PharmaZell group. All plants are in compliance with current Good Manufacturing Practice, cGMP. A combination of European and Indian sites generates flexibility and attractive cost structures.



#### **USA**

#### **GERMANY**

Germany:

**DENMARK** 

**INDIA** 

Cleveland, Ohio: Sales and Business **Development base** for North America and Canada

135 employees, corporate headquarters and business center, production, marketing/sales, customer service, project management, quality assurance and R&D

Denmark: 81 employees, drug product development, specialized amino acids and in controlled substances and niche products

Chennai: 201 employees, production of various APIs under GMP

Vizag: **R&D** Center: 28 employees, development center, development of generic APIs and custom projects at a laboratory level

**Production Site:** 46 employees, production of API on commercial scale

## "We really do have a good working climate at PharmaZell."



PharmaZell GmbH Rosenheimer Str. 43 83064 Raubling Germany



The fully integrated corporate headquarters in Raubling (near Munich), Bavaria, comprise both production and development facilities. Currently, 135 employees work in various functions such as production, marketing/ sales, customer service, project management, quality assurance, as well as research and development – and this number continues to increase.

Production follows GMP-standards (Good Manufacturing Practice) – as it is practiced in all PharmaZell locations. Regular inspections by the FDA and German authorities reflect the high standard of quality and regulatory compliance. Reliability regarding quality and timeline is of utmost importance at PharmaZell.

At the Raubling site, PharmaZell provides its customers with a wide range of services: production processes, customized active pharmaceutical ingredients, and analytical methods including all regulatory documents are all developed on-site by highly skilled employees.





PharmaZell Site in Kopenhagen

## Copenhagen, Denmark

GEA Pharmaceutical A/S was acquired in 2007 from Novartis/Sandoz and is now a fully owned PharmaZell affiliate. GEA's history is going back to the late 1920s.

This acquisition in Denmark puts PharmaZell in a position to offer its customers the full range of services required to bring a drug product on the market: Starting from API development and production over the development of a pharmaceutical formulation under cGMP to the registration dossier; clients benefit from one-stop shopping.

The Copenhagen site specializes in solid dosage formulations and in addition offers also individual modules as a service with respect to pharmaceutical development.

GEA is particularly specialized in handling controlled substances. The production and development facilities of this recently acquired European site employ currently 81 highly specialised pharmaceutical and chemical specialists. GEA Pharmaceutical A/S (PharmaZell A/S) 2650 Hvidovre Denmark



## PharmaZell (India) Pvt. Ltd. Chennai India



This plant was established in 1994 and is the largest site of the PharmaZell Group with a headcount of 201. Furthermore, the location at Chennai is PharmaZell's first production site outside of Germany. Following the slogan "German quality made in India", the German management team works together with the highly qualified Indian workforce. Originally, the plant had been built to produce amino acid derivates. During the last years however, the facilities were expanded to perform also complex syntheses. Today the plant produces various APIs and intermediates. Furthermore in 2003, PharmaZell has established a development group here that focuses on developing generic APIs. In April 2008, this department was relocated to Vizag, where a larger and even more effective development center is now in operation.

This site, too, has been audited by the FDA and German authorities for compliance with GMP regulations.



Green Plant for PharmaZell (in Vizag)





## Vizag, India

### **Production Site**

Established in 2007, this site is the most recent in the history of the global company and employs 46 individuals – a number that is on the rise.

The Vizag, India, production site is located in the Pharma City Industrial Park, which provides state of the art infrastructure and services required for chemical production and is precisely tailored to the needs of pharmaceutical companies.

## PharmaZell (Vizag) Pvt. Ltd. Visakhapatnam India

#### **Development Center**

PharmaZell Group's Vizag Development Center is about an hour's drive away from the production plants. There is currently a team of 28 chemists that focuses on developing generic APIs at laboratory scale. Additionally projects for customers on an exclusive basis are handled there. After completion of the laboratory phase the manufacturing process is transferred to one of PharmaZell's 4 production plants or pilot plants. By late 2009, development center headcount is expected to total close to 50 chemists. PharmaZell R&D (India) Pvt. Ltd. Visakhapatnam India



## What We Offer You

PharmaZell's Range of Services

"Not only are all my colleagues highly qualified but they are also very dedicated to their work." PharmaZell develops and produces active pharmaceutical ingredients, intermediates, dosage forms and the respective registration documents for both originator and generic pharmaceutical companies. PharmaZell continuously strives for the best quality, reliability and the intention and ability to innovate.

Partnering with its customers, PharmaZell provides customers with one-stop shop solutions by developing active ingredients as well as drug products. This is facilitated by a large pool of talented and specialized chemists and pharmacists, extensive and flexible technology platforms as well as a global presence at strate-gically selected locations.

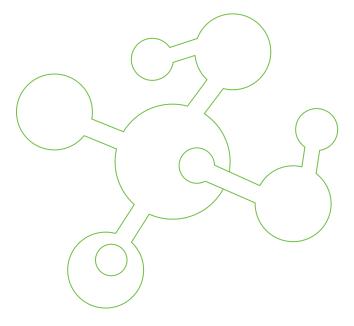
PharmaZell relies on intensive and trustful collaboration with its clients. Combined with the company's know-how that approach ensures to maximize the result of customized solutions.

## Products

As a leading chemical manufacturer of small molecule actives and advanced intermediates, PharmaZell has been supplying the pharmaceutical industry for years with Active Pharmaceutical Ingredients (APIs) in a wide range of specifications.

No matter what solutions customers may require for their formulations: PharmaZell will provide comprehensive support during development and production.

PharmaZell's development pipeline continues to expand just like its range of generic APIs manufactured on an industrial scale. Of course, the toughest standards apply to PharmaZell's manufacturing on behalf of its customers – with cost structures remaining competitive. This is achieved by efficient processes, maximum exploitation of synergies, and a high-performance supply chain that consistently strives for quality, reliable supply and further cost savings.



## Development & Production: Comprehensive Customer Support

PharmaZell provides comprehensive support to its customers during product development – in many ways: From active ingredient development on laboratory scale to ramping up to pilot scale for clinical trials to producing at large scale manufacturing facilities in quantities of up to several hundred tons, PharmaZell remains a dependable partner all the way through. However, PharmaZell also closely collaborates with its customers when it comes to developing a suitable formulation or preparing the required registration documents. More than 20% of its staff worldwide works in development and thus allow projects to be conducted optimally. PharmaZell has mastered a wide range of diverse technologies, such as batch and continuous processes, numerous chemical reactions such as nitrations, chlorinations hydrogenations, electrochemical reductions and reactions with organo-metallic compounds, etc. It also develops bio-technological processes that involve, e.g. enzymatic reactions.

Comprehensive, goal-oriented research and development ensures that PharmaZell's technology is state of the art and that the company blazes new trails, supporting its clients with innovative approaches.



## Services: From Analysis to Registration

Producing active ingredients is one key element of PharmaZell's entire range of services. The company offers a wide range of services for various phases of drug development – both for originators in the pharmaceutical industry as well as producers of generic drugs thus covering large parts of the pharmaceutical value chain. For the former, the services provided by PharmaZell include elements in the early phases for pre-clinical and clinical trials, as well as support for the registration of the active ingredient and formulation. For vendors of generic drugs, PharmaZell arranges bio-equivalency studies and provides the necessary documents for registration of both the active ingredient as well as the finished dosage form.

In addition, PharmaZell is in a position to supply finished dosage forms of any active ingredient. Small quantities can be produced and the respective processes developed. The company thus employs a fully integrated approach that ranges from product development and development of analytical methods, to API production in multi-purpose or dedicated plants under a comprehensive project and quality management.

## Regulatory Requirements: Complying and Consulting

PharmaZell provides a particular service in supporting its customers in the field of legal requirements and any regulations that apply to active ingredients and drug products. This includes preparing and assessing any officially required documents. Last but not least, PharmaZell supports and advises its customers with an eye to effective strategies for dealing with legal requirements and any developments to be expected. As it prepares and updates documents for worldwide product registration and precise coordination with all parties involved (i.e. authorities, customers and its own manufacturing as well as R&D department) PharmaZell ensures that the respective products can be marketed in a timely manner – which is crucial to success or failure of its customers. Especially when marketing drugs worldwide, a speedy and efficient registration process is crucial. PharmaZell's customer support is correspondingly intensive.

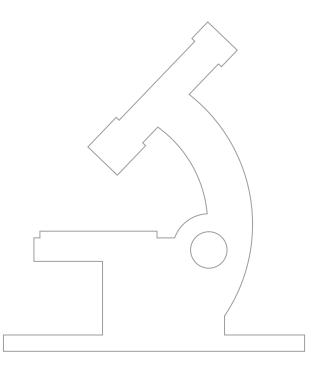
#### Looking Beyond Possible Limitations

It is only a profound understanding of customer needs that allows us to achieve optimal results. This includes finding innovative solutions for customers' problems and travelling uncharted paths. PharmaZell uses an interdisciplinary approach and works in multi-dimensional project teams. This means specifically that large projects are tackled in parallel at various locations and simultaneously in several functions. Projects are centrally led and closely managed to allow all project participants to be coordinated both efficiently and effectively. Even external resources such as contract manufacturers or universities are seamlessly integrated into project management.

Permanent enhancement is not a luxury but of the essence, given continuously evolving new challenges. PharmaZell continues to evolve when it comes to resources, processes and its entire portfolio of offerings.

## Where do we go from here?

A look ahead



Quality, innovation, dynamism: these are the cornerstones of PharmaZell's corporate philosophy, having played a pivotal role in the development of PharmaZell into a key partner for the pharmaceutical industry. In order to remain a dynamic enterprise, PharmaZell has committed itself to stable, sustainable growth: growing in step with the market – or even faster, if possible.

The challenge is to find the right strategy, the ideal combination of organic growth and mergers or takeovers. The crucial parameter for PharmaZell in this context is its range of products and services – with quality much more important than quantity. We aim to provide our customers with an ever wider, ever deeper range of technologies and with even more extensive services.

More offerings also qualify us for better, longer-term customer retention. Lasting strategic partnerships with a common purpose and common aims thrive best on the basis of proven technological competency, responsible action and mutual trust. The most enduring relationships are those whose elements blend together perfectly. This is our goal, this is what our growth strategy is geared to.

The trend toward outsourcing in the pharmaceutical sector is set to continue. What's more, an increasing number of companies are on the lookout for outsourcing partners who will help them save time and costs without any impairment of quality. And who can offer them modular packages that are tailored precisely to the individual needs of customers. Geographical coverage is increasingly important to be represented on all key markets – both present and future. PharmaZell has responded to this trend and is expanding in those areas which have the greatest potential for the future. Our objective: to be wherever our customers and partners are – close companions in the conquest of global markets.

As for the future, our aspirations and expectations are considerable. But only those firms which show ambition have the capability of excelling themselves. At the same time, true success is dependent on maintaining a sense of proportion and keeping in close touch with reality. These, too, are decisive factors in our corporate philosophy.



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