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TECH OUTLOOK

EUROPE SPECIAL



CMO 
EDITION



THIERRY DURAND,
MANAGING DIRECTOR

**DEVELOPING
FINE CHEMICALS
FOR THE
LIFE SCIENCES**

MINAIKEM[®]

FINE SERVICES FOR LIFE

\$15



COVER STORY

“

We offer customised services to life sciences industries in delivering active ingredients, advanced intermediates, and other building blocks of novel drug candidates

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By Stacey Smith

The drug development paradigm traces a progressive discovery curve since the mass availability of penicillin—the “miracle drugs”—during the 1950s. That same decade also saw the rise of synthetic organic chemistry, which had progressed to the point that the large-scale preparation of synthetic drugs or drug candidates was economically feasible for pharma companies. As the industry started leveraging this shift in favour of better medicine, pharmaceutical contract development, and manufacturing organisations (CDMOs) emerged as the catalysts of a favourable change. In the past 20 years, these organisations have become a critical element in bio/pharmaceutical company operations, and are now at the crossroads of yet another revolution.

As the pharmaceutical industry shifts from the traditional blockbuster model to one focused on more niche products and targeted delivery, taking drug discovery to the next level may require an entirely new approach. The market demand revolves around the more advanced synthesis and formulation expertise to develop cost-effective, efficacious, and sophisticated medicines. Consequently, modern CDMOs are now expected to bring together a more comprehensive and profound knowledge of chemistry to find efficient solutions and accelerate the successful development and commercialisation of modern candidate therapies. Rising to these challenges, Minakem has continuously built its offer and services to help pharmaceutical manufacturers to control costs and gain access to specialised expertise, with a strong focus on R&D and a robust supply chain.

A Global Fine Chemicals Developer and Manufacturer

MINAKEM, a unit of MINAFIN Group, was founded in 2005 by Frédéric Gauchet. The journey of MINAKEM started when MINAFIN acquired SEAC—a custom fine chemical manufacturing business—to become a fully-integrated company that offers services from research and development up to commercial-scale manufacturing. Since then, MINAKEM has acquired former AstraZeneca “prazoles” and budesonide production site in Dunkirk (2009) and Ajinomoto’s business and site (2015) to expand MINAKEM’s expertise and develop high potency active pharmaceutical ingredients (HPAPIs) in high-level containment facilities. Notably, MINAKEM was one of the pioneers in high containment technology through triple-level protection for coworkers, products, and the environment.

The tagline of the company, ‘Chemistry for life,’ summarises the core mission of MINAKEM, i.e., supporting its clients to deliver better and affordable medicines to patients in a time-efficient manner. MINAKEM offers a combination of innovative development and manufacturing solutions through a wide range of flexible assets, specialised technologies, and advanced process capabilities for the synthesis of intermediates, APIs, and HPAPIs at all production scales. “We offer customised services to life sciences industries in delivering active ingredients, advanced intermediates, and other building blocks of novel drug candidates,” highlights Thierry Durand, managing director of MINAKEM.



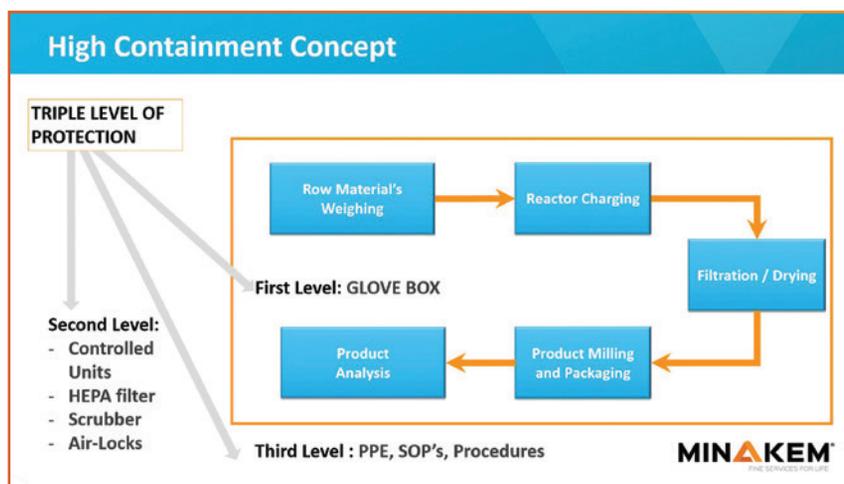
THIERRY DURAND,
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An Illustrious Suite of Products and Services

MINAKEM is a leader in processes like flow reactions, handling of hazardous chemicals, and HPAPIs, including cytotoxic molecules and low-temperature reactions. The company weaves a worldwide network with representatives in all key countries to provide its customers with a full suite of services through its experience in regulatory and project management services, in addition to solid-state chemistry. Moreover, catering to growing customer demands, MINAKEM also provides analytical services. The chemical expertise of the company includes, but is not limited to, particle size control and allotropic forms, C-C coupling, cryochemistry, enantioselective chemistry, along with high containment production and continuous flow processes. Innovation is part of MINAKEM’s DNA and is also catalysed by a worldwide collaborative research network with academic and private institutions to accelerate the resolution of chemical and process challenges.

Striving for competitive excellence, MINAKEM follows high-precision procedures for manufacturing pure products to meet stringent specifications with reduced carbon footprint and waste. Durand enthuses, “Our state-of-the-art cGMP (Current Good Manufacturing Practice) compliant manufacturing facilities, coupled with robust supply chain management, enable us to serve the global chemical and pharma industry.” MINAKEM delivers the right products to its customers upholding high supply performances through modern equipment (Around 8 percent of sales are invested in CAPEX per year), teams, and working processes (under Lean and Six Sigma). To highlight the brilliance of MINAKEM’s supply chain, Durand shares a recent engagement with a pharmaceutical





company. The client had a raw material supply shortage due to an explosion at a supplier manufacturing site—that could potentially impact their multi-billion business. MINAKEM has been able to qualify a new supplier for the specific raw material from its existing supplier list and avoid final product shortage.

Such proven knowledge and experience of MINAKEM give its customers the possibility to enhance their synthesis while improving their operational costs. To this extent, MINAKEM ensures the safety and reliability necessary to comply with regulatory protocols (sustainable development, GMP), and guarantees total confidentiality. Beyond MINAKEM's recognised expertise in process development, scale-up, commercial cGMP production, and HPAPI capability, their talented team also ensures high-quality services in quality assurance, route scouting, regulatory dossier approvals, and safety health and environment (SHE).

A Strong Geographic Footprint

MINAKEM made headlines in June last year as it entered the final qualification run to open a new close-controlled environment at the former Ajinomoto-Omnichem site in Louvain-la-Neuve, Belgium. This manufacturing site, serving as the current corporate headquarters of

MINAFIN Group, is specialised in vinca alkaloids HPAPI synthesis. Its activities in this area began with vinca alkaloids (vinblastine, vincristine, vinorelbine, and vindesine), a set of anti-mitotic and anti-microtubule alkaloid agents used for anti-cancer drugs with an operational exposure limit (OEL) as low as 0.1µg/m³. During the same period, the company also entered into several partnerships with the scientific community to develop laboratory processes further for the safe production of HPAPIs.

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Apart from the manufacturing site in Louvain-la-Neuve, MINAKEM has operations in two additional locations (Beuvry-la-Forêt and Dunkirk, France), which are all cGMP, FDA, and local

health agencies approved for large-volume or niche APIs and repeat or one-shot productions. These three main hubs are capable of handling 400 cubic metre reaction volumes, 1-20 steps organic synthesis, which can be scaled up from few grams to 300 tons for repeat commercial/generic APIs, with ten certificates of suitability (CEP) and 17 drug master file (DMF). The excipients of MINAKEM are manufactured to comply with the high pharmaceutical grade required by the industry (USP and EP Pharmaceutical Grades).

Furthermore, MINAFIN Group has its facilities across Leuna in Germany (Minascent), along with Pittsburgh (Pressure Chemical) and Memphis (Pennakem) in the U.S. Strong synergies between these MINAFIN Group facilities offers clients the flexibility, responsiveness, and cost-effectiveness in combination with the strong technical know-how to create significant value within their supply chains.

Foraying Into the Future

Having established itself as a global fine chemicals developer and manufacturer over the last 15 years, MINAKEM is now looking at an ambitious future. As Durand highlights, MINAKEM is currently poised to double its 2017 revenue to 200 million euros by 2023 through both organic growth and M&A. Besides, MINAKEM also aims to become a preferred partner for increasingly sustainable pharmaceutical solutions. To achieve this, the company will be extending its services around solid-state chemistry and analytics, along with the development of flow chemistry and continuous separations. MINAKEM, at the same time, is also poised to extend its global presence with additional sites either in the U.S. or in Asia. “We aspire to be one of the best places to work in the chemical industry with everyone contributing to support our clients to deliver timely, affordable, and sustainable medicines to the patients,” concludes Durand. 

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TECH OUTLOOK

CMO Edition

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Top 10 CMOs in Europe – 2020

The contract manufacturing sector is witnessing significant growth as the global pharmaceutical expands at a rapid rate. More and more companies are outsourcing drug manufacturing to contract manufacturing organisations (CMOs) to streamline production and reduce risks. The rising demand for generic medicines and the capital-intensive nature of the business has necessitated collaboration with efficient CMOs for clinical and commercial stage manufacturing. Also, it allows pharmaceutical organisations to focus their resources on research and development, thus, enabling them to gain a competitive edge in the pharmaceutical market.

In order to assist pharmaceutical companies in the daunting task of finding accomplished CMOs, we have crafted this issue of Pharma Tech Outlook. In this edition, we have compiled a list of the leading CMOs in Europe that are making significant contributions to the pharmaceutical sector. The companies listed here showcase extensive business knowledge and exhibit competence in delivering cutting-edge technologies and solutions that meet the needs of the customers.

We present to you Pharma Tech Outlook's "Top 10 CMOs in Europe – 2020."



Company:
MINAKEM

Description:

A fully integrated development partner and commercial manufacturer of APIs, HPAPIs, key intermediates, and building blocks for pharmaceutical companies

Key Person:
Thierry Durand,
Managing Director

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