

Saltigo at CPhI 2017, Frankfurt,
October 24-26, 2017, Stand 111H21

Even more attractive to life science and fine chemical industries

- Successful FDA audit – GMP recertification
- Saltigo keen to unlock new customer sectors
- Process development, production and registration expertise

Leverkusen – Saltigo GmbH, a subsidiary of specialty chemicals company LANXESS, will be exhibiting at CPhI 2017 as a flexible service-provider and one-stop supplier for the life science industries and users of fine chemicals. At the trade show in Frankfurt on October 24-26, 2017, the company will focus on its wide-ranging services for the exclusive synthesis of active chemical ingredients and intermediates.

Successful FDA audit – GMP recertification

Independent assessments have been confirming the high quality of the services on offer. In summer 2017, Saltigo passed another audit by the U.S. Food and Drug Administration (FDA) with a “No findings” rating. The auditors inspected its production and quality assurance systems in Leverkusen over a period of four days. During an inspection of this kind, the FDA assesses whether a medical product can be manufactured at the company’s production facilities using technology that is recognized in the United States as complying with the state of the art and applicable cGMP (Current Good Manufacturing Practice) rules. The auditors also examined quality assurance systems and all facilities used – from water treatment and clean rooms to filling plants and process control technology.

Shortly after this, in September 2017, the ultramodern multipurpose plant for manufacturing active pharmaceutical ingredients (APIs) and intermediates in Building O10 in Leverkusen obtained GMP (Good Manufacturing Practice) recertification. The official auditors did not have any objections. A total of over

Saltigo GmbH
Contact:
Ilona Kawan
LANXESS AG
Corporate Communications /
Trade & Technical Press
Kennedyplatz 1
50569 Köln
Germany

Phone +49 221 8885-1684
Fax +49 221 8885-4865
ilona.kawan@lanxess.com

200 metric tons of APIs and registered intermediates can be manufactured annually in the plant's four production modules.

"The result of these two audits acknowledges all the work we have put in. They are internationally recognized quality criteria and show not just U.S. customers but also pharmaceutical companies throughout the world that with us the production of active ingredients is in safe and reliable hands," says Saltigo's head of Marketing and Sales Andreas Klein.

Saltigo keen to unlock new customer sectors

In addition to the wide range of GMP-related services, which are primarily aimed at regulated industries such as the pharmaceutical sector, Saltigo also sees the manufacture of ISO products as an important and attractive area of business. This includes activities such as the custom synthesis of regulatory starting materials – i.e. starting materials for syntheses under GMP conditions – and other precursors. "Our extensive process development expertise, together with the piloting and production options at ZeTO, our Central Organics Pilot Plant, make Saltigo an increasingly sought-after partner for new, chemically challenging syntheses," says Saltigo's head of New Business Development Guido Giffels. "The company's broad technology base also offers attractive solutions in other fine chemical segments such as flavors and fragrances, performance chemicals or electronic chemicals. We are in the process of stepping up our involvement in these segments," he adds.

Saltigo is currently implementing a major investment program to ensure its synthesis capacity remains at the cutting edge of technology and meets the needs of customer projects. Some EUR 60 million is being invested at the Leverkusen site for this purpose. The redevelopment and expansion work, mainly at ZeTO, is on schedule and is due for completion by the end of 2017.

Process development, production and registration expertise

"Standing still is equivalent to taking a step backward. This is also true of synthesis chemistry and process technology, which are constantly undergoing dynamic further development. It is important for us to keep on augmenting our project pipeline with new, innovative synthesis tasks from all chemical substance

News Release

applications so as to be able to optimize the development and utilization of our technology portfolio and skills,” continues Giffels.

Saltigo is working on optimizing existing technical packages by improving space-time yields or simplifying processing sequences. It is also developing entirely new processes following consultation with its customers. This ensures that sufficient product volumes – for requirements such as clinical trials of an active ingredient or other use tests – are available quickly and reliably, with smooth upscaling to industrial volumes.

For example, Saltigo has developed a completely new synthesis route as an alternative to an existing pharmaceutical phase III project process that is difficult to implement. This new solution proved to be easily transferable to an industrial scale and also improves product quality. Saltigo has now successfully used this process to produce initial tons of the product for the market launch.

This is not the only example of Saltigo acting as a full-service provider in custom manufacturing. The LANXESS subsidiary’s service portfolio extends across the entire value chain – from synthesis planning through process development and piloting to campaign planning, standard production and supply chain optimization in consultation with the customer. Saltigo can also help its customers with the registration of new substances. In this way, the company supports them all the way through to market readiness of the end products and beyond.

Detailed information about Saltigo’s services can be obtained online at www.saltigo.com.

Saltigo GmbH is a leading supplier in the field of custom synthesis. The company of specialty chemicals group LANXESS belongs to the Advanced Intermediates segment, which achieved total sales in 2016 of EUR 1,742 million. Saltigo, headquartered in Leverkusen and with production facilities in Leverkusen and Dormagen, employs around 1,200 staff worldwide.

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Forward-looking statements

This news release may contain forward-looking statements based on current assumptions and forecasts made by LANXESS AG management. Various known and unknown risks, uncertainties and other factors could lead to material differences between

News Release

the actual future results, financial situation, development or performance of the company and the estimates given here. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

Information for editors:

All Saltigo news releases and their accompanying photos can be found at <http://press.lanxess.com>.

Detailed information about the company can be found on the internet at <http://www.saltigo.com>. You can find information concerning LANXESS chemistry in our WebMagazine at <http://webmagazine.lanxess.com>.

Pictures



Saltigo is investing currently EUR 60 million in Leverkusen – so as to increase our synthesis capacities for customer projects by around one third. The conversion and development work that is mainly being carried out at ZeTO (Central Organics Pilot Plant) as part of this investment project is running according to plan. The project is due for completion by the end of 2017.
Photo: Saltigo GmbH



The cGMP plant O10 of Saltigo GmbH in Leverkusen for manufacturing active pharmaceutical ingredients (APIs) and intermediates obtained GMP (Good Manufacturing Practice) recertification in September 2017 with “no findings”. The picture shows an eight-cubic-meter glass-lined vessel at the reactor level in the ultramodern multipurpose plant. Photo: Saltigo GmbH