Press Release

MARCH 2021

EXCiPACT certification for c-LEcta's high production standards

- Certified by EXCiPACT, c-LEcta's production and distribution quality standards exceed ISO 9001 requirements
- Certification is deemed an international seal of approval and guarantees the highest quality standards for pharmaceutical excipients and other critical materials used by the pharmaceutical industry, such as DENARASE, a c-LEcta enzyme product that is used in the production of biopharmaceuticals and vaccines
- Certification confirms c-LEcta's high quality standards and facilitates supplier audits by customers

Leipzig, March 2, 2021 – c-LEcta, a global biotechnology company with technology leadership in enzyme engineering and bioprocess development, can significantly reduce the cost of supplier audits for customers thanks to its recent award of EXCiPACT certification. The certificate confirms compliance with particularly high quality standards in production and distribution. For customers from the pharmaceutical industry in particular, these standards are an important criterion for qualifying suppliers and the closure of contracts. The certification significantly eases cooperation with new and existing customers for c-LEcta. EXCiPACT certification is internationally recognized and confirms that c-LEcta complies with "Good Manufacturing Practice" and "Good Distribution Practice" for pharmaceutical excipients.

As a manufacturer of enzyme products for the food and pharmaceutical industries, c-LEcta places major importance on the highest quality standards in production and distribution. Customers, especially in the pharma industry, conduct audits regularly of their suppliers to verify their compliance with strict standards. As early as 2011, c-LEcta introduced an ISO 9001-certified quality management system that covers all areas of the company and also meets additional requirements for the internal manufacturing of products for the food industry. As EXCiPACT certification sets out further strict standards that can also be found in the corresponding U.S. standard ANSI NSF 363, cooperation with U.S. pharmaceutical customers will be facilitated as well.

Dr. Ramona Schmiedel, Head of Operations, explains: *"Our EXCiPACT certification contributes to enhanced transparency and improved quality across the entire pharmaceutical value chain; it defines binding quality standards of Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) and combines them with ISO 9001 requirements. We therefore make a significant contribution to patient safety in the manufacture of our relevant products. c-LEcta is subjected to regular detailed audits as part of its supplier qualifications, and we work tirelessly to continuously improve our processes. We are therefore proud of the EXCiPACT certification, which demonstrates our successful work in this area and makes our efforts visible*

to customers. While this does not mean our work is over, it does show that we are at the forefront. We will, of course, continue to invest in improving quality; this is a matter of course for us."

The EXCiPACT certification program, launched by an international initiative of industry experts in January 2012, defines binding quality standards of GMP and GDP. EXCiPACT focuses on the production and distribution of pharmaceutical excipients and is internationally recognized in the pharma industry. The certificates therefore ensure transparency and improved quality. At the same time, they promote efficiency since recognized standards can be checked independently and fewer audits need to be repeated by customers. Following an extensive initial audit, surveillance audits are performed annually, followed by recertification after three years. In-depth tests and plant inspections are carried out on site.

As Dr. Marc Struhalla, founder and CEO of c-LEcta comments: "*The highest quality standards are a very important requirement for the production of excipients and critical materials used by the pharmaceutical industry. Proving compliance with these standards can be a major time and cost factor in this and other areas. With EXCiPACT certification for certain products, such as DENARASE, it will be even easier for us to attract new customers in the future. The additional certification saves customers time and money and guarantees that they always offer patients the highest standard of quality. The EXCiPACT report also helps us to explain our quality management system to our customers in other markets and to inspire their trust."*

The certification was carried out by DQS GmbH, an independent certification body recognized by EXCiPACT. The EXCiPACT certification is valid for three years and includes annual surveillance audits.

About c-LEcta

c-LEcta is a world-leading biotechnology company with a focus on enzyme engineering and application in regulated markets like the food and pharma industries. The company is based in Leipzig, Germany, and has established itself as a leading player in the realization of high-value biotech products, either in the form of in-house developments or in close cooperation with industry. The company currently employs more than 100 people.

c-LEcta delivers cost-efficient and sustainable production processes which open new markets and allow for better penetration of existing markets. The company is characterized by fast and efficient development of best-in-class biotech solutions and a rapid and successful market introduction and commercialization of the resulting products. This enables c-LEcta to leverage the unique potential of its core technologies. c-LEcta has a proven track record of more than ten successfully commercialized high-value industrial biotech products.

Contact

cometis AG
Matthias Kunz
Phone: +49 (0) 611 - 205855 – 64
Fax: +49 (0) 611 - 205855 – 66
e-mail: kunz@cometis.de