

Reinforcing Commitment to Quality and Safety:

## **ASKA Biotech Achieves ISO 13485 Certification**

Hennigsdorf, 30.06.2023

**ASKA Biotech, a leading contract manufacturer specializing in the production and purification of recombinant proteins and monoclonal antibodies and development and production of immunoassay, is proud to announce its recent achievement of the DIN EN ISO 13485:2016 certification, a significant hallmark in the field of quality management.**

This certification is a testament to ASKA Biotech's successful implementation of a robust quality management system that adheres to the globally recognized standard for medical device and in vitro diagnostic (IVD) manufacturing.

From the initial stages of production to the final release, customers in the clinical diagnostics and molecular biosciences sectors can now have full confidence in the safety and effectiveness of all ASKA Biotech's services.

By meeting the stringent requirements of the ISO 13485 Quality Management Standard, ASKA Biotech demonstrates its commitment to upholding the highest standards in manufacturing of raw materials for IVD-products. This certification further ensures the utmost product safety and effectiveness for customers.

"This ISO 13485 certification marks a significant milestone for our company, reinforcing our dedication to delivering exceptional quality and service to our valued clients. We strive to provide consistent quality to our customers, and this accreditation serves as tangible evidence that we have the necessary processes and systems in place," commented Alexandra Rindermann, Managing Director.

"With this important certification, ASKA Biotech is well-positioned to provide our customers all needed documentation and data for their IVD-product approval as we continue to serve them with the utmost dedication and excellence," agrees Siegmund Karasch, Managing Director.

### **About ASKA Biotech**

ASKA Biotech GmbH is an independent ISO 13485 and ISO 9001 certified contract manufacturing organization for the development and production of recombinant proteins, monoclonal antibodies and immunoassays for research, in-vitro diagnostic and preclinical trials. ASKA Biotech provides customized and flexible solutions for each specific requirement. In addition, ASKA Biotech offers various analytical methods to characterize the produced proteins. Immunoassay development, production and sample analysis complete the service portfolio. Based in Hennigsdorf, next to Berlin, ASKA Biotech was founded in 2018.

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