

Biognosys Announces GLP Certification of its Proteomics Facility by the Swiss Health Authorities

Biognosys is the first global proteomics service provider that is GLP certified for preclinical studies and GCP compliant for clinical studies

January 13, 2022 – ZURICH – Business Wire. Biognosys, a leader in next-generation proteomics solutions for drug discovery and development, announced today that it has obtained Good Laboratory Practice (GLP) certification from Swiss health authorities for preclinical studies. With this certification, Biognosys has become the first global proteomics service provider to be GLP certified, alongside being fully compliant with Good Clinical Practice (GCP).

This regulatory milestone showcases Biognosys' rigorous adherence to international research standards for preclinical and clinical studies. This achievement resulted from a [partnership with Roche](#) and the setup of an extensive quality management system for the purpose of using discovery proteomics in clinical trials, an effort that spanned several years.

Nadine Frankenberg, PhD, Head of Quality Assurance at Biognosys, commented: "The GLP certification by the Swiss health authorities is a strong recognition of our highly qualified personnel and the rigorous quality standards across all aspects of our services."

Karel Novy, PhD, Chief Operating Officer of Biognosys, stated: "Delivering the best possible data in terms of depth and quality has always been at the core of Biognosys' proteomics approach. Our recent GLP certification formalizes this long-standing effort and provides our customers with the opportunity to expand the use of proteomics across the full spectrum of preclinical and clinical studies."

The [GLP certification](#) is based on the Swiss Ordinance on Good Laboratory Practice and the Organisation for Economic Co-operation and Development (OECD) principles on GLP. The [certificate](#) has been granted following an inspection of the Biognosys test facilities by the Swiss GLP Monitoring Authorities.

For clinical studies requiring GCP compliance, the company conforms to the [ICH guideline](#) for good clinical practice and the [EMA reflection paper](#) for laboratories that perform the analysis or evaluation of clinical trial samples.

Biognosys operates one of the largest high-end mass spectrometry laboratories in the world for large-scale proteomics contract research, offering industry-leading throughput while maintaining unprecedented precision and depth. Thanks to its [experienced lab personnel, high-quality sample processing and high-throughput instruments park](#), Biognosys delivers projects with a fast turnaround time as required for clinical trials and routinely performs large-scale studies with more than 1,000 samples for global pharma and biotech customers, academia, or consortia.

Biognosys' discovery proteomics solutions deploy proprietary, patented Hyper Reaction Monitoring (HRM™) technology and optimized liquid chromatography - mass spectrometry (LC-

MS) workflows to search the complete proteome and quantify thousands of the most relevant proteins and peptide-level datapoints. They can be applied to tissues or biofluids across all biological species to provide a deep understanding of key disease pathways. In addition, the clinical transferability of this technology allows quick transition from early-stage discovery to specific, targeted panels that can be applied in a regulated setting.

About Biognosys

Biognosys is a leader in next-generation proteomics, dedicated to transforming life science by inventing and developing cutting-edge proteomics technology and solutions and making them widely available for pharmaceutical and biotechnology researchers and proteomics experts. The Company offers a versatile portfolio of proprietary proteomics services, software, and kits that provide a multi-dimensional view of protein expression, function, and structure in all biological species and sample types. Biognosys' unique, patented technologies utilize high-resolution mass spectrometry to quantify thousands of proteins across thousands of samples with industry-leading precision, depth, and throughput. Through advanced data analytics, Biognosys translates data into actionable insights for R&D and clinical research. More information at biognosys.com.

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