accelerō bioanalytics

Pressemitteilung / Press Release

Accelero Bioanalytics Approved as GLP Test Facility by Competent Authority

Berlin, October 12, 2015

Accelero Bioanalytics announced today that the *Berlin State Office for Occupational Safety, Health and Technical Safety* as the competent authority has performed an intensive GLP inspection in the company´s bioanalytical testing laboratories at the Berlin Adlershof location on 30 September 2015 and 01 October 2015. The facilities and archives as well as bioanalytical studies have been inspected.

As a result of the GLP inspection the authority recognized that the test facility Accelero Bioanalytics works in accordance with the principles of Good Laboratory Practice (GLP).

The GLP certificate according to Section 19 German Chemicals Act will include the testing categories 1 and 8. Testing category 1 comprises tests for the determination of physicochemical properties and content determination of drugs or drug-excipient mixtures. "In a so-called Impurity Test according the ICH Q3 A guideline bioengineered drugs are being tested for residues of the host organism", explains Christian Lange, the founder and test facility manager.

The testing category 8 includes analytical and clinical chemistry testing on biological material, for example, the detection of drugs in tissues, blood or urine, to allow a characterization of the active ingredient in accordance with regulatory requirements.

With the establishment of a GLP quality assurance, the Accelero team was supported by the expertise of Dr Knoell Consult GmbH in Mannheim. Mr Lange goes on: "We are very pleased that with Mr. Joachim Hajok we could inspire an GLP expert with decades of experience for our small but nice team". Mr. Hajok formerly was the head of the GLP quality assurance unit at the BASF experimental toxicology and ecology site in Ludwigshafen, Germany.

"Four years after the company was founded our motivated Accelero team has reached a new level of quality, which has not been seen before in this form. In retrospect it was not easy to assign positions of the classical GLP organization chart to the Accelero collective members, "Mr. Lange notes with a grin. "But we already register an increased attention in terms of our expertise and our services. Together with our clients we look forward to innovative and exciting projects ".

About Accelero Bioanalytics

The company is a privately held contract research organization (CRO) with headquarters in Berlin. Main focus is the marketing of bioanalytical services for research-based pharmaceutical and biotechnology companies. The service team develops and validates custom-made bioanalytical testing methods as requested for the characterization of novel drugs or therapies prior to an authorization procedure.

After its foundation in 2011, followed by an intermediate phase of establishment, the company opened new laboratory facilities in February 2015 in Berlin Adlershof. The laboratories are approved for projects of the genetic engineering safety level S2. For processing human pathogen projects the company was granted a permission according to Section 49 German Infection Protection Act. Since 01 October 2015, all projects can also be covered by a quality assurance program which fully complies with the principles of Good Laboratory Practice (GLP).

Your Contact to Accelero Bioanalytics:

Christian Lange

Test Facility Management

Managing Partner

GLP Test Facility Address:

Accelero Bioanalytics GmbH

Center for Biotechnology and Environment

Volmerstrasse 9A

12489 Berlin

GERMANY

Telefon: +49 30 610 910 300 (Office)

+49 30 610 910 307 (GLP Testing Laboratories)

Email: service@accelero-bioanalytics.com

Internet: www.accelero-bioanalytics.com