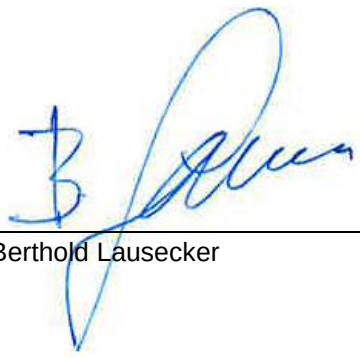
Management change at the
Analytisches Zentrum Biopharm GmbH

Ladies and Gentlemen,

with this letter we would like to inform you that **Dr. Berthold Lausecker** and **Dr. Martin Reinsch** have been appointed equal managing directors of the Analytical Centre Biopharm GmbH with effect from 01.01.2019.
Dr. Lausecker has thus strengthened the team as of 01.01.2019 and will take care of R&D and business customer support in his function. Dr. Reinsch, who has held various key positions in the company since 2005, will continue to be responsible for operations as Head of the Testing Facility (GLP) and Head of Quality Control (GMP). Both will work together with their analytical competence on the further development of AZ Biopharm for the benefit of our customers and will be available to them without restriction as contact persons. Dr. Berthold Lausecker and Dr. Martin Reinsch are looking forward to the upcoming tasks and hope for a fruitful cooperation with our clients and partners.



Dr. Berthold Lausecker

Dr. Martin Reinsch

Dr. Berthold Lausecker studied chemistry at the University of Leipzig. After his studies, he worked as a graduate chemist at the Central Institute for Organic Chemistry of the Academy of Sciences in Berlin-Adlershof in the Central Analytics Department. In 1991, he joint F.Hoffmann-La Roche, Basel, where he initially worked in the bioanalytics of clinical development with the establishment of an LC-MS assay for retinoids. In 1992, the analytical laboratories of clinical research were integrated into the bioanalytical department of the preclinical development department as part of a reorganization. Under the direction of Prof. G. Hopfgartner (now University of Geneva), electro- and ionspray- LC-MS/MS was introduced into bioanalytics as an analytical tool.
From 1993-1997 he did his PhD thesis as an external PhD student at the Organic Institute of the University of Zurich under Prof. Manfred Hesse on a hyphenation theme of micro-LC or capillary zone electrophoresis to electrospray-MS/MS as a possible tool in bioanalytics. In 1996 he was promoted to head of laboratory and in 2002 to head of bioanalytics department. From 2002 until he left the company in 2011, he was head of Bioanalytics at F. Hoffmann-La Roche with more than 30 employees, including up to 7 academics. During this time, he completely replaced HPLC-UV with LC-MS and LC-MS/MS as standard methods in bioanalytics. In addition, a group for the analysis of biomolecules was established during this time. In 2004, he founded the German-Swiss 7-Circle for Bioanalytics, which brought together the responsible bioanalysts of the leading Swiss and German pharmaceutical companies to discuss upcoming regulatory and scientific topics related to bioanalytics. Finally, the 7-Circle was the founding source of the EBF (European Bioanalysis Forum), which celebrated its inauguration in Berlin in 2006. From its inception until 2011, Dr. Lausecker was a Steering Committee Member and one of Board of Directors member responsible for the development of the EBF. In addition to organizing the annual open symposia and internal EBF meetings, Dr. Lausecker was instrumental in preparing the European Guideline for Bioanalytical Method Validation (Brussels 2011).
From 2011 to 2015, Dr. Lausecker worked as Director of Bioanalytics at CRS (Clinical Research Services) Mannheim, where his tasks included bioanalytics of chemical and biological drugs from preclinical and clinical trials as well as advising clients on pharmacokinetics and ADME. From 2015 to 2017, Dr. Lausecker worked in the GMP test laboratory Phytos in Neu-Ulm as site manager and managing director. In 2017, he moved to IIS (Innovative Injektions Systeme), a subsidiary of Lohmann Therapie Systeme (LTS) in Andernach, as head of Analytical Development. IIS is engaged in the development of needle-free and microneedle systems as an alternative drug administration route.

Dr. Martin Reinsch studied food chemistry at the Technical University of Braunschweig. After completing his studies, he completed a one-year practical phase at the Braunschweig Food Testing Office and the Lüneburg Institute for Consumer Goods, graduating as a state-certified food chemist. He then moved to the Federal Institute for Materials Research and Testing (BAM) where he received his doctorate from 2002-2005 under the direction of Prof. U. Panne on the topic "Development of analytical methods for the determination of ochratoxin A in foodstuffs" using LC-ESI-MS/MS as well as complex enrichment and purification methods such as immunoaffinity and mixed-mode SPE. Another key point of the doctoral thesis was a feasibility study on the production of ochratoxin A containing certified matrix reference materials (CRM) based on food. In 2005, he moved to AZ Biopharm GmbH as study director, where he was promoted to head of the bioanalytics laboratory in 2007, head of the bioanalytics department in 2011 and deputy head of quality control with general power of attorney, and plant manager in 2016. In this position, he was head of the testing facility (GLP) and head of quality control (GMP) at the same time as managing the company with a total of 22 employees and up to six academics. During his time at AZ Biopharm GmbH, he established numerous new techniques, including LC-MS/MS in bioanalytics as well as numerous standard methods in pharmaceutical quality control and computer-aided systems for the calculation, condensation and documentation of regulatory relevant bioanalytical results (LIMS). From the time he joint AZ Biopharm more that 500 regulatory studies (safety and mainly BE studies) were successfully completed under his supervision.

About Analytisches Zentrum (AZ) Biopharm GmbH Berlin

AZ Biopharm Berlin GmbH is a German contract research organization located in Berlin with a broad experience in bioanalytical and pharmaceutical analysis for human and veterinary medications. Our goal is to relieve our sponsors from routine practices reaching a high quality standard in analytical service processes. Achieving these goals, AZ Biopharm adhere to strict quality criteria and specialization in bioanalytical and pharmaceutical analytics. Also validated state-of-the-art equipment and trained laboratory staff helps us guaranteeing highest quality. All studies are carried out according to national and international guidelines (ICH, ChemG, Ph.Eur., USP, FDA, EMEA) following our own developed and validated assays or assays transferred from our sponsors. Our test facility is GLP (category 1 and 8), GCP and GMP certified by responsible national authorities and was successfully audited by BfArM and AGES. The facility helds the manufacturing authorization according § 13 AMG, the permission to handle narcotic (BTM) and highly active and toxic substances. AZ Biopharm has currently the capacity to run anually 75´000+ samples and to test and release 200+ batches of drug product on a monthly basis. For more detailed information please visit:
https://www.az-biopharm.de/