

## Contract quality control of biopharmaceuticals

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More and more companies understand the advantage of contracting services such as those offered by NewLab BioQuality. Contracting out these services instead of developing them in-house will assist companies in maintaining their timelines and allow them to stay focused on their core strengths. We consider our clients to be long-term partners and not strictly clients. Our partners have included virtual and small biotechnology companies, medium sized pharmaceutical companies as well as global pharmaceutical corporations.

NewLab BioQuality AG is a service provider of quality control analysis to the biopharmaceutical industry. Our broad-based technologies as well as our commitment to customer satisfaction has convinced many companies that we are a reliable partner. Our services and quality control systems are internationally recognized as GLP/GMP compliant and satisfy the regulatory authorities worldwide.

NewLab BioQuality's modern laboratories are located in Erkrath near Düsseldorf, Germany. The company currently employs a multidisciplinary team of more than 60 individuals and has the following core businesses:

- Cell line characterization and safety testing of prokaryotic and eukaryotic cell banks
- Genetic stability studies
- Process Evaluation for viral and prion inactivation or removal
- Determination of residual impurities including DNA, host cell proteins, media components, etc.
- Protein chemistry for product characterization (identity, purity, integrity)
- Bioassays
- Plasmid analysis and DNA sequencing
- Stability testing of proteins and plasmids

NewLab BioQuality is also actively involved in process development for mammalian cells. Experts are available in both upstream and downstream development to assist our clients. We can develop their production process up to the 100 liter scale. As a provider of contract quality control analyses using both classical and innovative methods together with our ability to develop production processes, we can minimize the time it takes our clients to get into clinical trials.

### **Quality**

The analytical testing performed at NewLab BioQuality AG is compliant to Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) standards. The results of the analysis and our reports are accepted by regulatory authorities worldwide. In addition to routine inspections by the German authorities and our clients as well, an FDA audit was successfully passed in 2004.

Our quality system insures that all analyses are fully and transparently performed from the planning stage, the execution of the study itself, through to the reporting of the results. This type of quality service allows our clients to integrate the analytical results directly into their drug authorization documentation. NewLab BioQuality AG offers a comprehensive validation program in accordance to the ICH Q2A, Q2B guidelines. Our assays are fully validated before they are used for our clients test samples. Matrix-specific validation is also performed when required and requested.