Hessen: Gateway to Biomanufacturing in Europe
A Practical Guide to Sites and Services for GMP-Production - Quality Management - Contract Manufacturing
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Sites and Services for Biomanufacturing
Biopharmaceuticals are the drugs of the next generation and will help to fight major diseases such as cancer, diabetes and infections. The life science industry therefore faces the challenge to satisfy the growing demand of safe and effective biotherapeutics by establishing a competitive biomanufacturing sector.

Key to success are cooperations and networks between all players in the drug development process. In this brochure, renowned experts provide insights on various aspects of biomanufacturing, followed by a business directory of companies and institutions in Hessen that are involved in the production of biopharmaceuticals.

Hessen is in pole position for biomanufacturing: The state covers the entire value chain of biopharmaceutical production – from expertise in drug discovery, process and plant development, contract manufacturing, quality management to a strong service sector in the areas of registration and marketing. And with the Paul-Ehrlich Institute in Langen, Hessen hosts a central national regulatory authority which is in charge of approving particularly innovative recombinant drugs or gene and stem-cell therapies.

Roundabout 50 companies offer single or comprehensive biomanufacturing solutions for drug development firms on various cooperation levels. This industry has been built on the foundation of a substantial concentration of pharmaceutical companies. Especially the Rhine-Main Region is thus a prime global production and distribution spot for biopharmaceuticals.

In addition, the sheer size of the pharmaceutical industry in Hessen in general and the underpinning life science research taking place at universities and high ranking research institutions in Frankfurt, Giessen and Marburg have led to the development of highly specialized skills.

The Hessian Ministry of Economics, Transport, Urban and Regional Development intends to pave the way for cooperative ventures between biotech and other branches in the biomanufacturing industry. Therefore, this brochure is designed to provide insight into the potential of Hessian’s competence in biomanufacturing and to serve as a business guide for companies that are seeking cooperation partners for the production of biopharmaceuticals. Please make use of it and try out the business-opportunities in Hessen.

Dr. Alois Rhiel
Hessian Minister of Economics, Transport, Urban and Regional Development
Biopharmaceutical market on the rise

Biotechnology is gaining ground in the pharma market: As a result, many medicines today are now manufactured by biotechnological methods. Approximately one-fourth of all newly approved pharmaceuticals in Germany are bioproducts, such as antibodies, hormones or therapeutic proteins. Their main applications include treatments for major diseases such as cancer, viral infections, and diabetes.

Biomanufacturing: Essential part of the drug development value chain

The biopharmaceutical boom demands efficient production sites to accommodate a growing pipeline of therapeutics. Recent advances in bioprocess technologies have resulted in high outputs, thereby minimising costs and time to market - exactly what the pharma market calls for. Therefore, investors and biotherapeutic companies increasingly draw their attention to biomanufacturing issues as a key step to secure the whole drug development value chain.

The production of biopharmaceuticals is a complex process that must be closely coordinated with clinical development. Typically, designing the biotechnological process occurs parallel to target identification. As soon as a biotechnological drug candidate needs to be tested for efficacy and toxicology in preclinical studies, the biological substance has to be produced at a small scale and with consistent high quality - a process that many companies can handle internally. The appropriate time to step into professional biomanufacturing is during or at the end of the preclinical stage. Before drug candidates can be tested in humans as part of clinical tests, the complete manufacturing process has to be outlined according to the strict rules of Good Manufacturing Practice (GMP). These regulations include a seamless, quality controlled production process, from cell line or expression organism up to the production of clinical testing material along with exact documentation of all steps.

Hessen offers the complete landscape of bioproduction

When it comes to GMP-production, Hessen has it all: The region offers a wealth of products and services to biomedical companies via its comprehensive and closely knit network of contract manufacturers, process engineering companies, quality management and control services as well as national regulatory authorities.

Large biopharmaceutical production capacities in Hessen

The state hosts the world’s most innovative manufacturing facilities for recombinant insulin at the sanofi-aventis facilities in Frankfurt as well as the Sandoz Industrial Products GmbH. With Novartis-Behring in Marburg, Hessen also possesses a world leading vaccine production facility.
Contract manufacturing in the Rhine-Main area

Hessen’s contract manufacturing companies are concentrated in strategic proximity to the pharmaceutical cluster in the Frankfurt area. W.C. Heraeus in Hanau, for example, is known as a leading manufacturer of metal compounds but also serves the pharma market not only with the development of metal-based active pharmaceutical ingredients but also with biotechnological contract manufacturing. Another partner for biomanufacturing is the Frankfurt-based Cellular Products Division of Miltenyi Biotec, which provides the biotech industry with a variety of clinical-grade cellular products and offers GMP contract manufacturing of cellular therapeutics, including regulatory/legal issues and logistics.

Unique GMP-engineering expertise

Hessen’s competitive edge in GMP-biomanufacturing is its concentration of expertise and experience in industrial engineering, such as process development or plant building. This sector, historically linked to the pharmaceutical business, now also offers state-of-the-art solutions for biomanufacturing.

Industrial parks: Biomanufacturing under a single roof

Industrial parks provide a wealth of services for drug development, an advantage that saves time and money. The Industry Park Höchst in Frankfurt is a classical chemical and pharma location with more than 22000 employees, offering all competence areas of a professional infrastructure - ranging from R&D laboratories to production sites. Another potent biomanufacturing management and service location is the industrial park Behringwerke in Marburg, situated in the North of Hessen. The park offers support for various production steps of biopharmaceuticals, such as buildings, plants, energy, technologies, and consulting.

Sartorius BBI Systems in Melsungen, for example, is a specialist for bioreactor technology. Pharmaplan, a Fresenius subsidiary in Oberursel, or Chemengineering in Wiesbaden provide technologies and consulting services in process development for GMP-production of mammalian or microbiological cell culture plants.

In addition, being a traditionally strong IT-location, Hessen offers a broad spectrum of bioinformatic services for biopharmaceutical applications.

Hessen: Platform for biopharmaceutical production

The growing biotech market needs to create value from its growing pipeline of biopharmaceuticals and therefore demands broadened biomanufacturing services. To save time and money, biomedical companies will be looking to outsource various drug development steps or require expert advice on in-house production. They will find the entire biomanufacturing network in Hessen: The state combines GMP-expertise and experience with the proximity of all industries required for production of biopharmaceuticals to a tightly knit, internationally competitive business network, topped off with a broad financial and consulting sector.

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The biotechnological production of pharmaceuticals according to the regulations of Good Manufacturing Practice (GMP) involves a multitude of steps in different areas of research, development, production and quality management.

Planning ahead minimizes risks and expenses

Many factors influence a company’s decision to produce biotechnology-derived active pharmaceutical ingredients (API) for clinical studies. Usually, minimizing the “time to market” has highest priority. Therefore, this precious resource should be used efficiently by planning ahead. Before a decision is made for or against an in-house GMP-production, a detailed evaluation of the entire process should occur. In principle a company chooses between two venues with resulting strategies:

- Experts forecast a high chance (> 50%) that the API will succeed in the clinical studies or
- A success prognosis can only be made after the evaluation of the clinical studies (Phase II, Proof of Concept)

In the first case, a quick proceeding of the API from development to market approval is essential. All project teams involved should engage in preparations for registration as early as clinical phase I. Essential steps are the specification of the commercial scale, the swift transition to production scale-up, and the development of analysis systems, such as HCP-ELISA or validation programs.

In the second case, the overall goal is to get to the proof of concept quickly and cost-saving by lean and efficient GMP-management in order to keep eventual losses small in case the API should not succeed.

There are a number of cost and timesaving options to fulfil GMP-regulations in the development and biotechnological production of APIs without exceeding the authorities’ requirements for this phase.
High hurdle GMP-production: Reaching the goal with a plan

Deciding to undertake GMP-production poses high demands especially on small companies. Careful planning with a definite aim (either a swift market entry or a quick accomplishment of the proof of concept) is therefore imperative. To this end, a project leader defines milestones and sets up a project plan including regulatory requirements, process development details, critical test parameters, validation steps and a time line.

Especially the execution of GMP-licensing requirements requires careful preparation. Typical mistakes in this context are a lack of knowledge of relevant regulations, along with their incorrect interpretation or application on individual project specifications. In addition, the need for qualified personnel should not be underestimated: Depending on the product, a staff of 10 - 30 will be tied up with the project for a considerable period of time.

Specific requirements for the production of clinical test material

Already during preclinical development, GMP-requirements govern the process- and plant development. As soon as APIs are produced for clinical test phases I and II, patient safety is of highest priority. Manufacturing of the pharmaceutical ingredient must take place in suitable facilities under stringent conditions. Individual GMP-concepts have to be carried out and documented for the production and release of each single API-batch. In addition, the German pharmaceutical law requires a license for the production of clinical grade test material and the assignment of a manager in charge of biomanufacturing, quality control and sales. Since 2005, this so called “qualified person” has to be approved by authorities and is liable for the release of APIs.

In the early phase of preclinical development, the manufacturing process and the quality control procedures should still be kept flexible to allow for necessary adjustments. At the beginning of clinical studies, for example, a “Master Cell Bank” of the production cell lines has to be set up and approved. Usually at clinical phase III a validated “Working Cell Bank” has been established.

Validation and quality control

Before their application in humans, pharmaceutical ingredients have to be tested for efficacy and toxicity. Quality control includes not only the final active ingredient but also intermediate products and even packing material. Appropriate analytical methods are therefore of tremendous importance, and all specifications and steps of quality control have to be documented before-hand. If the manufacturing process involves toxic components, a toxicologist should be involved early on.

In addition, potential viral contaminations have to be removed or inactivated before starting clinical phase I. The inactivation and removal requirements during clinical phases II and III are extended. Despite elaborate control programs, an action plan should define necessary steps to deal with production or quality problems, and a recall-system for later detected faults should be established in due time.

SellWiss provides advice on the entire biomanufacturing process

SellWiss GmbH supports companies in their effort to master the plethora of regulatory requirements and the elaborate project management demands in the production of APIs and subsequent drug products, from clone selection to commercial scale production. SellWiss’ consultation services also include advice on authority requirements and are based on many years of experience in obtaining authority approvals in the area of GMP.

SellWiss chooses a systematic approach for its consultations: At the beginning, all requirements of the clients’ API-production are summarized in a table which is subsequently analysed. These data are the basis of a thorough inventory which leads to the development of decision aids, strategies and necessary steps.

SellWiss’ competencies cover the entire value chain for API production, and its consultation services include cost- and process analysis as well as advice on personnel and authority requirements.

Dr. Karl-Heinz Sellinger
SellWiss GmbH
Biotechnological substances for the manufacturing of pharmaceuticals are highly active and sensitive ingredients, which are subject to restrictions imposed by the pharmaceutical law. The import and biotechnological production of active pharmaceutical ingredients (API) and their processing into medicines must therefore undergo authorization. In Hessen, the District Government in Darmstadt issues the necessary production licences for Good Manufacturing Practice (GMP). The GMP-monitoring activities of the competent authorities focus on the inspection and approval of production plants for APIs. Inspections at production sites in Hessen or European countries are held on a regular basis, on average every other year.

National and international interfaces and cooperation

A multitude of regulatory hurdles have to be passed before a biopharmaceutical product can be released to the market: After the approval of a production license by the District Government in Darmstadt, the European Medicines Agency (EMEA) in London conducts the evaluation of the medicinal product. The EMEA-approval is a prerequisite for the registration of a drug for the European market.

The District Government’s international contacts facilitate direct communication at the approval-interfaces between European authorities. In all cases, the international monitoring of the pharmaceutical trade in Hessen demands a high degree of cooperation with domestic and foreign institutions. To promptly deal with license applications, members of the competent authority are therefore represented in relevant national and international boards. They are actively involved in decision making, e.g. at the expert committees of the “Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten” (ZLG) or the Ad Hoc Inspectors Working Group of the EMEA. In this manner, German expert groups – with the involvement of Hessian authorities – compile working papers according to the European framework as basis for international approvals. This quality assurance system, which contains guidelines for inspections and instructions for approval procedures, has been highly acclaimed by the European Commission and Canada. Therefore, Hessian certificates are recognized internationally. The systematic approach of the District Government, along with its internal and cross-national coordination, grant companies a high degree of planning reliability as well as quick and transparent decision-making.

The authorities in Darmstadt focus on the prompt handling of registration procedures. The combination of measures for new applications or the project coordination with other authorities or internal offices set an example for time-efficient teamwork.

Thorough preparation for inspections is a prerequisite to success

The manufacturing of biotechnological substances requires a number of precautions. Especially the compliance with technical specifications and the microbiological status of sterile products have to be monitored closely. The main task of the Hessian inspectors is therefore to control biomanufacturing plants for APIs on-site. Audits of industrial facilities are conducted by Department VI 65.2, with its seven inspectors and nine fellow employees at the District Government in Darmstadt.

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<th>District Government</th>
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<td>Licence for import, production and processing of APIs and pharmaceutical products, Inspections, Certificates</td>
<td>Evaluation and handling of registration applications for biopharmaceuticals, Coordination of inspections</td>
<td>European Registration</td>
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 Authorities and registration procedures involved in the approval of APIs and biopharmaceuticals in Europe.
The overall goal of the competent authorities is to provide proficient and efficient consultation for “bio-”manufacturing companies on licences and certificates in the forefront of inspections, thereby granting planning reliability.

In addition, companies can do their own preparations by looking up inspection proceedings and procedures, which are defined by the pharmaceutical law. Yet, time and again, companies underestimate the requirements for a licence approval. Typical, upfront mistakes include inapt zoning concepts or insufficient plant qualifications. Companies planning to build a plant for biotechnological API production should therefore follow the EU-guidelines and the relevant national and European body of rules and regulations. In case of doubt, they should contact the competent authorities. By establishing a communication platform for all relevant issues, potential problems can be openly discussed upfront, and the actual inspection can proceed smoothly with a high likelihood that the audited company will meet the necessary requirements.

In the case of complaints, faults or pharmaceutical incidents, however, the District Government in Darmstadt reacts quickly and transparently.

The District Government has long standing experience with approvals in various branches of the biotech or pharmaceutical industries. Examples include the insulin research facilities at sanofi-aventis in Frankfurt, the manufacturing of APIs and pharmaceuticals at ZLB-Behring (Marburg) and the cancer research business unit at Merck in Darmstadt, where APIs and drugs are produced.

In addition, inspections in China, India, Cuba, South-Korea, the USA and other countries are on the agenda as well as auditing activities in Hessen. A team of inspectors evaluates compliance with international standards and regulations by examining the manufacturing site and by checking required documents. In these projects, the District Government in Darmstadt cooperates with the other federal authorities either directly or via the ZLG.

When a company has passed inspection, the certificates for a production plant or import/export are issued immediately. The regional authority’s competent and efficient proceedings ensure not only the quality and safety of APIs, but also a quick approval policy - an advantage that companies in Hessen highly appreciate.

The district government Darmstadt: responsible for many aspects of public life

The District Government in Darmstadt is one of Hessen’s largest regional authorities, responsible for the Rhine-Main/South-Hessen region - an area with approximately 3,7 Mio. people. The agency governs many areas of public life, such as infrastructure advancement, environmental protection, health care, data protection, immigration law, consumer protection as well as occupational and radiation safety. These fields entail a multitude of approval, monitoring and control tasks. The District Government in Darmstadt is also responsible for the supervision of pharmaceuticals and hence for GMP-inspections in Hessen. The inspections, licenses and certificates are recognized by European countries and MRA-nations (which signed a Mutual Recognition Agreement).

Rudi Völler,
Regierungspräsidium Darmstadt
Head of the Pharmacy-Department II
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Novel biomanufacturing processes require special expertise

Modern biotechnology has a growing impact on the production of fine chemicals and food or dietary supplements. In recent years, industrial applications of biotechnological methods have profited from significant progress in proteomics and metabolomics. Novel technologies that utilize technical enzymes are therefore gaining ground and demand special expertise in biomanufacturing. The typical drug discovery company needs partners for plant and process development, especially when it comes to scale-up from pilot to commercial production. In addition, the production of innovative biopharmaceuticals requires a solid foundation in Good Manufacturing Practice (GMP), which is usually brought in through external consultants.

Flexible Multi-Purpose Units cut production times for innovative biopharmaceuticals

The development of innovative biopharmaceuticals is a cost and time intensive process. Short patent protection periods require rapid and efficient exploitation of production capacities, often even before the drug candidate has successfully passed clinical tests. Therefore, "time to market" is a crucial issue in the design and development of biopharmaceutical plants - equally as important as safety and quality.

Modern production plants in the biopharmaceutical industry are characterized by their high degree of flexibility and efficiency. Multi-purpose units are especially well suited to adapting to the specific requirements of dynamic production strategies, which is made possible by a complex automated process control. In addition, modular plant construction reflects the flexible nature of bioproduction processes. Special attention has to be paid to the design of the interfaces between the different modules. In general, planning and building of multi-purpose units is a challenge that requires special expertise and know-how, quality features with which Chemengineering has proven its competence.

Since timing is crucial in biomanufacturing, the final stages of plant and process development should already be completed in the early phases of drug development, during small scale production of clinical grade test material. This step is often outsourced to contract manufacturers and allows the simultaneous realization of a custom tailored, in-house production facility.

Always in mind: GMP-Regulations

The complexity of biological systems requires specific measures in facility construction ranging from pipeline design and reactor geometry to keeping premises sterile. All these features have to comply with the strict GMP-regulations. Therefore, biopharmaceutical production is particularly subject to meticulous supervision by control authorities. The effort associated with the mandatory procedures for plant and equipment qualification or process validation should not be underestimated, and authorities should be involved at an early stage.

Customized bioproduction is a matter for experts

Biotechnological production processes are in a unique way characterized by the employed biological system. The plant has to meet the terms of the specific process requirements of a given cell type or microorganism. Optimal yields and a cost-effective production can only be achieved when bioreactors, cultivation parameters, cell harvest, and purification procedures are adapted to the particular cell type and to the valuable and often highly sensitive product. Therefore, product specific downstream processing plays a crucial role alongside optimized cultivation conditions. Multiple-step chromatography systems and membrane filtration procedures such as micro- and ultrafiltration are often part of the complex routine of purification and concentration. Chemengineering is an expert service provider with relevant biotechnological references: Our references cover
plants for all common cell types and microorganisms. The production spectrum includes recombinant proteins, secondary metabolites and nucleic acids.

**Integrated project teams can handle complex issues**

Chemgineering handles projects successfully by combining technical know-how in biomanufacturing with the expertise of experienced process engineers from diverse backgrounds. Any given project team cooperatively solves the recurring issues related to pharmaceutical and biopharmaceutical plant design. Our technical biomanufacturing personnel work hand in hand with process engineers to establish infrastructure, plants, and machinery, e.g. in the areas of CIP/SIP, media preparation, supply and waste treatment. Specialists in process automation and architecture (clean room design, zoning) as well as in quality control and validation are integrated into the project team. The complexity of issues from design to construction of biopharmaceutical plants demands well adjusted project teams with experienced project leaders and qualified engineers. Our customers benefit from our longstanding record in the field.

**Chemgineering: experienced and competent partner for plant development**

In previous years, Chemgineering, with its subsidiary in Wiesbaden, has demonstrated its expertise in the expanding biotechnology market. Its client project portfolio includes the fermentation of vitamins, the purification of blood plasma products and the manufacturing of bacterial vaccines. The size of designed and completed plants ranges from small pilot plants with a fermentation capacity of 50 l up to production facilities with a yearly production of some 10 kt.

*Dr. J. Carsten Hempel*

*Chemgineering GmbH*
Trends in Bioproduction: Modular Systems and Disposable Components

The production of active pharmaceutical ingredients is a multi-step process with increasing complexity along the way. For example, the reaction parameters and volumes of a substance vary several times during bioproduction. Interfaces in process development, e.g. the transition from small to commercial scales, often represent major challenges for the producing company. Previously optimal reaction parameters have to be adapted to the requirements of a larger bioreactor within a short period of time to achieve a higher yield, while at the same time maintaining the biological substance’s high quality and reactivity. Furthermore, the system has to meet the high regulatory requirements of Good Manufacturing Practice (GMP). It is therefore obvious that process optimization harbours increasing entrepreneurial risk rises.

Comprehensive process optimization by modular systems facilitates interface management

Biomanufacturers are hence looking for solutions that cover the entire scope of fermentation and bioreactor technology and that are suitable for all applications and volumes, thereby eliminating all troubles with process interfaces and facilitating quality management. Modular systems with a clear platform strategy are advantageous because they offer machines and plants with the same equipment and automation scheme within a certain performance class (Economy, Standard and Mass Customization). The rationale is to smooth the sequence of transition from lab to pilot and finally to commercial scale.

Next generation bioproduction with disposable components

The current trend in process and plant development focuses on the issue of “single-use” products. Validation and purification procedures can be reduced to a minimum by utilizing disposable systems. Along with improved process safety and easier handling, single-use components offer additional advantages: they are always available, flexible and enable a quick and inexpensive change of products. The development of disposable components for bioreactors began years ago in the area of gassing and perfusion systems. The future will bring single-use systems into the entire biopharmaceutical process chain; the first qualified complete systems will be on the market this very year. Sterile, ready-to-use modules for the complete fluid handling process promise to render biopharmaceutical production safer, more flexi-

Multiple Purpose Units enable cost-efficient production
ble and more cost-efficient. The advantage is obvious: customers can decide for themselves which areas of the process chain they want equipped with disposable components and which parts they would rather run with conventional equipment.

**Adherent cell cultures for a higher yield**

Human or animal cells usually live adherent, meaning they grow on a natural substrate. For many industrial processes however, these cells have been adapted to a life in suspension or, as is the case for shear-sensitive cells, are cultured on microcarriers. An example is the production of blood-derived factors from cultured blood cells. Since the productivity of most cells is higher in their natural environment than in suspension, more and more adherent cell cultivating processes will be used in the biopharmaceutical industry in the future. Especially in the growing field of tissue engineering, adherent cell culture systems will be needed for the development of tissues or organ systems.

**Sartorius BBI Systems combines innovation and tradition**

As a biotechnology system supplier, the focus of Sartorius BBI Systems in Melsungen is on the development of novel technologies for bioproduction, e.g. in the area of process automation. Furthermore, Sartorius BBI Systems utilizes synergies with the Sartorius-corporation to integrate various steps of the downstream process into the increasingly complex systems. Over the last decades, Sartorius has also acquired considerable expertise on disposables in collaboration with developers of synthetic-based materials. This expertise is of particular advantage when it comes to the registration of novel materials by the FDA (Federal Drug Administration).

Since 2000, Sartorius BBI Systems is a subsidiary of the Sartorius AG in Göttingen, which currently employs around 3,600 people and goes back to 1870, when it first started becoming an internationally acclaimed provider of laboratory and process technologies. For the development of innovative technologies, Sartorius BBI Systems relies entirely on the skills and experience of its employees in Melsungen, where its team, consisting predominantly of engineers, focuses on the areas of sterile design, automation and software development. Clients can get advice on the entire bioproduction process chain: from research to commercial production, Sartorius offers the suitable system for every scale-up step.

Bernd-Ulrich Wilhelm
Sartorius BBI Systems GmbH
Capitalizing on Synergies: Contracting out Bioproduction

Demand is on the rise for pharmaceuticals that can only be produced economically with a biotechnological, rather than classic chemical approach. With novel medicines, as well as with generics, the key to success lies in minimizing expenses. Many companies therefore save themselves the cost, time, and regulatory burden of producing biotech substances in-house by opting for collaboration with a contract manufacturer.

Recipe for success: Close cooperation right from the start

Contract manufacturing for biologicals demands a great deal of close cooperation and trust. Effective teamwork is a prerequisite to fully taking advantage of synergies between biotech company and biomanufacturer. The best time to initiate contact is right at the start, because a drug’s development, scale-up, and the ultimate commercial production is a long, complex process – one to two years lead time is therefore not uncommon.

A variety of substances from a single production plant

Multi-purpose units enable the production of various substances with the same production plant. Such units, however, demand extra effort when it comes to cleaning and approval. Using the same plant for multiple biologicals requires manufacturers to come up with plans to switch to producing a new substance as seldom as possible. One plant is in principle used for only one product, or as is the case with biotech production, with one strain of genetically modified microorganism to preclude cross-contamination.

Production plants and procedures are validated and approved only for the production of one specific substance. If another substance is to be produced in the same plant (or parts thereof), the designated components must undergo a thorough cleaning before use. The cleaning procedure must be validated according to GMP and FDA requirements.

Dividing up responsibilities

Dividing up and securing responsibilities are a vital prerequisite for successful cooperation. Development projects are generally described and structured by setting out a series of milestones. Responsibilities and competencies are precisely defined and divided in the cooperation contract: on one side, the manufacturer is responsible for appropriately developing or producing the respective substance – while on the other side, responsibility lies with the customer for processing the substance into the final drug and overseeing its medicinal application.

Mutual benefits: Patents and licences on procedural steps

Another important point that collaborators must address early on is dealing with patents, licences and intellectual property (IP). The rights to certain production steps generally reside by the contract manufacturer. It is of course entirely possible to contractually transfer such rights if both sides strike an agreement. This is particularly the case for exclusive contractual agreements. When the IP comes from the side of the biotech company, it generally remains with this party. In some cases, the bio-
manufacturer has the option to use the IP from the bio-tech company for other projects as part of a licensing agreement.

**Contracting out to more than one bioproduction partner?**

Changing contract manufacturers midstream is essentially possible, although it involves a considerable amount of extra work. Approval paperwork and files for the substance and the drug have to be modified for the new bioproduction partner. Likewise, expenses for audits by authorities at the site of the new producer have to be kept in mind.

**Heraeus: specialized on cancer-fighting active pharmaceutical ingredients**

Heraeus’ pharmaceuticals business unit is a service provider for the production, synthesis, and analysis of active pharmaceutical ingredients (APIs). Starting with foundational work during the drug development’s pre-clinical phase, Heraeus accompanies drug development companies throughout the various steps of the clinical phase to ultimately take on commercial production. Heraeus’ role in the process is to produce APIs rather than pharmaceuticals themselves.

The company’s focus lies in the production of highly effective, generic biologicals used in chemotherapy. They are currently being produced as metabolic products of genetically modified microorganisms (bacteria, yeast, and fungi) with the help of a unique fermentation procedure. The fermenter has a capacity of 2 x 3,000 L, which is enough to satisfy the entire world market for that particular agent and expansions of the company’s current bioreactor capacity is planned for the future.

Despite its global business activities, Heraeus opts for Hanau as an ideal location for the production of APIs due to its central position in Europe and the existing infrastructure. In addition, the strict regulation rules are an advantage of the German market, when it comes to selling high-quality products to regulated markets such as USA, Japan and Europe.

**Dr. Michael Lambert**  
**W. C. Heraeus GmbH**
Most people recall big names when they think of biotechnology or pharmaceutical companies. However, there is a multitude of smaller firms in the industry that represent an enormous innovative force and possess considerable economical potential.

If a small or medium sized enterprise chooses to develop GMP (Good Manufacturing Practice)-production for biopharmaceutical substances, the decision for an appropriate location comes next. This issue has a far-reaching influence on the operational structure and the microeconomic factors of a biotech company and hence on its overall competitiveness.

Just like other industries, biotechnology needs an ideal environment to thrive. Above all, having a proper environment means that a company can concentrate entirely on its core business and is not weighed down by administrative and other secondary operative tasks. Therefore, many factors should be considered and evaluated when choosing a biomanufacturing location. Merely comparing fixed costs for rent and plant investments is insufficient, as a considerable amount of running costs are caused by recurrent operational tasks.

When bidding for a GMP-production site, a specialized industrial park can therefore offer clear advantages over technology centres, incubators or operations out in the countryside. In addition, smaller companies seek close proximity to “big names” when they do research and try to establish themselves.

**Core competencies are the bread and butter of GMP-production**

Managing biotechnological production steps entails a number of secondary processes. These must be accomplished with a high degree of competence and proficiency, because they are often part of registration requirements according to the pharmaceutical law.

For example, specialists have to be on site from plant development to maintenance. They are in charge throughout the entire lifecycle, from project development, ordering, supervision and build-up of turn-key production plant on site to daily production routines.
Employees and suppliers working in the GMP-field need special occupational medicinal care to be eligible for positions in quality management of production processes. The central occupational health service in an industrial park supports companies and provides safety.

Moreover, qualified personnel at all levels are required to continuously meet the highest standards of cleaning and safety procedures. For example, regular cleaning personnel are not trained for the sterile environment of clean room technology. Additional qualifications are a must. An industrial park usually offers a wide variety of these competences. Specialists on site are permanently active in these profiles and therefore possess the necessary skills. Consultations and trainings are available for all working areas and can be tailored to suit individual needs. In this context, companies profit from neighbours with similar structure and focus.

Finally, a logistic centre for GMP-products plays an important role for biomanufacturers because it provides supply management and transport as well as the control of the steady flow of goods. Comprehensive storage and postal delivery are additional services.

Another argument for moving into an industrial park has to do with security and fire protection. According to need, companies can equip their production area with an entry control system and engage the park’s security, who guard the area around the clock, 365 days a year. Overall, an industrial park satisfies all the needs of a biomanufacturing company: from supplying pharmaceutical grade water and technical solutions for plant and process development to constant quality management and even elaborate administration for documentation and registration. All of these issues are covered on the spot, making it possible even for smaller companies to realize their own production.

Close proximity opens up synergistic potentials

A company’s growth goes hand in hand with structural changes and process adaptations. In addition to the concentration of competencies, an industrial park offers synergies in infrastructure development based on long standing cooperation experience with producing companies. The filing of building applications, the communication with authorities or the support with the development of technical specifications can not be offered to this degree by a university or start-up environment.

Behringwerke Marburg: specialized in pharmaceutical biotechnology

The industrial park Behringwerke Marburg with approximately 4,000 employees in 21 companies is a biotech-centre with innovative pharma-firms and is not - as is often the case - a classical “chemical park”. Here, a great variety of companies have the opportunity for development and production. The location is managed by the Pharmaserv GmbH, which specializes in support of biotechnology and pharmaceutical production. The park’s tenants include globally active pharma producers such as ZLB Behring, Novartis Behring and Dade Behring. Pharmaserv offers a comprehensive technology and maintenance service for complex GMP-production sites, including plant calibration and qualification. Core competences of Pharmaserv include comprehensive facility management, information technologies, the whole range of supply and waste management as well as central services in environmental protection, safety and occupational health. One of Pharmaserv’s unique developments is the construction of a GMP-logistic centre.

Overall, through the concentration of pharmaceutical and biotechnological companies, new tenants find an ideal network of industry-insiders who provide a wealth of synergies and therefore help to create long lasting success for biotech companies.
Finding Partners in Biomanufacturing: Opportunities and Challenges

Do you know how to wash your hands properly? Maybe you do, but do your business partners know? And even if they claim to know, did you ask them if they have a standard operating procedure (SOP) for doing so, or if they instruct their employees on a regular basis how to wash their hands properly?

These intentionally provocative questions are meant to convey a serious issue: research based drug discovery companies face a multitude of challenges when looking for a biomanufacturing partner.

Sanofi-aventis, third-largest pharmaceutical company worldwide and market leader in Europe, operates its fully integrated German research and production site with close to 8,000 employees at the Industry Park Höchst in Frankfurt. All phases of the pharmaceutical value chain are covered on the spot – from early research, development, production, and manufacturing to the marketable product. Therefore there is no direct need to search for external biomanufacturing partners.

Nevertheless, the German sites are in direct competition with other sanofi-aventis production sites all over the world and it is not a given that Frankfurt gets the bid for the manufacturing of a new drug substance - even if the product has been developed there. In a global world, other criteria govern this decision - criteria which in this respect are the same for biotech companies looking for biomanufacturing partners.

GMP-compliance as quality label

Washing your hands properly is an analogy for the tremendous demands of the Good Manufacturing Practice (GMP) procedures that biotechnological production must comply with. Many aspects of the biomanufacturing process have to be considered by those who are looking for a plant to produce their innovative product:

Is the complete equipment as well as the production process qualified and approved? Is a continuous documentation procedure installed? Are production features constantly monitored and adjusted? What are the cleaning procedures, what are the storage conditions, and is a cold chain required? How are all of these parameters screened? Are there validated tests and defined detection limits?

These matters and many more not only guide the search for a production partner but are also central issues for inspections by authorities. The “inspection history” of a company is therefore a good indication of its GMP-performance. Nonetheless, it is still recommended to personally evaluate the location.

Sanofi-aventis comprises an extensive inspection history. Biotechnological products, in particular various insulins, are produced for a global market at the Industry Park Höchst, which means that local and international authorities regularly visit the site. In this respect, inspections by the United States Food and Drug Administration (FDA) make for a unique quality criterion.

Inspection of a running production site is one important aspect, but approval procedures at the forefront is another hurdle that demands effective and constructive cooperation with authorities - an issue that can be a knock-out criterion for a location or a bid. In this respect, it is beneficial, that the duration of approval procedures for biomanufacturing plants in Hessen has significantly declined over the last years.
Proximity facilitates cooperation

The company history of sanofi-aventis in Germany contributes another advantage to the production site Industry Park Höchst: all functions of the pharmaceutical value chain, from research and development to production and manufacturing and at last distribution, are integrated at the same location in close proximity. This is extremely helpful for the transfer of products to new plants as well as for routine production further down the line.

For example, process development works hand in hand with plant engineering on scale-up adaptation procedures from laboratory to commercial scale. In addition, this proximity facilitates downstream process control and validation.

Which production steps require a partner?

Biotech companies should ask potential production partners early on how they manage the interface between research and process development and whether they comply with GMP-standards even in that early phase – as does sanofi-aventis.

When choosing a production partner, proximity is one factor in deciding the extent of cooperation. Will it end after production or does the company also require a partner for the final manufacturing steps or even distribution and sales? The scope of the cooperation will ultimately determine the legal form of the alliance and can range from contract manufacturing or out-licensing to a true joint venture.

To avoid misunderstandings: sanofi-aventis does not offer contract manufacturing but operates its plants exclusively for the production of proprietary biologicals. The tips given in this article are not intended to be comprehensive, rather they were presented for general edification.

For sanofi-aventis, the concept of an integrated production site has been paying off. The Frankfurt site builds on know-how, qualification, and quality, which enables a close-knit network of functions all along the biomanufacturing value chain. These factors taken together set the stage for a successful future.

Dr. Uwe Wirth
Sanofi-Aventis Deutschland GmbH

Frozen cell banks of microorganisms for the biotechnological production
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### Applerera Deutschland GmbH

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**E-Mail:** germany.order@eur.appliedbiosystems.com  
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**Management:** Herr Karsten Wilking

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**core activities**  
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**  
Applied Biosystems Group (NYSE:ABI), an Applera Corporation business, serves the life science industry and research community by developing and marketing instrument-based systems, consumables, software, and services. Customers use these tools to analyze nucleic acids (DNA and RNA), small molecules, and proteins to make scientific discoveries, develop new pharmaceuticals, and conduct standardized testing. Its broad portfolio of technologies—which includes systems for DNA sequencing and genetic analysis, gene expression measurement, genotyping, protein identification, quantitation and characterization, small molecule analysis, and information management—enables genomic, proteomic, and other molecular-based analyses. Applied Biosystems is headquartered in Foster City, California. Visit http://www.appliedbiosystems.com for more information.

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**Telefon:** +49 (0) 5681 / 812  
**Fax:** +49 (0) 5681 / 1516  
**E-Mail:** LVK@applikon.com  
**Internet:** www.applikon.com  
**Management:** Lutz-Volker Kornemann

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- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**  
Applikon is a privately-owned Dutch company developing, manufacturing and supplying bioreactor systems for both research and production use. Starting in 1973, Applikon has grown to a dynamic worldwide enterprise capable of supplying a broad and diverse line of bioreactor systems. Our autoclavable bioreactor systems are the world wide industry standard. Applikon Biotek is the trade organization, who distributes the Applikon products in Germany.
BAG-BiologischeAnalysensystem GmbH

**contact**
- Adress: Amtsgerichtsstr. 1-5, D-35423 Lich
- Phone: +49 (0) 6404 / 9250
- Fax: +49 (0) 6404 / 92550
- E-Mail: sachsenberg.nicolas@bag-germany.com
- Internet: www.bag-germany.com
- Management: Dr. Nicolas Sachsenberg
- Contact: Dr. Arno Gessner

**statistics**
- Foundation: 1947
- Employees (total): 150
- Employees in R & D: 5

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
We are a pharmaceutical contract manufacturer with emphasis on genuine filling and lyophilization.

Other core activities are the development, production and sales of in-vitro-diagnostics and products for monitoring of cleaning and sterilization processes.

Biaffin GmbH & Co.

**contact**
- Adress: Heinrich Plett Str. 40 / AVZ 2 3.OG, R 3125-3130, D-34132 Kassel
- Phone: +49 (0) 561 / 8044661
- Fax: +49 (0) 5618044665
- E-Mail: info@biaffin.com / sales@proteinkinase.de
- Internet: www.biaffin.com / www.proteinkinase.de
- Management: Dr. Bastian Zimmermann
- Contact: Dr. Bastian Zimmermann

**statistics**
- Foundation: 2001
- Employees (total): 7
- Employees in R & D: 4

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Animal Services, Transgenics
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
BIAFFIN is a company which is specialised in providing reliable services for biomolecular interaction analysis using biosensors based on surface plasmon resonance (SPR, Biacore). These services are applied for the quality control of recombinant proteins and the kinetic characterisation of antibodies. PROTEINKINASE.DE is the distribution platform of Biaffin GmbH & Co KG providing products for exploring cellular signaling networks. The range of products includes recombinant protein kinases, kinase inhibitors, substrates, antibodies, bioluminescent assays for ATP determination and a novel expression system for a rapid purification of proteins combined with a subsequent stable capturing on surfaces.
BioConnect AG

**Contact**
- **Adresse**: Niedenau 36, D-60325 Frankfurt/Main
- **Phone**: +49 (0) 69 / 907466-0
- **Fax**: +49 (0) 69 / 907466-20
- **E-Mail**: sekretariat@bioconnect.de
- **Internet**: www.bioconnect.de
- **Management**: Klaus Nestler
- **Contact**: Klaus Nestler

**Statistics**
- **Foundation**: 1999
- **Employees (total)**: 5
- **Employees in R & D**: n/a

**Core Activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**Profile**

BioConnect AG is a specialised consulting group in the Life Sciences sector. Founded in 1999, the company is focused on financial and strategic advisory services for Life Sciences companies and sector-driven investors. Due to its comprehensive network and a highly motivated team of experienced specialists in the fields of Finance/M&A, Venture Capital and Sciences, BioConnect AG has established itself as a leading advisory firm in the sector. BioConnects' track record comprises more than 15 investments, 20 funding rounds, over 40 due diligence assignments and numerous strategic advisory mandates, including M&A and licensing. This enabled the company to become a reputable partner for the investment community in Life Sciences. As a result of the high level of innovation and the ongoing consolidation process in the Medtech environment, BioConnect is placing further emphasis on this sector.

Biomar Diagnostic Systems GmbH

**Contact**
- **Adresse**: Im Rudert 2 + 2A, D-35043 Marburg
- **Phone**: +49 (0) 6421 / 95140
- **Fax**: +49 (0) 6421 / 951450
- **E-Mail**: info@biomar.de
- **Internet**: www.biomar.de
- **Management**: Dr. Sokolowski

**Statistics**
- **Foundation**: 1984
- **Employees**: 6
- **Employees in R & D**: 2

**Core Activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**Profile**

For twenty years Biomar has been supplying in vitro diagnostics for research and routine use: 125 I-labelled radio-immunoassays, enzyme immunoassays, reagents and rapid tests.

Biomar Diagnostic Systems develops and distributes immunoassays (RIA/EIA) for research and routine use in the areas of peptides, hormones and tumour markers, as also a wide selection of point-of-care rapid tests.

Biomar’s competence in top-grade diagnostics is evidenced by high quality standards, innovative products and affordable prices.
### BioPartners GmbH

**contact**

| Address       | Eisenstr. 3  
<table>
<thead>
<tr>
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<tbody>
<tr>
<td></td>
<td>D-65428 Rüsselsheim</td>
</tr>
<tr>
<td>Phone</td>
<td>+49 (0) 6142 / 70800-0</td>
</tr>
<tr>
<td>Fax</td>
<td>+49 (0) 6142 / 70800-6</td>
</tr>
<tr>
<td>E-Mail</td>
<td><a href="mailto:sobel@biopartners.de">sobel@biopartners.de</a></td>
</tr>
<tr>
<td>Internet</td>
<td><a href="http://www.biopartners.com">www.biopartners.com</a></td>
</tr>
<tr>
<td>Management</td>
<td>Dr. Cornelius Sobel</td>
</tr>
</tbody>
</table>

**statistics**

- **Foundation**: 2000
- **Employees**: 23 (5 in Germany)

**core activities**

- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**

Biopartners is a leader in the development of biosimilars, an emerging field of the biopharmaceutical market. Biopartners were the first company to submit a marketing authorization application to the European Agency for the Evaluation of Medicinal Products (“EMEA”) for a biosimilar. We are one of the only two companies to have received EU marketing authorization, which was for Valtropin®, a biosimilar formulation of recombinant human growth hormone. Biopartners expect to be among the first companies to market a biosimilar in the European Union. In addition the company has innovative biopharmaceuticals in its pipeline. Biosimilars are biological pharmaceuticals that are produced by recombinant DNA technologies and designed to have the same clinical effect and safety profile as a target reference product for which the key patents have expired or will soon expire. As key patents for first-generation biopharmaceuticals begin to expire, and regulatory pathway for the approval of biosimilars continues to develop, a significant market opportunity exists to market competitively priced, biosimilar versions of these compounds.

### BioSciTec GmbH

**contact**

| Address       | Westerbachstr. 47  
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<tbody>
<tr>
<td></td>
<td>D-60489 Frankfurt / Main</td>
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<tr>
<td>Phone</td>
<td>+49 (0) 69 / 42082884</td>
</tr>
<tr>
<td>Fax</td>
<td>+49 (0) 69 / 42082886</td>
</tr>
<tr>
<td>E-Mail</td>
<td><a href="mailto:info@bioscitec.de">info@bioscitec.de</a></td>
</tr>
<tr>
<td>Internet</td>
<td><a href="http://www.bioscitec.de">www.bioscitec.de</a></td>
</tr>
<tr>
<td>Management</td>
<td>Dipl. Biol. Felix Dirla</td>
</tr>
<tr>
<td>Contact</td>
<td>Dr. Robert Jäger</td>
</tr>
</tbody>
</table>

**statistics**

- **Foundation**: 1997
- **Employees (total)**: 8
- **Employees in R & D**: 4

**core activities**

- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**

BioSciTec is specialized in providing Software & Hardware solutions for Imaging Applications in Medical Diagnostics and Research. Its leading technology is implemented in a number of OEM solutions for Automation of Immunoblot-Analysis, Laser-Micro-Dissection, Drug Screening, Colony-Counting etc.

Located in Frankfurt / Main, Germany, the company is serving customers around the world through a wide distributors network.
**BioSpring GmbH**

- **Contact**
  - Address: Alt Fechenheim 34, D-60386 Frankfurt / Main
  - Phone: +49 (0) 69 / 40807222
  - Fax: +49 (0) 69 / 40894489
  - E-Mail: info@biospring.de
  - Internet: www.biospring.de

- **Management**
  - Dr. Sylvia Wojczewski, CEO,
  - Dr. Hüsein Aygün, CSO

- **Statistics**
  - Foundation: 1997
  - Employees: 16

- **Core Activities**
  - Biopharmaceutical Drug Production
  - Cell & Tissue Culture, Tissue Engineering
  - Molecular Services
  - Toxicity Testing
  - Bioinformatics
  - Quality Management & Control
  - Marketing, Sales, Distribution
  - Registration
  - Medical Technologies
  - Antibody Production
  - Industrial Plants
  - Contract Manufacturing
  - Consulting
  - Analytical Services
  - Training

- **Profile**
  BioSpring is a biotech and chemical company that specializes in the field of nucleic acid technologies and enzyme evolution. BioSpring carries out the chemical production of DNA/RNA, antisense and other type of oligonucleotides from the research scale to API manufacturing of drugs. Moreover together with our research partners we also develop new nucleic acid based therapeutics/drugs. BioSpring has high expertise in the production of modified oligonucleotides. Production is carried out under a quality assurance system.

**Caliper Life Sciences GmbH, Germany**

- **Contact**
  - Address: Eisenstr. 9c, D-65428 Rüsselsheim
  - Phone: +49 (0) 6142 / 834930
  - Fax: +49 (0) 6142 / 162821
  - E-Mail: jean-louis.rufener@caliperls.com
  - Internet: www.CaliperLS.com

- **Management**
  - Jean-Louis Rufener

- **Statistics**
  - Foundation: 1981
  - Employees: 18
  - Employees in R & D: 4

- **Core Activities**
  - Biopharmaceutical Drug Production
  - Cell & Tissue Culture, Tissue Engineering
  - Molecular Services
  - Toxicity Testing
  - Bioinformatics
  - Quality Management & Control
  - Marketing, Sales, Distribution
  - Registration
  - Medical Technologies
  - Antibody Production
  - Industrial Plants
  - Contract Manufacturing
  - Consulting
  - Analytical Services
  - Training

- **Profile**
  Caliper Life Sciences combines microfluidics, liquid handling and laboratory automation to deliver unique research tools for today’s Drug Discovery and Development and Genomics and Proteomics laboratories. We manufacture and sell products such as the LabChip 3000 Drug Discovery system, Caliper Sciclone liquid handler, Staccato Assay Workstations, and the LabChip 90 Automated Electrophoresis system. Each of these products addresses critical applications within the life sciences industry; each of these applications is on the critical path to improving human health.
Chemgineering GmbH

**contact**
- Adress: Kreuzberger Ring 13
  D-65205 Wiesbaden
- Phone: +49 (0) 711 / 78194359
- Fax: +49 (0) 711 / 781943511
- E-Mail: axel.roehm@chemgineering.com
- Internet: www.chemgineering.com
- Management: Axel Röhm

**statistics**
- Foundation: 1996
- Employees: 150

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
Chemgineering is one of the leading European engineering consultants for complex plant construction, qualification and validation projects.

Chemgineering offers pharmaceutical, biotechnical, fine chemical, consulting, engineering and IT services.

VTU Engineering GmbH

**contact**
- Adress: Industriepark Höchst, Geb. D 710/EG
  D-65926 Frankfurt / Main
- Phone: +49 (0) 69 / 30522260
- Fax: +49 (0) 69 / 30522432
- E-Mail: office@frankfurt.com
- Internet: www.vtu.com
- Management: Dipl.-Ing. Wolfram Gstrein

**statistics**
- Foundation: 1990
- Employees: 110
- Employees: 87

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
VTU Engineering is an engineering company concentrating on process engineering services. Customers come primarily from pharmaceutical and chemical industry. Biodiesel, Oil/Gas, pulp&paper and metallurgy are further areas of activity.

The scope includes projekt management, concept, basic engineering and technical controlling throughout the detail and construction phase and plant startup. Qualification services are offered for pharmaceutical industry. Consulting services for plant safety and GMP complete the service portfolio.
engineo GmbH

- **contact**
  - **Adress**: Ginsheimer Str. 1
  - **D-65462 Gustavsburg**
  - **Phone**: +49 (0) 6134 / 557460
  - **Fax**: +49 (0) 6134 / 557461
  - **E-Mail**: info@engineo.com
  - **Internet**: www.engineo.com
  - **Management**: Dr. Karlheinz Preuss

- **statistics**
  - **Foundation**: 2001
  - **Employees**: 4
  - **Employees in R & D**: 3

- **core activities**
  - Biopharmaceutical Drug Production
  - Cell & Tissue Culture, Tissue Engineering
  - Molecular Services
  - Toxicity Testing
  - Bioinformatics
  - Quality Management & Control
  - Marketing, Sales, Distribution
  - Registration
  - Medical Technologies
  - Antibody Production
  - Industrial Plants
  - Contract Manufacturing
  - Consulting
  - Analytical Services
  - Training

- **profile**
  - engineo’s core competence lies in the combination of biotechnology, process engineering, automation and software technology:
  - Process Analytical Technologies and Data-Mining for the purpose of process optimisation
  - software-solutions for plant automation, control, optimisation, monitoring (Soft-Sensors), process simulation and design of experiments
  - PC-interfaces for measurement and control devices
  - development of technical software (under GMP)

FIZ Frankfurter Innovationszentrum Biotechnologie GmbH

- **contact**
  - **Adress**: Altenhoferallee 3
  - **D-60438 Frankfurt/Main**
  - **Phone**: +49 (0) 69 / 800865-0
  - **Fax**: +49 (0) 69 / 800865-19
  - **E-Mail**: kinfo@fiz-biotech.de
  - **Internet**: www.fiz-biotech.de
  - **Management**: Dr. Christian Garbe
  - **Contact**: Carmen Schulz

- **statistics**
  - **Foundation**: 2002
  - **Employees**: 5

- **core activities**
  - Biopharmaceutical Drug Production
  - Cell & Tissue Culture, Tissue Engineering
  - Molecular Services
  - Toxicity Testing
  - Bioinformatics
  - Quality Management & Control
  - Marketing, Sales, Distribution
  - Registration
  - Medical Technologies
  - Antibody Production
  - Industrial Plants
  - Contract Manufacturing
  - Consulting
  - Analytical Services
  - Training

- **profile**
  - FIZ, the Frankfurt Biotechnology Innovation Center, was founded by the State of Hessen, the City of Frankfurt, and the Chamber of Commerce and Industry, Frankfurt am Main.
  - Today, FIZ is the Frankfurt-Rhine-Main business area’s platform for research and innovation in the life science sector. By combining key location factors in the science, business, and infrastructure sectors, FIZ provides a platform for value-added innovation and enables the transfer of ideas to marketable products.
GenXPro GmbH

**contact**
- **Adress**: Altenhoeferallee 3
  D-60438 Frankfurt / Main
- **Phone**: +49 (0) 69 / 95739710
- **Fax**: +49 (0) 69 / 95739706
- **E-Mail**: info@genxpro.de
- **Internet**: www.genxpro.de
- **Management**: Dr. Peter Winter
- **Contact**: Peter Berndroth

**statistics**
- **Foundation**: 2005
- **Employees**: 7
- **Employees in R & D**: 5

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
The Company was founded by researchers of the University of Frankfurt. GenXPro offers the patented Super Tag Technology for:
- Genome-wide, quantitative gene expression profiles of all eukaryotic cells and tissues
- Identification of unknown genes, low abundance transcripts and alternatively spliced variants
- Simultaneously profiling expressed genes from a host and its pathogen (parasite) without physical separation of both organisms
- GenXpro develops diagnostic and prognostic genomic and gene markers for all organisms

Hima Paul Hildebrandt GmbH + Co KG

**contact**
- **Adress**: Industriepark Höchst, Geb. K 801
  D-65926 Frankfurt / Main
- **Phone**: +49 (0) 69 / 95294507
- **Fax**: +49 (0) 69 / 95294508
- **E-Mail**: u.wahrmann@hima.com
- **Internet**: www.hima.de
- **Management**: Uwe Wahrmann

**statistics**
- **Foundation**: 2000
- **Employees**: 3

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
HIMA develops and produces intelligent products and solutions for safety-related automation tasks of the process and factory industry. These solutions are applied within certified applications up to levels SIL 4 (IEC61508) or Kat. 4 (DIN EN 954). These are primarily on emergency shut down (ESD), fire and gas (F&G), burner management (BMS) and high integrity pressure protection systems (HIPPS). In addition safety-related applications like conveyor systems, presses, paintshops, body shops and assembly systems are addressed. The safety-related networking of HIMA systems takes place via safeethernet.
**Honeywell GmbH**

**contact**
- **Adress**: Kaiserleistr. 39
  D-63067 Offenbach
- **Phone**: +49 (0) 69 / 8064-0
- **Fax**: +49 (0) 69 / 8064-249
- **E-Mail**: Industrieautomation@honeywell.com
- **Internet**: www.honeywell.com/ps
- **Management**: Matthias Maaz

**statistics**
- **Foundation**: 1885
- **Employees**: 115.000 (worldwide, 4 business units)

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
Honeywell delivers the entire portfolio of Automation for Biopharmaceutical Manufacturing incl. Process- and Buildings Solutions as well as an integrated Manufacturing Execution System. The delivery includes all required engineering applications and validation services. Honeywell is a leading supplier of automation solutions and services to pharmaceutical and biologics manufacturers. Honeywell supplies solutions that meet regulatory requirements, lower costs, improve operational efficiency and reduce project delivery, operations and support risks. Honeywell has integrated solutions for process automation, building controls, MES, environmental monitoring, conformance management, validation and calibration services (text trunck).

**ID-Labor GmbH**

**contact**
- **Adress**: Rheingaur. 190-196
  D-65203 Wiesbaden
- **Phone**: +49 (0) 611 / 6098335
- **Fax**: +49 (0) 611 / 6098336
- **E-Mail**: info@ID-Labor.de
- **Internet**: www.id-labor.de
- **Management**: Dr. Angelika Lösch, Dr. Kirsten Thelen

**statistics**
- **Foundation**: 1998
- **Employees**: 4
- **Employees in R & D**: 4

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
Infraserv GmbH & Co Hoechst GmbH

**contact**
- Address: Industriepark Hoechst D-65926 Frankfurt / Main
- Phone: +49 (0) 69 / 3056767
- Fax: +49 (0) 69 / 30582877
- E-Mail:
- Internet: www.infraserv.com

**statistics**
- Foundation: 1998
- Employees: ca. 2000

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
The Industriepark Höchst is an innovative chemical and pharmaceutical site in Europe’s heartland. The site, with its highly evolved infrastructure, is an ideal environment for research and manufacturing companies. Its attractiveness is only enhanced by its perfect access to international transit routes and its proximity to key supplier, sales and financial markets. Another benefit is the dense regional network of world-class research institutes and universities.

More than 80 companies with approximately 22,000 employees have found the perfect home for their business in a park measuring more than four square kilometres.

From international corporations to creative service providers, the companies in the Industriepark Höchst flourish in this strong business and science environment.

LifeScience Vision AG

**contact**
- Address: Villa im Park D-65835 Liederbach (Frankfurt)
- Phone: +49 (0) 69 / 3640460
- Fax: +49 (0) 69 / 36404626
- E-Mail: contact@lsvision.com
- Internet: www.lsvision.com

**statistics**
- Foundation: 2001
- Employees: 30
- Employees in R & D: 10

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
LifeScience Vision is an International Pharma Consulting Company; specializing in comprehensive life cycle strategies, management and performance support of health care products, services and companies. With our Global Innovation Development Services we consistently combine top-level experience from academia and industry, alike. We offer local top-level expert consulting and contract management service platforms which can be combined in multiple ways to exactly meet our client’s needs. We serve clients in the pharmaceutical, medical device, biotech and investment industry from start-ups to large market leaders throughout the world. Our service focus is the optimisation of our client’s business performance, medical and market presence in the main world markets USA, EU and Japan, and includes licensing and partnering activities.
### LORENZ Archiv-Systeme GmbH

| Contact          | eschborner landstr. 75  
|------------------|------------------------
|                  | D-60489 frankfurt / main    
| Phone            | +49 (0) 69 / 78991-123   
| Fax              | +49 (0) 69 / 78991-129    
| E-Mail           | ASchneider@Lorenz.cc     
| Internet         | www.Lorenz.cc            
| Management       | Wolfgang witzel          
| Contact          | Andrea Schneider         

| Statistics       | foundation 1990  
|------------------|----------------
| employees        | 50+           

| Core Activities  | Biopharmaceutical Drug Production  
|------------------|----------------------------------
|                  | Cell & Tissue Culture, Tissue Engineering  
|                  | Molecular Services  
|                  | Toxicity Testing  
|                  | Bioinformatics  
| Quality Management & Control |  
| Marketing, Sales, Distribution |  
| Registration |  
| Medical Technologies |  
| Antibody Production |  
| Industrial Plants |  
| Contract Manufacturing |  
| Consulting |  
| Analytical Services |  
| Training |  

**Profile**

LORENZ Life Sciences’ vision is to develop solutions that are engineered to reflect the knowledge the company has and is accumulating within a highly focused market, thereby developing purpose-built solutions that can be integrated at ease within any organization - large or small. We aim to excel through the superiority and practicality of our design and the consultation we deliver to our customers.

Our mission is to develop document assembly & publishing solutions for regulated environments within Life Sciences and help customers progress in their transition towards a digital world. Our goal is to continuously reduce the transaction units in assembly, publishing and submission of due diligence materials and marketing applications.

docuBridge customers assemble and publish some of the world’s biggest new drug application dossiers - also, but less challenging, the smallest too (text trunck).

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### LSMW GmbH

| Contact          | Max-Planck-Strasse 21  
|------------------|-----------------------
|                  | D-63303 dreieich      
| Phone            | +49 (0) 6103 / 3036-400    
| Fax              | +49 (0) 6103 / 3036-410   
| E-Mail           | germany@lsmw.com       
| Internet         | www.lsmw.com           
| Management       | Hermann schwarzkopf, dr. tobias lücke 
| Contact          | Ulrike lieber (head of marketing) 

| Statistics       | Foundation 1995       
|------------------|-----------------------
| employees        | 329 (total)           
| employees in R & D| in production/service  

| Core Activities  | Biopharmaceutical Drug Production  
|------------------|----------------------------------
|                  | Cell & Tissue Culture, Tissue Engineering  
|                  | Molecular Services  
|                  | Toxicity Testing  
|                  | Bioinformatics  
| Quality Management & Control |  
| Marketing, Sales, Distribution |  
| Registration |  
| Medical Technologies |  
| Antibody Production |  
| Industrial Plants |  
| Contract Manufacturing |  
| Consulting |  
| Analytical Services |  
| Training |  

**Profile**


The service spectrum includes Consulting, Design, Realization, Compliance and Technical Facility Management. We focus on process technology, cleanroom technology, GMP consulting and qualification / validation.

The customers of this M+W Zander subsidiary include both large and medium-sized enterprises as well as start-up enterprises.
### Microfluidics a division of MFIC Corp

<table>
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<tr>
<td><strong>Adress</strong></td>
<td>Edisonstr. 15</td>
</tr>
<tr>
<td></td>
<td>D-68623 Lampertheim</td>
</tr>
<tr>
<td><strong>Phone</strong></td>
<td>+49 (0) 6206 / 503700</td>
</tr>
<tr>
<td><strong>Fax</strong></td>
<td>+49 (0) 6206 / 503705</td>
</tr>
<tr>
<td><strong>E-Mail</strong></td>
<td><a href="mailto:microfluidics@t-online.de">microfluidics@t-online.de</a></td>
</tr>
<tr>
<td><strong>Internet</strong></td>
<td><a href="http://www.microfluidicscorp.com">www.microfluidicscorp.com</a></td>
</tr>
<tr>
<td><strong>Management</strong></td>
<td>Irwin Gruverman, Robert Bruno</td>
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<table>
<thead>
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<td><strong>Employees</strong></td>
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<td><strong>Employees in R&amp;D</strong></td>
<td>in production/service</td>
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<table>
<thead>
<tr>
<th><strong>core activities</strong></th>
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<tr>
<td>Biopharmaceutical Drug Production</td>
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<td>Cell &amp; Tissue Culture, Tissue Engineering</td>
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<td>Medical Technologies</td>
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<td>Antibody Production</td>
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<td>Contract Manufacturing</td>
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<td>Consulting</td>
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<tr>
<td>Analytical Services</td>
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<td>Training</td>
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| **profile** | Microfluidics provides patented and proprietary high performance Microfluidizer® materials processing equipment to the biotechnology, pharmaceutical, chemical, cosmetics/personal care and food industries for the production of stable emulsions, suspensions, liposomes and for cell disruption applications. Microfluidics applies nearly 20 years of high pressure processing experience to produce the most uniform and smallest liquid and suspended solid structures available, and has provided manufacturing systems for nanoparticle products for more than 15 years. |

### Miltenyi Biotec GmbH, Cellular Products Division

<table>
<thead>
<tr>
<th><strong>contact</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adress</strong></td>
<td>Weismüllerstr. 45</td>
</tr>
<tr>
<td></td>
<td>D-60314 Frankfurt / Main</td>
</tr>
<tr>
<td><strong>Phone</strong></td>
<td>+49 (0) 69 / 133894611</td>
</tr>
<tr>
<td><strong>Fax</strong></td>
<td>+49 0) 69 / 133894612</td>
</tr>
<tr>
<td><strong>E-Mail</strong></td>
<td><a href="mailto:gabriele@miltenyibiotech.de">gabriele@miltenyibiotech.de</a></td>
</tr>
<tr>
<td><strong>Internet</strong></td>
<td><a href="http://www.miltenyibiotech.com">www.miltenyibiotech.com</a></td>
</tr>
<tr>
<td><strong>Management</strong></td>
<td>Dr. Rainer Knaus</td>
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<td>Training</td>
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| **profile** | Miltenyi Biotec’s Cellular Products Division provides the medical community and biotech industry with a variety of clinical-grade cellular products and services. |

35
nadicom Gesellschaft für angewandte Mikrobiologie mbH

**contact**
- Adress: Pflanzgarten 10
  D-35043 Marburg
- Phone: +49 (0) 6421 / 13175
- Fax: +49 (0) 6421 / 917874
- E-Mail: info@nadicom.com
- Internet: www.nadicom.com
- Management: Dr. Bernhard Nüßlein
- Contact: Dr. Bernhard Nüßlein

**statistics**
- Foundation: 2002
- Employees: 7
- Employees in R & D: 5

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
nadicom is active in the fields of molecular mycology and bacteriology. We specialize in the identification of bacteria and fungi via molecular methods, and in contracted research directed at solving client-defined problems. Special areas of expertise for contracted research include optimization of biochemical transformations in fungi, as well as protein analysis and expression in microorganisms.

Paul-Ehrlich-Institut

**contact**
- Adress: Paul-Ehrlich-Str. 51-59
  D-63225 Langen
- Phone: +49 (0) 6103 / 770
- Fax: +49 (0) 6103 / 77123
- E-Mail: pei@pei.de
- Internet: www.pei.de
- Management: Prof. Dr. Löwer (President),
  Prof. Dr. Cichutek (Vicepräsident)

**statistics**
- Foundation: 1896
- Employees: 650

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
The Paul-Ehrlich-Institut (PEI) is an independent senior federal authority within the responsibility of the Federal Ministry of Health. Regulatory tasks of the PEI include approval of clinical trials, granting of marketing authorizations and official batch releases for (immuno)biological medicinal products including sera and vaccines, monoclonal antibodies, blood and blood products, allergens and tissue preparations as well as advanced therapy medicinal products (e.g., gene transfer and cell therapy medicinal products).

The PEI supports the development of these medicinal products by providing scientific advice to biotechnology companies and academic groups in biomedicine, nationwide and also for the European Medicines Agency EMEA. Scientists of the PEI are members in international expert groups and chair working parties at the EMEA, e.g. the Gene Therapy Working Party, the Cell-based Product Working Party and are representatives in working groups at the European Pharmacopoeia and the WHO (working groups, consultations) (text truncated).
PerkinElmer LAS (Germany) GmbH

**contact**
- **Adress**: Ferdinand-Porsche-Ring 17
  D-63110 Rodgau
- **Phone**: +49 (0) 800 / 1810032
- **Fax**: +49 (0) 800 / 1810031
- **E-Mail**: cc.germany@perkinelmer.com
- **Internet**: www.perkinelmer.com
- **Management**: Dr. Henning Menke
- **Contact**: customer care center

**statistics**
- **Foundation**: 2003
- **Employees**: 140
- **Employees in R & D**: 140

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**

Pharma-Consulting u. Dienstleistungen Dr. Bernhard Bräunig

**contact**
- **Adress**: Teichweg 14
  D-35091 Cölbe-Schönstadt
- **Phone**: +49 (0) 6427 / 930790
- **Fax**: +49 (0) 6427 / 930791
- **E-Mail**: Dr.Braeunig@t-online.de
- **Internet**: www.Dr-Braeunig.de
- **Management**: Dr. Bernhard Bräunig
- **Contact**: Dr. Bernhard Bräunig

**statistics**
- **Foundation**: 1993
- **Employees**: 140

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**

We offer the medical writing of non-clinical and clinical overviews according to CTD for drug approvals
- study protocols
- scientific publications
in cooperation with external specialists.
Pharmaserv GmbH

**contact**
- **Adress**: Emil-von-Behring-Str. 76
- **Phone**: +49 (0) 6421 / 39-6000
- **Fax**: +49 (0) 6421 / 39-6300
- **E-Mail**: info@pharmaserv.de
- **Internet**: www.pharmaserv.de
- **Management**: Thomas Janssen

**statistics**
- **Foundation**: 1997
- **Employees**: 350
- **Employees in R & D**: 220

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
As an innovative management and service partner for complex secondary processes, Pharmaserv creates the general conditions with which customers can consistently concentrate on their own core business.

Our range of services includes:
- Project planning, preparation and complete support of systems and buildings
- Energy management with high supply guarantee Integrated technical services from planning up to turnkey production system
- Development and realisation of modern information and communication solutions
- Industrial medical services, advice with environmental, occupational safety and waste disposal measures

Pharmaplan GmbH

**contact**
- **Adress**: Borkenberg 14
- **Phone**: +49 (0) 6171 / 9704791
- **Fax**: +49 (0) 6171 / 9704781
- **E-Mail**: info@pharmaplan.com
- **Internet**: www.pharmaplan.com
- **Management**: J. Ludwig, G. Jakobi

**statistics**
- **Foundation**: 1974
- **Employees**: 130 (in Germany)
- **Employees in R & D**: 220

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
Pharmaplan offers worldwide Consulting, Engineering, Validation, GMP-Compliance and Turn-key Services for the pharmaceutical and GMP-oriented industry. In the last 15 years, numerous projects for biopharmaceutical production, vaccine production, blood plasma fractionation etc. were realized. Pharmaplan has also experience in GMP-compliant clean room production sites in laboratory scale which may be used for the production of clinical trials. Special feature is the application of pre-frabricated and equipped modules. Modular facilities enable much shorter project periods, are suitable for new, but also for difficult building sites and ensure the flexibility for an extension of existing production sites or even for the relocation of a manufacturing facility.
Prolytic GmbH

**contact**
- **Adress**: Alt Fechenheim 34
  D-60386 Frankfurt / Main
- **Phone**: +49 (0) 69 / 41092534
- **Fax**: +49 (0) 69 / 42694784
- **E-Mail**: info@prolytic.de
- **Internet**: www.prolytic.de
- **Management**: Dr. Dorothee Krone, Peter Romeis
- **Contact**: Peter Romeis

**statistics**
- **Foundation**: 2002
- **Employees**: 10
- **Employees in R &D**: 10

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
Prolytic GmbH in Frankfurt provides expert services in the area of bioanalytics, toxicokinetics and pharmacokinetics. The focus lies in the development and validation of methods (HPLC, HPLC-MS/MS, ELISA, EIA, RIA) as well as drug determination in biological samples. Thus, a broad variety of procedures are available for the characterisation of drugs regarding their stability and metabolic breakdown. All the above is performed according to GLP standards.

RCC Cytotest Cell Research GmbH

**contact**
- **Adress**: In den Leppsteinwiesen 19
  D-64380 Roßdorf
- **Phone**: +49 (0) 6154 / 807-211
- **Fax**: +49 (0) 6154 / 807-228
- **E-Mail**: voelkner@rcc-ccr.de
- **Internet**: www.rcc.ch
- **Management**: Dr. Wolfgang Völkner

**statistics**
- **Foundation**: 1986
- **Employees**: 60

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
RCC Cytotest Cell Research GmbH is a contract research organisation in the fields of genetic toxicology, cell biology and bio-analytics. Biologists, biotechnologists, biochemists, immunologists, chemists and technical assistants carry out tests on behalf of the pharmaceutical, chemical and cosmetics industry. The studies carried out by RCC-CCR according to internationally recognised testing methods serve to meet legal requirements for the safety of humans and the environment and are, therefore, of utmost relevance for the authorisation and registration of new products.
Sartorius BBI Systems GmbH

**contact**
- **Adresse**: Schwarzenberger Weg 73-79
- **Phone**: +49 (0) 5661 / 713400
- **Fax**: +49 (0) 5661 / 713702
- **E-Mail**: info@sartorius-bbi-systems.com
- **Internet**: www.sartorius.com
- **Management**: Franz Alig Managing Director

**statistics**
- **Foundation**: 1987
- **Employees**: 186

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
Sartorius BBI Systems GmbH, a subsidiary of Sartorius AG, Göttingen Germany – has for around 40 years provided a range of innovative bioreactor products (BIOSTAT *) and support services to major biotechnology and pharmaceutical companies worldwide. This range includes bench top, laboratory and pilot scale fermentation systems through to fully qualified, high volume automated production plants and cross-flow-filtration systems.

Sandoz Industrial Products GmbH

**contact**
- **Adresse**: Brüningstr. 50
- **Phone**: +49 (0) 69 / 305-17641
- **Fax**: +49 (0) 69 / 305-35158
- **E-Mail**: Katrin.Kilb@sandoz.com
- **Internet**: www.sandoz.com
- **Management**: Dr. Johann Demel
- **Contact**: Katrin Kilb

**statistics**
- **Foundation**: 1998
- **Employees**: 380
- **Employees in production/service**: 380

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
Sandoz is a world leader in generic pharmaceuticals and biotechnology-products. The HQ is based in Holzkirchen near Munich. It is one of the world’s biggest suppliers of antibiotics and other biotechnological active ingredients. Industriepark Höchst hosts the group’s 2nd-largest fermentation base named Sandoz Industrial Products GmbH. Cephalosporin and penicillin intermediates and API’s as well as enzymes and coccidiostatics for the veterinary market are produced there. Sandoz is the generics arm of Novartis. It offers a wide range of pharmaceutical active ingredients all the way to ready-to-use preparations.
Scientific Research and Development GmbH

**contact**
- **Adresse**: Köhlerweg 20
  D-61440 Oberursel
- **Phone**: +49 (0) 69 / 79829533
- **Fax**: +49 (0) 69 / 79829527
- **E-Mail**: hauf@srdbiotec.de
- **Internet**: www.srd-biotec.de
- **Management**: Dr. Dr. Jörg Hauf

**statistics**
- **Foundation**: 1995
- **Employees**: 7
- **Employees in R &D**: 5

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
  - Toxicity Testing
  - Bioinformatics
  - Quality Management & Control
  - Marketing, Sales, Distribution
  - Registration
  - Medical Technologies
  - Antibody Production
  - Industrial Plants
  - Contract Manufacturing
  - Consulting
  - Analytical Services
  - Training

**profile**
Scientific Research and Development GmbH (SRD) was founded in 1995 aiming to intensify the cooperation and interaction between industrial and academical research. Our core activities are divided into research projects and molecular services such as DNA sequencing. SRD is also responsible for the maintenance and administration of the EUROSCARF Saccharomyces cerevisiae strain and plasmid collection. The core expertise of our team lies in genetical, molecular and biochemical techniques.

SellWiss GmbH

**contact**
- **Adresse**: Emil-von-Behringstr. 76
  D-35041 Marburg
- **Phone**: +49 (0) 6421 / 396181
- **Fax**: +49 (0) 6421 / 396182
- **E-Mail**: sellwiss@sellwiss.de
- **Internet**: www.sellwiss.de
- **Management**: Dr. Karl-Heinz Sellinger

**statistics**
- **Foundation**: 2001
- **Employees**: 4
- **Employees in R &D**: 3

**core activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**profile**
SellWiss stands for providing manufacturing services of active pharmaceutical ingredients, APIs, starting from pre-clinical, clinical production up to market and routine production of novel biopharmaceuticals and biogenerics. Furthermore, SellWiss provides advice and guidance in the production of biotechnology-derived APIs, and supports you from clone selection up to commercial scale production.
SGS INSTITUT FRESENIUS GmbH

- **contact**
  - Adress: Im Maisel 14
  - D-65232 Taunusstein
  - Phone: +49 (0) 6128 / 744245
  - Fax: +49 (0) 6128 / 744700
  - E-Mail: de.qualitycontrol@sgs.com
  - Internet: www.sgs.com
  - www.institut-fresenius.de
  - Management: Matthias Oppermann
  - Contact: Dr. gerhard Prößl

- **statistics**
  - Foundation: 1848
  - Employees: 600
  - Employees in R & D: 100

- **core activities**
  - Biopharmaceutical Drug Production
  - Cell & Tissue Culture, Tissue Engineering
  - Molecular Services
  - Toxicity Testing
  - Bioinformatics
  - Quality Management & Control
  - Marketing, Sales, Distribution
  - Registration
  - Medical Technologies
  - Antibody Production
  - Industrial Plants
  - Contract Manufacturing

- **profile**
  SGS is the world’s leading inspection, verification, testing and certification company. SGS is recognized as the global benchmark for quality and integrity. With 42,000 employees, SGS operates a network of about 1,000 offices and laboratories around the world. SGS INSTITUT FRESENIUS is part of this company since 2004.

---

Tebodin Consultants & Engineering GmbH

- **contact**
  - Adress: Rheingaustr. 94
  - D-65203 Wiesbaden
  - Phone: +49 (0) 611 / 505610
  - Fax: +49 (0) 611 / 5056110
  - E-Mail: info@tebodin.de
  - Internet: www.tebodin.de
  - Management: Matthias Glaese
  - Contact: Peter Stockhoff

- **statistics**
  - Foundation: 1970 (D), 1945 (NL)
  - Employees: 230 (in Germany), 2300 worldwide

- **core activities**
  - Biopharmaceutical Drug Production
  - Cell & Tissue Culture, Tissue Engineering
  - Molecular Services
  - Toxicity Testing
  - Bioinformatics
  - Quality Management & Control
  - Marketing, Sales, Distribution
  - Registration
  - Medical Technologies
  - Antibody Production
  - Industrial Plants
  - Contract Manufacturing

- **profile**
  Tebodin Consultants & Engineers GmbH is an independent organisation with six offices in Germany.
  The integration of engineering expertise and strategic consultancy makes Tebodin one of the few companies of its kind that can offer a truly global service.
  We offer our clients the following services, starting from project inception right through to completion:
  - Consultancy
  - Project Management
  - Design and Engineering
  - Procurement
  - Construction Management
**Temmler Pharma GmbH & Co KG**

**Contact**
- **Address**: Temmlerstr. 2
- **Phone**: +49 (0) 6421 / 4940
- **Fax**: +49 (0) 6421 / 494200
- **E-Mail**: info@temmler.de
- **Internet**: www.temmler.de
- **Management**: Hans Joachim Ricken
- **Contact**: Hans Joachim Ricken

**Statistics**
- **Foundation**: 1917
- **Employees**: 180

**Core Activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**Profile**

Since its foundation 1917 as an independent pharmaceutical company, Temmler Pharma has grown into a highly successful key player in the development, registration and marketing of drugs and pharmaceutical products.

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**Valicare GmbH**

**Contact**
- **Address**: Eschborner Landstr. 130-132
- **Phone**: +49 (0) 69 / 7909343
- **Fax**: +49 (0) 69 / 7909345
- **E-Mail**: info@valicare.com
- **Internet**: www.valicare.de
- **Management**: Mathias Hartmann, Dr. Berthold Düthorn
- **Contact**: Dr. Torsten Schmidt-Bader

**Statistics**
- **Foundation**: 1992
- **Employees**: 10

**Core Activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**Profile**

Valicare is a service company offering support in the area of qualification and validation of manufacturing and laboratory equipment for the Pharmaceutical and Life Science industries.
### W. C. Heraeus GmbH Chemicals Division/Business Unit Pharma

**Contact**
- **Adresse**: Heraeusstr. 12-14, D-63450 Hanau
- **Phone**: +49 (0) 6181 / 35-5446
- **Fax**: +49 (0) 6181 / 35-165446
- **E-Mail**: pharma@heraeus.com
- **Internet**: www.wc-heraeus.de/pharma
- **Management Contact**: Dr. Friedrich Wissmann, Michael Schwarz Alexander Wörner

**Statistics**
- **Foundation**: 1851
- **Employees**: more than 3,500 N.C. Heraeus
- **Employees in R & D**: 60 / 40

**Core Activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**Profile**
Weiss Klimatechnik offers solutions for laboratories and clean rooms, among others:
- The complete planning, execution and official acceptance of clean room air-conditioning plants and clean room systems
- Further performances are: laboratory cabins, safety work places, microbiological safety work benches, clean room locks and monitoring systems
- Services such as qualification according to GMP as well as re-qualification

---

### Weiss Klimatechnik GmbH

**Contact**
- **Adresse**: Greizer Str. 41-49, D-35447 Reiskirchen
- **Phone**: +49 (0) 6408 / 8471
- **Fax**: +49 (0) 6408 / 84-8722
- **E-Mail**: info@wkt.com
- **Internet**: www.wk.com
- **Management Contact**: Karl-Heinz Lotz (Head of Sales Dept.)

**Statistics**
- **Foundation**: 1956
- **Employees**: 210
- **Employees in R & D**: 60 / 40

**Core Activities**
- Biopharmaceutical Drug Production
- Cell & Tissue Culture, Tissue Engineering
- Molecular Services
- Toxicity Testing
- Bioinformatics
- Quality Management & Control
- Marketing, Sales, Distribution
- Registration
- Medical Technologies
- Antibody Production
- Industrial Plants
- Contract Manufacturing
- Consulting
- Analytical Services
- Training

**Profile**
Weiss Klimatechnik offers solutions for laboratories and clean rooms, among others:
- The complete planning, execution and official acceptance of clean room air-conditioning plants and clean room systems
- Further performances are: laboratory cabins, safety work places, microbiological safety work benches, clean room locks and monitoring systems
- Services such as qualification according to GMP as well as re-qualification
WS Partners Management Consulting

- **contact**
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    - D-35094 Lahntal
  - Phone: +49 (0) 6423 / 969714
  - Fax: +49 (0) 6424 / 969715
  - E-Mail: info@ws-partners.com
  - Internet: www.ws-partners.com
  - Management: Dr. Werner Stüber
  - Contact: Dr. Werner Stüber

- **statistics**
  - Foundation: 2002
  - Employees: 2
  - Employees in R & D: 2

- **core activities**
  - Biopharmaceutical Drug Production
  - Cell & Tissue Culture, Tissue Engineering
  - Molecular Services
  - Toxicity Testing
  - Bioinformatics
  - Quality Management & Control
    - Marketing, Sales, Distribution
    - Registration
    - Medical Technologies
    - Antibody Production
    - Industrial Plants
    - Contract Manufacturing
    - Consulting
    - Analytical Services
    - Training

- **profile**
  WS Partners can offer dedicated industrial know-how in various areas of life science, pharmaceutical and chemical business:
  - Peptide Chemistry (Solid Phase, Solution Chemistry etc.)
  - Protein Chemistry
  - PEGylation techniques for peptides and proteins
  - Blood, blood components and anticoagulants
  - Development of GMP - Compliant Production Processes
  - Validation and Qualification Concepts and Documentation
  - Creation and Implementation of GMP/GLP/GCP – compliant QA Systems (including “ghost – writing” of required SOPs, MBRs etc.)
  - Preparation for Authority Inspections (European and US-FDA)
  - Project Management: Leading of complex projects
  - Business Development: Partnering, Deal making etc.
  - Patent analyses and patent strategies
  - Start up management
  (text trunk)

ZL GmbH

- **contact**
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  - Fax: +49 (0) 6196 / 481199
  - E-Mail: m.tawab@zentrallabor.com
  - Internet: www.zlgmbh.com
  - Management: KSylvia Hoffmann-Müller

- **statistics**
  - Foundation: 2005 as subcompany of ZL
  - Employees: 35
  - Employees in R & D: 25

- **core activities**
  - Biopharmaceutical Drug Production
  - Cell & Tissue Culture, Tissue Engineering
  - Molecular Services
  - Toxicity Testing
  - Bioinformatics
  - Quality Management & Control
    - Marketing, Sales, Distribution
    - Registration
    - Medical Technologies
    - Antibody Production
    - Industrial Plants
    - Contract Manufacturing
    - Consulting
    - Analytical Services
    - Training

- **profile**
  ZL GmbH is an accredited renowned and worldwide accepted laboratory. All processes are conform with GMP and GCP standards. ZL GmbH operates a comprehensive and systematic quality management system. ZL GmbH is a competent partner in all questions dealing with the analysis of drugs,
  - Peptide Analysis
  - Analysis of Active Pharmaceutical Ingredients and Finished Products
  - Stability studies
  - Development and Validation of Analytical Methods according to ICH Guidelines
  - Bioanalysis in the frame of Clinical Studies
Listing of a company profile within this publication is strictly voluntary, all Companies in Hessen have the opportunity of being entered in this database since its online version is being continually expanded and updated.