

Chemgineering Group 2014



chemgineering

Chemengineering has its roots in the German-speaking regions of Europe; from this base, we support customers and projects around the world. Our origin shapes our culture and is the starting point for our work and motivation. Our employees present to you pictures of their home, which forms the foundation of our style of implementing projects and bringing them to successful completion.

Cover image: Icicles in MuttENZ, Baselland, photographed by our employee Judith Breger

Image on page 24: Grünsee, Riederalp, Valais, also photographed by Judith Breger

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## Dear readers,

If you ask what «home» means, you'll probably get different answers from everyone you ask. For Chemengineering, the question has two facets: the life sciences industry is the area we call home, where we literally know every corner like the backs of our hands. And the German-speaking regions of Europe make up our home market, from which we implement projects for international customers that often take us around the globe. You can read about our progress in 2014 in this annual report.

The market environment in our home countries remained good. After a longer period of restraint, we enjoyed the second consecutive year of high investment activity, especially in the life sciences industry. Particularly in Germany we experienced a boost in sustainable investment and innovation. This positive environment permitted us to continue pursuit of our successful growth strategy, with a consistent orientation to the market, organic growth, efficient internal processes and continuous development and training of our staff as the cornerstones. Our staff played a key role in all this – in the year under review we employed 274 people in the company and in projects, more than ever before in our company history! Although competition for the best talent continues unabated, we succeeded in inspiring highly qualified and motivated people to join us and to stay with us due to our attractive working environment.

Thanks to our competence in project management, we successfully completed several fixed-price projects last year. Various large-scale projects and numerous new medium-sized projects gave us the best year in the history of our company. The newly enlarged Energy & Infrastructure and Management Consulting segments also contributed to sales of 49 million CHF (2013: 41 million CHF). After the numerous large-scale projects commissioned in the last several years, the order volume in the year under review declined slightly, as expected. However, the supply of work is still plentiful. The increase of 50% in sales and marketing capacities will lead to increased order development, so that we expect good results for the current year as well.

Just as there are different definitions of «home», people have different views of their home. We'd like to show you this diversity with photos of Germany, Austria and Switzerland taken by our employees. We would like to express our warm thanks to you, our customers and business partners for the trust you place in our company. And we thank our employees most cordially for their tireless commitment and loyalty to Chemengineering.

Cordial regards,



Steven G. Tappan  
President of the Board of Directors



Dr. Armin Mayer  
Vice President of the Board of Directors



Dr. Gerhard Bauer-Lewerenz  
Member of the Board of Directors



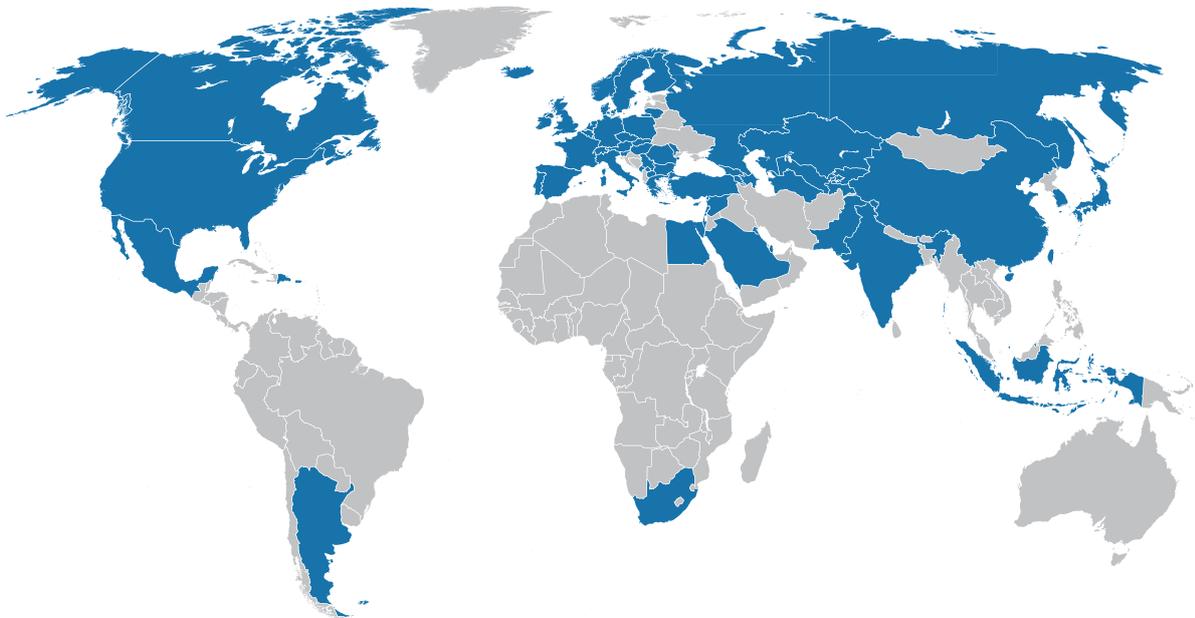
Dr. Ernst Staehelin  
Member of the Board of Directors

## Our focus

Chemengineering offers high-quality, proven consulting and engineering services for the GxP-regulated life sciences industries including pharmaceuticals, biotechnology, fine chemistry, hospital pharmacies, medical technology, cosmetics, vitamins, diagnostics and food. The Business Designers support clients with services that are entirely independent from capital investment programs. The Technology Designers master complex investment projects complete with all the trades involved. Founded in 1996, the corporate group is based in Münchenstein near Basel, Switzerland, and has offices in Germany, Austria and Serbia.

## Our projects

We are constantly on the road for our customers all over the world. Audits, gap analyses, concept studies and other projects have taken us to some of the most remote regions on earth. Our consultants and engineers have left their (blue) footprints for example in Iceland, across the Outer Hebrides, Tunisia, Indonesia, South Africa, Japan, China, Russia, India, Pakistan, Canada and the United States of America.

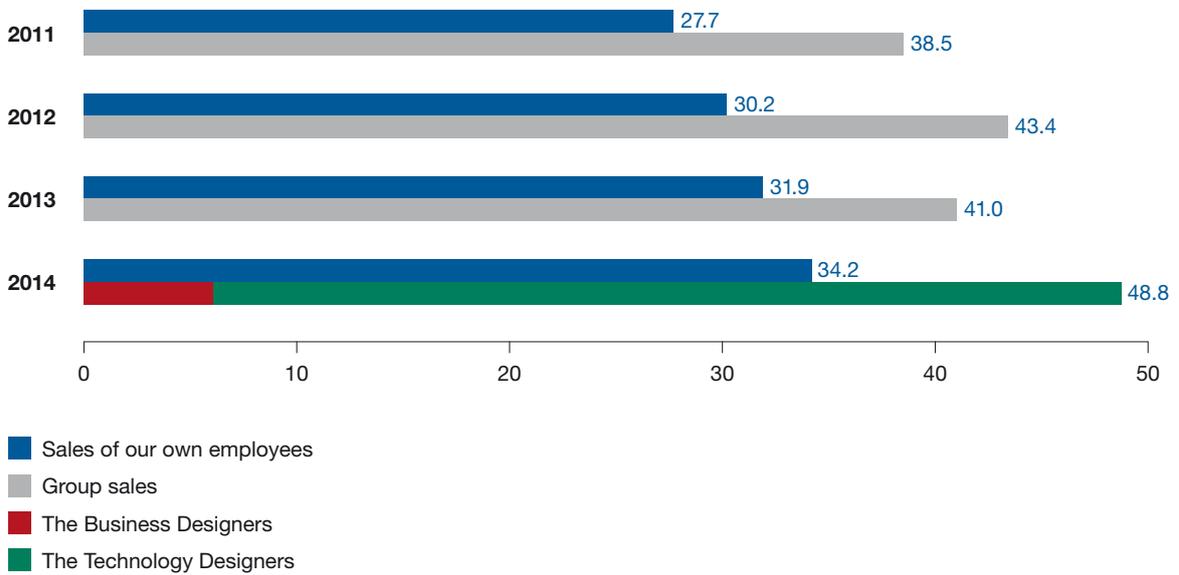


## Key historical data

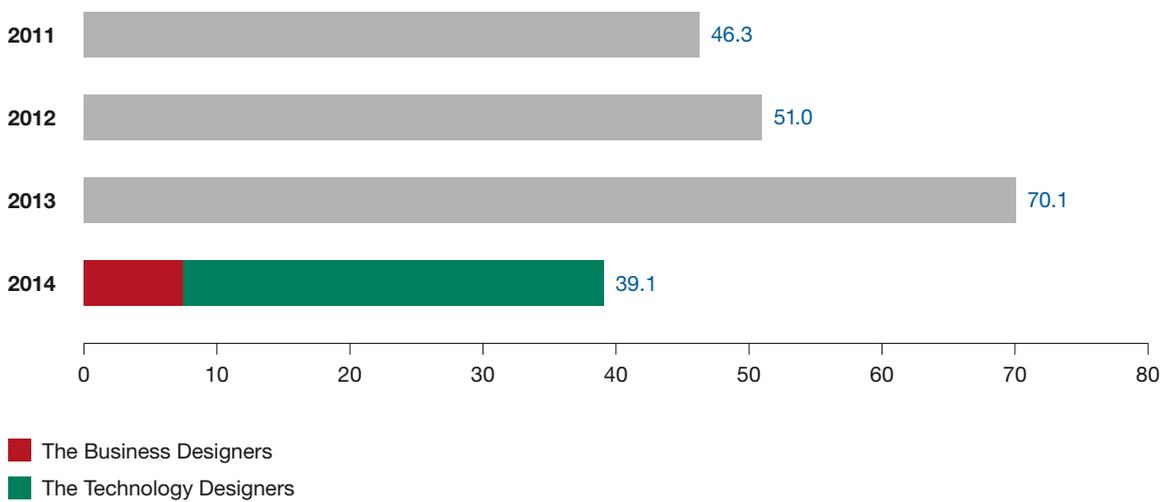
- 2014** The growth strategy has been successfully implemented: We had the highest number of employees and the highest sales figures in the history of our company. In particular, large-scale engineering projects in Switzerland, Germany and Austria contributed to an excellent result. Overall, the order inflow was good, due in part to international projects.
- 2013** Continuous streamlining of the organization and reinforcement of the Business Units.
- 2012** Chemengineering is growing and hires 45 new staff members. The company is awarded one large-scale project each in Switzerland and Austria, and opens an additional branch in Kirchbichl (Austria).
- 2011** Good market development and outstanding result thanks to a favorable economic climate and consistent implementation of the approved strategy throughout the organization.
- 2010** Examination of the strategic situation: Focus on growth in the home markets and developing opportunities in the «Operational Excellence» business segment.
- 2009** Both the Consulting and the Engineering unit feel the worldwide economical crisis with regard to earnings. However, by awarding large construction and qualification projects, clients show their confidence in Chemengineering.
- 2008** Founding of Chemengineering Serbia d.o.o. in Belgrade. The Chemengineering Business Design (Consulting) and Chemengineering Technology (Engineering) companies operate independently.
- 2007** The Chemengineering Management buys back the shares of Uhde AG.
- 2004** The large-scale project MAB, Roche-Basle, is launched. Chemengineering delivers all of the process technology.
- 2003** Strategic alliance with Uhde AG, a Thyssen-Krupp company. Projects and employees of the former «Uhde Pharma Consult», Heidelberg, have been integrated in Chemengineering Deutschland GmbH. The Novartis large-scale project PHAD is launched.
- 2001** The Chemengineering Management buys the shares of Fluor Daniel Inc. Chemengineering is now fully in the hands of its executive committee.
- 2000** The Chemengineering Group extends the executive committee to seven members and establishes three strategic business units: Engineering, Information Systems and Consulting. Large-scale vitamin project at Roche, Grenzach, is completed successfully.
- 1999** The Chemengineering management buys the shares of Bertrams. Shortly afterwards, Bertrams AG declares bankruptcy.
- 1998** Fluor Daniel Inc. founds Advanced Solutions International B.V. (ASIBV), whose name was adopted from ASI GmbH. Chemengineering acquires 60% of SCInformatik AG. The large-scale project Centeon in Marburg is successfully completed.
- 1997** The office in Stuttgart opens, offering services in computerized system validation (CSV) and logistics. Chemengineering Planung GmbH launches its operations in Austria.
- 1996** Bertrams AG (MuttENZ) and Fluor Daniel Corp. (USA) found the joint venture Chemengineering.

## Facts and figures 2014

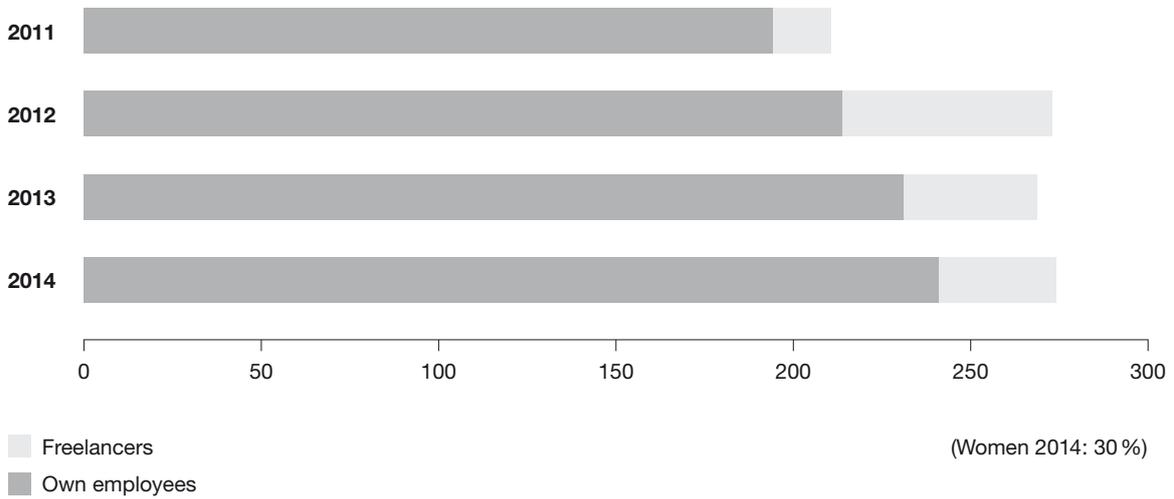
### Sales development in millions CHF



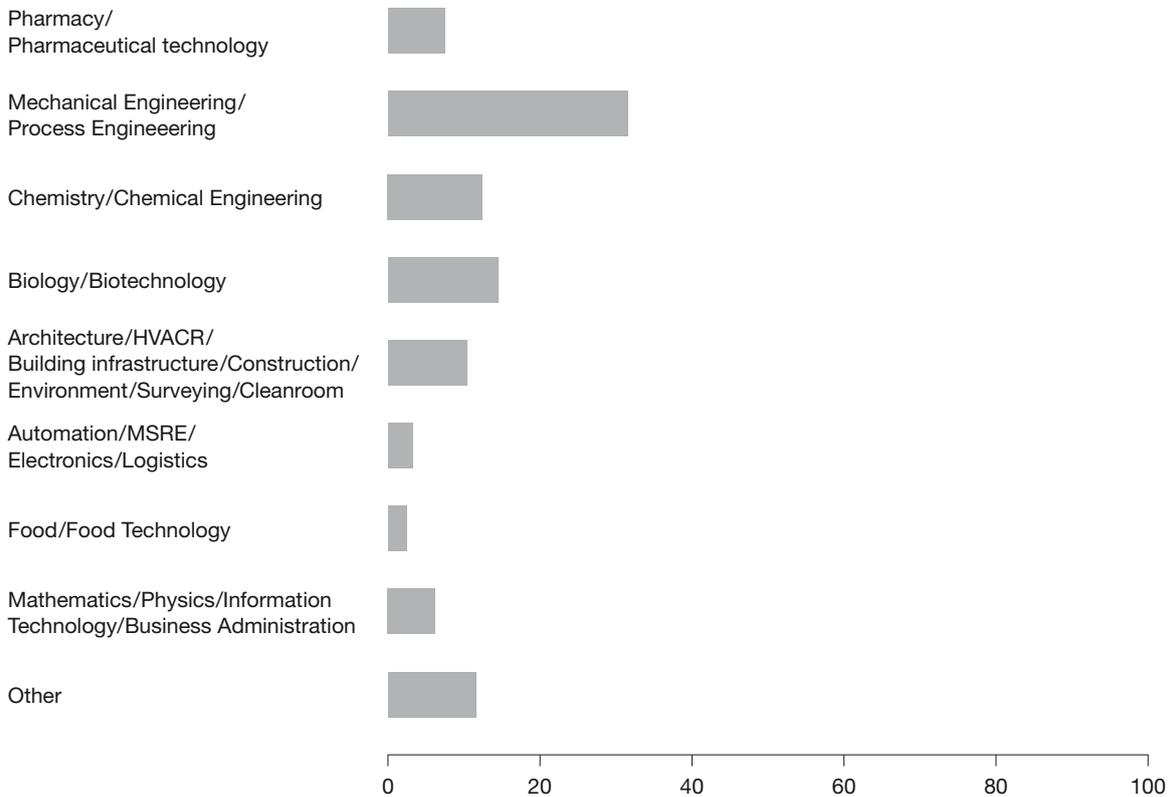
### Awarded orders in millions CHF



### Number of employees



### Employees according to technical disciplines in %





Liebe Brä  
wunderschönen  
Wir genießen das  
die Bergw  
das g

## **Focused on efficiency, cost-effectiveness and compliance: The core business of the Chemengineering Business Designers**

The projects of the Chemengineering Business Designers are focused on services that are entirely independent from capital investment programs. The management consultants ensure efficient, cost-effective processes and organizations, while the medical technology and pharmaceutical compliance consultants are responsible for the introduction, implementation, auditing and maintenance of internationally oriented quality management systems. Our IT consultants ensure efficient, valid implementation of effective and future-capable IT environments. The Business Designers provide you not only with proven implementation experts, but temporary managers as well, who streamline and revitalize your organization while ensuring that compliance and cost-effectiveness are not neglected. Strategy development, implementation and temporary management are tailored precisely to the needs of our customers.

Our business activities at a glance:

### **Management Consulting**

Process Cost Optimization  
Organization Development  
Target Costing

### **Pharma Compliance**

Q-Systems Life Cycle Management  
Rent an Expert  
International Inspection Management

### **Medical Devices Compliance**

Applying risk management principles efficiently  
Practical implementation of quality management systems  
Ensuring global compliance

### **Efficient IT**

IT Process Efficiency and Effectiveness  
Validation of Information Systems  
GMP Compliant IT Integration Management

## Growth on course – Staff further enlarged – Management Consulting very successful

**The Business Designers continued to pursue their growth strategy in 2014. The staff increased by just under 25% to 39 employees. To maintain our high qualification level, we rely heavily on internal education and ongoing training. The steady development in Management Consulting was rewarded with a high volume of incoming orders, significantly increased market presence and strong demand. We will continue to invest in enhancing our expertise and the quality of our services in the current year as well.**

In their «People Business», the Chemengineering Business Designers are always faced with the same challenge: finding outstanding staff members and inspiring them to join and stay with the company. The principle that quality attracts quality holds true. Interesting people with high levels of expertise create an environment that attracts others. This starts with applicant interviews, spills over into the internal work in practice groups that improve our range of services and results in sophisticated projects for clients. The continuous challenge in the best sense of the word found in working with competent colleagues forms the background for this. The open communication culture and high level of cooperation throughout the entire Chemengineering Group complements this environment. In 2014, this combination enabled us to succeed in increasing our staff by just under 25% and to improve the quality of our services even more. Staff was hired at both the senior and junior level. Our students in dual programs of study successfully completed their bachelor's degrees and will be followed by new colleagues. In addition to two places in the course of study in «International Business», the business designers now offer medical technology students a place in the dual system as well.

### Management Consulting

With their focus on the interfaces between production, quality control and logistics, our Management Consultants offer much-needed solutions to highly topical issues. This was impressively confirmed by the high order volume in 2014 and the numerous new inquiries. The top priorities in this regard are the utilization of cost potentials and the rapid implementation of pragmatic measures. Our Management Consultants also provided support in successful projects in the areas of strategic site selection and make-or-buy decisions. In this new consultancy field, we remain true to our specialization in process cost reduction, organizational development and selected strategic issues.

### Pharma Compliance

The continuously increasing demand for «third-party audits» resulted in the internal training of additional auditors, so that our audit team has now grown to include nine superbly qualified auditors. We will continue to develop our business in this field. The orders received for 2015 prove, that we are on the right course. The strong operational background of our consultants also enabled us, to provide direct support for production and methodology transfers in extremely interesting projects. Inquiries and orders for risk management and purification validation projects also increased.

### Medical Device Compliance

The inspection activities of the FDA prompted our customers to prepare intensively for audits in the past year as well. With their accustomed efficiency, the Business Designers provided support with Mock Audits, operative implementation of the required measures and accompanied FDA inspections in the front and back office with expertise, translation and interpreting services and creative solution approaches. Our wide range

of customers is represented in very diverse areas of the medical device industry, including implants, dental materials, devices, components, disposables and in-vitro diagnostics. We were also able to provide support in the exciting field of combination products with regard to regulatory issues. In addition, a further highly topical area opening up in 2015 is the sustainable qualification of supply chains.

### Computer Validation/Efficient

IT Classic validation of computerized systems as well as support in IT project management were the primary fields for our projects in 2014. Our consultants have been in the market for over 20 years and possess outstanding expertise and experience, which always results in efficient solutions for our customers. The now firmly established computer system validation requires increasingly cost-effective approaches in the meantime. These efforts are directly reflected in our range of services aimed at reducing IT process costs, which our customers happily utilized in several projects.

Another issue that our clients are increasingly focusing on is «Secure Track & Trace», so that we have already conducted a number of in-house workshops in this regard. The synergies that we also offer via our experts for good distribution practice are extremely helpful and greatly valued by our customers.

### Our expectations for 2015

We will continue our course of growth, but ensure healthy consolidation as well. New, highly qualified staff members have already signed on with us and will reinforce our Management Consulting and Pharma Compliance teams in the first half of the year. We will keep a close eye on new challenges and issues arising from the expected changes in European Union legislation for medical devices and in the German Medical Device Act. As in previous years, we will participate in the discussions and debates via publications in renowned trade journals and presentations with our partner organizations VDI, TÜV and Concept Heidelberg.

We are continuously increasing our expertise through the work of our internal practice groups, where we explore the issues compiled based on our distinctive experience in inspections with domestic and international authorities and that are therefore already of interest to our customers or certainly will be in the near future. In this way we try to peer into the future and develop economical approaches early, so that we are always able to provide state-of-the-art and continuously improving services to you, our customers.

Dr. Gerhard Bauer-Lewerenz  
Head of Consulting Chemengineering Group

We will continue to invest in enhancing our expertise and the quality of our services in the current year as well.



Viele Grüsse aus  
Sind ganz gut  
heute abend



## **Long-term planning: The core business of the Technology Designers**

Our Technology Designers deliver customized solutions tailored precisely to the demanding requirements of our customers and master sophisticated investment projects from conception to handover.

### **Where we work**

Pharmaceutical Industry  
Specialty Chemistry  
Hospital Pharmacies  
Vitamins/Cosmetics  
Medical Technology

### **What we plan and implement**

Production Plants for all Forms of Pharmaceuticals  
Synthesis Facilities for Active Substances and Special Chemistry  
Packaging Systems  
Laboratories  
Clean Rooms  
Process Infrastructure Systems  
Media and Energy Systems  
Storage and Logistics Facilities  
Automation Systems

### **Our areas of special expertise**

Sterile Filling & Finishing  
Track & Trace  
Highly Active Substances  
Biotechnology (Upstream + Downstream)  
Blood Plasma Fractionation  
Process Simulation  
Safety Technology  
High-purity Media  
Exhaust Gas Treatment  
Cryogenics

### **The services we provide**

Feasibility Studies  
Concept Design/Concept Planning  
General Planning/General Contracting  
Plant Design (Including 3D CAD)  
Project Management  
Construction Management  
Commissioning  
Qualification/Validation

## Strong growth and excellent results in all three country organizations

**By the end of 2013 we could already foresee, based on the high volume of orders received, that fiscal year 2014 would bring outstanding results for the Engineering Business Unit – The Technology Designers. The first few months have already shown that these expectations can be fulfilled. Parallel to the expansion of the project completion capacities we also adapted the sales and marketing organization of the Technology Designers to the new requirements.**

The goals for fiscal year 2014 were:

- achieving the budget targets for 2014, including sales, profitability and staffing levels in accordance with our «Strategy 2014» program
- adapting our range of services to the rapidly changing market conditions.

The budget specifications for sales, profitability and staffing levels were achieved and partially even exceeded. Details of these can be found in the section entitled «Facts and Figures» on page 6. At the end of the fiscal year we were able to report that the business unit had achieved the highest sales, earnings and staffing level since the company was founded. This success is the result of the excellent international collaboration among the departments, project directors, sales organization and internal services that were/are of enormous assistance particularly in recruitment.

As the highlight of 2014, we'd particularly like to note the brilliant success of all three regional units, which together contributed to the most successful fiscal year in the company's history.

In 2014 as well, we continuously expanded and streamlined our entire operational organization so that we can continue to respond quickly and efficiently to the constantly changing needs of our clients.

The strong growth of the business unit in recent years and the increasing requirements of our customers made the restructuring of our account management and marketing organization an important step into the future.

The Account Management and Marketing departments were merged to form an international unit under Mr. Ivo Jegge. The sales team was enlarged to 5 members, who are supported by a powerful back-office team.

### Market situation

Over the past several years we have found that our project business with many of our customers has been changing. Two general trends were noted:

1. Massive outsourcing of engineering and construction management as well as qualification and validation activities.

For some time now, we as a contractor have been increasingly taking over tasks that were largely performed by our customers in the past. These tasks begin in the initial phases of the projects; our clients involve us in project definition, so that we bear part of the responsibility for the success of the projects very early.

Additional focal points over the course of the project include many aspects of quality management such as development of the qualification/validation strategy, drafting project-specific SOPs, the design and implementation of qualification and validation activities and performance and process validation.

In addition to expertise in the subject matter, management and communication skills as well as flexibility on the part of our staff are required to meet our clients' needs properly. We are following

this trend by enhancing our range of services via intensive and ongoing training of our staff and selective hiring.

2. The clients manage all phases of their projects themselves and generally want only expert support in the implementation of their plans.

This trend as well has required us and our staff to rethink some aspects of the way we work: the customers have their own standards that they want seamlessly implemented and the work must be done in accordance with these standards. The demand for creativity is then not as strong, but may sometimes be desired by the customer as well.

We can look forward to the future with optimism. The result for the first quarter of 2015 indicates a continuation of the success of 2014. We are very pleased with the figures for sales, earnings and staffing levels. The further expansion and streamlining of the operational organization will enable us to respond to the constantly changing needs of our customers even faster in the future.

Dr. Armin Mayer  
Head of Engineering Chemengineering Group

The high order volume, the excellent international collaboration among departments, project directors and the more powerful sales and marketing organization led to the most successful fiscal year in the history of the company.

## Client relations 2014

Chemengineering succeeded in strengthening its business relations with existing clients as well as establishing new contacts. Listed below is a majority of the companies for whom we implemented projects in 2013.

ABB | Actelion | Aenova | Aliud Pharma | Almirall Hermal | Allpack Group | Anteis | Ara Rhein | B. Braun | Bachem | Bausch + Lomb | Bau und Verkehrsdirektion Basel | Bayer | Bio Rad Medical | Biotest | Biofrontera | Blutspendendienst München | BODE Chemie | Boehringer | CABB | Cargill | Cilag | Cinfa Biotec | Concept Heidelberg | Cromapharma | Crucell | CSL Behring | Curevac | Dentsply DeTrey | Deutsche Bundeswehrapotheke | Dr. Falk Pharma | Dr. Kade Pharmazie | Dr. Paul Lohmann | DSM | DSM Nutritional | EBEWE Pharma | Em Tec | Estee Lauder | Evonik Degussa | Ferring | Fresenius Kabi | Frueh Verpackungstechnik | Frutarom | GE Healthcare | Gesundheitsdirektion Zürich | GHZ Gewerbe und Handelszentrum Schlieren | G.L. Pharma | GP Grenzach Produktion | Grace | Greiner Bio-One | Haupt Pharma | Helm | Hennig Arzneimittel | Heumann Pharma | Hevert Arzneimittel | Hexal | HFR Freiburger Spitalapotheke | Holopack Verpackungstechnik | IDT Biologika | Infrapark Baselland | Intervet | Ivers-Lee | Ivoclar Vivadent | Kantonsapotheke Zürich | List | LTS Lohmann Therapie Systeme | Luzerner Kantonsapotheke | Maquet Cardiopulmonary | Merz | Metrohm | Nestlé | Normed Medizin Technik | Novartis | Octapharma | Onko Ilac | Pangas | PharmaZell | Phyton Biotech | Riemser Arzneimittel | Roche | Rohrer | Routil | Sandoz | Sanofi Aventis | Serto | Stada Arzneimittel | Städtisches Klinikum München | Steiermarkische Krankenanstalten | Steigerconcept | Swiss Surface Solutions | Syngenta | Tau Tanklager Auhafen | Thommen Furler | The Graymor Chem | Universitätsspital Basel | URS Switzerland | Vetter Pharma | Vibalogics | Zeochem

## Publications 2014

In three issues of the Chemgineering Newsletter 2013, with a total of 22 specialist articles, we provided you with information on current topics relating to GMP. These and other articles can be retrieved directly from our website at [www.chemgineering.com](http://www.chemgineering.com) using a key word search. And you probably also will have read the following contributions of our Business and Technology Designers in trade journals.

### **Remodeling during ongoing production – no problem!**

Gita Enderlein, Project Manager, TechnoPharm, April 2014

Ideally, an investment project should be implemented only as a new facility in the green belt. But how often is that actually possible? Instead, projects increasingly have to be carried out in existing facilities during ongoing production. Such conditions are anything but optimal, but they can be successfully managed. Intervention in ongoing production requires intensive planning and systematic preparation. The essential criteria are established in the initial planning phase. A coherent schedule, a strategically oriented approach, a detailed list of measures to be taken and clearly defined responsibilities are the tools for successful project management.

### **GxP-compliant operation of computerized systems**

Dr. Peter Schober, Senior Consultant, Chemie Plus, May 2014

To ensure smooth operation in the automated manufacturing of products in the life sciences industry and to prevent critical incidents, regulation and validation of the systems is essential. Validation covers the entire life process of the system. The validation of the system must be continuously maintained to ensure high standards of safety. The goal is to document compliance with the requirements, that the system is suitable for the intended use and that the specifications have been fully implemented. Those working with the system in practice can utilize the appendices of GAMP 5. Risk management in particular covers measures for the systematic detection, analysis, assessment, monitoring and control of risks. This requires good collaboration of the manufacturer with all suppliers, a risk assessment, integrity, confidentiality and data security. At the seminar «GAMP 5 – Practical Implementation» hosted by Swiss Cleanroom Concept, Dr. Peter Schober gave a presentation on «Risk-based Validation of Computerized Systems».

### **Pharmaceutical quality control: process cost optimization**

Dr. Thorsten Ebbinghaus, Senior Consultant, Pharma+Food, August 2014

Sand in the gears of pharmaceutical quality control grinds and grates and increases wear. However, the focus of quality control on its core tasks is absolutely essential, as quality control (QC) is an important link throughout the entire value creation chain. Any friction affecting this subprocess results in costs, which are reflected either directly or indirectly in your product and thus in your margin. It's not only that all the release analyses for a batch of a pharmaceutical active substance can easily amount to the price of a mid-range car, but the time required between production and release directly affects the work in progress (WIP). This negative influence on corporate key data such as return on capital invested (ROCI) or economic value added (EVA) is especially large in this case, as the cost-intensive manufactur-

ing steps have already been completed at this point in time. Not without reason is this form of capital lockup counted among the seven deadly types of waste (Japanese term: «muda») in lean management.

- Classical value stream mapping based on a work distribution analysis (WDA) is an outstanding option for identifying grains of sand in gears in the regulated GMP environment as well.
- A clearly formulated, well-regulated escalation model accelerates the process so that competent and authorized staff bears the responsibility for the necessary decisions only as far as required.
- Well-structured sample and order logistics ensure that an overview is maintained and planning of the daily laboratory work is made easier.

### **Good Manufacturing Practices for Excipients**

Dr. Martin Melzer, Senior Consultant, pharmind No. 6, 2014

The Falsified Medicines Directive 2011/62/EU introduces a formalized risk assessment for the appropriate GMP level for the manufacturing of excipients of medicinal products for human use. The manufacturing authorization holder is in charge to identify the risks with regard to the quality, safety and function of each excipient. An on-going risk-based review of the manufacturer of the excipient should be performed.

## Lectures and events 2014

We regularly present our proven expertise in lectures and specialist events. In 2014, Chemengineering conducted the following lectures and training courses:

Validation of computer-based systems (CSV) Sieghard Wagner

Outsourcing and supplier management Frank Studt

In focus: manufacturers of active substances from China and India Frank Studt

The computer validation officer: blocks 1+2 Dr. Peter Schober, Dr. Thomas Karlewski, Sieghard Wagner

Product quality review: practical solutions for PQR Frank Studt

GMP for medical devices Dr. Gerhard Bauer-Lewerenz

New regulations for medical devices: the most important changes for manufacturers Rolf Lietzke

GAMP 5 for use in practice: illustrated with the example of a cleanroom monitoring system Dr. P. Schober

From raw material to active substance. From active substance to pills. Dr. Wolfgang Minas

MIS: keeping management focused on the important things Dr. Thomas Lellau

Water and steam for pharmaceutical use: ISPE Ozone Guide in Focus Jochen Schmidt-Nawrot

IT projects and system implementation: ERP validation made easy Dr. Thomas Karlewski

Designing process and product development efficiently: transferring proprietary medicinal products  
Frank Studt

GMP guidelines and trends: deviation management in the pharmaceutical industry Frank Studt

Planning and construction of a production area in an existing facility under complex conditions  
Christian Hepfer

Clean rooms with special requirements Dr. Alexander Slanina

No pharmaceutical products without ultrapure water! Jochen Schmidt-Nawrot

Quality management in medical devices Martin Rümke

Single use vs. stainless steel Dr. Wolfgang Minas

Scale-up considerations in an industrial environment Dr. Wolfgang Minas

UDI – Unique Device Identifier Nina Hönig

### Conferences and trade shows

In 2014 you met the Business and Technology Designers in Germany at Lounges in Stuttgart, as presenters at various Concept Heidelberg GMP seminars and at the BABTEC event «Quality management in medical devices» in Hamburg. In Switzerland our specialists gave presentations during the Swiss Cleanroom Concept training courses in Rheinfelden. Our Technology Designers also gave presentations at TechnoPharm in Nuremberg.

**You can find up-to-date information on seminars, lectures and events of and with Chemengineering on our website, [www.chemengineering.com](http://www.chemengineering.com). Furthermore you find informations about selected events in our Newsletter.**

## Lectures and events 2015

### Concept Heidelberg

Validation of computer-based systems (CSV) Sieghard Wagner

Product quality review Dr. Martin Melzer

Outsourcing and supplier management Frank Studt

The computer validation officer: blocks 1+2 Dr. Peter Schober, Dr. Thomas Karlewski, Sieghard Wagner

GMP for medical devices Dr. Gerhard Bauer

Change control Dr. Martin Melzer

The GDP audit Dr. Martin Melzer

Outsourcing Supplier Management Dr. Georg Sindelar

### Swiss Cleanroom Concept

GAMP 5 for use in practice Dr. Peter Schober

Hospital pharmacy Matthias Juffa, Judith Breger

Quality design for clean rooms, Cleanrooms in packaging Vera Hangst, Bernhard Binnwerk

Water requirements in hospitals Sven Müller

### SGVC Training Day

Procurement of systems and components subject to technical material factors Peter Bilger

### Lounges Stuttgart

Qualification of cleanrooms Dr. Gerald Banko

House of quality – controlling quality processes with key data Dr. Thorsten Ebbinghaus

Transferring proprietary medicinal products – a delicate task Frank Studt

Deviation management in the pharmaceutical industry Frank Studt

Highly active substances in packaging Vera Hangst, Bernhard Binnwerk

New good practice guide commissioning and qualification, volume 5 Jochen Schmidt-Nawrot

ERP validation – efficient as well as compliant Dr. Thomas Karlewski

Planning and construction of a production area in an existing facility Christian Hepfer

Alternatives for the generation, storage and distribution of cold WFI Jochen Schmidt-Nawrot

Superordinate automation concepts for pharmaceutical manufacturing and their interfaces Steffen Wöllner

### TÜV Academy

Various presentations on the Medical Device Act Martin Rümke

Test method validation and preventive supplier management in medical device Nina Hönig

### Polymesse ETH Zürich

From the raw material to the active substance – from the active substance to the pill. Dr. Wolfgang Minas

### Conferences and trade shows in 2015

Pharma Congress Düsseldorf 24–25 March

Polymesse, ETH Zürich 22 April

Lounges, Messe Stuttgart 19–21 May

## Management of the Chemengineering Group

### Board of Directors

Steven G. Tappan, President  
Dr. Armin Mayer, Vice President  
Dr. Gerhard Bauer-Lewerenz, Member  
Dr. Ernst Staehelin, Member

### Finance Committee

Dr. Gerhard Bauer-Lewerenz, Chairman  
Steven G. Tappan, Member  
Daniel Käslin, External Member  
Dr. Simon Mayer, Permanent Member  
Christoph Stettler, Permanent Member

### People Committee

Dr. Gerhard Bauer-Lewerenz, Chairman  
Dr. Armin Mayer, Deputy Chairman  
Dr. Simon Mayer, Permanent Member  
Markus Meier, Permanent Member  
Frank Studt, Permanent Member

### Operations Committee

Dr. Gerhard Bauer-Lewerenz, Head of Consulting  
Dr. Armin Mayer, Head of Engineering  
Dr. Simon Mayer, Head of Services

### Managing Directors

#### The Business Designers

Dr. Gerhard Bauer-Lewerenz  
Frank Studt  
Chemengineering Business Design Companies  
Germany, Switzerland, Austria

#### The Technology Designers

Markus Meier  
Dr. Wolfgang Müller  
Chemengineering Technology AG  
Switzerland

Dr. Gerhard Bauer-Lewerenz  
Dr. Armin Mayer  
Chemengineering Technology GmbH  
Germany

Dr. Armin Mayer  
Carol Notdurfter (since 1.1.2015)  
Chemengineering Technology GmbH  
Austria

Dr. Armin Mayer  
Chemengineering d.o.o.  
Serbia

### Corporate auditors

PricewaterhouseCoopers AG, Basel

## Corporate offices

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