
Chemgineering Group 2012
chemgineering

Chemgineering has enjoyed success in the life sciences sector for over 15 years, in activities ranging from consulting services for the pharmaceutical and medical technology industries to planning and implementation of complex investment projects involving all the relevant trades.

Photos: In the pharmaceutical industry, hamamelis (witch hazel, front cover) as well as chamomile (back cover) are used as medicinal plants.

Dear reader,

The economy underwent major changes in 2012. Long-established structures and institutions experienced upheaval due to new market conditions.

In order to assert themselves in these changing markets and to cope with the trend of continuously increasing regulatory requirements, all companies will have to undertake major efforts with regard to increased transparency, greater flexibility and cost reduction as well as to invest in production and staff in order to remain competitive.

Chemgineering established its strategy for growth in 2011, successfully launching it in 2012. In order to focus more intensively on and meet new market requirements faster as well as to support the targeted growth, Chemgineering redefined the ownership structure, the composition of the board of directors and group management as well as the organizational form of the Engineering business unit. This expanded the latitude for decision-making of the business units and significantly increased their operational responsibility. The owners and management are now more closely involved with the business than ever.

Moreover, the development of strategy and management consulting was accelerated in the Business Unit Consulting. In the future, Chemgineering will increasingly offer our clients services tailored specifically to the development of effective and sustainable marketing strategies in selected areas as well as to the implementation of cost saving potentials in business processes.

In 2012 the Business Units Consulting and Engineering were in great demand in the relevant markets, enjoying numerous orders received for new, large-scale projects. Total sales at Chemgineering rose by 13% compared to the previous year to CHF 43.4 million, stabilizing its market position. Despite the shortage of engineers and scientists in the market, over 50 new specialists were hired in the past year. Chemgineering continues to pursue sustainable, organic growth in its traditional markets with a focus on the life sciences industry. Our goal is to implement all of your projects successfully and to meet or exceed your expectations.

We'd like to express our warm thanks to our staff for their outstanding personal commitment and to our clients and business partners for their loyalty and support.

Cordial regards,

Steve 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

Inspection reliability and cost-efficient processes for health

For the Business Unit Consulting – The Business Designers – 2012 was one of the busiest year so far.

Numerous visits to our clients from the regulatory authorities were announced at the end of 2011, so that the turn of the year transitioned smoothly into the inspections. To start things off, we provided support to a smaller medical device manufacturer during an FDA inspection of the front and back office. This was followed immediately by an ANVISA inspection (Brazilian authority) of a Swiss pharmaceutical manufacturer lasting several days, which was likewise completed without complaints to speak of. Once again, the sustained international trend towards issues of cleaning validation, deviation and complaint management, Computerized System Validation (CSV), Annual Product Review (APR) and Product Quality Review (PQR) was in evidence – all issues for which our compliance consultants always provided practical, effective solutions prior to the inspections.

Our own team of auditors grew to include seven members in 2012. In addition to numerous one- and two-day supplier qualification audits of manufacturers of active substances or proprietary medicinal products, which we carried out on behalf of European and American manufacturers worldwide, we were given the opportunity to integrate ourselves in the international auditing team of one of the world's leading pharmaceutical manufacturers. In four-member auditing teams, we carried out a large number of intensive gap analyses, some of which lasted up to two weeks, at manufacturing sites in Asia and Europe. For part of the time, former FDA inspectors were also active in the teams, so that in addition to the usual front-office support we gained another opportunity to experience the procedures of the FDA firsthand and to integrate this experience in the ongoing development of our own practices.

Once again, our IT experts also managed highly complex ERP implementation projects, including the validation which is obligatory for pharmaceutical applications. Provider selection was also done for purely commercial modules based on the previously prepared, detailed process descriptions.

Our management consultants worked intensively on cost-saving potentials and the accompanying reorganization of obsolete organizational structures. Statistical systems for Quality Assurance / Quality Control processes (QA/QC), Overall Equipment Efficiency (OEE), process and product cost analyses were the drivers that took our customers to more economical and efficient workflow and organizational management.

We, the Chemgineering Business Designers, are increasingly becoming specialists for economical process and inspection reliability. Together with the Chemgineering Technology Designers, we offer an inestimable added value for our customers in the life sciences industry: everything from a single source.

Streamlined organization and optimized growth strategy bring success

For the Business Unit Engineering – The Technology Designers – 2012 was a year with many positive developments.

We streamlined our organization, improving our ability to respond even faster and more flexibly to the needs of our clients. For this purpose, a single operational unit for all country subsidiaries was created that facilitates better and more flexible allocation of personnel. Each specialist department acts as an international knowledge pool and is headed by a department manager who has organized his teams in specialist groups with group managers. The project directors, who each head a team of project and construction managers, are responsible for successful project completion. Our sales and marketing organization likewise has an international structure, so that it can focus more intensively on the relevant regions.

The growth strategy initiated in 2011 was also driven forward with great commitment last year: at our Kundl site in Austria, we established a site engineering team. In addition to Chemgineering staff who have been with the company for many years, a number of newly hired, local staff members implement numerous projects for our clients. The success of these projects is the basis for further development of this business model in the current year.

Likewise in Tyrol, we as the general contractor are implementing a large-scale project: a sterile filling facility for prefilled syringes including refrigerated storage. For this purpose we have opened a new office in Kirchbichl, close to our client's site. This location, nestled amid Tirol, Vorarlberg, Salzburg and Bavaria, enables us to provide localized support for our clients in this economic region.

The highlight of the past year is indisputably the acquisition of a large-scale project in the Rhine Valley region. This project is a trailblazer for Switzerland as a place of business for the pharmaceutical industry: a state-of-the-art production facility for pharmaceutical solids is being built here. We largely met our growth targets for 2012: the Engineering business unit now has more than 180 staff members for the first time. The targeted integration of our new staff members and continuous advanced training for our personnel are safe investments and will give us a good basis for 2013 and the future.

In autumn 2012 we moved into our new office in Münchenstein/Basel, where more space and open structures facilitate even better collaboration.

We are optimistic about the future: our new staff members, ideal working conditions at our sites and an extraordinarily high number of orders in the fourth quarter of 2012 and the first quarter of 2013 have given us an excellent foundation for sustained growth.

Our services

The Business Designer consultants provide strategic management consulting to the pharmaceutical and medical technology industries to develop effective, sustainable marketing strategies and to realize cost saving potentials. Our management consulting includes business process management and organization, investment consulting and strategic development for operations. Compliance consulting, focused on regulatory requirements, deals with the cost-effective implementation of regulatory requirements. Finally, information system consulting covers all issues of computer validation and the selection of suitable systems for the GxP-regulated industry.

Portfolio Management

Strategy Consulting

Marketing Effectiveness

Life Cycle Competitive Readiness

Process and Value Chain Optimization

Management Consulting

Development and Implementation

Cost and Sales Optimization

Daily Business Support

Validation

Qualification

Compliance Consulting

Gap Analyses and Mock Inspections

GxP Audits for Third Parties

QS-Systems

IT Integration Management

IS/CSV Consulting

GAMP 5/Part 11 Consulting

Validation of Computer-based Systems

Our services

Our engineering specialists master complex investment projects complete with all the trades involved. Technology design from Chemgineering covers conceptualization, planning, implementation and qualification of complex large-scale projects. This includes the planning and implementation of systems, including new construction and remodeling of production, development and research centers, infrastructure or entire factories – particularly when we function as general contractors.

The Technology Designers also offer engineering services in the fields of special chemistry and fine chemistry.

Qualification

Validation

Concept Development

General contracting

Project Management

General Planning

Services

Basic and Detailed Engineering

Construction Management

Initial Startup

Solid, Semi-solid, Liquid Forms

Active Substances, Vitamins, Special Chemicals

Production and Pilot Plants and Systems

Sterile and non-sterile pharmaceuticals

Media preparation

Laboratory process infrastructure

Logistics

Systems and Infrastructure

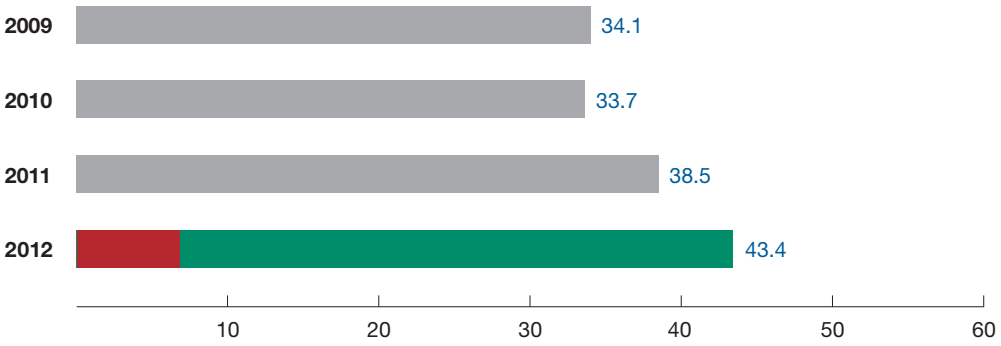
Warehouses

Clean Rooms

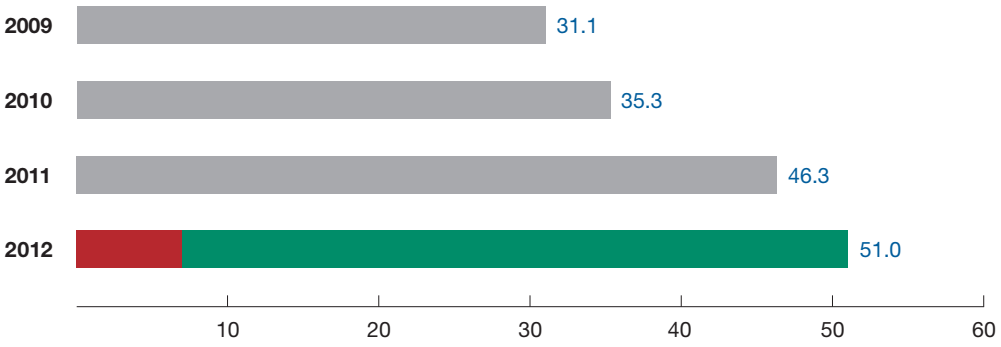
Special Buildings

Facts and figures 2012

Sales development in millions CHF

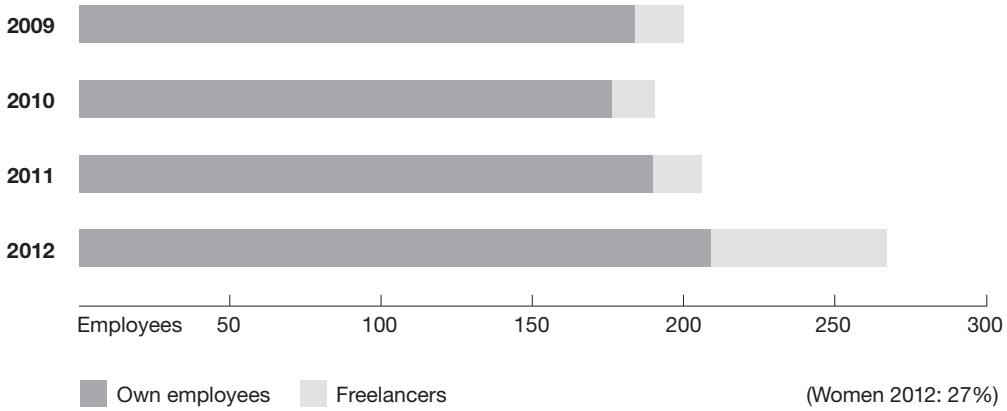


Awarded orders in millions CHF

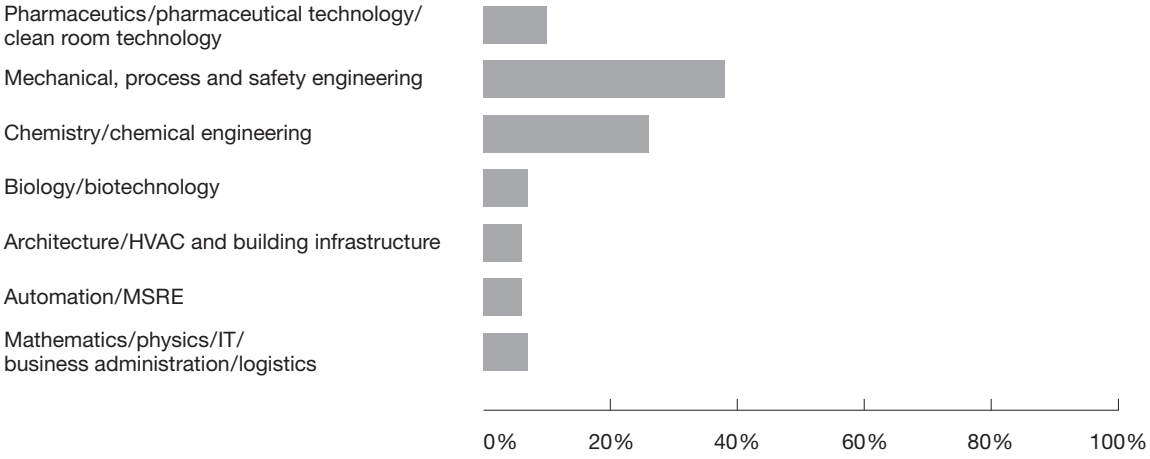


The Business Designers
The Technology Designers

Number of employees

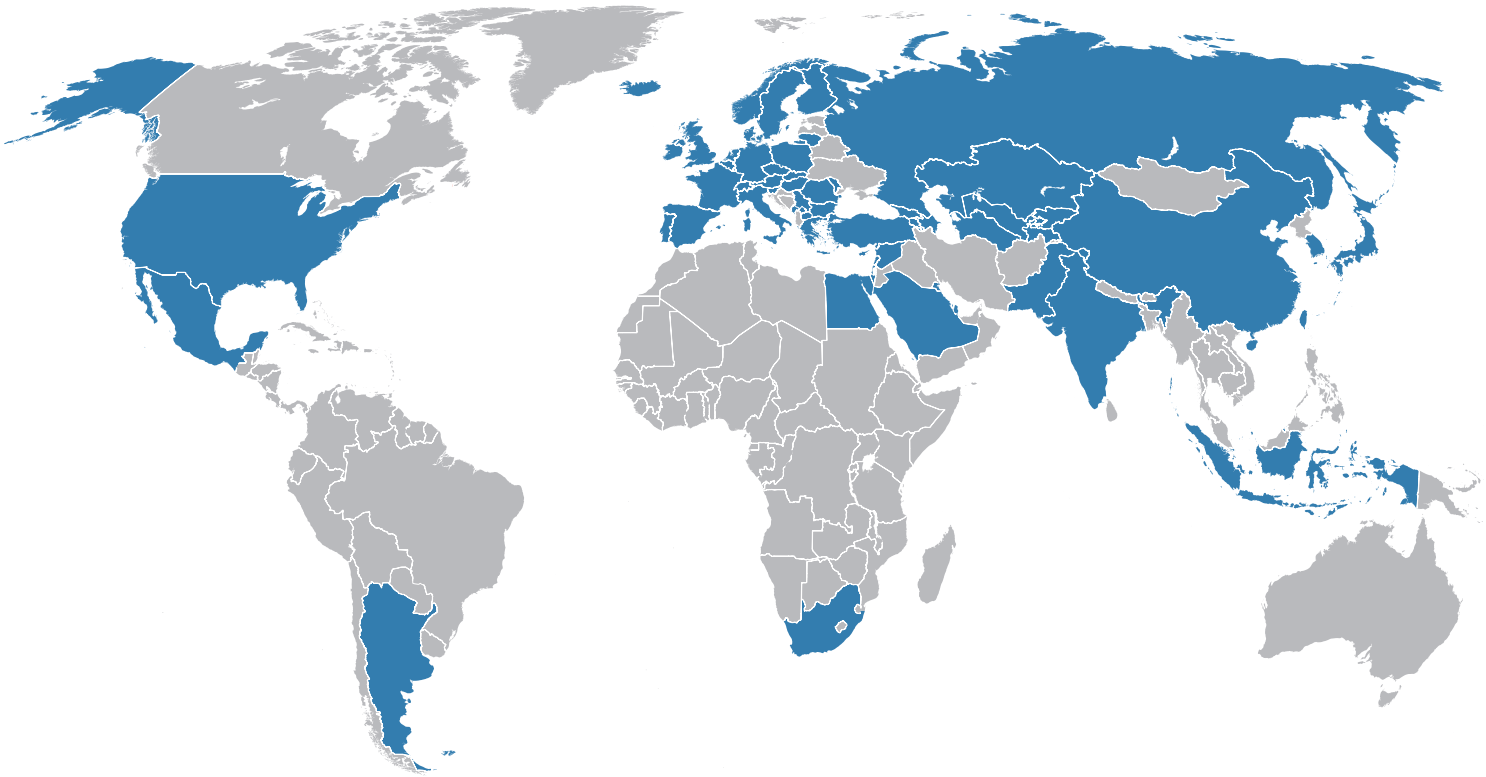


Employees according to technical disciplines in %



International Client Relations

Germany | Austria | Switzerland | Liechtenstein | France | Italy | Spain | Portugal | Greece | San Marino | Macedonia | UK | Ireland | Iceland | Finland | Sweden | Denmark | Norway | Netherlands | Czech Republic | Romania | Turkey | Malta | Poland | Bulgaria | Serbia | Hungary | Slovakia | Russia | Kazakhstan | Slovenia | Lebanon | Egypt | Saudi-Arabia | Lithuania | South Africa | Israel | Syria | India | Indonesia | Pakistan | China | Japan | South Korea | Mexico | USA | Argentina



Client relations 2012

In 2012, Chemgineering managed to strengthen its business relations with existing clients as well as to establish new contacts. Listed below is a majority of the companies, for which we could realize projects in 2012.

4SC | ABB Schweiz | Abbott | Acino | Actelion | Advanced Pharma | Antisense Pharma | Astra Industrial | B. Braun | Universitätsspital Basel | Baxter | Bayer Schweiz | Bayer Technology | Bio-Rad Medical | Biotest | Biotronik | BIPSO | Bilfinger Berger Rohrbau | BODE CHEMIE | Boehringer Ingelheim | CABB | CABOT | Cargill Deutschland | Centroprojekt | Ciba Vision | Clariant | Cleangrad | COMAR Chemie | Concept Heidelberg | Croma-Pharma | Crucell Switzerland | CSL Behring | Degudent | DOMO Caproleuna | Dottikon Exclusive Synthesis | Dr. Paul Lohmann | Dr. Kade Pharma | DSM Pentapharm | DSM | EBEWE Pharma | Edl Anlagenbau | Elca Informatik | Excella | Excelvision | Falcon Medical | Fresenius Kabi | Freyler Industrial | Friadent | Frutarom | G.L. Pharma | Apotheke Zürich | GP Grenzach Produktion | Hameln Pharmaceutical | Hanag Steriltech | Hennig Arzneimittel | Hevert-Arzneimittel | HEXAL | HFR Freiburger Spitalapotheke | Hoffmann Neopac | IL-Medtec | Intervet | Ivers-Lee | Ivoclar Vivadent | John Brown | Kantonsspital St. Gallen | Kantonsspital Luzern | Kirsch Pharma | Konapharma | Lehmann Engineering | Limeco | Linde Gas | Linde Gas Italia | Linde Kryotechnik | Linde Sogas | List | Lohmann Animal | Mediagnost | Merck Serono | Merz Pharma | Metrohm | Mip Pharma | Mövenpick Foods | Nolax AG | Normed Medizin | Novartis | Novi | Nycomed | PAA Laboratories | Pharma Product | Pharma Zell | Philip Morris | PM Group | Provectus Techno | RIEMSER Arzneimittel | Roche | Roche Diagnostics | Sandoz | Schott Forma Vitrum | Segliwa | Serto | Siegfried | SMS Siemag | Solvias | Sorin Group | STADA Arzneimittel | Steigerconcept | Straumann | Stryker Osteosyn | Sulzer Chemtech | Syngenta Crop | Synthes | Testo | The Graymor Chemicals | Tillotts | Tuev | Tutogen Medical | Uhde Services | Umicore | Technische Universität Leipzig | Universität Reutlingen, Institut für Medizintechnik | Varus | Vetter Pharma | Warner Chilcott | Weleda | Werum Software | West Pharmaceutical | Z-Systems

Lectures and events 2012

Regularly, we present our proven expertise in lectures and specialist events. In 2012, Chemgineering conducted the following lectures and trainings.

GMP for Medical Devices Dr. Gerhard Bauer-Lewerenz
Reinigungsoptimierte Planung und Errichtung von pharmazeutischen Anlagen Gerd Liebers
Praktische Beispiele zur Planung und Errichtung von Pharmaanlagen Gerd Liebers
Umsetzung der ICH Q9-Richtlinie im Qualitätssystem Dr. Christoph Heberlein
Abweichungsmanagement in der pharmazeutischen Industrie Frank Studt
Containment Systeme – Verpackung hochaktiver Substanzen Silke Eisel
Was hat der neue EU-GMP Annex 11 für die Computervalidierung verändert? Sieghard Wagner
Anlagenqualifizierung: Schnittstellen Betreiber-Lieferant-Dienstleister Ralf Telljohann
Anlageneffektivität (OEE) als zentrale Kennzahl Dr. Thomas Lellau
Best Practice Prozessvalidierung: pragmatisch, risikobasiert und compliant Martin Rümke
Was ist eine effiziente pharmazeutische Produktion und ist das für Sie relevant? Dr. Thomas Lellau
Neubau einer parenteralen Abfüllung für Neurotoxine Andreas Baumgardt
ERP Validation approach of efficient validation of ERP Systems Dr. Peter Schober
Validierung computergestützter Systeme (CSV) Sieghard Wagner
Lieferantenqualifizierung in Asien, Osteuropa und Südamerika Frank Studt
Medizinproduktegesetz Martin Rümke
Qualifizierung im QS/GMP und Medizintechnik-Umfeld Martin Nägelin, Dr. Rolf Lietzke
Investitionssicherheit dank überlegter Planung Chemgineering Technology Designer
Hochaktive Arzneimittel in der Verpackung Bernhard Binnwerk
Lean Qualification: Qualifizierungsaktivitäten effizient und sinnvoll umgesetzt Nicole Niklaus
Product Quality Review versus Annual Product Review Frank Studt
Den Product Quality Review valide einführen Frank Studt
Projektmanagement bei Transferprojekten Frank Studt

Specialist Conferences and Congresses

In 2012, you met the Business and Technology Designers at Lounges in Karlsruhe, Metav in Düsseldorf, the World Medtech Forum in Lucerne, the Pharma Congress Production & Technology in Düsseldorf and Swiss Cleanroom Concept in Reinach. Our Technology Designers also gave presentations at the Technology Forum in Muttenz and at the 7th SVI Pharma Packaging Forum in Basel. Our Business Designers were at the 5th Congress for the Biotech/Pharmaceutical Industry (FESTO), at the Pharma Symposium in Istanbul, at various «Medical Technology for Metal Machining» roadshows and at the Concept Heidelberg GMP seminars.

You can find up-to-date information on seminars, lectures and events of and with Chemgineering on our website, www.chemgineering.com. Further, the site includes the Chemgineering Newsletter with information concerning selected events.

Specialist contributions 2012

To further spread awareness of our services, publishing specialist articles is essential. The three 2012 editions of the Chemgineering Newsletter, contained a total of 18 specialist articles concerning general and specific challenges of the GMP environment. Apart from that, you will most likely have discovered technical essays by or interviews with our Business and Technology Designers in specialist publications. If you are interested, we will be glad to give you more detailed insights.

What are the new requirements of the 16th reform of the German Medicinal Products Act?
by Dr. Friedrich Elstner and Dr. Jan-Carsten Hempel in Pharma-Food, June 2012
The draft bill for the 16th reform of the German Medicinal Products Act (Arzneimittelgesetz [AMG]) and other pharmaceutical regulations. Its objective is the implementation in German law of the new European Union directives on pharmacovigilance, pharmaceutical safety and prevention of / protection against falsification in relation to their identity, history or source.

Systematic and investigative – Deviation management increases process reliability
by Ralph Lindemann in ReinRaumTechnik 3/2012
Protection of patients and other persons is a top priority for all manufacturers of pharmaceutical products. In addition to the qualification and validation of systems and processes, this is achieved via work instructions and defined processes in the case of deviations. For several years now, regulatory authorities have increasingly focused their attention on deviations and corrective measures. Thus, all manufacturers are required to establish a corresponding system for recording and processing deviations.

Effective operational organization in practice and for good system utilization
by Dr. Thomas Lellau in PROCESS (Chemie-Pharma-Verfahrenstechnik), May 2012
The chemical and pharmaceutical industries need a paradigm shift with regard to organization, sectoral collaboration and the value of operational excellence. Thanks to effective operational organization (in German: EGO – effective Geschäftsorganisation), customer-oriented teamwork and a focus on solutions can be systematically anchored in your organization.

Optimized maintenance thanks to effective operational organization
by Dr. Thomas Lellau in PROCESS (Chemie-Pharma-Verfahrenstechnik), August 2012
System maintenance processes can also be optimized according to the principles of effective operational organization. Ideally, this business-critical task is carried out with a focus on targeted implementation and cost savings as an integral part of the value chain.

Lean qualification – implementing qualification activities efficiently and sensibly
by Nicole Niklaus in SWISS PHARMA No. 1–2
Recently, the requirements and costs for system qualification have been steadily increasing. As there are few binding regulations, each pharmaceutical company has tried to implement these on their own. In addition, they have had to deal with complaints from inspections by customers, regulatory authorities or internal departments. The goal should be to have a simple program that can be adapted for both smaller and more complex projects of all types. Such a program can be easily and clearly explained at any time during inspections and audits. The solution is a risk-based approach as required today by both regulatory authorities and the market.

Management of the Chemgineering Group

Board of Directors
Dr. Herbert Matthys, President [1]
Steve Tappan, President [2]
Dr. Armin Mayer, Vice President [3]
Dr. Gerhard Bauer-Lewerenz, Member

Finance Committee
Dr. Gerhard Bauer-Lewerenz, Chairman
Dr. Roland Grimm, Permanent Member
Konrad P. Wirz, External Member

People Committee
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Dr. Armin Mayer, Deputy Chairman
Dr. Roland Grimm, Member

Operations Committee
Dr. Armin Mayer, Head of Engineering
Dr. Gerhard Bauer-Lewerenz, Head of Consulting
Dr. Roland Grimm, Head of Finance

Managing Directors

The Business Designers
Dr. Gerhard Bauer-Lewerenz
Frank Studt
Managing Directors,
Chemgineering Business Design
Companies in Germany, Switzerland, Austria

The Technology Designers
Markus Meier
Dr. Wolfgang Müller
Managing Directors,
Chemgineering Technology AG
Switzerland

Andreas Baumgardt
Horst Strnad
Managing Directors,
Chemgineering Technology GmbH
Germany

Dr. Armin Mayer
Horst Strnad
Managing Directors,
Chemgineering Technology GmbH
Austria

Dr. Armin Mayer
Managing Director, Chemgineering d.o.o.
Serbia

1) Until 28 February 2013
2) Vice President until 28 February 2013, President as of 1st March 2013
3) Member until 28 February 2013, Vice President as of 1st March 2013

Corporate auditors
PricewaterhouseCoopers AG, Basel

Offices

Chemgineering Holding AG

Binningerstrasse 2
4142 Münchenstein | Switzerland
Phone +41 61 467 54 00

The Business Designers

Chemgineering Business Design AG
Binningerstrasse 2
4142 Münchenstein | Switzerland
Phone +41 61 467 89 00

Chemgineering Business Design GmbH
Kreuzberger Ring 13
65205 Wiesbaden | Germany
Phone +49 611 77 88 70

Chemgineering Business Design GmbH
Gusshausstrasse 22
1040 Vienna | Austria
Phone +43 1 255 74 13 14

The Technology Designers

Chemgineering Technology AG
Binningerstrasse 2
4142 Münchenstein | Switzerland
Phone +41 61 467 54 54

Chemgineering Technology GmbH
Kreuzberger Ring 13
65205 Wiesbaden | Germany
Phone +49 611 77 88 70

Chemgineering Technology GmbH
Gusshausstrasse 22
1040 Vienna | Austria
Phone +43 1 255 74 13 13

Chemgineering d.o.o.
Subotička 23
11000 Belgrade | Serbia
Phone +381 11 241 25 55

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