

**Chemengineering Group  
2016**



The year 2016 marked an anniversary for the Chemengineering Group. We have been actively supporting our customers with consulting and engineering services in the GxP-regulated industry for 20 years now. The images shown in this annual report showcase facts and figures from over 20 years of company history.

- 03 Foreword  
Report of the Board of Directors
- 04 Chemengineering Group  
Our Focus, Our Projects, Customer Relations 2016,  
Key Dates, Facts and Figures
- 13 The Business Designers  
Core Business, Market Report
- 17 The Technology Designers  
Core Business, Market Report
- 21 Chemengineering Group  
Publications, Lectures and Events, Management, Offices

## Dear Reader,

Chemgeneering not only celebrated its anniversary in 2016 but also looks back on a very successful year. That is because we recorded the highest number of employees in our company history with the purchase of the Spanish company IPB exactly 20 years after our founding in 1996. We are currently intensively focusing on merging the companies and look forward to working with our Spanish colleagues. IPB is an established specialized company that oversees international projects in the life sciences and will thus bring Chemgeneering a great step forward on its path to global expansion. In addition to the headquarters in Barcelona, IPB has locations in Madrid, Peru, and Mexico City.

After 20 years of Chemgeneering, we have also experienced a changing of the guard. Dr. Armin Mayer, company founder and long-time head of the Group, entered into his well-deserved retirement at the end of the year. He will, however, remain with Chemgeneering in the future as a member of the Board of Directors and assist us by sharing his many years of experience. We would like to express a warm thanks to Dr. Armin Mayer for his dedication and 20 years of service to the company.

Our 2016 annual report looks back on the company's history over the past 20 years and estimates how much material we've consumed in this span of time. A definite must-read where you'll find out much more than just how many kilograms of birthday cake we've eaten together during this time. As always, the annual report presents the year's facts and figures alongside staff publications and presentations as well as information on the work of our business units.

Chemgeneering can look back on 20 years with great pride! We would like to take the opportunity to thank all our employees who've made Chemgeneering's success possible through their hard work, talent, and dedication, some of whom have even been on board since the very beginning. Loyalty like this shouldn't be taken for granted, and it's something we truly appreciate.

We would also like to thank our customers and business partners, some of whom have also been with us since the year we were founded. The trust you've placed in us throughout our long-standing relationship proves to us that we have done a lot of things right. We look forward to completing many exciting projects with you in the future.

Kind regards,



**Steven G. Tappan**  
Chairman of the Board of Directors



**Dr. Armin Mayer**  
Vice-Chairman of the Board of Directors



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



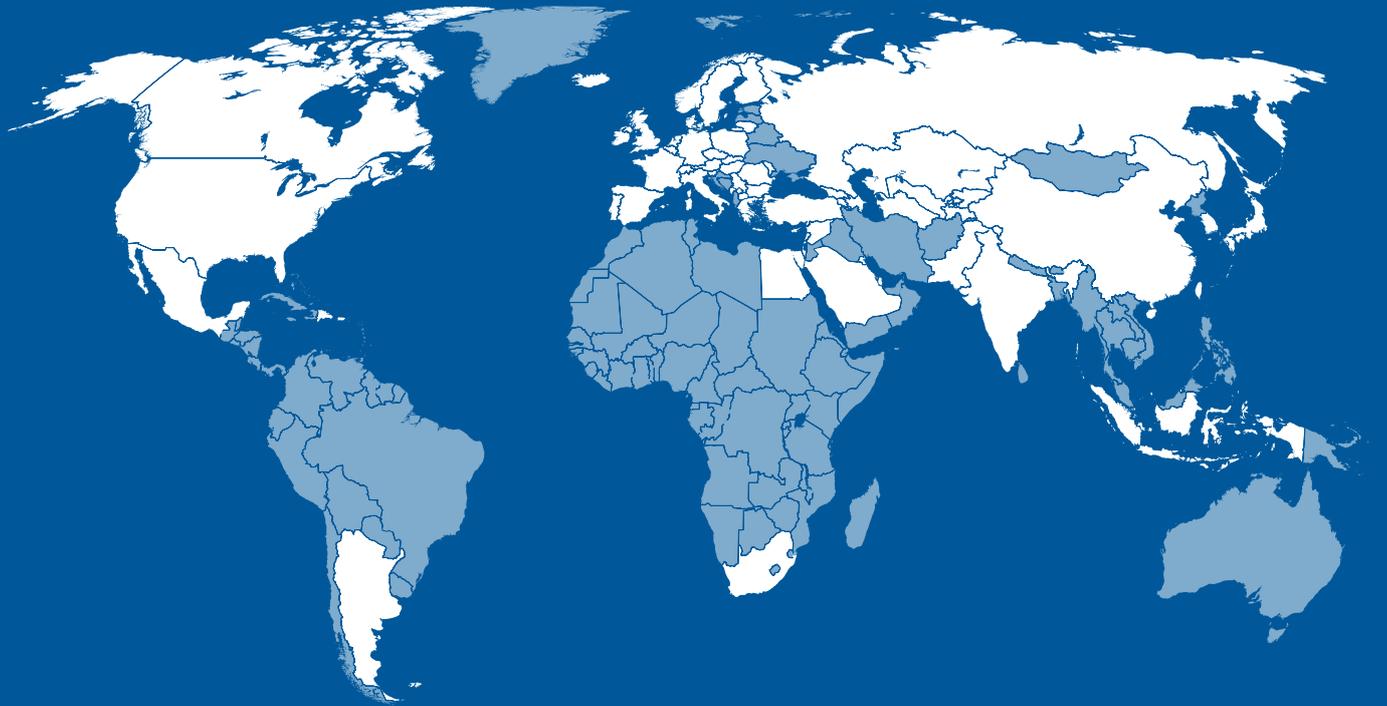
**Dr. Ernst Staehelin**  
Member of the Board of Directors

## 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 of capital investment programs. The Technology Designers master complex investment projects complete with all types of trading. Founded in 1996, the corporate group is based in Münchenstein near Basel, Switzerland, and has offices in Germany, Austria, Serbia, Spain, Peru and Mexico.

## 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.



## Customer Relations 2016

**Chemengineering strengthened its relationships with existing clients and established new contacts. Below is a selection of companies with which we completed projects in 2016.**

Aarepapier / AAR Brauer und Wolter / AbbVie / Acino Pharma / A.F.P Antiseptica / Aga Gas / Agomed Medizin Technik / Akorn / Almirall Hermal / AOP Orphan Pharmaceuticals / Ara Rhein / Astra Industrial / Bachem / BASF / Basilea / Bau und Verkehrsdepartement Basel / B. Braun / Baxalta / Bayer / Bego Bremer / Bego Medical / BFB Architekten / BGS Beta Gamma / Bio Rad Laboratories / Bio Strath / Biotest / Bode Chemie / Boehringer Ingelheim / Brauns Heitmann / Burckhardt Partner Cargill / Carl Zeiss / Cesra Arzneimittel / Cilag / Cinfa Biotech / Colep / CompAir / Comet / Concept Heidelberg / CSL Behring / DanMed Dannoritzer / Data Center Plan / DeguDent / Domaco Dr. med. Aufdermaur / DRK Blutspendedienst NSTOB / Dr. Falk Pharma / Dr. Kurt Wolff / Dr. Paul Lohmann / DSM / Ebewe Pharma / EDL Anlagenbau / Em Tec / Engie Services / ETH Zürich / Evolan Pharma / Exorka / Fresenius Kabi / Frutarom / GEA Pharma / Gelita / Gesellschaft für Micronisierung / GHZ Schlieren / G.L. Pharma / Göhler / GP Grenzach Produktion / Grace / Groninger / Hager Elsässer / Hänssler / Helm / Hennig Arzneimittel / Heraeus / Heraeus Kulzer / Hennig Arzneimittel / Hermes Arzneimittel / Heumann Pharma / Hexal / Hochbauamt Zürich / IDT Biologika / Infrapark Baselland / Inosim / Institut Pasteur / Intervet / Iron Mountain / Ivers Lee / Ivoclar Vivadent / Janssen Vaccines Johnson Controls / Jungbunzlauer / Juno Therapeutics / Kantonsapotheke Zürich / Kantonsspital Chur / Kern Pharma / Kirsch Pharma / Königsee Implantate / Kwizda Pharma / K.W. Pfannenschmidt Leonhard Lang / Legacy Pharmaceuticals / Linde / LLC Infamed K. / L. Molteni C. Scandicci / LTS Lohmann / Luzerner Kantonsspital / Meda Pharma / Medice / Merck / Merz / Metrohm / Migasa PiVs / Nabriva Therapeutics / Nateco / Neuraxpharm Arzneimittel / Noramco / Novartis / Octapharma / Omnicon / Ostfriesische Tee Gesellschaft / Pangas / Paul Hartmann / Pharmatec / Phytion Biotech / Pro Med Instruments / ProReno / PDA Europe / PharmaZell / Nordmark Arzneimittel / Richter Pharma / Roche / Sandoz / Sanofi Aventis / Schenck Process / Schott / Seattle Genetics / Stada / Siemens / SK Schwaben Kunststoff Chemietank Apparatebau / Steiermärkische Krankenanstaltengesellschaft / St. Claraspital / Steigerconcept / Störtebeker / SW Pharma / Syngenta / Tabuk Pharmaceuticals / Testo / The Graymor Chemical / TSJ Tönies Schroeter Jansen / TÜV Rheinland / TÜV Süd / Universitätsspital Basel / Vistin Pharma / 4SC / Weleda

## Key Dates

**1996**

Bertrams AG and Fluor Daniel Corp. found the Joint Venture Chemgeneering.



**1997**

The office in Stuttgart opens. Chemgeneering Planung GmbH launches its operations in Austria.

**1999**

The Chemgeneering management buys the shares of Bertrams.

**2003**

Strategic alliance with Uhde AG. The Novartis large-scale project PHAD is launched.

**2007**

The Chemgeneering management buys back the shares of Uhde AG.



**1998**

The large-scale project Centeon in Marburg is successfully completed.

**2001**

The Chemgeneering management buys the shares of Fluor Daniel Inc.

**2004**

Large-scale project MAB, Roche, is launched. Chemgeneering delivers the construction management «process».

**2000**

The Chemgeneering Group extends the supervisory board to seven members and establishes three strategic business units.

## 2010

Examination of the strategic situation: focus on growth in the home markets.

## 2011

Good market development and outstanding result.

# 2016

## 20 Years Anniversary.

Chemengineering acquires the majority interest in the Spanish company IPB S.L.



## 2008

Founding of Chemengineering Serbia d.o.o. in Belgrade. CBD and CTD operate independently.

## 2014

Highest number of employees and the highest sales figures in the history of our company thanks to international projects.

## 2013

Continuous streamlining of the organization and strengthening of the business units.

## 2015

Another good year for Chemengineering. The 2020 strategy is developed.

## 2009

The global economic crisis can clearly be seen in the earnings situation.

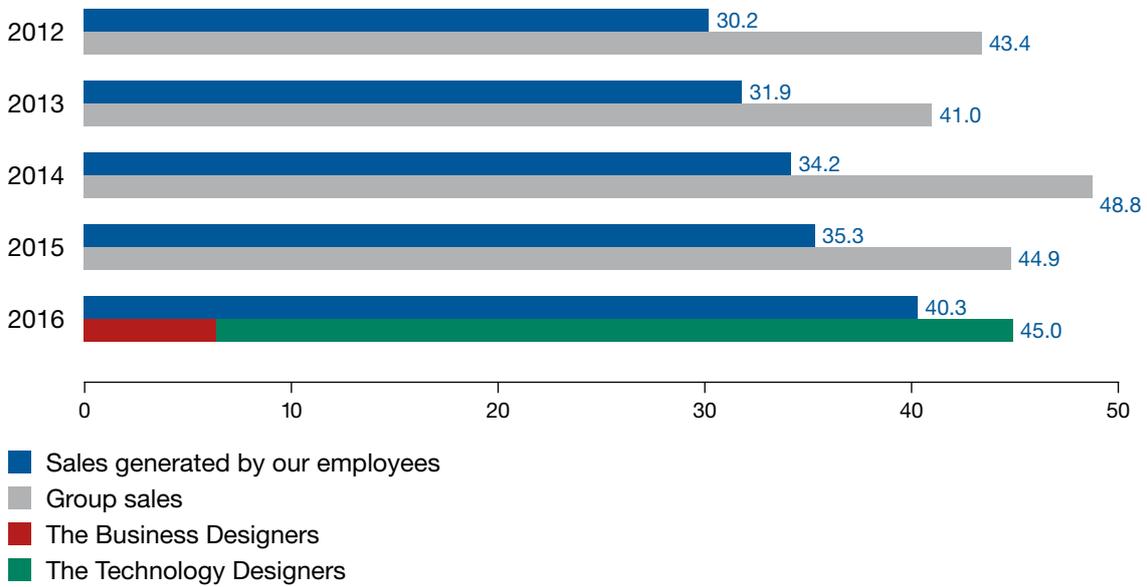


## 2012

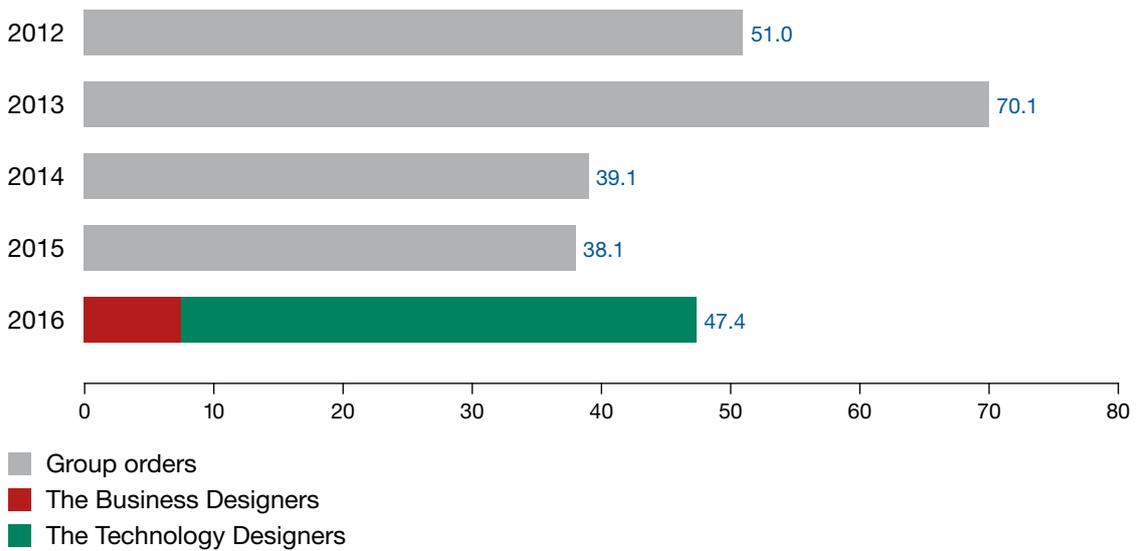
Chemengineering hires 45 new staff members. Additional branch in Kirchbichl (AT) opens.

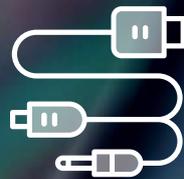
## Facts and Figures 2016

### Sales in CHF millions



### Orders awarded in CHF millions

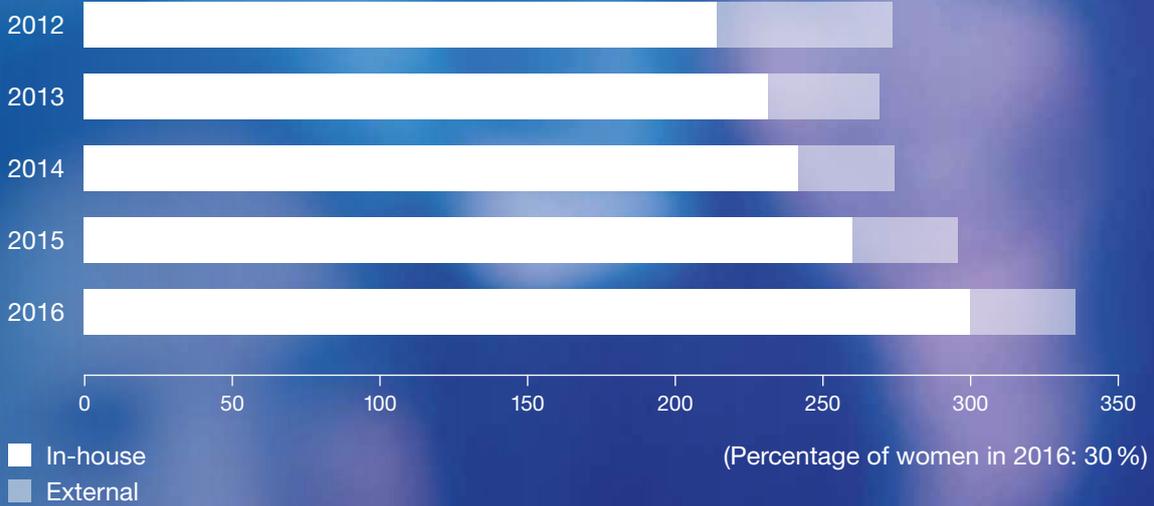




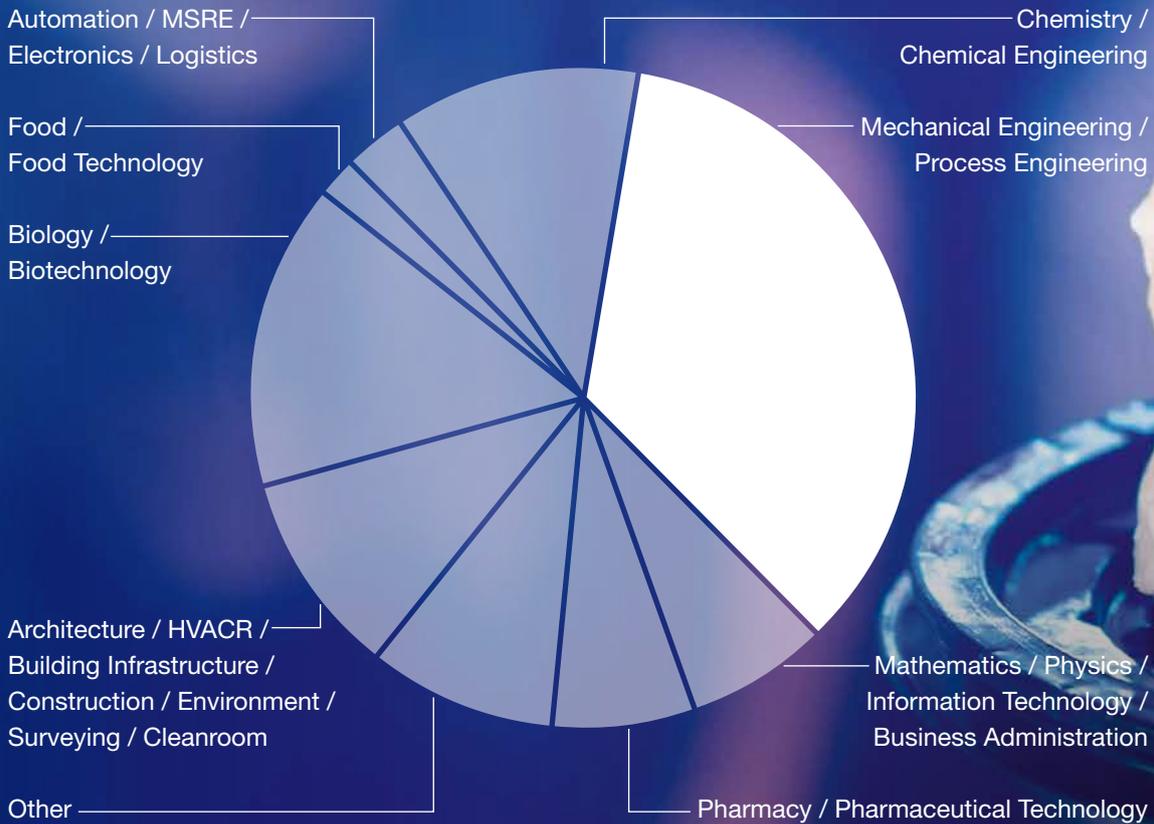
## 120000\* kilometers of installed cable

Our construction and installation supervisors coordinate the entire execution process and monitor compliance with planning, specifications as well as applicable regulations. We draw up comprehensive schedules and organized construction plans right from the very beginning of a project.

**Headcount development**



**Employees according to technical fields in %**





**Together, we've consumed  
2520\* kilograms of birthday  
cake.**

Our 300 employees make up the heart and soul of Chemgeneering. They get our customers' processes up and running worldwide. This is a feat we are proud of and look forward to eating many more kilograms of birthday cake with you in the future. After all, it has now become tradition for every birthday child to bring a birthday cake.



### Summary



### Summary



**Through 3500\* consulting projects, we have helped our customers become more efficient**

Whether production, packaging, maintenance, supply chain management, or quality assurance, we put the finishing touches on your processes to assist you in improving your organization's efficiency and also improving your quality.

## **Efficiency, cost-effectiveness, and compliance: the core business of the Chemengineering Business Designers**

The Chemengineering Business Designers focus projects on services that are entirely independent of 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 international quality management systems. Our IT consultants ensure efficient, sound implementation of effective and future-capable IT environments. The Business Designers provide you not only with proven implementation experts but also with temporary managers as well who streamline and revitalize your organization while ensuring that aspects such as 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, Efficiency, cost-effectiveness, and compliance: the core business of the Chemengineering Business Designers

## Market Report the Business Designers

### **Bull's eye once again:**

**We reached our target at the end of 2016. We were able to achieve everything we set forth for ourselves. Our four divisions Management Consulting, Pharmaceutical Compliance, Medical Technology, and Efficient IT completed more than 250 individual projects. This represents a strong performance by our workforce of nearly 40 employees. There was a slight increase in the average order volume, signifying the strong demand for management and compliance consulting.**

However, we noticed that much time and effort were invested in the network by both us and our customers as well as prospective clients to handle the volume of orders. We then asked ourselves once again how decision-makers gain access to highly qualified information today. Trade fairs, for example, work well today if presentations are simultaneously offered that provide expert knowledge and thus some kind of professional added value. Based on these findings, we then came up with the idea of creating an expert network in 2016 and using it to work with our external consultants to offer cutting-edge knowledge combined with so called assets of added value. The result: [www.how2lifescience.com](http://www.how2lifescience.com) content platform which went online just before the end of the year. The platform articles, which are released almost weekly, are also published on social networks, such as XING, Twitter, and LinkedIn by the responsible agency. Within just a few weeks, around 100 registered readers and more than 4,000 recurring visitors read and obtained information on current subjects pertaining to compliance, organizational development, and costs and budget. A great success.

### **Management Consulting:**

One of our renowned Swiss customers decided to transform the carve-out of an independent entity into a new company. A carve-out is defined as the «cutting out» of a smaller entity which can, for example, be sold separately. An endeavor such as this is often associated with a large number of activities that Chemengineering

can perform in cooperation with those employees who are affected. These activities included the entire project management, valid transition of the IT infrastructure, process transfers as well as the entire physical relocation of the company. We carried out another very interesting project by restructuring the quality department of a medium-sized contract manufacturer. In addition to processes, organizational charts, and meeting structures, the entire quality management system was also audited and streamlined: true to the spirit of an economical organizational structure.

### **Pharmaceutical Compliance:**

As in previous years, «audits» were once again a hot topic in the Pharmaceutical Compliance business, and with nearly 100 audits performed, this has been our strongest year to date. Our Business Designers were also assigned with other topics that were relevant to customers, including ICH Q3D (Elemental Impurities) projects, large FDA readiness programs, etc. plus associated FDA mock inspections and many compliance process optimizations for customers from the cosmetics and food industries. In the second half of the year, a study and later the resulting comprehensive support program for building a completely automated manufacturing facility for individualized vaccines were also secured.

### **Medical Technology:**

Our foresight pays off. As we already observed in 2015, the impacts of changing legislation on medical products in the EU had a strong influence in 2016. Keen interest was shown in the upcoming changes, especially in the case of compliance projects completed by our medical technology specialists. We supplied the speakers for many VDI and TÜV seminars and were then frequently invited to in-house training events. As a result, we carried out a large number of coaching projects aimed at enabling our customers' specialist departments to complete much of the compliance work to be executed in the future on their own. Where this was not possible, our consultants were, of course, ready to help.

### **IS CSV:**

We've been known as the «Computer System Validator» for more than two decades now. At Concept Heidelberg as well as during other countless company events, we teach participants how to validate computerized systems and how valid conditions can be maintained. IT project management brought us, for example, to Austria and Spain for an introduction to MES, to Saudi Arabia for an ERP validation assignment and to some other European countries as well. The time has come for our customers to address Secure Track & Trace. While many companies were still waiting for legislation to be released, some entered into a cooperation with us to launch pilot projects in 2016. Considering the extensive range of changes to be made to packaging lines and IT systems, the implementation period of just three years is rather short.

To ensure timely implementation, efficient management is a must to avoid unnecessary delays. That's where we've prepared and come in with our well-founded methods for integrating new systems into existing company IT infrastructures.

### **2017 Outlook**

The year 2017 began with a long list of orders and a well-staffed team of consultants. Training, especially for our new consultants who have come to us straight out of school, is naturally very important to us. After all, our customers pay us to apply the latest knowledge in their company. That's why we encourage every consultant to publish their work in their own name on our expert platform [www.how2lifescience.com](http://www.how2lifescience.com) and to engage in discussion with interested persons.

Medical technology promises many interesting projects in 2017 since new jurisdiction now bases the legal framework for medical products on that of pharmaceuticals. For medical device manufacturers, this means fundamental changes will inevitably lead to increasingly complex tasks that require the help of external consultants to implement them in those cases in which in-house staff is not capable of performing such work.

We look forward to an exciting 2017 filled with a wide array of assignments and creative solutions. Doing our part to help improve patient safety once again and working with our customers to shape «economic compliance» are our biggest priorities in 2017.

### **Frank Studt**

Managing Director Chemengineering Business Design Switzerland, Germany, Austria



## 1075\* kilometers of pipe-line installed in the GxP-regulated industry

Our experience has helped us to develop customized solutions for your needs. We always start out by developing a concept to verify your feasibility study and demonstrate implementation in practice.

## Market Report the Technology Designers

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 conceptualization to handover.

### Our fields of 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

### Our services

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

## On-course for success with the 2020 Strategy

**The engineering business unit focused on continuing to successfully implement the 2020 Strategy in the 2016 financial year. We made significant progress in this area, above all, in terms of globalization, an expanded workforce, and quality management. Our acquisition of the Spanish company IPB has put us in an even stronger position to offer and realize international projects. However, we are not quite living up to our expectations when it comes to incoming orders and earnings.**

### **As a reminder, here are the 2020 Strategy's six initiatives:**

- › **Sustainable market expansion of the GxP business segment**  
Qualification, validation, compliance
- › **Large-scale project management**  
Project management, costs and scheduling, purchasing, and construction management
- › **Energy and infrastructure**  
Technical building systems and media
- › **Internationalization of the business**  
Projects with old and new customers outside the DACH region (German-speaking countries)
- › **LSTK clean room systems**  
Clean media, EMSR, and automation
- › **Hospital sector services**  
Hospital pharmacies, central sterilization systems, clean media supply, qualification, validation

The highlight of the year 2016 is unquestionably the acquisition of 87.36 % of the Spanish engineering and construction company IPB S.L. which is headquartered in Barcelona, Spain. The «International Business» strategy initiative made a huge leap forward by acquiring the Spanish company: a success that has and will continue to have a big and very positive impact on the Chemengineering Group's business today as well as in the future. IPB, which has a workforce of 60 employees, is one of Spain's most successful medium-sized engineering companies with subsidiaries in Peru and Mexico. IPB's technical work focuses on architecture, technical building equipment, and process engineering. In its history of more than 30 years,

the company has carried out many projects for national as well as international clients in Spain, Central America, South America, Southeast Asia, and China. During this time, it built up a worldwide network of local partners which we now access to benefit for our customers. This acquisition has enabled us entry into the international market and increased our engineering capacity by 25 %. Our cooperation with the new colleagues has run smoothly right from the start and we look forward to continuing working with them. The appointment of Christian Hepfer, one of our most experienced process technicians, to Barcelona for a period of two years, as well as the permanent exchange of sales and project development experience with our new colleagues quickly led to success: the first jointly acquired projects have already been completed.

In addition to building mutual understanding and trust, our company's organization also needs to adapt in order to cope with this large growth in personnel and the rapid entry into international markets. As a result, we put country organizations back in charge of their own commercial success while keeping other specific functions centrally managed. Apart from finance and accounting, these central operations include quality management, HSE, and CSR.

Quality management, HSE, and CSR have also been bundled under one function which is active and responsible for the entire Group. Andreas Baumgardt, who has always worked for Chem-

gineering in a variety of different roles since its founding and who thus fulfills all requirements for this position, was given the task of managing this post. The implementation of this groupwide function ensures that we will continue to take the growing HSE and quality requirements of our customers into account in the future. Since its establishment, Chemgineering has maintained a process-oriented quality system in which all relevant business processes are defined and illustrated. This system is continually adapted to the needs arising most notably out of an ever-widening range of services, the rapid growth of staff, and the global expansion of our business. Furthermore, this function ensures that defined processes and procedures are implemented and realized across the group in all areas of the company.

As the main point of contact for our customers regarding any issues concerning quality and HSE, this central group function was introduced so we can consistently pursue objectives to ensure the quality of our project results and further improve them, meet new and increased customer requirements, and ultimately increase customer satisfaction.

**The market situation – Chemgineering has also been internationally active since 2016**

As we have known for many years now, our customers continue to invest in their national and international locations without any restraint. Despite the many projects which are currently available on the market worldwide, it's becoming increasingly harder to successfully win new ones. Many customers prefer working with large, international engineering firms for major, large-scale projects. We have recognized this trend and acted accordingly. Chemgineering, which celebrated its 20th anniversary in 2016, has always been an interesting and reliable partner to its customers

since its foundation thanks to its many years of experience as well as proven planning and cGMP skills.

Since 2016, we have been very well positioned for the years to come thanks to our workforce of 300 employees and international locations. As a result, we are very confident about our future. I resigned from my post as Head of the Engineering at the end of the 2016 financial year. I would like to take this opportunity to express my deepest and sincerest thanks to all employees, customers, and business partners. It has been a pleasure working with you throughout the many years.

**Dr. Armin Mayer**

Head of Engineering Chemgineering Group  
(until end of 2016)



**We've prepped 750\* plants for official inspection.**

Using highly sophisticated qualification strategies, we're able to reconcile costs and resources and reliably accompany you throughout your plant's entire lifecycle.

## Publications 2016

In three editions of the Chemengineering Newsletter and a total of 14 professional articles, we provided information about current issues in the GMP environment.

### Newsletter No. 75 | April 2016 | Volume 22

#### **Cleaning Validation and Toxicology: Quo Vadis?**

**Raimund Brett, Senior Consultant  
Pharma Compliance / Dr. Hiltrud Lenke,  
Senior Compliance Consultant**

A brief guide through the jungle of toxicological requirements of the revised Annex 15 of the EU GMP Guideline. The revised Annex 15 brings not only innovations and clarifications for the qualification of devices and systems and process validations but also several new requirements for cleaning validation that should not be underestimated.

#### **Data Migration in Life Sciences – Secure and Compliant? (Part 1)**

**Léon van Deurse, Senior Consultant  
Efficient IT**

Data migration projects are often underestimated. Migrations are complex, as multiple data sources have to be harmonized, and data quality is essential for GxP-compliant systems. This article explores a data migration framework. The next newsletter will explore the QA role in that framework.

#### **Practical Risk Management in IT – What Does That Mean in a CSV Project?**

**Dr. Thomas Karlewski, Managing  
Consultant Efficient IT / Sieghard Wagner,  
Senior Consultant Efficient IT**

With GAMP® 5, a concept for risk management in the life cycle of a computer system in the regulated industries was presented for the first time. Knowledge of the possible systemic risks with regard to product quality or patient safety is the key to scaling the related measures in the validation project and in the regular operation of a system.

#### **Laboratory Relocation Project**

**Olaf Maassen, Project Engineer**

Moving QC and R&D laboratories into a new building. In 2014, Chemengineering was commissioned by Biotest AG to move various laboratories (QC and R&D) and the Plasma Receiving department into a new building. The particular challenge was posed by the necessity of maintaining the ongoing operations of the relocating departments, and unforeseen difficulties which typically arise in a new building.

#### **The BIM Boom: More Than Just 3D Planning**

**Tamàs Kapsa, Architectural Engineer**

Building Information Modeling (BIM) is a computer-based method used to optimize the exchange of information in the planning, execution, and operation of buildings. During the BIM planning process, a 3D model of an entire building is created in which all relevant building data is digitally recorded and linked.

#### **Explosion Protection – ATEX, EX Zones, et al**

**Dr. Heinrich Dörr, Project Engineer**

Duties of the plant operator with regard to explosion protection requirements. Operators and planners of process systems and plants in a wide range of industries including chemicals, pharmaceuticals, and biotechnology are frequently confronted with the question of what criteria their plants and systems must meet to fulfill explosion protection requirements (ATEX).

#### **Data Integrity – Is There Something More That Needs to Be Done?**

**Dr. Peter Schober, Senior Consultant Efficient IT**

A closer look at an old goal. Since the most recent publication of several warning letters<sup>1</sup> regarding the issue of data integrity, the FDA is once again focusing on this topic in particular during inspections. This article presents back-

ground information and practical experience with this issue.

**Newsletter No. 76 | November 2016 |  
Volume 22**

**Time is Running Out – ICH Q3D –  
«Guideline for Elemental Impurities»**

**Christoph Heberlein, Senior Consultant / Heiko Jencio, Senior Consultant Pharma Compliance**

Since June 2016, proof of testing for metallic contamination in accordance with the ICH Q3D guideline is required when filing for new approvals for drugs. As of December 2017, this requirement will be legally binding for pharmaceuticals that are already on the market as well.

**Data Migration in Life Sciences –  
Secure and Compliant? (Part 2)**

**Léon van Deurse, Senior Consultant Efficient IT**

In Newsletter 01/2016, a best-practice approach to data migration projects was described that reduces risks, prevents budget overruns, and supports an efficient information governance process. The second part of the article discusses the quality assurance role (QA role) within this approach and an approach to sampling for validating large volumes of data during a data migration project.

**Preparing Investment Projects  
and Justifying Decisions**

**Paul Grube, Senior Consultant  
Management Consulting.**

**Managing International Projects  
with Virtual Teams**

**Manuel Puerto, Project Director and International Business Development Manager /  
Gerard Martinez, Project Manager**

For a company with the appropriate engineering know-how and adequate resources, it is relatively straightforward to manage a project in a local context. However, new factors come into play when the same project has to be managed in another country where the technical

support team is small or non-existent and engineering know-how scattered across several locations and time zones.

**Different Versions of GMP – A comparison  
of Food and Pharmaceuticals**

**Astrid Wunderer, Qualification Engineer**

Health protection and health maintenance are the two goals of the Good Manufacturing Practice (GMP) guideline for the production of pharmaceutical products and food.

**Good Manufacturing Instructions Save Money**

**Markus Reichardt, Project Engineer**

Efficient and well-organized manufacturing documents are essential to success in production. The issue is familiar: every year, the time comes to prepare your tax returns. Do you still do it yourself, or have you decided to hire a tax consultant? These days, some employees find the preparation of manufacturing documentation at work similar to doing one's tax returns.

**Pharmind 78 | No. 2 2016**

**Retrospective Validation of Computerized  
Systems**

**Sieghard Wagner**

The retrospective validation of computerized systems is a controversial topic of discussion. No established procedures exist for this yet and specific, official regulations are still being gradually withdrawn.

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You can download all the issues of our newsletter at [www.chemengineering.com/de/Downloads/Publikationen/Newsletter](http://www.chemengineering.com/de/Downloads/Publikationen/Newsletter).

## Lectures and Events 2016

We regularly share our wealth of experience through lectures and seminars. In 2015, Chemengineering presented the following technical papers and conducted the following training courses:

### Lounges 2016

- › Simulation of Clean Media Systems, Philipp Michel
- › The ICH Guideline Q3D/An Overview of Elemental Impurities, Heiko Jencio
- › What Are the Effects of Revising Ultrapure Water Systems?, Jochen Schmidt-Nawrot
- › Germs? No problem! Effective Sanitation of Ultrapure Water Systems, Jochen Schmidt-Nawrot
- › Preparing Investment Projects, Justifying Decisions, Paul Grube
- › Restructuring of Control Systems in Pharmaceutical Plants, Steffen Wöllner
- › Problems with Ultrapure Water Systems, Tim Thomas
- › Microbiology in Ultrapure Water, Microbiological Problems with the Ultrapure Water System, Tim Thomas
- › Revision of the WFI Monograph in the European Pharmacopoeia, Jochen Schmidt-Nawrot

### Polymesse ETH Zurich

- › From the Raw Material to Active Substance, from the Drug to the Pill – Engineering Services in the GMP-Regulated Environment, Dr. Wolfgang Minas

### Powtech 2016

- › Simulation of Clean Media Systems, Philipp Michel
- › Preparing Investment Projects, Justifying Decisions, Paul Grube
- › Restructuring Control Systems in Pharmaceutical Plants, Steffen Wöllner

### IImac 2016

- › Secure Track & Trace – Successful Implementation in Pharmaceutical Production, Léon van Deurse / Simone Glasbrenner

### Concept Heidelberg

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Group Auditors : PricewaterhouseCoopers AG, Basel

## Corporate Offices

### **Chemengineering Holding AG**

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

### **The Business Designers**

#### **Chemengineering Business Design AG**

Binningerstrasse 2  
4142 Münchenstein | Switzerland  
Phone +41 61 467 89 00

#### **Chemengineering Business Design GmbH**

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

#### **Chemengineering Business Design GmbH**

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

### **The Technology Designers**

#### **Chemengineering Technology AG**

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

#### **Chemengineering Technology GmbH**

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

#### **Chemengineering Technology GmbH**

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

#### **Chemengineering d.o.o.**

Subotička 23  
11000 Belgrade | Serbia  
Phone +381 11 241 25 55

#### **IPB S.A.**

Plaça Xavier Cugat, 2  
Edifici A – Planta 1<sup>a</sup>  
08174 Sant Cugat del Vallès | Spain  
Phone +34 932 384 990

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