

# GEMÜ® news

Magazine for the customers, partners and friends of the GEMÜ Group

Edition 01/2016

## GEMÜ Group On the path to innovation and growth

We have had an eventful year. With GEMÜ CONEXO, we presented the valve technology of the future at AICHEMA, the leading international trade fair for the processing industry. We have focussed not only on innovations, but also on our international growth strategy. Alongside our subsidiary in Ireland, we also founded another site in Mexico and inaugurated a new factory in Shanghai.

Innovations and new technologies are important. They are changing the world and building the foundation for growth and employment. GEMÜ can look back on an interesting and eventful week at AICHEMA. With GEMÜ CONEXO, we presented the future of intelligent valve technology at this trade fair. This represents a major step in the intelligent networking of valve components and, through paperless maintenance using RFID technology, is actively helping to increase process reliability in the customer's system. Innovations must be considered as part of a much wider picture. It is not just all about new technologies. Behind every innovative company are the people who contribute to this, such as a well-functioning sales department, logistics, effective management and, above all, cost-effective production. As an innovative company, we strive towards further development, growth and economic success. With our newly defined business strategy, we have our sights firmly set on the future. Our new organizational orientation is an important and essential tool in supporting innovative technologies and encouraging further growth.

Our strong growth can be seen over the past year by the new subsidiaries founded in Ireland and Mexico as well as by the new factory for production

and administration in Shanghai. Having achieved these international milestones, the GEMÜ Group currently has 26 subsidiaries all over the world. "We are well-positioned throughout the world, but of course always on the look out for promising new markets," explains Gert Müller. In Ireland, a commercial partner has been removed from the process, in order to look after customers in the country directly. Customers are predominantly from the pharmaceutical and biotechnology industries here. The company also believes there is every reason to expect success in these industrial sectors in Mexico as well. In this case, the country changed its economic framework conditions, making it more attractive for establishing new business. "This location policy brings us close to the market and therefore close to our customers," explains Gert Müller.



**Gert Müller**  
Managing Director/Partner  
Engineering & Sales

**Stephan Müller**  
Managing Director  
Finance & Operations

## Another step towards South America Foundation of a subsidiary in Mexico

GEMÜ's international presence has further strengthened by establishing a subsidiary in Mexico in May last year, completing our direct presence in the NAFTA region which integrates a market over 478 million inhabitants in Canada, USA and Mexico.

With the office being located in the German Center in Mexico City and reasonably close to the airport, it provides a central location from where we can build our business in pharmaceutical, food, beverage and other industrial markets.

Gemue Válvulas was introduced to the Mexican market in a recognizable way by participating in 2 major exhibitions, the Expo Farma and Expo Pack receiving very positive feedback from local

customers. Many foreign companies have production locations in Mexico utilizing equipment supplied from Europe, Asia and the USA. Servicing these locations with original replacement parts is an important support being provided. Plus, the expansion of pharmaceutical production is another important area for growing our business.

What may be interesting to know is that at 2240 meters above sea level, Gemue Válvulas resides higher than

any of our other subsidiaries around the globe. For sales manager Enrique Galan it is a motivating challenge to grow business and build an organization to service customers in a country measuring nearly 2 million square kilometers or about six times the size of Germany. The support for GEMÜ's youngest subsidiary is provided mainly by Gemue Valves in Atlanta, US where a 3 hour flight distance / 1 hour time difference from Mexico City allows for the access to supply of goods and the technical support.



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# Processing industry 4.0 – Traceability and service

The topic of Industry 4.0 is continually leading to new technical findings and developments. GEMÜ is acknowledging a trend in process technology towards intelligent and networked process components such as valves, with the aim of increasing system availability.



Every system operator is required to operate systems as cost effectively as possible, thereby also minimizing unplanned downtimes. To do this, it is essential that the operating states and processes in the system are understood, right down to the component level.

Scheduled downtimes should also be kept as short as possible – any simplification in the maintenance process shortens the duration of the maintenance work and thus the system downtime.

GEMÜ CONEXO is ensuring that the first step towards simplified and faster maintenance processes is taken, whereby GEMÜ will in the future equip valves and/or the relevant valve components, such as bodies, actuators and diaphragms, with RFID chips.

This not only enables components and wearing parts to be clearly traced electronically, but also improves identification in the field.

With an RFID reader, the CONEXO PEN and the CONEXO APP, GEMÜ valves integrated into systems and the external components equipped with RFID chips can be clearly recognized; all the information, documents and test reports associated with the valve or the component are available directly.



Process information such as the “Time of last maintenance” can also be displayed.

This also shortens the time-consuming “installation qualification” (IQ) process, for example, since all documentation on the valve can be downloaded directly and does not need to be compared at length against paper documentation from the archive.

In addition, the CONEXO APP features a function providing digital maintenance support. The maintenance technician is assigned the maintenance task electronically on their tablet and can clearly identify the relevant valves and perform the maintenance work. This also allows the maintenance technician to be clearly verified and the person who performed the maintenance work to be documented.

The relevant documents of interest for the maintenance task, such as the assembly instructions or assembly videos, can be downloaded and viewed directly. This helps to minimize maintenance errors.

All maintenance documentation can be processed electronically; the status and visual appearance of the diaphragm or component are electronically recorded and processed by the “diaphragm evaluation” and “photo documentation” functions.

Since the WLAN connection in a number of systems is not strong enough, all the information collected during maintenance work can be saved offline in the CONEXO APP. As soon as the technician returns to an area with good WLAN signal, the data will be uploaded to the CONEXO Portal.

The CONEXO Portal represents the central database of CONEXO, where all the information is pooled together. It is also possible to manage multiple sites and plant sections and to perform analyses across different sites.

The data electronically collected in the CONEXO Portal can be transmitted via interfaces to the customer’s maintenance software and processed. Direct communication with the customer’s ERP software is possible, but not necessary. The CONEXO Portal can also be used as a stand-alone solution.



## GEMÜ 567 – Aseptic control valve in stainless steel for small volumes

Aseptic diaphragm valves are frequently used to control sterile applications. However, small volumes can only be controlled with an inadequate level of accuracy, or not at all. GEMÜ has now developed the GEMÜ 567 valve in order to solve this problem.

The GEMÜ 567 is a 2/2-way globe valve with a regulating needle or regulating cone for high control accuracy and precise dosing. The valve seat on both versions is sealed using a soft-seated seal. The actuator is separated from the media-wetted area by an FDA-compliant PTFE diaphragm. This ensures a permanent, temperature-resistant seal and thus meets the high requirements of the pharmaceutical and food industries. Compared with bellows valves, cleaning the valve is significantly improved by the hygienic and minimal deadleg design. It is likewise possible to clean and sterilize the valve using a CIP or SIP procedure.

The valve is also available with an integrated bypass so that the flow velocities required for the rest of the system can be achieved during the cleaning process. At the customer's request, GEMÜ 567 can be integrated into a multi-port valve block. This is another special feature of the valve which not only requires considerably less space in the system, but also significantly reduces the installation and welding effort. All surfaces which come into contact with the product are precision-turned or polished. Furthermore, additional electropolishing can achieve a high surface quality of Ra 0.25 µm. EHEDG certification and testing in accordance with Procedure 3A are currently in preparation. The GEMÜ 567 valve is available as an angled design in nominal sizes DN 8, DN 10 and DN 15.



GEMÜ 567

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## Compact, intelligent combi switchboxes with a wide range of functions

The GEMÜ 4212 and 4242 combi switchboxes with integrated 3/2-way pilot valve are capable of intelligent and precise position detection and have additional diagnosis options.

In comparison to external variants, the integrated pilot valve offers both functional and economic benefits, such as fast reaction times, automatic programming of end positions and lower compressed air consumption. Local programming of the end positions is also possible without a connection to the control unit and without opening the housing using a magnetic switch.

Both product types have been designed so that they can be equipped with a large number of valves with a pneumatic linear actuator. Depending on the required actuating speed and stroke range, the GEMÜ 4242 can be used for small to medium valve sizes, whereas the GEMÜ 4212 is suitable for medium and large actuators.

The colour LEDs of the high-visibility display are very bright and can be seen from all around through the transparent housing cover. A "location function" can be used to activate an optical signal and identify the valve in the plant. High-quality electronic components complemented by a robust yet compact housing produce a qualitatively sophisticated overall image.

Thanks to the integrated manual override, the installation costs during servicing work in particular are significantly reduced, as there is no need for electrical energy to supply compressed air to the valve. The manual override can be operated using a standard tool. The covered layout prevents unintentional operation. A mechanical position indicator fitted on the side of the housing of the GEMÜ 4212 ensures that the position of the valve can be read even if the electrical supply voltage fails.

The combi switchboxes are available in a 24 V, AS-interface or DeviceNet version as well as with an IO-Link interface.



GEMÜ 4242

GEMÜ 4212

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# Focus on customers GEMÜ restructured

Owing to the international growth strategy and associated GEMÜ goal to become even more customer-oriented, GEMÜ has undergone organisational restructuring.

### Business area strategy

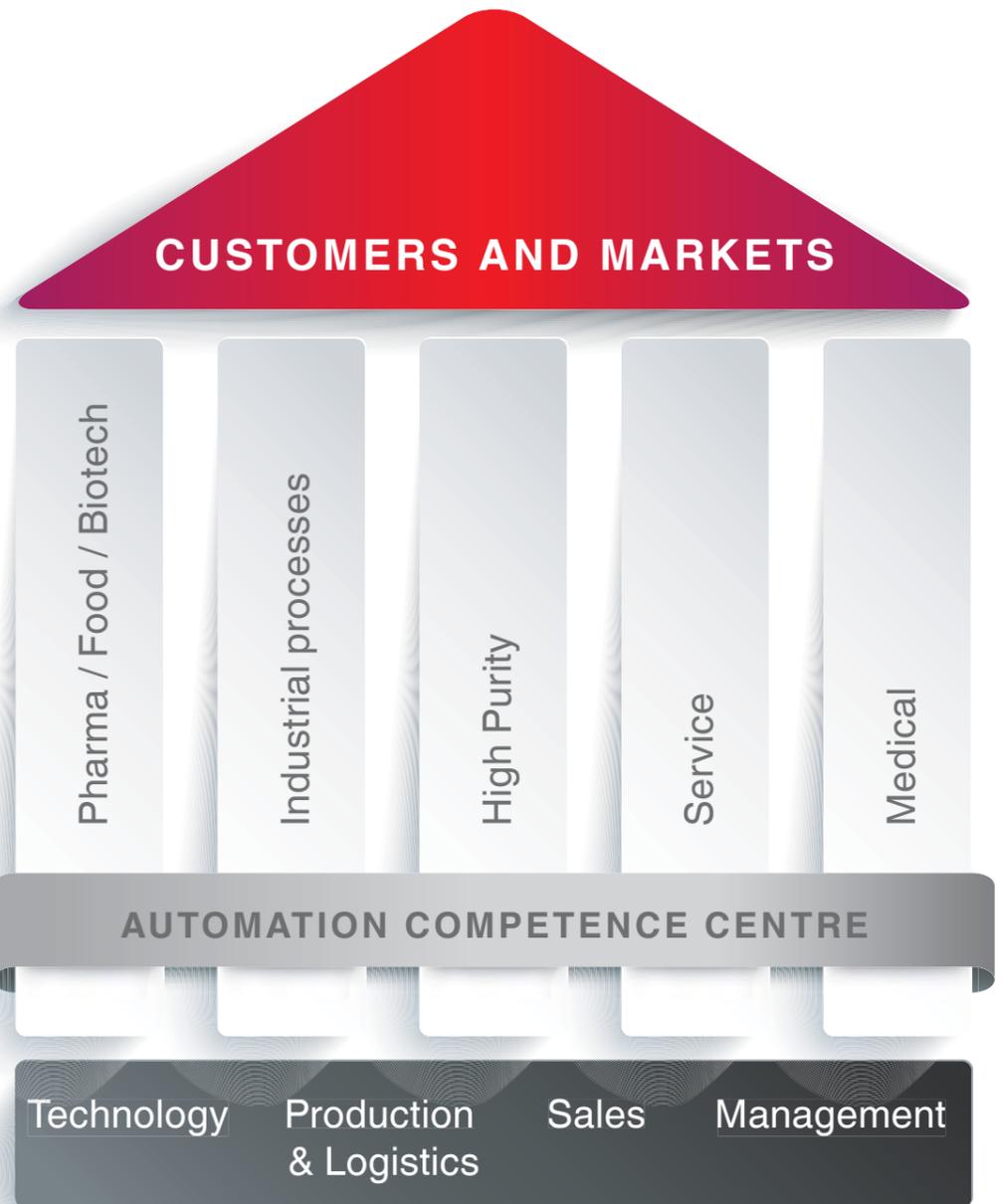
To be able to work the defined markets more efficiently, we will pool our strengths into strategic business areas. This will help us to ensure that we can better deal with the various customer requirements.

However, focusing on various business areas is just one element of our company strategy.

### Global responsibility

One further component is the strengthening of global responsibility. GEMÜ is not only international when it comes to where its customers are – it also has an international supply chain, with its own production plants and suppliers. This needs to be coordinated successfully in order to reach our international customers even more effectively.

In addition to the strategy, we would also like to go into more detail about our first new business unit – Pharma, Food & Biotech. Information about other business units will be provided in future issues of GEMÜnews.



## Business area strategy

- Pharma/Food/Biotech business unit**  
Continuing to expand our current market position in Europe and increasing our market shares in America and Asia.


- Industrial processes business unit**  
Focussing on the industrial sectors of the chemical industry, mechanical engineering, surface finishing and industrial water treatment.


- High purity business segment**  
Concentrating on applications for the microelectronics, semiconductor and solar sectors.


- Service business segment**  
Establishing and expanding customer-related services.


- Medical business segment**  
Focussing on developing and implementing injection moulding system solutions produced in a cleanroom.


- Automation Competence Centre**  
Coordinating automation activities across sectors.



# Introduction to the new business unit

## Pharma, Food & Biotech

*GEMÜnews: Ms Scherer, would you like to introduce yourself?*

Bettina Scherer: My name is Bettina Scherer. I have been married for 22 years and I have two children. I have one son, who is 20 years old, and one daughter, who is 17 years old. I completed a BA degree in Energy and Automation Technology in Erlangen. After university, I started working for Siemens. From 2001-2005, I then worked for the GEMÜ Group. After that, I moved to GEA Tuchenhausen. After 10 years, I have now returned to GEMÜ and am Head of the Pharma, Food & Biotech business unit.

*GEMÜnews: You mentioned that you're not a new face at GEMÜ: How have you found returning to your old workplace?*

Bettina Scherer: I felt like I was coming home after a long business trip. Through the intervening years, I could never have forgotten GEMÜ; I came across the company time and again at trade fairs and I had kept in touch with some of my "old" colleagues throughout these 10 years. At that time, my role was as Market Manager for measurement and control technology products. Our sales colleagues usually prefer mechanical valves. The electronic products were sometimes considered a necessary evil. Thanks to joint customer visits and product explanations, I was able to build up some good relationships with my colleagues. And now I have returned to the company to take on a different role. I have been able to use my diverse activities at GEA Tuchenhausen over the past 10 years to build up a great deal of experience and this experience will hopefully now help us to gain market share. So although I'm returning to my old workplace, I will face new challenges and I will happily face them not only with my "old" colleagues but also with a great many new colleagues.

*GEMÜnews: Can you go into more detail about the challenges you are facing with regard to the Pharma Food & Biotech business unit?*

Bettina Scherer: GEMÜ has been and still is successful; the foundation for this was laid many years ago when we began to build up a strong sales network and to create an outstanding image using high-quality and application-focussed products. In certain sectors, we are one of the market leaders and are perceived to be a technological leader. However, as you know, the competition is not sleeping – the challenge will be to build our market share in America, to maintain our high market share in Germany and Europe, and to gain new market share in Asia by using the right products. That said, we will only continue to achieve greater market access if we have new technologies and innovations that bring about benefits for the customer. Operators of process plants frequently receive products that are more or less the same as those of various manufacturers for their application. If we want to offer them further advantages, we must put ourselves in the position of the customer in order to be able to offer them services and integrated solutions for their applications. This means that we not only have to focus on certain regions in terms of sales, but we also have to impress customers with our innovations and service.

*GEMÜnews: Where specifically would you like to see changes in this business unit?*

Bettina Scherer: Identifying the challenges that plant operators have to overcome will help us to develop products that truly offer benefits to the customer. I think this is an important pillar of success. In this case, the sales discussions must be supported by experts who know the customers' processes. To assist in this, we have strengthened our team of Technical Consultants in recent months. To implement the ideas that arise from this (among others) in products, the strategic product managers, supported by market analyses and technology scans from the R&D department, will define user specifications for new products. The close collaboration with our Development department is also a major

advantage here. This means that another important pillar for success is to form a strong team that will recognise the needs of the market and implement innovative products accordingly. Specific requirements for valve combinations are already being included every day in new designs of multi-port valves. Our welded and block designs are developed based on the most diverse requirements from our customers. We have to serve the customers as best we can, however. This begins as early as the technical discussions and drafts in the offer phase. Unfortunately, due to limited capacity, in the past we have not always been able to react as quickly as we should have done. From January, this is an area that we will be able to strengthen thanks to adjustments to capacity and by utilising useful tools to achieve improvements in efficiency.

But if we do not ensure that we provide optimal support and technical advice for our existing products, all of these success strategies will only be effective in the short term. In the PFB business unit, the Operational Product Manager is taking on this task, in collaboration with the data managers. The organisational of labour in Product Management and the assignment of products has already been carried out and seeing its first successes. However, further processes and the interfaces to those departments that are participating still need to be defined.

The expansion of the Key Account Management department is responsible for a big leverage effect on the success. Some customers want GEMÜ to provide more intensive global support. This means not only drafting the relevant agreements, but also sustaining these and maintaining close communication within the GEMÜ Group in order to gain knowledge about procedures or projects, for example.

Thanks to the integration of the project team into the Key Account & Project Management area of the business unit, we have started on the organisational path towards networking the existing knowledge about projects. The GEMÜ Group's project business, which will hopefully increase as a result of this, will then also face the challenge of transferring this knowledge to GEMÜ's subsidiaries. This is because a global company should not only implement projects in Germany, for example – these projects should also be implemented within the subsidiaries. In future, standardised guidelines and workflows will make this global collaboration easier for us.

*GEMÜnews: In addition to all of the new tasks and responsibilities, how do you manage the balancing act between work and family?*

Bettina Scherer: 14 years ago my husband, Siegfried, decided to become a house-husband. Without dividing our responsibilities in this way, it would not have been possible for me to take on such a time-intensive role in my work. As a result of the children being older now, he expanded his wholefoods shop by adding the "Biokost Scherer" bistro about three years ago. The whole family feels very comfortable here in Assamstadt and we enjoy various activities together in our free time (in the local clubhouse as well, for example). Right now, we are in the middle of the preparations for the "fifth season". Assamstadt is transforming itself into carnival heartland. Incidentally, even if you have to cross two valleys, it will be worth it to stop by during our town's carnival just once.

*GEMÜnews: Getting back to your background – you are now moving from a large company back to a medium-sized one. What experiences are you bringing with you and what, in your opinion, are the biggest differences between the two?*

Bettina Scherer: When I moved to GEA Tuchenhausen in 2005, I was able to bring with me my experiences from the areas of Product Management and Market Management and put these to good use because GEA Tuchenhausen also focussed heavily on mechanical products.

At GEA Tuchenhausen, I was gradually entrusted with more and more tasks, such as leading Business Development Management, taking on the role of manager of the Product Management department, and managing the Business Line Hygienic Valve Technology sector. This allowed me to further expand my specialist expertise in the areas of Product Knowledge, Design & Development, and Sales.

A major advantage at a company like GEMÜ – and this was also a decisive factor in my decision to return – is the short decision-making channels. In a large company, the distance to those making the decisions is sometimes so great that the actual arguments that come from the strategic and operational activities have lost a lot of their meaning by the time they reach here and it is the key figures that become paramount.

Furthermore, a large company has customers in-house. This is, of course, helpful with regard to turnover, but it also means that services and support are expected, which have to be invoiced to the "internal customers" – something that does not always happen. However, I'm also bringing with me positive experiences from my time there – how we can make efficient, extensive and systematic use of the company's own services and tools.

All in all, I have to say that you can feel very comfortable whether you are in a large company or a medium-sized one – I personally need the opportunity to get things moving and this opportunity has been afforded to me in both companies. I therefore look forward to the future challenges that I will face in this role.



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# GEMÜ creates capacity for continued growth



With its new factory for production and administration, the GEMÜ group is paving the way for the future and continuing on its course of international growth, manufacturing products for both the local and the world market.

With state-of-the-art technologies and optimized production processes, the company will offer faster and better service not only for its customers in China, but also for the whole of the Asia-Pacific region. The customers in this strategically important market demand local customer support and service from their suppliers. GEMÜ recognized this need early on: Back in the '90s, GEMÜ company founder, Fritz Müller, decided to establish a subsidiary in Shanghai with just two employees. Over the years, GEMÜ China has grown to become the

second largest subsidiary in the group. Today, a total of 170 staff are employed here, producing and selling valves, measurement and control systems to European quality specifications. These products are used in the bio-pharmaceutical, semiconductor and solar energy industry, as well as in the industrial water treatment sector in China and other countries. With a total surface area of 21,000 m<sup>2</sup>, designed and constructed in the GEMÜ style, the new building complex demonstrates the "us feeling" around the globe. "We are a worldwide team, a unit,

and we want to continue to grow and achieve great things together," said Company Owner and Managing Director, Gert Müller, in his speech at the inauguration on 1st July 2015. The opening celebrations were very much focused on the unification of the different cultures and close cooperation between the German parent company and the Chinese subsidiary.



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# GEMÜ Denmark praised by financial newspaper Børsen for the second time

Each year, Danish financial newspaper Børsen votes for a few so-called "Gazelle" companies among the 500,000 Danish companies. This year, GEMÜ Denmark is among the award winners again and has been praised for its extraordinary business development.

"It was amazing to receive the "Gazelle" prize last year, but to receive yet another "Gazelle" prize this year is fantastic," explained Stefan A. H. Holmgren.

The prerequisite for the "Gazelle" prize is that the company in question must have doubled its turnover over the last four years and also achieved a certain volume of turnover. GEMÜ Denmark has exceeded these parameters, leading the financial newspaper Børsen to name it a "Gazelle" company.

"Our headquarters in Ingelfingen, the impressive products featuring German quality, and our exceptionally hard-working Danish team made a crucial contribution towards the success of GEMÜ Denmark. In addition, we are in the frontline thanks to optimising our procedures in the company and the use of Penta and PISA," explained Stefan A. H. Holmgren, Office Manager in Denmark. He accepted the award together with Lars Hillgren, Head of Sales Nordic Countries, on 18th November 2015, on behalf of all employees in GEMÜ Denmark. "In addition to the pharmaceuticals market, we are currently focusing on the industrial area. Our butterfly valves and ball valves for this sector provide the optimal solution for many applications," explained Stefan A. H. Holmgren.



Stefan A. H. Holmgren



Lars Hillgren

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**GEMÜ ApS in Denmark**  
 Founded: 2007  
 Employees: Eight, of whom five are in Internal Sales and three are in External Sales  
 Headquarters: Ballerup, near Copenhagen

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# 20 years of INTERCARAT GEMÜ subsidiary celebrates its anniversary

Rolf Meier has been the Managing Director of INTERCARAT since January 2015 and had the pleasure of organizing the anniversary celebrations after just a few months. The subsidiary of the GEMÜ Group was founded 20 years ago in Duppigheim, Alsace.

INTERCARAT produces moulded parts made of rubber (EPDM) and polytetrafluoroethylene (PTFE) which are used as diaphragms for GEMÜ valves in a variety of industries, from the pharmaceuticals sector to the foodstuff industry, and from the medical industry to water treatment and the chemical industry. Even the straps of luxury watches use elastomer cores made by INTERCARAT. As the Managing Director, Rolf Meier boasts expertise from previous activities in a leading position in the development of pneumatics and automation technology, as well as in aviation and defence technology. The anniversary celebrations provided a welcome opportunity for official guests, employees and their families to take a look behind the scenes, in the laboratories and in the production facilities, during plant visits and tours. Stephan Müller welcomed everyone on behalf of the

management, emphasizing the Group's responsibility as a family-owned enterprise in particular. "We believe that the solidarity of owner families is a guarantee for a reliable, sustainable and state-of-the-art company policy which provides us with a solid environment and secure jobs." Fritz and Gert Müller also attended the celebrations in Alsace together with their wives. The official part of the proceedings was followed by a lavish staff party. The marquee on the company premises – in true Alsace style – provided culinary delights, naturally accompanied by matching wine. "We were extremely lucky with the weather," commented Rolf Meier. "The celebrations were a great success and we received excellent feedback from guests and employees." The strategic foundation for the further development of INTERCARAT has been laid.

Workflows and the flow of materials are being optimized in current projects. This means that the project managers in Duppigheim are benefiting from the experience of their German colleagues in the Production and Logistics Centre at the Hohenlohe business park. Collaboration with other GEMÜ companies is also being intensified in other subject areas. Over the next few years, the intention is to establish INTERCARAT as a "Centre of Competence" for rubber (EPDM) and PTFE parts within the GEMÜ Group.

Stephan Müller emphasized the strategic dimension. "Over the last 20 years, INTERCARAT has acquired a great deal of expertise in the development and processing of thermoplastic materials such as PTFE and elastomers and has thus become an important strategic expert within the GEMÜ Group."

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F.l.t.r.: Rolf Meier, Stephan Müller, Gert Müller



## Topical training dates

### ALL-ROUNDER LEVEL

#### ⇒ Basic technical principles of valve design

- GV01GB Functional principles of valves and their selection criteria  
30th May 2016 (basic module)
- GV02GB Plastics, elastomers and their selection criteria  
31st May 2016
- GV03GB Metals and their selection criteria  
31st May 2016
- GV04GB Pipe connections and assembly information  
3rd June 2016

#### ⇒ Basic principles of application technology

- GA01GB Processes in the biotechnology, pharmaceutical, foodstuffs and cosmetics industry  
1st June 2016
- GA02GB Processes in the high purity, semiconductors and critical media industries  
2nd June 2016
- GA03GB Processes in the chemical, processing and water industries  
6th June 2016

#### ⇒ Basic principles of measurement and control systems

- GM01GB Introduction to electrics, electronics and pneumatic  
27th June 2016 (basic module)
- GM02GB Measurement variables and measurement principles in process engineering  
28th June 2016
- GM03GB Control circuits, their design and function  
29th June 2016

### SPECIALIST LEVEL

#### ⇒ Product training in valve designs

- PV01GB Valves for biotechnology, pharmaceutical, foodstuffs and cosmetics industries  
9th June 2016
- PV02GB Valves for high purity, semiconductors and critical media industries  
15th June 2016
- PV03GB Linear valves for chemical, processing and water industries  
7th and 8th June 2016
- PV04GB Valve designs - accessories and instrumentation  
16th June 2016
- PV06GB Single-use valves for biotechnological and pharmaceutical industries  
10th June 2016
- PV07GB Quarter turn valves for chemical, processing and water industries  
13th and 14th June 2016

The training courses will be held in English.

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## Trade fairs 2016 National – international

Unified Wine & Grape Symp.	26.01. – 28.01	Sacramento (USA)
Semicon Korea	27.01. – 27.01	Seoul (KR)
CFIA Rennes	08.03. – 10.03.	Rennes (FR)
Energy Storage	15.03. – 17.03.	Düsseldorf (DE)
Semicon China	15.03. – 17.03.	Shanghai (CN)
WIN Automation	17.03. – 20.03.	Istanbul (TR)
Expo Lounge (Vision Pharma)	05.04. – 07.04.	Stuttgart (DE)
Food Chain Nordic	06.04. – 07.04.	Malmö (SW)
Fluid Power & Systems	12.04. – 14.04.	Birmingham (UK)
Medtec	12.04. – 14.04.	Stuttgart (DE)
Pharma-Kongress	12.04. – 13.04.	Düsseldorf (DE)
MSR Rhein-Main	13.04.	Frankfurt (DE)
Powtech (TechnoPharm)	19.04. – 21.04.	Nuremberg (DE)
CIPM	20.04. – 24.04.	Chongping (CN)
Pumps & Valves	20.04. – 21.04.	Antwerpen (BE)
HMI	25.04. – 29.04.	Hannover (DE)
Cophex (KoreaPack)	26.04. – 29.04.	Seoul (KR)
Interpex USA	26.04. – 28.04.	New York City (USA)
FCE	10.05. – 12.05.	São Paulo (BR)
MSR Rheinland	25.05.	Leverkusen (DE)
IFAT	30.05. – 03.06.	Munich (DE)
Forum Industriearmaturen	15.06.	Essen (DE)
Interpex Japan	29.06. – 01.07.	Tokio (JP)
Innoprom	11.07. – 14.07.	Ekaterinburg (RU)
Semicon West	12.07. – 14.07.	San Francisco (USA)

# Controlled pressure with single-use diaphragm valve

Within the scope of a single-use system for treating biopharmaceuticals by means of cross-flow filtration, one company is using the world's first single-use diaphragm valve. Thanks to its controllability function, the valve enables the system to be operated safely and efficiently.

Single-use components and systems are now firmly established in the pharmaceutical and biotechnology industries. The trend towards simplified and flexible upstream and downstream plant design means that these components are becoming increasingly important – especially in the production of biopharmaceuticals. Competitive pressure is particularly high in this field, with sales figures often in the region of several million euros.

In order to respond flexibly to customer needs and the relevant market situation, large pharmaceutical companies are increasingly calling on what are referred to as CMOs (Contract Manufacturing Organisations) to manufacture various intermediate medicinal products or the final product on their behalf. This is particularly the case if a product needs to be produced to a different benchmark than the one usually applied in house or if the timeframe for production demands it.

One of the leading CMOs is Rentschler Biotechnologie in Laupheim, Germany. The company has been an independent contract manufacturer since 1997, specialising in the development and production of active biopharmaceutical substances. Rentschler not only serves large pharmaceutical companies throughout the world but also has medium and smaller customers that do not have their own production plants. In addition to an extensive range of stainless steel systems with a production capacity of 30 to 3000 l, there has been investment in several single-use concepts with a bioreactor volume of 1000 and 2000 l in recent years.

This now includes fully automated single-use filtration systems from Pall Life Science, which work according to the cross-flow principle. These complex systems have been developed to meet all manufacturer requirements and at the same time respond flexibly to the vast range of different products. There are also considerable cost advantages, since the use of single-use systems eliminates the need for intensive and time-consuming cleaning processes and considerably reduces the risk of cross contamination.



GEMÜ SUMONDO®  
single-use diaphragm valve

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## Filtering suspensions

Cross-flow filtration, also known as tangential-flow filtration (TFF), is a quick and efficient method for separating solid matter from suspensions and concentrating or desalinating them. Depending on the pore size of the filters used, this is classed as micro-filtration or ultra-filtration. It is used in a variety of biotechnological, biochemical and microbiological processes, for example in cell harvesting, the cleaning of culture supernatant or the fractionation of large and small biomolecules. Furthermore, cross-flow filtration is also used for the replacement of buffer solutions in chromatographic procedures, if for example different buffers need to be used one after the other.

The suspension (feed) to be filtered is pumped in parallel through a diaphragm at high speed and the permeate is drawn off transverse to the direction of flow. The liquid that does not pass through the diaphragm is fed back into the feed flow as retentate. In contrast to conventional filter methods, no filter cake is formed from the separated solids as a result of the turbulent flow. This would mean that more energy and equipment needed to be used due to the resulting pressure loss. The solids can therefore only be concentrated with the TFF method, as it must still be possible to pump the medium. The filtrate is, however, free from solids in both cases.

One of the most important variables when it comes to operating a TFF system efficiently is the transmembrane pressure (TMP). This is the force that the suspension to be filtered generates through the diaphragm, thereby causing a pressure drop between the feed and retentate connection. The transmembrane pressure can be increased by constricting the tube at the retentate connection.

In order to guarantee optimum filter performance according to the product and the filter and to process a larger product volume as quickly as possible, the transmembrane pressure must be controlled accurately. Until now, no suitable valves have been available on the market for this highly sensitive task in the field of single-use technology. Conventional pinch valves were susceptible to certain common problems, such as cracking, and were also unsuitable for these control tasks.

## Controllable diaphragm valve

GEMÜ, manufacturer of valves, measurement and control systems, has developed the first controllable single-use diaphragm valve, the GEMÜ SUMONDO®. This is a real milestone in single-use technology for the manufacturer: From manual systems to automated and controllable plants for safe operation and continual documentation by the plant monitoring system. "We have applied our expertise in diaphragm valve technology to single-use technology," explains Valentin Rüttimann, product manager for GEMÜ SUMONDO®.

Rentschler is using this new technology successfully in its TFF systems. Here the single-use diaphragm valves reliably control the transmembrane pressure between 0 and 2 bar at a maximum flow velocity of 1200 l per hour. When designed as a T valve, they are responsible for discharging the product. "Thanks to a precise control system, the single-use diaphragm valve makes an important contribution to process reliability," says Rüttimann.

The use of single-use systems almost completely eliminates the need for the cleaning and sterilisation processes (CIP/SIP) involved with the classic stainless steel plant design. The required cleanliness is guaranteed by the



GEMÜ SUMONDO®: Stainless steel actuator



GEMÜ SUMONDO®: Valve body assembly

# GEMÜ receives an award from the BPSA

In spring 2015, the Bio-Process Systems Alliance (BPSA) presented its members with a poster to thank them for their membership and their dedication to single-use technology. With a team comprising members from research and development, product management and the GEMÜ USA subsidiary, GEMÜ contributed to the test matrix for testing single-use components with a focus on single-use valves.

The aim of the BPSA is to promote the development and manufacture of biopharmaceuticals around the world through the implementation of more robust, more reliable and more sustainable single-use technology. The BPSA was founded in 2005 as an industry-led corporate member trade association dedicated to encouraging and accelerating the use of single-use production plants for the manufacture of biopharmaceuticals and vaccines. The BPSA promotes education, knowledge sharing, the development of consensus-based guidelines and increased networking amongst members. The BPSA currently has 55 members who are manufacturers and users of single-use systems.

The BPSA currently coordinates various activities of interest to manufacturers and users of single-use systems. These include tracing particles, regulating processes and the integrity tests of single-use systems. The BPSA also deals with the topics of change notification and the requirements of single-use users. In addition, it is involved in the organization of activities relating to the sustainability of single-use systems and the training of specialist technicians in the single-use area. Various work groups within the BPSA work on these topics. You can find further information about the BPSA on the website [www.bpsalliance.org](http://www.bpsalliance.org).



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sterilisation of all process components used with gamma rays. This not only reduces the investment costs for such a plant as well as the running costs and loss of production associated with cleaning, but also renders the laborious cleaning validation process superfluous.

## Special locking technology

GEMÜ SUMONDO® links the valve body and actuator together using a patent pending locking technology: Once used, i.e. after a process is complete, only the valve body is removed; the stainless steel actuator itself stays in place to be reused repeatedly in the plant. The valve body is manufactured from polypropylene in a cleanroom and is gamma-sterilizable up to 50 kGy. It isolates the working medium hermetically from the environment and from the actuator through an ultrasonically welded diaphragm. The medium remains closed off from the environment by the internal welded diaphragm not only during operation, but also after removing the valve body.

The major advantage of this technology in comparison with conventional pinch valves lies in the exact controllability of processes. Using a tried and tested actuator design from conventional plant engineering, the actuator can also transmit feedback to the plant monitoring system as required to ensure complete monitoring of the controlled system. According to Valentin Rüttimann, "The modular concept is very important to us at GEMÜ. This means that single-use systems, standard stainless steel valves and feedback units need to be compatible with one another."

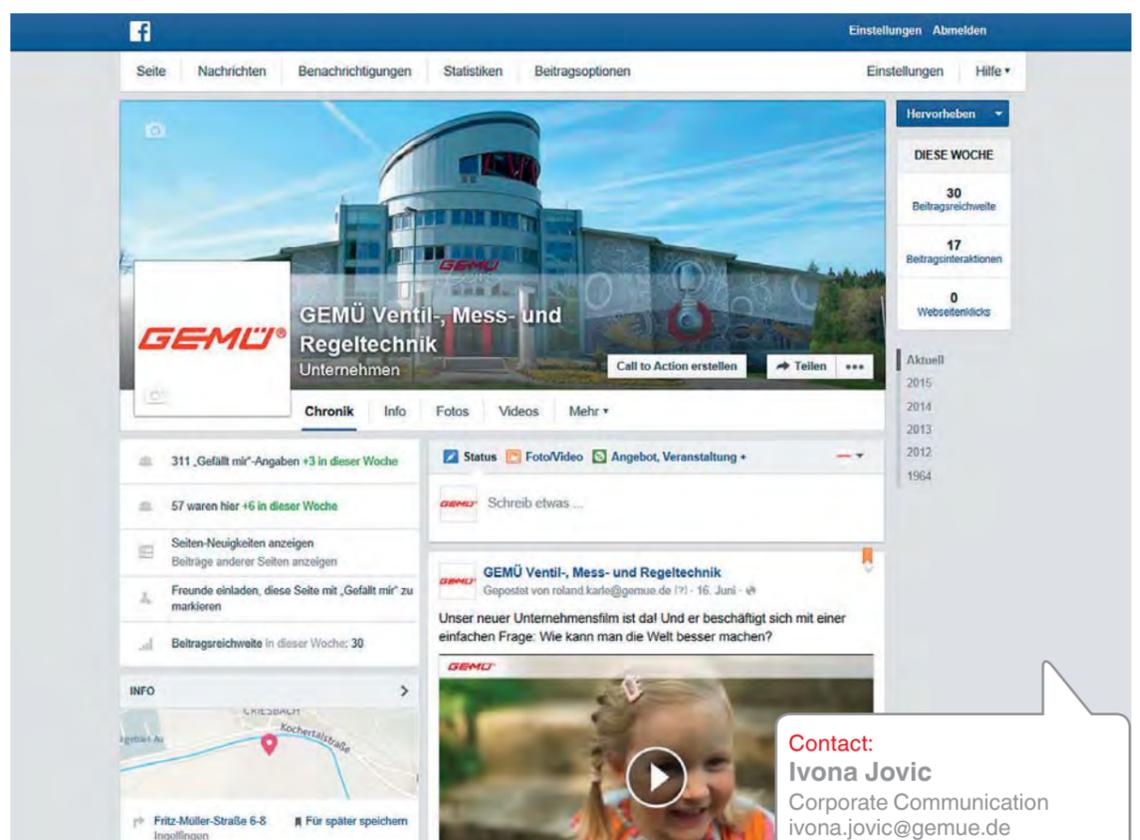
Pharmaceutical processes in particular will be made easier to document, reproduce and validate thanks to the ability to send feedback to the plant control system. The increased levels of automation also mean that the systems are less susceptible to faults.

## Social Media Our Facebook presence



Social networks are now an important way in which companies can present themselves.

Social media allows customers and employees to be kept up to date by ensuring continuous communication. Social networks provide visitors with the latest company information and allow them to network with GEMÜ. For example, our Facebook page features information about events, products, training, trade fairs and much more. Curious? Then simply visit our page. The links to social media are also integrated into our GEMÜ website. In addition to Facebook, you can find us on YouTube, Xing, LinkedIn and Google+.



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A fully automated single-use filtration system that works according to the cross-flow principle.

Photo: Pall Life Science

# Compact. Flexible. Cost effective.

## GEMÜ 3030 mFlow

Plant engineering demands compact, flexible and versatile components. Thanks to its varied applications, the GEMÜ 3030 mFlow magnetically inductive flowmeter is a more cost-effective option than conventional flowmeters.

### Magnetic induction as a measurement principle

With this measurement principle, a conductor induces a voltage in a magnetic field which is proportional to the speed of the medium. Here the flowing medium, which must be electrically conductive, is this moving conductor. This makes it possible to measure the flow velocity of liquids precisely. The flow rate is then calculated using the pipe cross section previously entered by the user. The measurement result is largely independent of process pressure, temperature and viscosity.

### Simple connection to the plant control system

There is a selection of different interfaces available for the electrical connection to the plant control system. As a result, status information and error messages can be displayed and the operating range can be adjusted easily and conveniently. Via the two status displays integrated in the housing, connection problems or data transfer errors, for example, can also be seen from a distance.

Calibration at the factory ensures the flowmeter is immediately ready for operation once the operating voltage has been connected. Where necessary, the device can also be calibrated locally or readjusted in order to adapt to plant-specific conditions.



### Quick and easy commissioning

The GEMÜ 3030 mFlow flowmeter is easy to install and, thanks to its intuitive operating concept, simple to commission. The device can be configured via the fascia buttons or via the web browser. The software required for browser-based operation is already integrated in the GEMÜ 3030 mFlow, rendering any additional software superfluous. The configuration menu has a clear and transparent structure. A help text, available in different languages, provides assistance in answering questions.

### Application in many sectors

Due to the fact that there are no moving parts in the medium, the GEMÜ 3030 mFlow flowmeter is suitable for a wide range of uses. Thanks to the contactless measurement principle, it can also determine the flow rate of media with particles.

The device continues to feature two totalizers. These enable the flow to be determined over a specific time period. The device can also be fitted with a temperature sensor which makes it possible to detect the flow rate value and the medium temperature simultaneously.

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# Standard systems for complex control tasks

At present, control valves are increasingly becoming the focus of a wide variety of applications. In order to provide the customer with a simple selection guide, GEMÜ has now summarized all the relevant components of a control system under the term Process Control System, or PCS.

The PCS type combines the standard GEMÜ control valves with mounting kit, compressed air line and positioner. In this way, the customer has the option of ordering the appropriate control system and all the necessary components quickly and without error. Each nominal size has two regulating cones (linear and equal-percentage) to choose from as standard.

The operators for the GEMÜ 554 (plastic), GEMÜ 514 (aluminium) and GEMÜ 550 (stainless steel) series are available in the form of actuators. GEMÜ 1434, 1435 and 1436 have been integrated into the PCS as controllers. The standard versions of each controller are regarded as basic versions. The GEMÜ 514, 530, 532, 534, 550 and 554 series contain the nominal size range of DN 15 to DN 50. The GEMÜ 536 globe valve covers the nominal size range of DN 65 to DN 150.



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# Klasse2000 sponsorship Strong and healthy in primary school

Klasse2000 is the most widespread programme in Germany aimed at promoting healthy living and preventing violence and addiction in primary schools. Since 2015, GEMÜ has been sponsoring a second-year class at the Georg-Fahrback School in Ingelfingen, thereby enabling all 23 children in the "Ladybird class" to participate in the health programme for a whole year.

Healthy, strong and confident – that's how children should grow up. The Klasse2000 teaching programme supports children from the first to fourth year of primary school. It deals with important topics relating to healthy nutrition, exercise and relaxation. The children also learn important life skills such as the right way to deal with emotions and stress, how to solve problems and conflicts without using violence, how to think critically and how to say "no".



### Sponsors get to know "their" class

Sponsors are more than welcome to attend any Klasse2000 session. GEMÜ paid a visit to its "Ladybird class" in October 2015 and the children were delighted to meet their sponsor. Management also assured the school that it would support the project for other classes that year in order ensure that it can continue to make a small yet long-term contribution to the children's education.



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