

FA 15 The lifesavers

The economy may be stuttering or booming – the pharmaceutical industry remains on track. Everyone wants to stay healthy. And the demographic change keeps on boosting production to new heights. For plants manufacturers, the pharmaceuticals industry is a lucrative sector. However, highest requirements pose a challenge for valve makers. The bar is set extremely high in terms of hygiene.

The pharmaceuticals industry is very robust. “Compared to other industries it is far less exposed to weak economic environments,” emphasises the Cologne Institute for Economic Research (IW), on the pharmaceutical industry in Germany. Compared to other goods, production and sales of pharmaceutical products react less to economic ups and downs – in contrast to, for example, the manufacturing sector. Taking a look back to the second quarter 2009, which was hit hard by the recession, production volume of the pharmaceuticals industry merely shrank 4.5 percent compared to the same period a year before. As a rule, the sector is seen as a “stabilising element in times of crisis,” states the IW.

Medical needs keep on increasing

There are two reasons behind the pharmaceutical industry's health: one is people become ill regardless of the economic situation. The second is that medical needs will keep on increasing in the medium to long term, “as global population is growing and the people in industrialised countries are becoming older and older,” explains the IW. Based on jobs and turnover, Germany is Europe's largest pharmaceuticals market. “More than one in seven euro turnover in Europe's pharmaceutical industry comes from Germany“, states Dr. Jasmina Kirchhoff, Senior Economist for the Pharmaceuticals

Industry in Germany, of the IW. In addition, following Switzerland Germany is the second largest pharmaceuticals producer in Europe, with a share of 13 percent. “The strong industrial location, a highly qualified labour force, a good infrastructure and high-performance clusters support the development of the industry in the location Deutschland”, Kirchhoff continues.

Europe and China as growth markets

Good prospects for the valve industry. Growth in the next few years remains moderate, but continuous. It will mainly take place in Europe and China. Nonetheless, the positive outlook for valves manufacturers also has its challenges. The demands placed on the purity and the reproducible quality of raw materials and active ingredients, as well as on the finished products, have become increasingly stringent over the past few years,” claims German valve and pump manufacturer GEA Tuchenhausen. “It is not without reason that the planning and implementation of production lines for the pharmaceutical industry is regarded as the supreme discipline of plant engineering,” the company adds. Very strict hygiene rules, often restricted space as well as being entirely easy to service are some demands that need to be met during construction. Valves need to have as little dead space as possible, the amount of welding joints needs to be as low as possible.

Corrosive and ultrapure media

Various materials are used by valve manufacturers to meet the requirements, such as stainless steel, steel, brass and different types of plastics. Valves need to be suitable for corrosive, hazardous, pure and ultrapure media.

Seals used in valves need to meet special requirements in the pharmaceutical industry. They especially need to remain sterile. The trend is moving away from cold sterilisation to heat sterilisation. Higher and higher cleaning temperatures need to be coped with. A

lot of importance is placed on the mix-up and counterfeit protection of the seals used in a valve.

Numerous rules and standards

The valves are mainly lined with PFA and PTFE. PFA is resistant against nearly all chemicals and is highly temperature-resistant. Both properties are of great importance in the production and cleaning process of pharmaceutical production.

The ASME BPE standards for instance play an important role. End users also often want valves to be in line with the USP Class VI standard. The materials are tested and classified according to their biological reactivity on living tissue. USP is short for US Pharmacopeial Convention, a nonprofit organisation created to set standards amongst others for purity and quality of medicines, food supplements.

Valve production orientates itself towards the GMP (“Good Manufacturing Practice”) rule. The “good manufacturing practice for medicines” is codified in national and international rules and standards. The main points of GMP for instance are requirements in terms of hygiene, facilities, equipment, documentation and controls.

Avoiding leaks

Material 1.4435 is of great importance in the production of valves for the pharmaceutical industry. It is similar to material 1.4404, but has a higher content of nickel and molybdenum. Thanks to the higher molybdenum content, this valve material is more robust against localised corrosion in comparison to 1.4404.

Pharmaceutical production requires a great amount of different valves. This includes basically all plastic lined valves, such as check and cut-off valves, diaphragm valves, butterfly and control butterfly valves, control valves and safety valves. They regulate

production and filling of insulin, monoclonal antibodies, eye ointments and other active pharmaceutical ingredients.

Industry expects leading-edge technology

Valves for the pharmaceutical industry are the leaders of the pack. With more than 8.5 percent R&D investments, the industry is very R&D intensive. Pharmaceutical production is a leading-edge technology. Valve makers that accept the challenge are rewarded with lucrative orders.

However, the political and institutional framework for the pharmaceutical industry has been “unreliable, for instance the introduction of the price moratorium and the higher mandatory discounts,” states Dr. Jasmina Kirchhoff, Senior Economist, Pharmaceutical Industry in Germany, IW. “In view of long development cycles and high R&D investments the predictability of health policies is a central locational factor”. Kirchhoff also regrets the “lacking tax incentives for research and development”.

Despite all uncertainties the pharmaceutical industry offers great opportunity for its suppliers. The industry appears to be a neverending source of new revenues that keeps on growing. And it also saves lives!

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