Application report

A great plus for process safety in the pharmaceutical industry

Industry:	**P**harmaceutical industry
Customer/Location/Year:	Pfizer, Freiburg (Germany), 2010
Use of compressed air:	Conveyor air, in production
Installed products:	METPOINT OCV

In the pharmaceutical industry, the quality of compressed air plays a decisive role. Impurities or oil contaminations in medicaments through compressed air can quickly have fatal consequences. To improve the process safety in the production, the Pfizer production location in Freiburg, Germany, relies on continuous quality control of the compressed air by means of the METPOINT OCV residual-oil monitoring device by BEKO TECHNOLOGIES.

More than 250 million medicament packs leave the Freiburg pharmaceutical factory per annum. Behind this enormous figure are employees who produce tablets and capsules against cardiovascular diseases, pain and epilepsy. The Pfizer factory is equipped with one of the most advanced production plants for solids nationwide. But that's not all. This place is also an outstanding location in several other ways, for example as far as the subject matter "energy" is concerned. Environmental protection and energy management are declared corporate goals of the pharmaceutical group and are practically experienced. Pfizer operates Europe's largest pellet heating plant in Germany's greenest city. The plant produces 85% of the thermal heat required for the production plant from renewable energies. In the pharmaceutical industry, quality management and process safety are

equally important and are also at the highest level in Freiburg. It was only in 2008 that the world-wide Pfizer quality award was granted to the Pfizer location in Freiburg.

What applies to the overall contexts of the factory in Freiburg can also be applied to the compressed-air supply. Four computer-controlled compressed-air stations feed on average 78 Nm³/h into the compressed-air system with an operating pressure of 7.5 bar. Supply availability and quality reliability of the compressed-air are paramount.

Compressed-air quality in the pharmaceutical industry

Ensuring and controlling the quality of compressed air is in many aspects an unknown element in the different bodies of rules and regulations or the production guidelines which apply to the pharmaceutical industry. General recommendations and requirements can be taken from DIN-ISO 8573-1, DIN-EN 12021 and from the pharmacopoeia. Pfizer quality management specifies the requirements following DIN-ISO 8573-1. It is very important for Pfizer to meet these requirements or even to outperform them for safety reasons.

Compressed air in contact with the product

All persons in charge at Pfizer recognize that compressed-air quality in the pharmaceutical production needs to be particularly high, as the compressed air comes into direct contact with the medicaments during coating, where tablets are provided with a protective film, and during blow-out processes at production machines for the in-process control. Contamination of the products with oil could have fatal consequences. In addition, breathing air needs to be provided in the Freiburg factory for special production sectors where hazardous substances are employed. There, the employees need to wear, similar to astronauts, protective suits which are fully impermeable and in which they are provided with breathing air.

Concerning the processing technology in all stations, Pfizer relies on adsorption dryers with pressure dew points of -40° C for compressed-air drying. To remove the oil vapor, oil-vapor adsorbers are employed by means of which a compressed-air quality for oil vapor can be achieved which is better than class 1 in accordance with DIN-ISO 8573-1, provided that the exchange intervals are adhered to. Until today, meeting the compressed-air quality requirements at Pfizer was ensured by taking samples at regular intervals with subsequent analysis of the latter in the laboratory.

During a consultation regarding the condensate technology subject BEKO TECHNOLOGIES, Pfizer´s compressed-air experts last summer also talked about processing, for which BEKO also offers comprehensive solutions. During the visitation of the stations and by analysis of the available technology, BEKO TECHNOLOGIES detected an improvement potential in the different compressed-air stations. In one of the stations, a complete system solution could thus be developed with the aim of bringing compressed-air processing to an increased process-safety level. In other stations, the condensate technology was analyzed in addition to the filter technology, and adjusted to the requirements.

Monitoring of the compressed-air quality

Besides the analysis and optimization of the compressed-air processing technology, BEKO TECHNOLOGIES was able to score with a second solution at Pfizer: the METPOINT OCV residual oil vapor monitoring device for the continuous monitoring of the compressed-air quality. The constantly

updated indication of the residual oil content of the compressed air with the METPOINT OCV residual oil vapor monitoring device convinced Pfizer quickly. The values on the display in the stations, constantly in view, and also via the network at computer workstations in the office. The traditional method of oil vapor monitoring with the laboratory analyses of compressed-air samples was rather unsatisfactory, as it only showed a snap-shot of the compressed-air quality and did not allow conclusions to be drawn concerning the state of the oil vapor adsorbers. The continuous monitoring of the residual oil content in the volume flow which is possible with the METPOINT OCV residual oil vapor monitoring device is therefore a quantum leap towards process safety. With this measuring device, BEKO TECHNOLOGIES has brought state-of-the-art technology regarding compressed-air quality control to a new level. So, it was a matter of course that Pfizer wanted to retrofit their compressed-air supply with this technology in the sense of good manufacturing practice.

TÜV-certified measurement technology

Therefore, all four compressed-air stations in the Pfizer factory in Freiburg were equipped with the measuring sections, sensor units and display units in the fourth quarter of 2009. At regular intervals, the measured data is transferred to a control center via a network. Now, alarm messages ensure optimum protection of the pharmaceutical production against oil-containing compressed air when limit values regarding the residual oil content are exceeded. Since the end of February 2010, an independent certificate, issued by TÜV Nord, confirms that the devices from BEKO function perfectly and that they reliably carry out measurements in accordance with DIN-ISO 8573.

Besides the great plus for the process safety regarding the compressed-air supply, Pfizer is happy about another positive effect of the new residual oil monitoring: There was always an uncertainty between the sample checks concerning the degree of saturation of their oil vapor adsorbers, and

therefore concerning process safety. With the METPOINT OCV devices, Pfizer will be able to detect, at an early stage, whether there is need for action and when maintenance of the processing technology will be necessary.

Future-oriented solution

In view of the improvements achieved for the process safety, Pfizer engineers are very satisfied with the optimization of compressed-air processing and in particular with BEKO TECHNOLOGIES as a solution provider. In Freiburg, not only the compressed-air quality in the pharmaceutical production is right but also the chemistry between Pfizer and BEKO TECHNOLOGIES. And at the same time, the future-oriented and exemplary standard which Pfizer follows regarding the monitoring of the compressed-air quality is a signal for the entire industrial sector of pharmaceutical and food production.