



bürkert
FLUID CONTROL SYSTEMS

Customer Testimonial – Astra Zeneca

“Robolux valves shortened cycle times and eliminated deadlegs in our Sterile Filling Unit – giving us a much more efficient process”

As one would expect, production requirements at a global pharmaceutical company such as Astra Zeneca are extremely demanding. In Södertälje, Sweden, where the company produce *Pulmicort*®, one of the world's leading asthma medicines, Ulf Nilsson, Project Manager for Astra Zeneca Engineering, quickly understood the advantages of Robolux over traditional diaphragm valves. After the success of the first installation, two new systems using Robolux valves have now been added to the facility.

Continuous flow

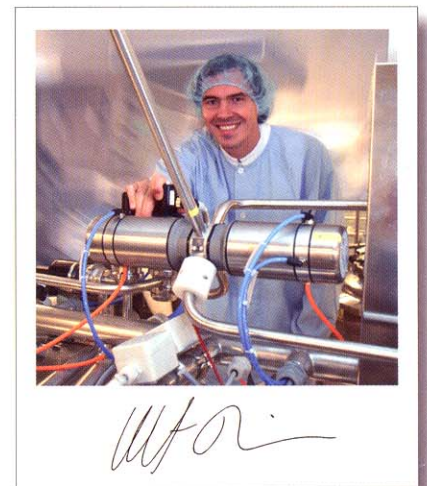
The production of *Pulmicort* Respules for nebulization requires the ingredients to be mixed together with water to create a final formulation, which is then packaged in plastic ampules (Blow Fill Seal) as part of a closed cycle process.

However, the active ingredient in *Pulmicort* is not soluble so the mixture is a suspension rather than a solution. To avoid sedimentation occurring it is imperative that once compounded and mixed the formulation is kept in continuous motion until filled and sealed. Any deadlegs in the system, where sedimentation might potentially occur, have to be minimized to ensure correct product concentrations are maintained.

Better by design

Back in 1999, Ulf Nilsson was already aware of the new innovative multi-way-multi-port valves from Robolux. So when Astra Zeneca wanted to increase their production capacity Ulf contacted Robolux and together they defined the best process solution for the compounding unit.

The problem with deadlegs, inherent in traditional systems, was simply solved by using Robolux 4Connection 4Seat valves. By arranging the required valves and flow paths in single units above and below the holding tank deadlegs were eliminated.

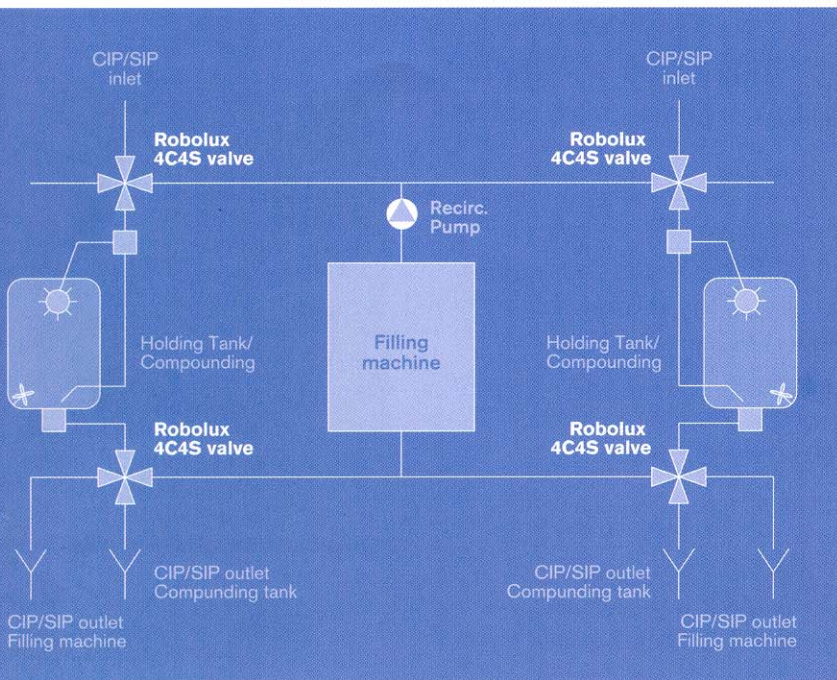


In addition, the Robolux solution greatly simplified the design and installation of the new systems, reducing the number of valves from 8 to 2, as well as reducing the number of T-pieces required and subsequently the overall cost of installation. The neater design also made future maintenance and cleaning procedures far easier.

Clean and sterile environment

The installation using Robolux valves proved to be so successful that when production was again increased in 2005 Ulf did not hesitate to specify Robolux valves for the two new installations. One of these is to operate in a clean room – class 100 000 – (sterile environment) where stringent monitoring will be used to ensure product quality according to regulatory stipulations.

Commenting on the latest project, Ulf said, “Compared to conventional valves the Robolux valves give us a far better flow path and process function, shortening cycle times and making sure our filling runs smoothly”.



Simplified diagram of the production installation using Robolux valves. Two identical systems connect to the filling machine ensuring that one system maintains production whilst the other is being cleaned. Each system also includes a return pipe to the mixing vessel to ensure continuous circulation if the filling machine is off-line.

Buerkert would like to thank Ulf Nilsson and Astra Zeneca for their kind permission to develop and reproduce this customer testimonial.



This is just one example of how we are redefining process systems and equipment. To learn more about Robolux valves and their application, go to www.buerkert.com or contact your local representative.

About Pulmicort

- The World Health Organisation estimates that 100 million people worldwide suffer from asthma.
- *Pulmicort* (budesonide) is one of the world's leading asthma medicines. It is an inhaled anti-inflammatory glucocorticosteroid, primarily for once- or twice-daily maintenance treatment of asthma.
- Inhaled formulations of *Pulmicort* include: *Pulmicort Turbuhaler*, *Pulmicort pMDI*, and *Pulmicort* suspension (*Pulmicort* Respules) for use with a nebulizer. (Nebulizers are devices that change liquid medicines into a fine mist for inhalation.
- Nebulized therapy has an important role in the treatment of respiratory disease in infants and young children, patients of all ages with severe asthma, and patients who are unable to use other inhaled glucocorticosteroids.

About Astra Zeneca

- Astra Zeneca provide innovative, effective medicines designed to fight disease in important areas of medical need: cancer, cardiovascular, gastrointestinal, infection, neuroscience and respiratory
- Products are available in over 100 countries worldwide
- Over \$15 million is spent every working day on the research and development of new medicines
- 64,000 employees worldwide, including 15,000 people at 30 manufacturing sites in 20 countries
- Corporate headquarters: London, UK.
R&D headquarters: Södertälje, Sweden

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