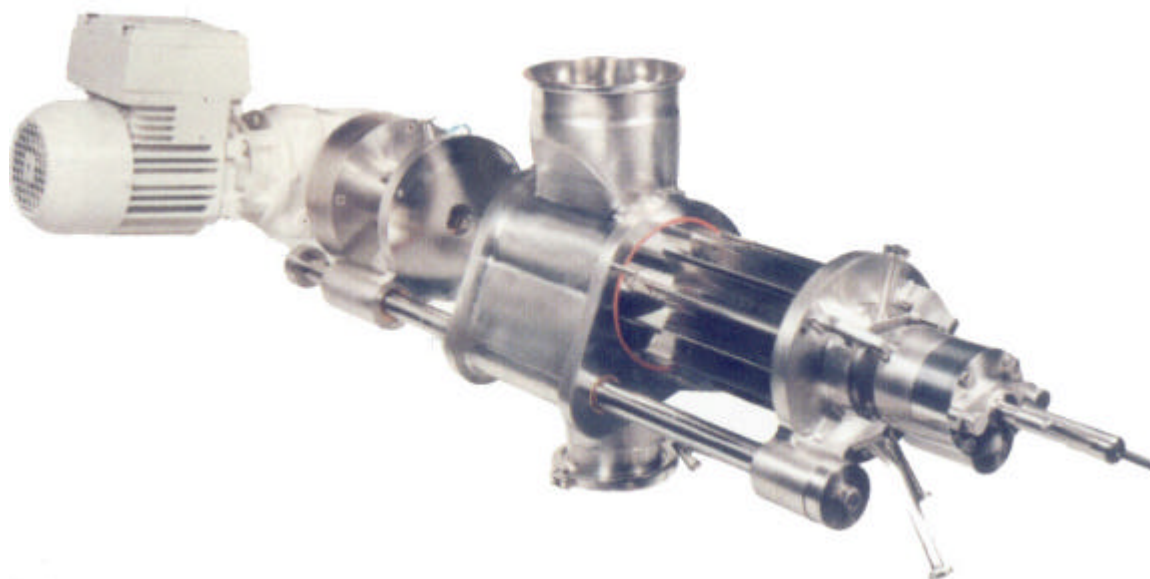


New 'Hypergienic' Rotary Valve Meets High Pharmaceutical Standards



In a joint development with AstraZeneca and Hosokawa Micron, RotaVal has produced a range of unique new rotary valves for pharmaceutical and food applications.

AstraZeneca is one of the world's leading pharmaceutical companies which provides innovative, effective medicines for serious medical conditions. The company has worldwide operations, employs over 50,000 people and had a turnover in 2000 of \$15.8 billion. Products are focused on seven important areas: cancer, cardiovascular, central nervous system, gastrointestinal, infection, pain control and anaesthesia, and respiratory conditions.

The company fully recognises that with a global business comes a global responsibility, especially in the areas of environmental, social and economic performance.

AstraZeneca has a well-developed culture that values employee contribution and promotes high standards throughout the company.

In particular, AstraZeneca has stated its total commitment to meet or exceed legal requirements and international agreements in respect of Safety,

Health and Environment (SHE), and to provide a safe and healthy work environment for all of its employees.

Constant Evaluation

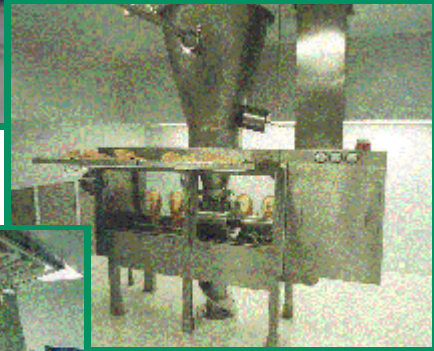
Against this background, the company constantly evaluates the manufacturing systems installed and seeks to make improvements where possible. New processes and the associated plant developments are subjected to intense scrutiny at every stage.

"If you have a very low Occupational Exposure Level, then the equipment should be designed so that the operators using that equipment should not have to wear respiratory protective equipment at all times when using that equipment" stated John Sherwood, Associate Principal Scientist and Product Development Engineer for AstraZeneca.

"There are so many good reasons to return to basic principles before specifying machinery. We do not



**Installations at
Avlon, near
Bristol (left) and
at Puerto Rico
(below)**



simply accept what is available off the shelf, but consider how to improve the overall process - and that includes looking at the way we ask our staff to operate and the conditions under which they work."

Challenge of New Facilities

This philosophy was brought into focus when AstraZeneca began to consider equipment for new production facilities at Bristol, Puerto Rico and Macclesfield. Essentially these facilities would be based upon fully-enclosed mills with rotary valves either side to control pneumatic feeding through the system. The products handled range from sticky, glassy particulates to fine powders. Bulk density is typically around 150kg/m^3 , and some products are susceptible to flood feeding. The fine powders test the containment capabilities of any system. Even the best valves previously available had to be fitted outside the high containment isolation (glove) boxes, meaning that workers had to wear full suits when cleaning.

The new facilities were conceived as totally enclosed, working to Occupational Exposure Levels between 0.01 gms/m^3 and 0.001 gm/m^3 . "We knew that if we could achieve complete enclosure of the rotary valves, there would be economic and environmental benefits, such as reduced waste of very expensive pure chemicals, lower disposal costs, better containment with a consequent improvement in working conditions, a reduction in downtime and enhanced productivity," commented Mr. Sherwood.

Seeking Perfection

"To meet this requirement two problems had to be covered. The first, that the rotary valve had to be redesigned so that it would fit inside an isolator (glove) box and could be disassembled and cleaned within this isolator (glove) box. Secondly, the existing design of valves used castings, which often have small inclusions. Although not important in most applications, the surface finish was unsuitable for enclosure in an isolator (glove) box. We needed to consider fabrication from stainless steel, and to totally redesign the valve to achieve complete freedom from pinhole porosity and inclusion defects. This would allow the valves to meet higher standards and gain full validation."

"With Hosokawa Micron, our mill supplier we decided to look for a development partner who was prepared to work with us to produce this new design of rotary valve to meet our requirements. After consideration of all current manufacturers, we chose RotaVal as the company most likely to be successful. In fact, it was probably the only British company capable of doing the job. RotaVal also had an established relationship with Hosokawa Micron, which would ease the design and development process. As a result, our three companies formed a small development team to work on the project. Did I mention the timescales? We began the process with



RotaVal in September 1999, and, for operational reasons, we were expected to have the valves installed by late 2000 and have fully working milling systems up and running by mid 2001. So in addition to the massive technical hurdles, especially when one considers that the valves had to be designed, tested

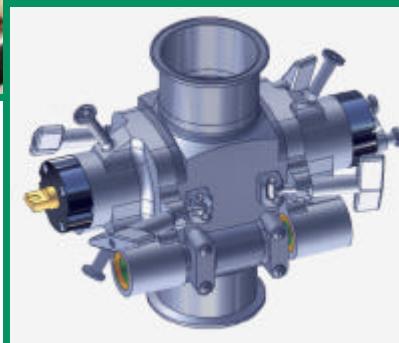
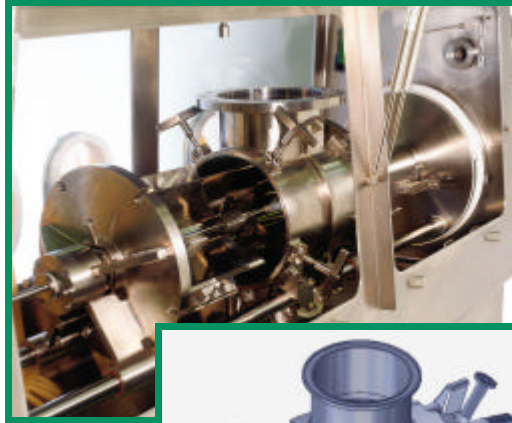
and configured in their isolator (glove) boxes, the project team had to battle against the clock."

The Hosokawa Micron Group is the world's largest provider of powder and particle processing equipment and systems. The Group maintains facilities for research engineering, manufacturing, contract processing and service in all major industrial market areas. At their Runcorn facility, Sales Manager Andy McLeish takes up the story: "Hosokawa Micron needed to have somebody with whom we knew we could work alongside on a very difficult project. RotaVal already had a reputation for high quality products and a "can-do" attitude to new developments, so we were happy with their approach. It was very much a team effort, with many meetings and many options considered before we all agreed on the final design. Our three companies worked closely together, each with defined specialisms and areas of responsibility."

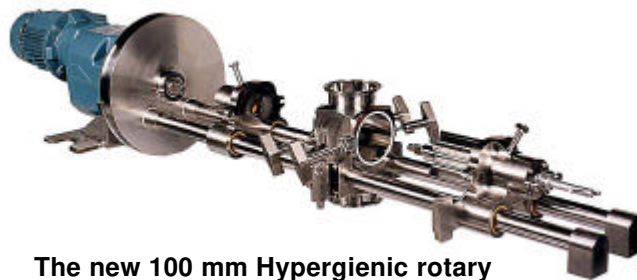
The specialist knowledge of Hosokawa Micron as a systems integrator proved to be an essential part of the project management of the complete process. As a result, the design and development of the integrated packages of mechanical equipment into isolator (glove) boxes was successfully achieved with all the major process items such as the Alpine Mill, Rotary Valves and Screw Feeder.

New Isolator Box Design

Amongst Hosokawa Micron's responsibilities was the production of a new rotary valve containment system based upon the company's proven range of Stott Isolator (glove) boxes. An early decision was made to place the drive motor outside the isolator (glove) box, introducing the need for a new approach to the contradictory requirements for secure motion transfer



Pre-production 3D CAD modelling



The new 100 mm Hypergienic rotary valve suitable for both pharmaceutical and sensitive food applications

through the isolator wall to the valve, and a system to allow easy removal of the drive shaft during CIP procedures.

"There were so many new features envisaged in this installation," continued Mr. McLeish, "that the team decided to build a full-size wooden mock-up of the whole isolator and valve assembly. This was made using early working drawings of the valve supplied by the RotaVal design team. By asking operators to simulate the normal running and clean down routines, we were able to fine-tune the designs to eliminate any problems before building actual equipment. This hands-on experience was complemented by a full computer simulation, resulting in the best balance between design, manufacturing techniques and ergonomics."

Leading Edge Technology

At RotaVal's Chippenham base, Managing Director Ian Blackmore revealed the size of the challenge his company faced. "RotaVal has been a major supplier of rotary and diverter valves for more than thirty years," he said, "and we have produced in that time a

very large number of one-off designs to meet special application requirements. This project, however, meant a complete rethink of valve design techniques, the creation of a number of new manufacturing processes, and a very steep learning curve at the leading edge of current technology. And, of course, we were trying to manage all this in a very short timescale to agreed budget limits."

Highest Specification Rotary Valve

A look at the final specifications of the new valve illustrates the degree of success the project team achieved. Now freely available to the food, chemical and pharmaceutical industries, Hypergienic Rotary Valves are offered as standard in sizes from 100 to 300 mm, fully tested and certified against 10 barg internal explosion and flame containment. (Hydrostatic testing is used to 13 barg) Valves are fabricated from 316L stainless steel with a 0.5Ra polished finish internal and external as standard with 0.2Ra electro polished as an option, using a

completely crack and crevice free design. All surfaces are self-draining to avoid fluid retention after washdown, and special features permit cleaning fluid injection or air blast for drying. As RotaVal have already demonstrated, the company is always prepared to consider alternative sizes and configurations of valve to meet special applications.

The new valves incorporate hygienic quick release anti-galling end cover fixings, fixed lower rails to aid easy opening of the valve assembly with minimal operator effort, a remote geared motor mounting with removable drive shaft, and full safety interlocks.

Fully Sealed Design

The bearings are contained within a sealed housing. Shaft seals are manufactured from FDA approved materials and fitted with leakage monitors and a Clean-In-Place facility. Position indicators provide operators with the essential information to check rotor pockets are empty before the valve is opened. Dummy end covers are provided, incorporating a spray ball. A range of options makes the Hypergienic Rotary Valve suitable for many applications within full containment isolation (glove) boxes, or for pharmaceutical, food and chemical applications requiring CIP features.

Commitment and Quality

"Naturally, I am pleased that we have been able to deliver such a complex, quality product to

specification and within budget," said Ian Blackmore. "The project has amply demonstrated our unique design and manufacture capabilities within the company, and I would like to express my thanks to everyone involved for their commitment, enthusiasm and skills which resulted in a successful outcome."

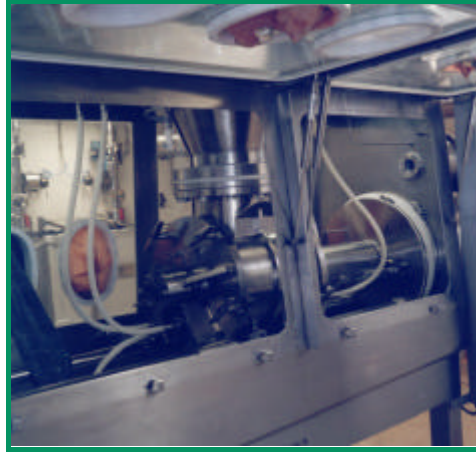
Andy McLeish said "I am very happy with the cooperation between our companies, and the end result is an excellent solution to the customer's needs. The new valves add a valuable system resource to Hosokawa Micron's product range, producing an integrated process capable of achieving very low OEL standards."

Finally, what does the end user think? "A clean, well-designed plant is actually looked after better by staff," observed John Sherwood.

"There is a knock-on effect on productivity, and operators feel valued in that their views have been considered closely at the design stage."

"We have improved our containment capability, made the working environment easier and safer and met a demanding set of specifications under tight timescales. We can justify the cost of the new design on improved operational considerations, but to this should be added savings in time and handling of equipment."

"Personally, I am very happy with the outcome and pleased with RotaVal's very high level of service throughout the project."



- * RotaVal 'Hypergienic' Valves are available in six standard sizes from 100 mm, 125 mm, 150 mm, 200 mm, 250 mm and 300 mm, with throughput capacities up to 48m³/hr.
- * All construction materials FDA approved.
- * Fully fabricated design, no castings, no porosity, allowing full validation
- * Fully tested and certified explosion resistant and flame containment to 10 Barg (Tested to 13 Barg)
- * Self-draining design with air purge facilities.

More technical and application data about the Hypergienic Valve is available from RotaVal's sales office in Chippenham, or our dedicated website www.hypergienic.co.uk



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