

Best practice

A weighing solution opens door for FDA compliance



The producer of active pharmaceutical ingredients LDO chooses a Minebea Intec weighing solution, enabling it the option of FDA compliance for API production and thus entering the US market.

Key facts

LABORATORI DERIVATI ORGANICI (LDO) specialises in the extraction of active pharmaceutical ingredients (API) from animal origins. Over the last decades, the company headquartered in Italy has continuously expanded across Europe, Asia and South America. For a new production facility and to enter the US market, LDO required API production compliance from the FDA.

Application

On account of the strict requirements GEASS, a Certified Minebea Intec Partner, brought in a weighing solution of load cells and different weighing electronics with Hygienic Design.

Products

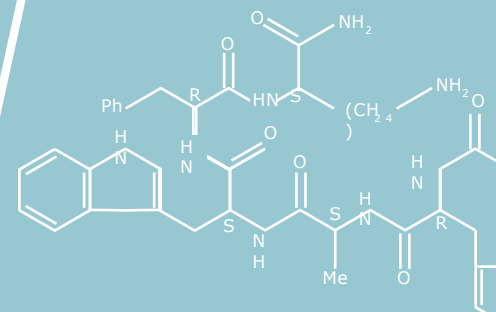
- Load cell PR 6211
- Weight indicators PR 5410
- Weight transmitters PR 5230

Customer benefits

The selected components for vessel weighing guarantee exact measurement results and ideal connectivity with superordinate systems. Their Hygienic Design reduces cleaning times and also enables LDO the option of FDA compliance for API production.

Customer

LABORATORI DERIVATI ORGANICI (LDO) was founded in 1960 in Italy and has since become a specialist for producing the glycosaminoglycans Heparin sodium, Heparin calcium and Heparinoids. These are used as medication to prevent clotting in blood and to treat, e.g., thrombosis and heart attacks.



Project goal and implementation

In the recent past, LDO has invested a lot of resources to implement new production divisions. Its projection building comprises an area of approx. 2,000 square metres, a space used for injectable, oral and topical use active pharmaceutical ingredients products. The plant is fitted with equipment, instrumentation and devices that need to comply with FDA requirements so as to be able to obtain the approval of North American authorities.

To obtain the FDA approval it is important that drugs are manufactured under conditions and practices required by the Good Manufacturing Practices (GMP) regulations. To assure that quality is built into the design and manufacturing process at every step, the Minebea Intec products meet those requirements. With the easy management for operations of cleaning, any cross-contamination of the components is prevented.

The load cells PR 6211 are hermetically sealed and resistant against vibrations and high temperatures. The weight indicators and weight transmitters PR 5230 process weight values reliably and highly accurately from process vessel scales. Their field housings enable direct, safe and hygienic installation.

The process with the Minebea Intec products is easy to control with the precise and reliable results of weighing with the load cell PR 6211. Moreover, the transmitters PR 5230 and indicators X3 ensure traceability and facilitate the operation of calibration procedures. Possible deviations can be investigated and documented quickly.

The initiating force behind these developments was GEASS, a member of Minebea Intec's Partnership Program based near Turin in Italy. It has been



working on the sales and service of a large range of instrumentation for process and laboratory in different industries. GEASS gave ample support to Minebea Intec Italy by providing the customer a comprehensive package of information and services. Knowing the value of Minebea Intec's products, GEASS collaborated with LDO to invest in 68 load cells PR 6211, ten weight indicators X3 and six weight transmitters PR 5230, all needed to fit the 14 process vessels at LDO's production line.

The Minebea Intec load cells and weighing electronics in Hygienic Design provided a weighing solution that was conducive to LDO's needs: it obtained the Italian AIFA approval in 2016 and has now also achieved FDA compliance for API production, allowing it to open up to the large new market that is the US market.



LDO is a global specialist for producing Heparin sodium, Heparin calcium and Heparinoids



Minebea Intec's load cells and weighing electronics provide reliable weighing of process vessels



Are you interested? We'll make you an offer! Simply send an email to sartorius@sartorius.hr



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