

High accuracy flow measurement for single use processes

Thomas Roemer, KROHNE Inc., Peabody (MA), USA; Christine Perfetti, KROHNE S.A.S., Romans sur Isère

When new market segments are emerging, manufacturers are challenged to adapt to these changes with new proposal, such as new product development.

An example for such new evolving market segment within the biopharmaceutical market is the so called “single use” market, using disposable process equipment.

The advantages of such “disposable” product lines are described in numerous articles and include reducing cross contamination, improvements in flexibility and cost reduction in drug manufacturing etc. As in any manufacturing process, instrumentation is used to control the process. Since the single use market as a whole is still evolving, instrumentation for this market is still developing as well, with manufacturers facing new challenges. For example flow meters: The adaption of existing flow meter technologies to single use applications is especially challenging since the measuring section now needs to be made out of biocompatible and sterilizable polymer materials and be removable from the instrument without compromising the measuring performance.

KROHNE as a world-leading manufacturer and supplier of industrial process instrumentation solutions has taken on this challenge. KROHNE is manufacturing flowmeters of various technologies including Coriolis, Ultrasonic and Electromagnetic for various industries. Building onto this knowledge, KROHNE now has designed the first electromagnetic flowmeter with biocompatible disposable flow tube specifically developed for single use downstream processes of biopharmaceutical applications, like TFF or chromatography, buffer and media preparation: The FLEXMAG 4050 C.

The FLEXMAG 4050 C consists of two parts, the transmitter and the flow tube.

The FLEXMAG 4050 C transmitter generates the magnetic field for the measuring tube and is responsible for the signal conversion. It also includes the holder for the disposable flow tube. The transmitter is factory calibrated and thanks to the electromagnetic principle it doesn't drift over time. It hence provides a completely stable, direct and accurate volumetric flow measurement, unaffected by fluid properties such as color or density.

The FLEXMAG 4050 C flow tube uses single barb fittings that meets biopharmaceutical requirements for adaptation to single use systems. The tube's full-bore construction is designed for minimal hold-up volume without obstruction, and the single barb fittings are suitable for braided as well as non-braided hoses. There are no electronic parts in the flow tube itself.

Most of the newly developed technologies for the FLEXMAG 4050 C are patented. Pins on the transmitter are contacting the electrodes of the flow tube, and transferring the signal of the fluid to the electronic for signal treatment. One transmitter accommodates flow tubes in two different sizes providing the flexibility of two different flow ranges by a simple exchange of the tube without the need of re-calibration.

The disposable flow tube is manufactured in an ISO 13485 certified site. The production is made in a clean room ISO 7 environment. The single-use flow tubes are Gamma sterilizable at usual 25 - 40 kGy irradiation and tested at 50 kGy. The wetted materials meet the USP Class VI and ISO 10993 requirements and are with animal free compounds. Each tube is individually packed in double layered PA/PE pouches.

Thanks to its small dimension and installation conditions without constraints the FLEXMAG 4050 C fits in compact machines. The product is designed in 4 diameters from 3/8" to 1", providing a complete scale up from laboratory to production.

Thanks to the accurate monitoring of the flowrate, mixing fluid is winning in gradient efficiency and filtration processes are optimized. As one of the first applications FLEXMAG 4050 C will be used for production of mAbs, vaccines...

