

PRESS RELEASE

LEWA ships first multi-column chromatography unit for use in GMP environment

- *New system is key to future biologics programs incorporating continuous processing.*

Stuttgart, Germany; Devens, MA USA; June, 2016 – LEWA became the first to market with a twin column low pressure chromatography system at the pilot scale designed for use in GMP environments with its recent shipment to the Fraunhofer Institute for Interfacial Engineering and Biotechnology (Stuttgart, DE). The GMP scale unit (EcoPrime® Twin LPLC) can be configured to allow drug manufacturers to use a twin column unit in multiple modes: full continuous purification, integrated (continuous) batch and batch – with built in capability to operate columns in series, parallel or alternating configurations. Future updates will permit two different chromatography steps (e.g. ProA / IEX) to be accomplished with the same unit.

This next generation purification system was developed using technology licensed from ChromaCon AG (Zurich, CH). With this milestone event, LEWA now offer pilot-to-production scale multicolumn systems based on ChromaCon's patented multi-column technology. A Contichrom® CUBE instrument which allows scale-up / scale-down studies is also installed at the Institute.

With the successful commissioning of the EcoPrime Twin LPLC the Fraunhofer Head of department Dr. Ursula Schliessmann commented “*This gives our institute the foremost capability in the evaluating continuous downstream processing – with both the Contichrom CUBE instrument and the LEWA EcoPrime Twin we have full scale-up / scale-down capability*”.

Further, Dr. Wolfgang Krischke, responsible for the project on site observed “*the simple design of the EcoPrime Twin column clearly makes this a straightforward system to integrate into our new downstream lab.*” He concluded “*LEWA will be a key participant in our biologics program in the future and with this installation we have an excellent starting point for the applied research for our customers in the field of molecular separations. In future continuous production, the necessary*

facilities are much smaller and easier to handle. Also the ecological footprint is smaller and new automation concepts can be better integrated. All together OPEX can expected to be lower.”

The EcoPrime Twin Capture LPLC is the product of a technical collaboration with and license by ChromaCon AG. Building on LEWA’s recently launched EcoPrime LPLC platform, the twin column unit borrows the proprietary fluid flow path and digitally controlled LEWA ecodos® pumps from this technologically advanced family of systems. *“With over 10,000 Hygienic LEWA ecodos pumps installed in chromatography systems over the past 3 decades, and the very simple design of the EcoPrime Twin, customers can be confident of robust design, innovative software and ease of implementation”* says Gerard Gach, CMO of LEWA Process Technology. *“With ChromaCon, who have many systems installed running the Contichrom software, LEWA have engineered out the complexity inherent in other multi-column designs making the implementation of this advanced technology easier to validate”*.

LEWA is presently in negotiations with companies in major regions of the world to acquire its new design for their next generation continuous production suites. Customers are attracted by the simple design and ability to integrate on-board buffer dilution. LEWA expects to have multiple of these systems in GMP facilities in the coming year. A second set of identical units are housed at LEWA’s center of excellence for life sciences in Devens, MA USA where parallel testing and customer demonstration is scheduled to begin this month.

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About LEWA:

LEWA through its Process Technologies operation provides advanced purification and fluid management technologies and services that are shaping a new age in biopharmaceutical manufacturing. Our broad expertise in process innovation and user adaptable software architecture helps our customers to deliver quality and cost effective engineered solutions, with precision, accuracy and reproducibility. Part of LEWA GmbH, and Nikkiso, Corporation we leverage the global sales and service and fluid engineering innovations of these multi-national leaders in fluid dynamics, precision pumps and other original technologies.

Headquartered in Devens, MA, USA LEWA Process Technologies is a unit of LEWA GmbH and its parent NIKKISO CO., LTD. Nikkiso & LEWA employees which number over 5000 are

committed to serving our customers in more than 100 countries. For more information about LEWA, visit our website at www.lewapt.com or email ecoprime@lewapt.com.

For our latest news, please visit <http://www.lewapt.com/company/news-and-events>

Video on EcoPrime Twin at: <https://www.youtube.com/watch?v=Q9VAaMknjgg>

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PHOTO

LEWA's new EcoPrime Twin LPLC with Contichrome CUBE Combined unit – both installed at the Fraunhofer Institute for Interfacial Engineering and Biotechnology (Stuttgart, DE) and a duplicate pair of systems in LEWA's Devens, MA and UMASS Lowell, USA sites

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