



PRESS RELEASE

FDA selects twin-column chromatography system by YMC ChromaCon for evaluation.

- Instrument equipped with YMC patented processes enabling advanced purification of both small and large molecules on continuous basis.

Devens, MA USA; - July, 2020

The FDA has placed an order for, and YMC will soon deliver, its Contichrom CUBE discovery scale instrument enabled with both the twin-column patented MCSGP* process (*multi-column countercurrent solvent gradient purification) and twin-column CaptureSMB continuous chromatography processes. The bench unit features MControl and AutoMab dynamic process control software as well as the capability to operate conventional batch chromatography, sequential orthogonal (pool-less two step polishing) chromatography and the unique N-Rich process. These units are designed with the intellectual property developed by YMC and are presently deployed at numerous GMP producers of mAbs, vaccines, peptide, oligo and other advanced bio-therapies in the USA, EU and Asia.

Using the proprietary semi-continuous chromatographic process of MCSGP that alternates the feeding of one of two identical columns while eluting the other column, users report 30-60% gains in yield while reducing solvent consumption up to 70% during purification of peptides and oligos. The automatic internal recycling maintains the high product purity while purifying a much greater percentage of valuable product from a feed solution.

Producers of mAb based therapies have scaled the CaptureSMB from the CUBE unit to over 20 liters per minute in clinical production. Reporting a reduction in Protein A resin and buffer consumption up to 60% with the CaptureSMB process, these users experience productivity gains of up to 3X over conventional single-column batch.

The deployment of continuous processing by both the pharmaceutical and biopharmaceutical industries has long been endorsed by the FDA. This instrument will be evaluated by the FDA

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and certain academic partners for further insights to enable acceleration of the implementation of continuous processing.

“The acquisition of YMC’s twin-column technology by the FDA is welcome and signals that this emerging technology will be evaluated by the world’s leading regulatory authority for its ability to significantly reduce costs through improved process efficiency, while maintaining product quality.” says Mark Dymont, CEO of YMC Process Technologies division and USA based supplier of the Contichrom CUBE instrument. *“The scalable technology, patented by YMC ChromaCon and already in use by many of the industries’ largest drug manufacturers, in the hands of the FDA will add further insights on continuous chromatographic processes for customers seeking to produce new therapies at cost effective quantities.”*

The units are manufactured in the USA and will be final assembled at YMC’s Center of Excellence for GMP scale in Devens, MA before shipping to the FDA’s Maryland labs.

-ENDS-

About YMC Ltd.



YMC is a private Life Science company headquartered in Kyoto, Japan. Founded in 1980, company has over 9 affiliates and facilities throughout Asia, Europe and America. The over 500 employees are providing best-in-class lab and process solutions to the bio/pharmaceutical industry. YMC focus is in the innovation, production and sales of packing materials, packed columns and systems for High Performance Liquid Chromatography (HPLC), Low Pressure Liquid Chromatography (LPLC) and custom purification and custom synthesis. YMC operates a CMO facility and has recently opened a new lab / pilot facility “Kyoto Works” incorporating state of the art multi-column purification. YMC Process Technologies (YPT), Devens, MA USA has supplied GMP scale downstream process system for nearly 20 years. Acquired by YMC in December 2018, YPT Bio/Pharma Systems Group along with its sister affiliate YMC ChromaCon AG, is a leading supplier of lab and production scale single and multi-column chromatography systems. YMC’s intellectual assets and know-how cultivated from many years of experience, will continue to push the limits to create a prosperous future for the purification and discovery of small and large molecule therapies. More at: <http://www.ymc.co.jp/en/>

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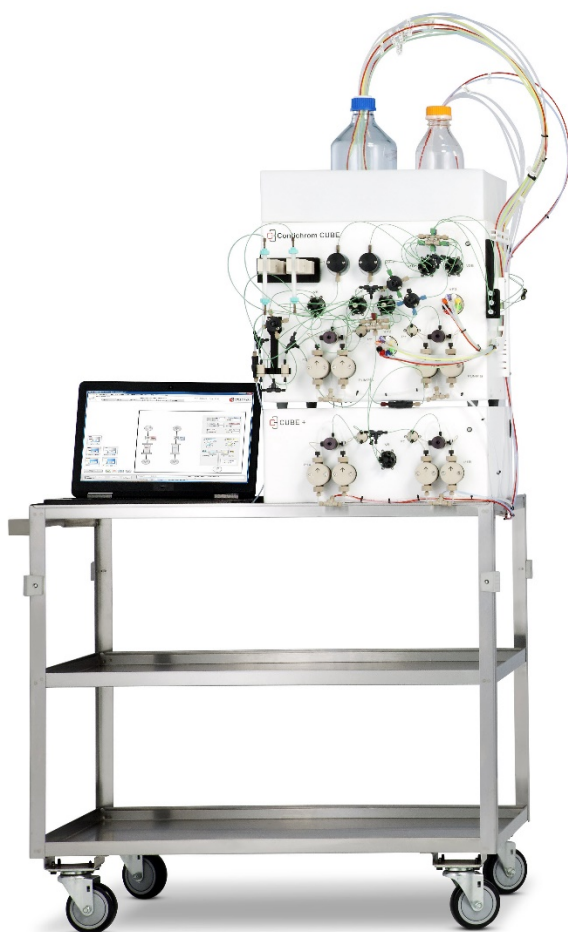
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YMC is a registered mark of YMC Co Ltd.

Photo: Contichrom CUBE shown below is a version of the unit under order described in the accompanying press release.



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