

PRESS RELEASE

Formal study of large-scale production of specialty peptide drug API with continuous chromatography system announced

YMC CO., LTD.—PeptiDream Inc.

PeptiDream and YMC groups announce a formal joint-task group to scale successful lab work to multiple GMP production lines for specialty peptide drug products at the main factory of PeptiStar Inc.. YMC's patented twin-column technology will be a key technology in the venture. Work is anticipated to result in implementation of the technology at large scale in late 2021.

Japan, February 2021

YMC CO., LTD. (YMC) has formalized a joint-study to scale continuous chromatography technology to the purification process at mass production scale of peptide based therapeutic drugs with PeptiDream Inc. and PeptiStar Inc.. PeptiDream Inc. and PeptiStar are developers and manufacturers of specialty peptide therapeutics. Extensive lab studies using YMC's twin-column continuous chromatography technology showed great improvement in productivity of these highly valuable drug substances. Further studies will be conducted at the main factory of PeptiStar Inc. (Settsu, Osaka), where same technology proven at research scale, will be implemented on a production scale system designed for GMP manufacturing. YMC expects it to have full-start of the industrial scale work by the end of 2021.

The joint-study group is presently using the lab results at PeptiStar for further optimization of a GMP compliant larger scale twin-column continuous chromatography system (known as "Contichrom TWIN") has begun. There are multiple production lines for specialty peptide drug at the main factory of PeptiStar Inc., (PeptiDream Inc. is a key investor in PeptiStar, Inc.). Currently conventional single-column chromatography systems are used in all purification processes. This will be the first case in Japan for both YMC and PeptiStar/PeptiDream for multi-column purification technology at production scale.

YMC has significantly increased resources for development of continuous chromatography technology used in the preparative purification process of smaller drug molecules such as peptides and nucleic acids, as well as larger antibody drugs for the biopharmaceutical industry. Following the take-over of the related business from LEWA-Nikkiso America, Inc. in 2018, YMC gained twin-column continuous chromatography systems for research and that for industrial use, which enable recovery of the target

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Publication free of charge, specimen copy requested

object in high efficiency and high purity by purchasing ChromaCon AG (Zurich) in April 2019. YMC also manufactures packing materials and columns which are essential to these systems.

The continuous chromatography systems attract attention from domestic/international major pharmaceutical companies. While many of those systems for research are already introduced domestically and internationally, the systems for industrial use are also starting to receive orders including from European and America's pharmaceutical companies. Last year, Food and Drug Administration (FDA) purchased the bench scale system for research for the purpose of evaluating the quality of the variety of pharmaceutical products manufactured using continuous production system.

- ENDS -

Product Image
found below

Photo 1: Shown are YMC DAC packed columns specialized for peptide purification on a YMC Contichrom TWIN HPLC system.



Photo 2: Shown is a GMP scale YMC Contichrom TWIN HPLC enabled with the patented MCSGP technology.



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