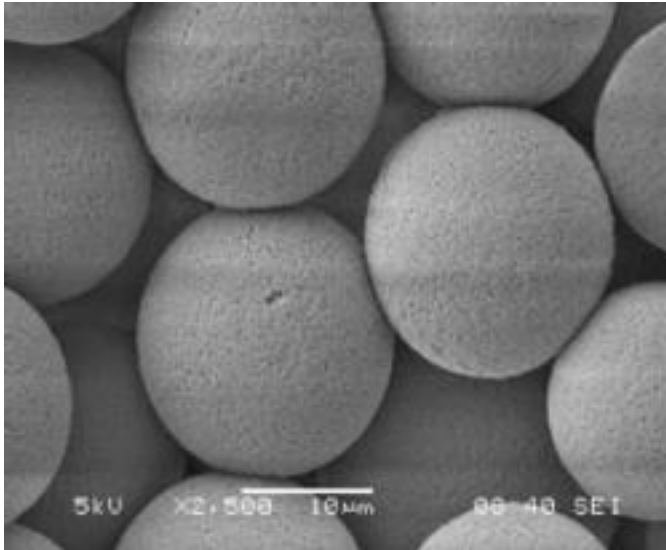


## Regulatory Support File for YMC-BioPro now available

Date: 07-26-2010 10:00 AM CET

Category: [Science & Education](#)

Press release from: [YMC Europe GmbH](#)



A further milestone for YMC-BioPro IEX materials has been reached. The Regulatory Support File (RSF) for these high performance IEX resins has been finalized and is now available.

The RSF provides detailed information on product characteristics, quality, stability data, safety data and extractables and so facilitates process development and validation. The document is available for all clients after signing a confidentiality agreement as some of the information is proprietary.

With the Regulatory Support File and the DMF, which has been filed with the FDA beginning of 2010, YMC provides comprehensive regulatory support to our Bioprocess customers. In accordance with YMC's commitment to deliver more than just very good chromatography media, YMC strives to deliver a complete package of product plus regulatory and scientific support. This ensures that our customers will get all the data needed for process development and validation. Our service is backed by 30 years of experience with clients in biopharmaceutical production.

YMC-BioPro IEX materials feature high dynamic binding capacity at high flow with very competitive pricing. They are available as strong anion and strong cation exchangers with particle sizes of 30 and 75µm, and a pore size of 100 nm. Customized product versions are also available on request.

For more information on the RSF or on YMC-BioPro IEX materials please contact:

From headquarters located in Kyoto, Japan, YMC has gradually and consistently matured to a level of international recognition, specifically within the pharmaceutical and biotech world, as one of the leading suppliers of analytical and process-scale silica-based stationary phases for High Performance Liquid Chromatography, preparative equipment, custom purification and method development.

New: Micro Reactor / Flow Chemistry scalable to production scale!

Qualified technical support and backup is available through operations in Japan, the United States (for the "Americas"), India, China and Germany (for Europe, Africa and the Middle East)

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