Rousselot® Biomedical Launches Quali-Pure™, a Range of Gelatins with Controlled Purity

Quali-Pure™ is a new range of biomedical gelatins with controlled purity, supporting full compliance with new EU Medical Device Regulations and ISO 22442

Rousselot Biomedical launches Quali-Pure

IRVING, USA, October 19, 2021 /EINPresswire.com/ -- Rousselot®, the Health brand of Darling Ingredients and the global leader of collagen-based solutions launches Quali-Pure™, a range of gelatins for biomedical applications with controlled endotoxin levels. The latest addition to Rousselot Biomedical's rapidly expanding portfolio, Quali-Pure, has been specifically designed for a variety of applications including embolization, wound healing, drug delivery, vaccines and hemostatics. Quali-Pure delivers biocompatibility, biodegradability, controlled endotoxin levels, and batch-to-batch consistency, and fully supports medical device compliance with ISO 22442 and the new EU Medical Device Regulation (MDR) standards.

Biomedical gelatins

The Quali-Pure range of high-quality gelatins offers device manufacturers an endotoxin-controlled gelatin that delivers the optimal functional properties, as well as meeting the standards required to comply with the enhanced regulatory requirements. Quali-Pure gelatins come with full traceability, documentation and viral safety.

"We are excited with this new product in our portfolio", says Tanja Vervust, Director at Rousselot Biomedical. "It will give peace of mind to our customers who can rest assured knowing the quality, batch-to-batch consistency and purity of our Quali-Pure gelatin range will contribute to overcoming the challenges they may face on the pathway to approval of their biomedical applications."

Quali-Pure is the latest addition to the Rousselot Biomedical portfolio that consists of X-Pure® biomedical gelatins, hydrolyzed gelatins and modified gelatins with endotoxin levels that are amongst the lowest in the world.

New EU MDR compliance requirements

Medical device producers are facing increased safety requirements for biomaterials. From May 2024, all devices placed on the European market must conform with the new EU Medical Device Regulation (MDR). Regulation (EU) 2017/745 on Medical Devices (the MDR) has replaced the existing medical devices Directive (93/42/EEC) (MDD) and the active implantable medical devices Directive (90/385/EEC) (AIMDD). In addition, the ISO standard 22442 has been updated to bring it further in line with global requirements for medical devices.

Quali-Pure provides the supporting documentation for full compliance of medical devices with the new MDR requirements and with ISO 22442. “We design all of our biomedical gelatins with safety in mind. We aim to pro-actively support our customers towards regulatory compliance with full and documented traceability up to the farm (ISO 22442-2), validated viral inactivation (ISO 22442-3) and IPEC GMP compliance,” says Kathleen Jacobs, Regulatory Affairs Director at Rousselot Biomedical.

Quali-Pure gelatins are available from October 2021, and Quali-Pure hydrolyzed gelatins are expected to be added to the portfolio in the near future.

New Quali-Pure gelatins will be presented for the first time at the Compamed trade fair (booth 13F70) from 15th to 18th November in Düsseldorf.

ENDS
Notes to Editors
Rousselot® Biomedical
As the most recent strategic segment within Rousselot, we have drawn upon Rousselot’s 130+ years of worldwide expertise and proven track record of pharmaceutical gelatins and collagens to develop innovative ranges of purified, modified and non-modified gelatins and collagens for biomedical applications. Offering unique advantages to assure performance, quality and safety from bench to clinic, Rousselot® X-Pure® and Rousselot® Quali-Pure™ provide consistent quality and are backed by strong scientific data and on-going research. Rousselot Biomedical is committed to support end-to-end partnerships to help “Advancing medical science”.
https://www.rousselot.com/biomedical

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