

News Release

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MilliporeSigma Receives Industry First EXCiPACT Certification for Cell Culture Media Manufacturing

- **New Pharmaceutical Auxiliary Materials cGMP standard introduced for cell culture media manufacturing**
- **Company first in the industry to receive EXCiPACT Certification**
- **Company's cell culture media production sites certified in Germany, UK, China, and USA**

Burlington, Massachusetts, September 3, 2024 – MilliporeSigma, the U.S. and Canada Life Science business of Merck KGaA, Darmstadt, Germany, today announced that the company's Life Science business achieved EXCiPACT cGMP (current Good Manufacturing Practice) certification for Pharmaceutical Auxiliary Materials (PAMs) at its major global Cell Culture Media (CCM) production sites. EXCiPACT is a widely recognized standard for the manufacturing of non-sterile excipients. The company is the first in the industry to receive this certification.

"We are honored to be the first cell culture media manufacturer audited and certified to the new EXCiPACT cGMP Guideline. This standard is critical to assure the safety, quality, and efficacy of cell culture media in the use of drug components and a testament of the value we bring to our life science customers," said Ivan Donzelot, Head of Integrated Supply Chain Operations, Life Science business of Merck KGaA, Darmstadt, Germany.

CCM is an essential raw material used in the manufacture of life-saving therapies and in processes as varied as vaccine manufacturing, gene therapy, and monoclonal antibody manufacturing. Because of its central role in biomanufacturing, a consistent supply of high-quality media is required to deliver the necessary concentration and protein quality for therapeutics.

EXCiPACT is a non-profit organization that owns and manages the Certification Scheme available to pharmaceutical excipient manufacturers and distributors worldwide. Together with the Life Science business of Merck KGaA, Darmstadt, Germany, it developed the industry-first cGMP standard for Cell Culture Media. The new PAMs cGMP standard for CCM manufacturing was published in May 2023. Certified sites are located in Darmstadt, Germany, Irvine, United Kingdom, Nantong, China, St. Louis, USA and Lenexa, USA.

The Life Science business of Merck KGaA, Darmstadt, Germany provides a full range of innovative solutions to local and global biopharma customers. In addition to CCM, the Life Science business offers an extensive range of products, including cell lines, bioreactors, filters, resins, chromatographic, pharmaceutical raw materials, and excipients. Its end-to-end process solutions are designed to comprehensively support biopharma manufacturers from process development to scale-up, benefiting patients and contributing to the advancement of global health.

About the Life Science business of Merck KGaA, Darmstadt, Germany

The Life Science business of Merck KGaA, Darmstadt, Germany, which operates as MilliporeSigma in the U.S. and Canada, has more than 28,000 employees and more than 55 total manufacturing and testing sites worldwide, with a portfolio of more than 300,000 products focused on scientific discovery, biomanufacturing and testing services. Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across healthcare, life science and electronics.

Around 63,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From providing products and services that accelerate drug development and manufacturing as well as discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2023, Merck KGaA, Darmstadt, Germany, generated sales of € 21 billion in 65 countries.

The company holds the global rights to the name and trademark "Merck" internationally. The only exceptions are the United States and Canada, where the business sectors of Merck KGaA, Darmstadt, Germany, operate as MilliporeSigma in life science, EMD Serono in healthcare and EMD Electronics in electronics. Since its founding in 1668, scientific exploration and responsible entrepreneurship have been key to the company's technological and scientific advances. To this day, the founding family remains the majority owner of the publicly listed company. For more information about Merck KGaA, Darmstadt, Germany, visit www.emdgroup.com.

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