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Media Release

Clariant MEVOPUR® Medical Compounding Plants Certified Compliant with New ISO 13485 Standard

- **ISO 13485-2016 set to become mandatory for device manufacturers**
- **Compliant suppliers reduce risk for users of plastic materials**
- **Three sites in U.S.A., Europe and Asia**

Muttenz, February 1, 2019 – Clariant, a world leader in specialty chemicals, announces that its recently expanded facility in Lewiston Maine, and two other sites in Malmo, Sweden, and Singapore, have been certified to the stringent new quality standard for makers of plastic medical devices. The plants produce specialized polymer compounds and masterbatches offered for medical applications under the MEVOPUR brand.

After a 3-year transition period during which manufacturers could continue following an earlier version, ISO 13485-2016 goes into full effect at the end of February 2019. Device submissions under the old version will no longer be allowed.

“The completion of this process is a perfect example of Clariant’s strong commitment to creating value for its customers,” said Deepak Parikh, President, Region North America. “Demand is increasing for specialized, medical grade compounds and masterbatches. Compliance to the new standard and the significant expansion, will enable our state-of-the-art Lewiston facility to continue to globally deliver to our customers – high value products with unique technologies.”

Although ISO 13485 technically only applies to producers of medical devices, it is seen as an important standard for their suppliers, like Clariant, because it helps reduce risks such as risk of changes in raw materials impacting device performance, reliability, or regulatory compliance. Increased use of QbD (Quality by Design) processes means that more consideration needs to be given to materials used and impact on patient safety.

“With the introduction of the new standard and increased assessment of risk related to materials and change management, medical device and pharmaceutical companies may need to re-evaluate their reliance on materials and methods of the past,” explains Steve Duckworth, Head of the Global Medical and Pharmaceutical Segment for Clariant Plastics & Coatings. “Increasingly, they will need to ensure trust by using expertise coming from materials suppliers – like Clariant -- who have a good understanding of and products adapted to the needs of the healthcare market.

Clariant began introducing the MEVOPUR family of products and services more than a decade ago, to help minimize risk at every stage of a medical device's life cycle. A global team of specialists from R&D, production, sales and marketing, and customer service, works closely with individual customers to pre-test materials and assess risk in order to build compliant, targeted color and functionality into each application.

The three global facilities, almost entirely dedicated to medical and pharmaceutical applications, provide assurance of consistency in formulations and procedures, and supply-chain reliability for all MEVOPUR products. Raw materials are pre-tested to standards commonly required for device and drug filings, e.g.: USP <87><88> ('USP Class VI') and ISO10993, as well as the USP<661.1>, ICHQ3D and European Pharmacopeia monographs 3.1 covering drug packaging and delivery devices. Segregated storage and manufacturing lines, plus scrupulous change-control processes, reduce the risk of cross contamination.

The desire to comply with the requirements of the new ISO 13485-2016 standard presented additional challenges, however. For example, for the first time, computerized systems needed to be risk-assessed, and then the appropriate validation or verification activities carried out. Even if software is not directly controlling processes, it often present in test equipment used to control raw materials or end-product quality. The project to implement the new version ISO13485-2016 was conducted on a global basis with local site quality managers supported by Clariant's dedicated Global Quality & Regulatory manager for the healthcare sector.

LEWISTON EXPANSION

Compliance with the new ISO 13485-2016 standard, caps off a multi-million dollar, multi-year expansion program at the Lewiston, Maine. The facility, which was expanded by 40%, now accommodates not only extrusion equipment, but also materials handling, weighing stations, a maintenance area and additional water-cooling capacity that enable the Lewiston plant to more rapidly produce larger batch sizes of MEVOPUR pre-colored medical plastic compounds (e.g.: 3000 to 6000kg /6000 to 12000lbs or larger). A smaller line, installed last year, is configured to meet the rigorous processing requirements of fluoropolymer resins such as, FEP, ETFE, and PVDF.

Lewiston medical compounding site with "all polymer" capability. (Photo: Clariant)

MEVOPUR® IS A TRADEMARK OF CLARIANT REGISTERED IN MANY COUNTRIES.

GLOBAL TRADE MEDIA RELATIONS

STEFANIE NEHLSEN

Phone +41 61 469 63 63
stefanie.nehlsen@clariant.com

CAROLINE SCHMID

Phone +41 61 469 63 63
caroline.schmid@clariant.com

Follow us on Twitter, Facebook, Google Plus, LinkedIn.

www.clariant.com

Clariant is a globally leading specialty chemicals company, based in Muttenz near Basel/Switzerland. On 31 December 2017 the company employed a total workforce of 18 135. In the financial year 2017, Clariant recorded sales of CHF 6.377 billion for its continuing businesses. The company reports in four Business Areas: Care Chemicals, Catalysis, Natural Resources, and Plastics & Coatings. Clariant's corporate strategy is based on five pillars: focus on innovation and R&D, add value with sustainability, reposition portfolio, intensify growth, and increase profitability.