BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

US FDA picks Waters Corp software to support medical products testing labs

January 25, 2022 | News

The US FDA is expanding its use of Waters' compliant-ready Empower Chromatography Data Software (CDS)



Waters Corporation has announced that the US Food and Drug Administration's (FDA) Office of Regulatory Affairs (ORA) has purchased Waters™ Empower™ Chromatography Data Software (CDS) and NuGenesis™ Laboratory Management Software (LMS), expanding its deployment of Waters' software to support its medical products testing operations across its five field science laboratories.

Both Waters software applications will provide the ORA labs a common platform for acquiring, processing, reporting, and archiving analytical data from a variety of measurement instruments.

Transitioning to a fully-electronic, common data management strategy will also help ORA's laboratories realize greater operational efficiencies and bring them closer to compliance with the Paperwork Reduction Act of 1995 and the National Archives and Records Administration stated goals of phasing out paper records beginning in 2022.

In addition to supplying the software, Waters will install the computer hardware, assist with instrument qualification and software validation and train site analysts on the operation, configuration, and expansion of the data management system.