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Merck France unit plant gets compliance certification

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September: Merck Millipore has received good manufacturing practice certification for its Biodevelopment Center in France, certified by the French National Agency for Medicines and Health Products Safety (ANSM).

The audit included a thorough review of quality systems, supplier management, control of raw materials, documentation, calibration and validation. Prior certification consisted only of stainless steel equipment, while this recertification included complete single-use upstream and downstream suites, as well as a 2 x 1250 liter stainless steel suite.

Merck Millipore's Provantage biodevelopment and clinical supply services are delivered at the France facility. This innovative approach for biologics manufacturing incorporates the latest technologies in upstream, downstream and single-use systems.

This Provantage offering includes process development and GMP drug substance for pre-clinical to phase II and is available to a global customer base.

"We are proud to be one of the first facilities to attain GMP compliance utilizing single-use equipment for each unit operation from upstream through downstream. This recertification reflects the teamwork and dedication of our entire staff and provides our customers with complete confidence in our technical expertise and quality," noted Mr Richard Pearce, business and operations director, Biodevelopment Center.