

## GLAXOSMITHKLINE (GSK) receives FDA approval to use ChemScan RDI (CHEMUNEX) system for routine microbiological water analyses

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CHEMUNEX announced today the confirmed news that the GLAXOSMITHKLINE has received approval from the FDA to use the CHEMUNEX system, ChemScan RDI for the microbiological analyses of their pharmaceutical grade water.

Recent work with the ChemScan RDI has delivered confidence in the speed and sensitivity of the system to deliver accurate and early counts for the waters used in manufacturing. As part of the Process Analytical Technologies (PAT) initiative, the early detection of organism levels is seen to contribute to improved process control.

The sensitivity of the ChemScan RDI will be utilised to rapidly deliver "real time" microbiological trending of pharmaceutical waters.

The ChemScan RDI system delivers counts of viable microorganisms without the requirement for a growth phase. Laser scanning of a filter membrane supporting labelled organisms delivers sensitivity to a single cell inside two hours from sample.

Internal requirement and external regulatory bodies increasingly monitor the absolute requirement for water quality control in all aspects of product, production and cleaning processes.

The introduction of the specific elements of speed and sensitivity, inherent in the ChemScan RDI protocol, will offer further confidence and control to the pharmaceutical microbiologist.

Typically the standard growth plate method takes between 48 to 72 hours (TSA) or 5 to 14 days (R2A) allowing counts of culturable organisms. Such methods do not afford early detection of, or response to, excursions from approved limits within the water system, any such response being retrospective to the production process.

The discussed ChemScan RDI protocol enables real time counting and the consequent ability to react to any out-of-specification excursion, to then take early and remedial steps to return the water system to production, the plant to profitability, and to reduce the expensive risk of contaminated product.

Recent multi-site studies have shown the ChemScan RDI to offer further scientific, production and commercial benefits in the introduction new water system, biofilm characterisation, water system trending and rapid microbiological environmental monitoring.

For further information on CHEMUNEX technology, the ChemScan RDI, details of studies on pharmaceutical water systems and other applications, please contact:

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