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ASIA EDITION

ATMI launches ready to use pyrogen-free vials

19 September 2013 | News | By BioSpectrum Bureau

Singapore: US-based technology supplier company, ATMI, has launched a line of pyrogen-free vials in collaboration with Disposable Lab (D-Lab), a France-based contract-manufacturing company. Designed to meet biopharmaceutical filling and final packaging needs, the patent-pending Pyrofree vials are the only cost effective, ready-to-use vials guaranteed to be both

pyrogen-free and sterile upon delivery.

"We have come together with D-Lab to offer this comprehensive solution in support of our customers' end goal of advancing patient health and safety," said Mr Mario Philips, senior VP and general manager, ATMI LifeSciences. "Pyrofree vials can be incorporated into ATMI's existing ultra-clean sterile packaging and fill/finish technologies, or used independently."

Pyrogens are a substance that induce rapid onset of fever with the potential to cause sepsis or progressive septic shock if they enter a patient's bloodstream. This makes it critical to ensure that pyrogens are not present in biopharmaceutical products. While difficult, the most common techniques to remove pyrogens are either inactivation or destruction of the molecule through depyrogenation.

ATMI subjects all Pyrofree vials to a thorough depyrogenation process that includes washing (with water for injection) and heating the vials to high temperatures in a polyether ether ketone (PEEK) bag to achieve a three-log reduction. Process specifications can be further modified based on customer requests.

"Pyrofree brings several clear benefits including the most cost-effective solution on the market, scalability from small to commercial-scale batches, and availability in both molded and tubular formats," noted Mr Jean-Pascal Zambaux, inventor of Pyrofree and majority owner of D-Lab. "The vials may also be used for commercial safety stocks of injectables, and feature sizes up to 1 liter."

Pyrofree vials are made to withstand the high temperatures during depyrogenation and sterilization. After these steps, the vials are double-vacuum-packed in a PEEK bag for tamper-evidence, as well as to maintain sterility and guarantee no external contact. A third PE/PA film layer is added to the packaging under vacuum in a class C cleanroom to protect the vials from any breakage during transportation and eliminate the need for a support tray.