eurofins | Medical Device Testing



Bioburden Testing

Eurofins Lancaster Laboratories helps bio/pharmaceutical companies manage the transition from traditional methods to rapid methods for raw materials, intermediates and finished products utilizing the Celsis Rapid Microbial Detection Method for GMP testing.

Rapid methods can have a significant impact on pharmaceutical supply chains:

- The rapid release results shorten production cycle times and improve production efficiency.
- Inventories and hold times are reduced with screening performed using this method.

Eurofins Medical Device Testing supports transitional validation activities to move our clients onto rapid methods and implement in-house testing activity or test samples on an outsourced basis. Our three-tiered service models ensure the most cost-effective solution is implemented for your specific needs.

Choose Eurofins Medical Device Testing to help you:

- Develop, validate and test using rapid methods for over 200 products/materials.
- Detect contamination events faster to reduce financial and operational impact.
- Discover the most appropriate variable cost solution to achieve rapid method establishment and testing goals. Approaches are evaluated based on scope, timeline, cost and client capabilities to determine the best approach for your project.

Method Development and Validation

Eurofins Medical Device Testing use a multi-phase approach to method development and validation consistent with industry guidance, including those of the EP, USP and PDA.

- Initial method development is performed following current compendial approaches.

- Method validation includes sample effects testing to confirm lack of sample matrix interference with the rapid assay, time to detect studies to validate reduced incubation times and equivalency studies to statistically demonstrate equivalence between the rapid assay and the compendial method.

While there are industry and pharmacopeial guidances to assist companies with validation of rapid microbial methods, some companies find that they lack the available resources and/or expertise to do so. Outsourcing a validation project reduces the interruption of day-to-day operations and allows companies to utilize the expert resources of their contract partner.

The challenge with the transition is managing the increased workload associated with method development and validation activities. Once established, methods can be transferred to the client site or executed on an outsourced basis. If clients already have the facilities, instrumentation and quality systems in place, Eurofins Medical Device Testing can deploy analysts under our award-winning Professional Scientific Services[SM] model to undertake medium-term method establishment projects.

eurofins | Medical Device Testing



About Amplified Bioluminescence Technology

Celsis developed a proprietary enzyme-amplified ATP Bioluminescence technology to determine absence or presence of viable micro-organisms in products. The ATP amplification used in the AMPiScreen assay increases sensitivity and reduces time-to-results when compared with traditional bioluminescence methods. In the presence of micro-organisms, the assay produces a light signal that is measured and recorded in Relative Light Units. Elevated RLUs indicate the presence of micro-organisms.

The assay is suitable for bioburden testing of a wide range of non-sterile products such as raw materials, in-process materials and finished products, including those that are non-filterable, heavily pigmented or preserved. The assay can also be used as a rapid method for testing sterile products. Time to results is reduced by five to seven days for bioburden testing and seven days or more for sterility testing.

The flexible protocol for this method accommodates varying sample types, sample sizes, enrichment broths and volumes. With faster micro screening and shorter production cycle times, this method delivers significant cost savings and efficiencies.