charles river

FACILITY OVERVIEW

Ecully, France

Our Microbial Solutions site in Ecully, France offers a progressive portfolio of quality control testing solutions for the pharmaceutical, medical device, and consumer care industries to help bring products to market safely and efficiently. Our products and services are designed to streamline workflows and supply chains, ensure the integrity of test data, and allow you to release products with the confidence of total quality control.

Background

- Founded as Amilabo in Lyon, France in 1979
- Began distributing LAL reagents and accessories in 1984
- Acquired by Charles River in 1996

Laboratories and Facilities

- 2,300 m^2 facility
- Sample and order processing
- cGMP and non-cGMP studies
  - Contract testing laboratories
  - Endotoxin detection
  - Accugenix® Microbial Identification

Support

- Customer service and laboratory technical support

Staff

- Approximately 60 employees

Product and Service Offerings

- Contract endotoxin testing services (LAL assay)
  - Use of the 3 methods from USP and EP:
    - Gel-clot
    - Kinetic chromogenic
    - Kinetic turbidimetric
  - FDA licensed LAL cartridges
  - Rapid method instruments:
    - Endosafe® nexgen-PTS™, nexgen-MCS™, and Nexus™

EVERY STEP OF THE WAY

Product and Service Offerings Cont.

- Method development
- Routine endotoxin determination (for routine and backup)
- Product validation
- Stability testing
- Sample preparation
- Oven depyrogenation validation
- Training

- Microbial Identification Services
  - Genotypic identification of bacteria, yeast, and fungi (rDNA sequencing)
  - Proteotypic identification of bacteria and yeast (MALDI-TOF backed by sequencing)
  - Protein-coding gene sequencing (DNA sequencing on different target genes)

Compliance, Certifications, Accreditations, and Professional Affiliations

- Charles River's Ecully facility operates in compliance with the requirements of the following regulatory agencies or accredited organizations:
  - ISO 9001 certification by AFAQ
  - ISO 17025 accreditation by A2LA for Accugenix® and Endosafe® laboratories
  - FDA cGMP compliance for Accugenix® and Endosafe® laboratories

Quality and Process Initiatives:

- Excellent regulatory compliance history
- Data integrity and paperless approach for Accugenix®

Achieving Sustainability Through the 3Rs Imperative

- Reducing the use of animals in pharmaceutical testing is a well-established initiative influencing the industry. The 3Rs (Replace, Reduce, Refine) are fundamental principles for driving ethical research, testing, and education using animals. We are firm in our commitment and compliance to the 3Rs initiative, as these principles are being incorporated into legislation, guidelines, and practice.
- As an LAL manufacturer, Charles River has helped alleviate pressures on horseshoe crab populations through conservation and animal welfare practices.
- We have developed new models and tools based on the latest innovative technologies that use 95% less raw material than traditional endotoxin testing methods through our Endosafe® cartridge technology.
- This technology significantly reduces the amount of LAL per test, minimizes the need for retesting that is often necessary with traditional methods, and ensures the safety of an FDA-licensed method.
- If all global endotoxin tests shifted to cartridge technology, Charles River alone could meet the global supply from our current annual quota. This technology would allow us to reduce the numbers of horseshoe crabs collected, yet still keep conservation in place.

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