

## **SCANRDI**<sup>®</sup>

## When you Need to Know Now Bring your Sterility Testing to the Next Level



Your Ally in Advancing Quality

## Help ensure sterility and patient safety.

SCANRDI® enables same-shift detection of microbial contaminants in filterable drug products. The US Food and Drug Administration (FDA), European Medicines Agency (EMA), and other regulatory bodies support the use of validated Rapid Microbiological Methods (RMM) for sterile product release - especially in the case of shelf-life products, where a rapid result is more suitable than a compendial 14-day test.

#### 4 Steps in 4 Hours





#### ULTRA-RAPID

- Same-shift results
- Release your product faster

### ACCURATE

- Tested & proven technology
- Make decisions with confidence

#### COMPLIANT

- Full validation support: URS completion guide, IOQ guide, primary validation guide, suitability guide and Drug Master File (DMF)
- 21 CFR part 11 enabled software

## Improve productivity and compliance.

#### The right Solution for your Lab & Business



#### **PROVEN TECHNOLOGY**

- Long history of use for final product sterility, in-process bioburden control & water testing
- Down to 1 microbe/filtrable volume
- >200 compatible products



#### **BROAD SPECIFICITY**

- Universal fluorescent labeling
- Bacteria, yeast, and mold detection

>200 compatible products\* Antibiotics Isotonic solutions Chemotherapy drugs Hormones Anti-inflammatories Anti-coagulants Analgesics Diuretics Vitamins

\*non-exhaustive list

#### **INCREASE YOUR MARKET COMPETITIVENESS**

- Safely release your short shelf-life & generic products faster
- Optimize your distribution logistics with just-in-time inventory management of stock and choose your most affordable shipping option

#### **CONTROL YOUR MANUFACTURING PROCESS**

- Rapid in-process, bioburden and sterility results give you confidence that your production is operating properly
- Facilitate your investigation process to quickly return to normal operations
- Eliminate lab bottlenecks

#### **BE CONFIDENT IN YOUR COMPLIANCE**

- Ensure your electronic compliance with 21 CFR part 11 enabled software, barcode scanning traceability, several approval levels and a full audit trail
- Feel reassured in your validation process with support from bioMérieux including URS completion guide, IOQ guide, primary validation guide, suitability guide and Drug Master File (DMF)



# Services: Feasibility, Validation, and Instrument Support

With bioMérieux services, your productivity and product quality is our priority. Our mission is to provide the pharmaceutical industry with rapid, accurate, and cost-effective solutions to ensure smooth implementation and maximizing your return on investment.



### **Feasibility Studies**

Quickly confirm the compatibility of your product and method



#### **Validation Services**

Expedite implementation of your investment by reducing validation time and expense



### Instrument Service Plans and Support

Maximize the uptime of your instruments and ensure continuous operations



#### Smart Remote Support Solutions

VILINK® ensures the continuity of your operations