REGULATORY BRIEF

SCANRDI®
MICROBIAL DETECTION SYSTEM

Type V Drug Master File with FDA CDER

SCANRDI® provides benefits across your whole organization. The system immediately alerts you in the event of a positive sample, allowing a rapid response. Ultra-rapid detection enables your organization to release faster your sterile products to patients, eliminates lab bottlenecks, and improves compliance with Quality Control testing.

SCANRDI is an ultra-rapid solution for detecting microbial contaminants in filterable drug products. Testing with SCANRDI provides the following benefits:

- Get results in 4 hours.
- 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 economical shipping option.
- Rapid in-process, bioburden and sterility results give you confidence that your production is operating properly.
- Facilitate the investigation process to quickly return to normal operations.
- Eliminate lab bottleneck.
- Ensure electronic compliance with 21 CFR part 11 enabled software, barcode scanning traceability, several approval levels, and a full audit trail.
- Get validation support from bioMérieux including URS completion.

bioMérieux S.A. has placed a Type V Drug Master File (DMF) with FDA for its rapid automated microbial detection device, SCANRDI.

While not required by law or FDA regulation, Type V submissions may be used to support regulatory approvals of pharmaceutical products. With the availability of this information directly to the reviewer, separate requests for information are avoided thus expediting the review and approval process. The DMF shares confidential proprietary bioMérieux S.A. product information with the FDA. It allows FDA to evaluate companies' applications in conjunction with the SCANRDI DMF when referenced by a company in their FDA submission. Details regarding detection technology, reagents composition, internal R&D validations and typical applications are examples of information included in the file.

The SCANRDI DMF #14621 has been submitted at the Center for Drug Evaluation and Research.

To utilize the SCANRDI Industry system DMF:

Please submit a request to bioMérieux by letter:

- Using company letterhead.
- Including all sections of the Master File/Drug Master File intended for FDA to access (please reference table of contents below).

Please work with your local bioMérieux representative to submit any request letters for use of our DMF.

NOTE: Authorizations for FDA access to Master Files and Drug Master Files remain open indefinitely; however, if bioMérieux submits any updates to the files, we will notify all customers with open letters of authorization.

FDA TYPE V DRUG MASTER FILE SCANRDI INDUSTRY SYSTEM TABLE OF CONTENTS

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