Qualification of a Rapid Microbiological Method (RMM) – ScanRDI

A Case Study

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PDA Parenteral Drug Association

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Introduction of a Rapid Technology

Our Opportunity

To be the first company in Australia to develop rapid microbial detection testing methodology using ScanRDI® technology.

Our Solution

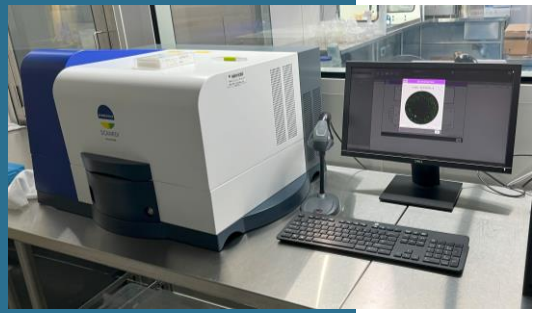
Our solution is to provide an alternative and faster solution to traditional sterility testing. This takes a minimum 14-day test down to a 1–2-day test turnaround time.

Our learning journey

Method development and partnership with ScanRDI® journey will transform companies wanting to safely and compliantly test their product. Taking product to patient in less time (especially products with short expiry)

ScanRDI System

The ScanRDI is capable of rapid detection and enumeration of very low numbers of microorganisms using solid phase cytometry.



Advantages of this real-time testing:

1. Avoids requirements for any cell multiplication
2. Potential extraneous contamination can be detected immediately
3. Storage can be dramatically reduced
4. Action can be taken before processes drift out of specifications
5. Cleaning actions can be implemented immediately
6. Ideal for short shelf-life products

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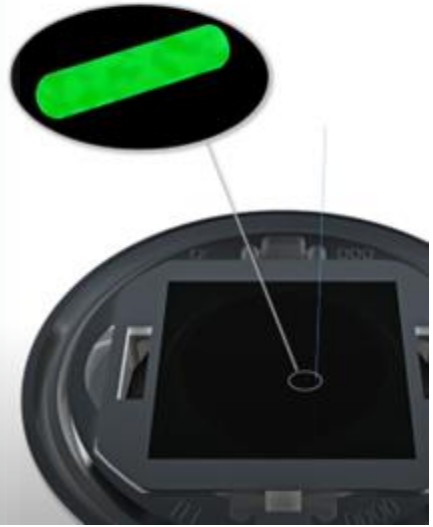
ScanRDI System

Why did we choose the ScanRDI?
ScanRDI is the ultimate combination of speed & sensitivity
Robust and easy to use
Not reliant on cell growth for detection

Detection
Direct detection of bacteria, yeast, moulds and spores
Linear response from 1 to 10,000 cells
Stressed cells, fastidious and bacteriostatic microorganisms detected
No multiplication required

Sensitivity
Down to one microbial cell in a sample
Large sample volume can be tested



Our Opportunity and Approach

Our opportunity

To bring a RMM into Australia, be a centre of excellence, offering customers a much faster and reliable method as an alternative to traditional testing.

1. **Meet the requirements**

   Ensure we meet the requirements of multiple pharmacopeia & recommendations

2. **Include a range of microorganisms**

   Compendial – Environmental – Additional

3. **Gain required skills and experience**

   Training – Research – Practise

4. **Show equivalence (or better!)**

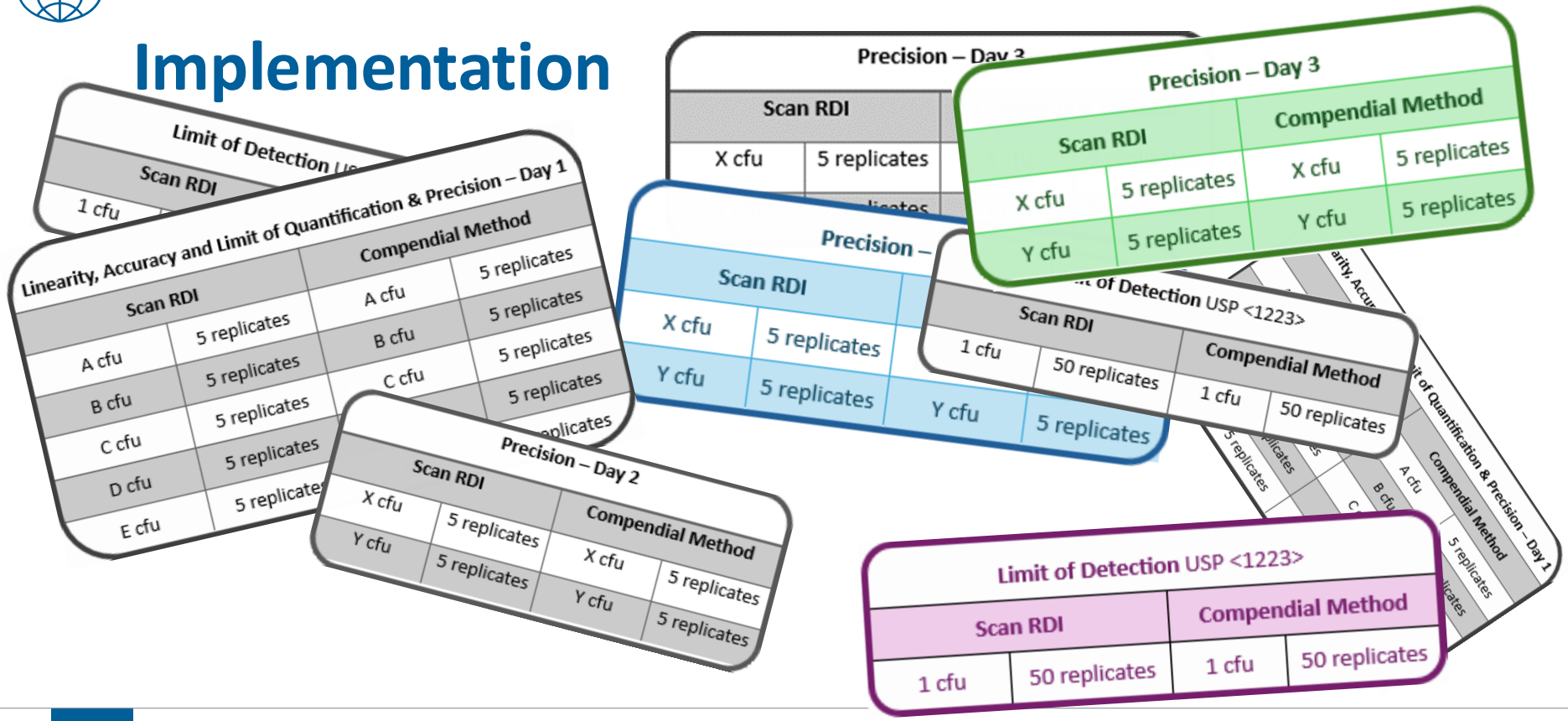
   Alternative method performed using the ScanRDI system must show equivalence or superiority to that of the traditional method

Stages of Test

Four major steps of the test:

1. Product filtration
2. Labelling of microorganisms
3. Laser scanning
4. Verification of detected events

Implementation



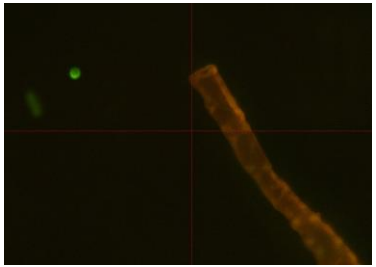
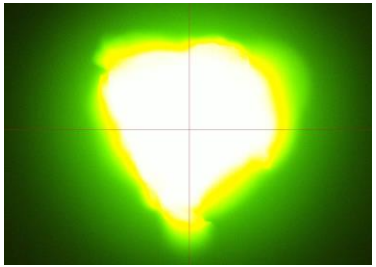
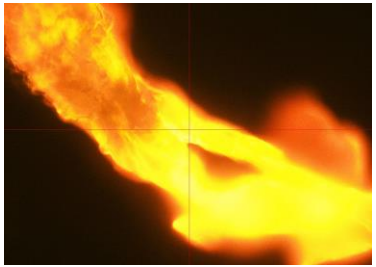
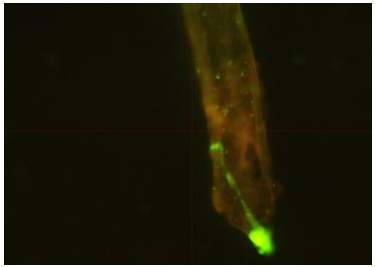
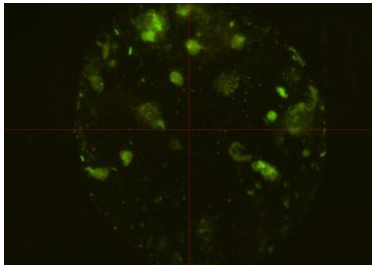
Linearity, Accuracy and Limit of Quantification & Precision – Day 1			
Scan RDI		Compendial Method	
A cfu	5 replicates	A cfu	5 replicates
B cfu	5 replicates	B cfu	5 replicates
C cfu	5 replicates	C cfu	5 replicates
D cfu	5 replicates		5 replicates
E cfu	5 replicate		

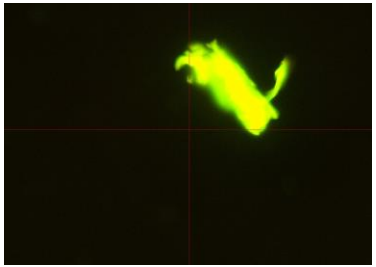
Precision – Day 2			
Scan RDI		Compendial Method	
X cfu	5 replicates	X cfu	5 replicates
Y cfu	5 replicates	Y cfu	5 replicates

Precision – Day 3			
Scan RDI		Compendial Method	
X cfu	5 replicates	X cfu	5 replicates
Y cfu	5 replicates	Y cfu	5 replicates

Limit of Detection USP <1223>			
Scan RDI		Compendial Method	
1 cfu	50 replicates	1 cfu	50 replicates

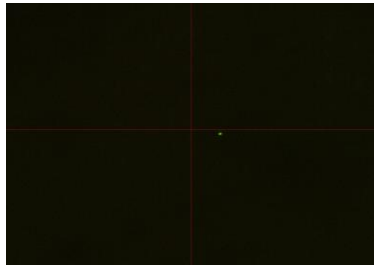
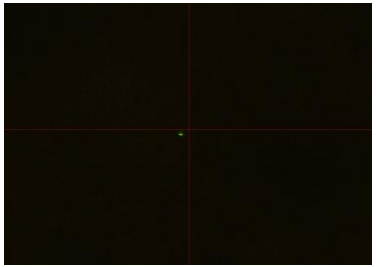
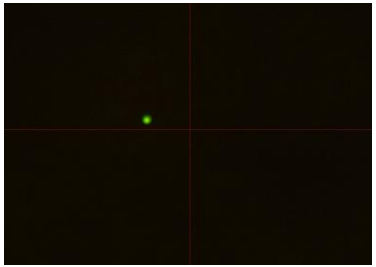
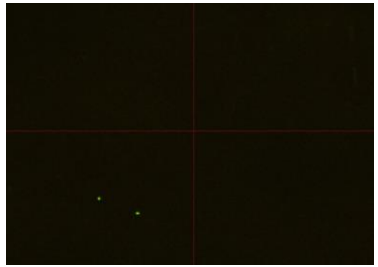
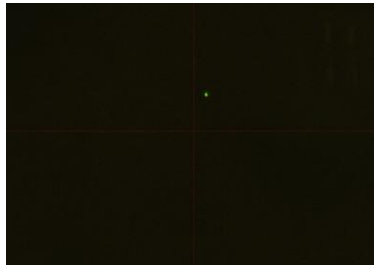
Skills – Early Days



Skills Gained

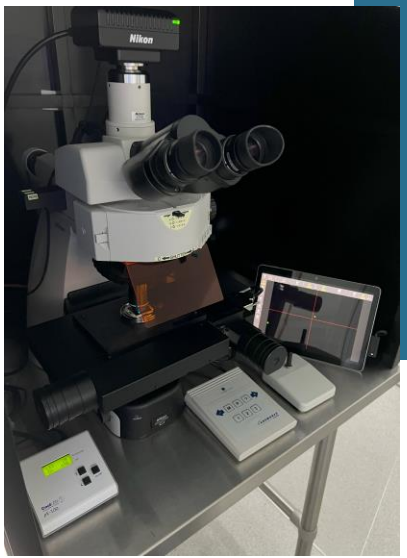


Our Outcome

The ScanRDI System has produced results equivalent to (and generally superior to) the traditional method regarding:

- Qualitative Sterility Testing
- Quantitative Testing



Our Learning Journey and Reflections

What worked well?

- Fast enumeration of cultures for use on same day
- Detection of all specified microorganisms using RMM successfully achieved
- Good relationship and communication with supplier

Where did we get stuck?

- Time management
- First in country – local supply of consumables is limited
- Available information / product availability

What would we do differently?

- Additional planning regarding consumable requirements
- Budgeting based on usage and expiry periods of reagents
- Assess viability of qualification to single compendia instead of multiple simultaneously

Thank You!

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