

IMAGING PLATFORM & ANALYSIS WORKFLOW

# Transforming Pharmaceutical Microbiology QC

**EMMA**

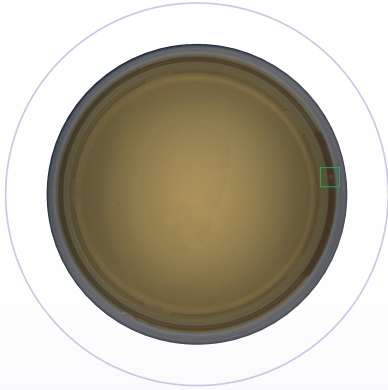


General brochure



*Shape the future*

**Enhance your environmental  
monitoring workflow**



# EMMA is transforming pharmaceutical microbiology QC

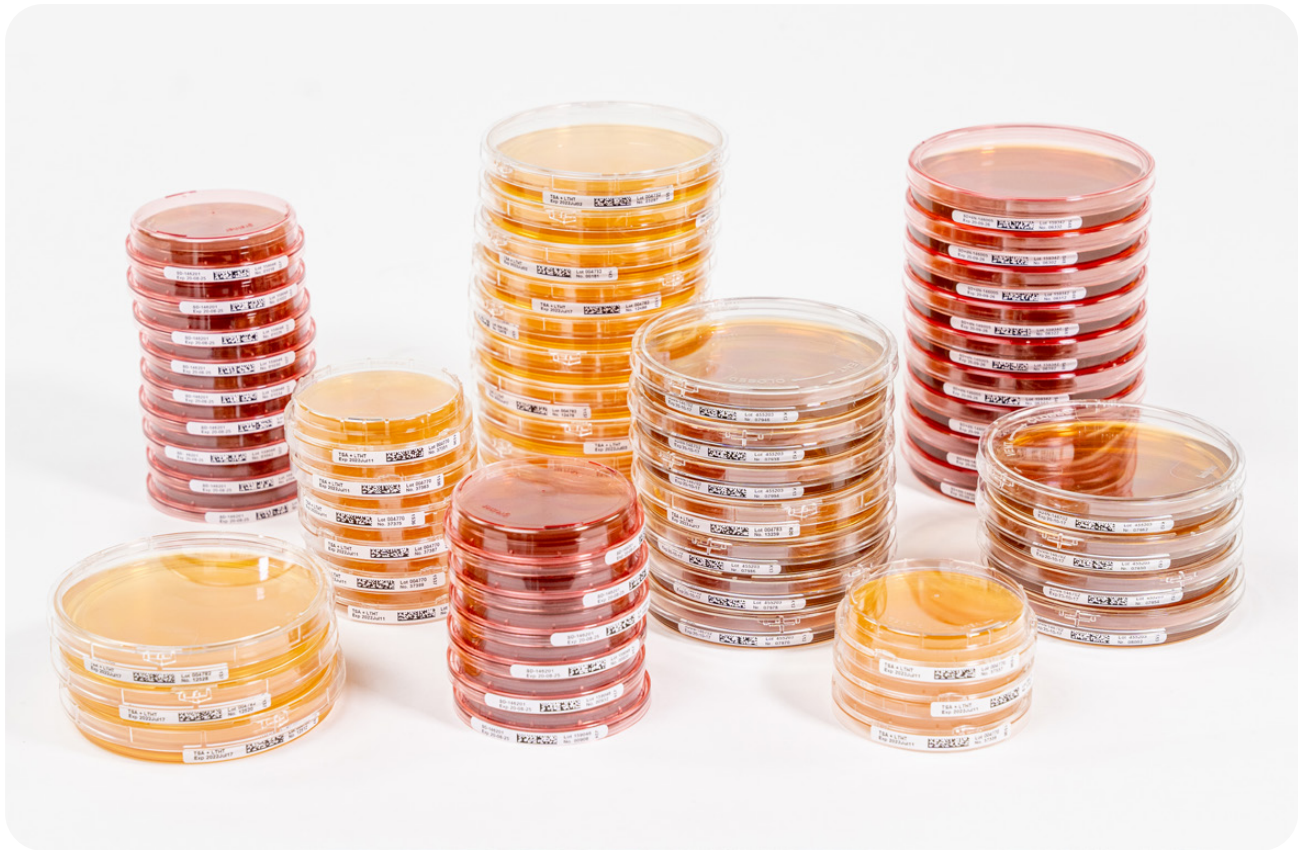
With an integrated barcode reader and a 21 CFR Part 11 compliant software platform, EMMA delivers enhanced data integrity, driving digitization and streamlining workflows to meet modern QC standards. Its patent-pending optical system ensures 100% acquisition of the Petri dish surface, including lateral walls, while maintaining the lid in place.

EMMA is available in 3 different configurations:

- ✓ **EMMA – Digitize microbiology QC**
- ✓ **EMMA RL – Digitize & automate microbiology QC**
- ✓ **EMMA HT – Digital high throughput automation**



Elevate your microbiology QC with limited validation efforts and maximum compliance.



**Any type of Petri dish – any type of medium**

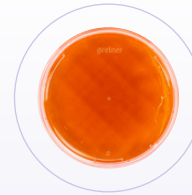
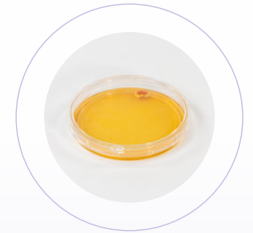
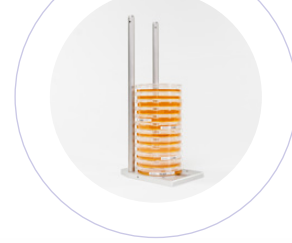
# EMMA is designed to digitize and automate Pharmaceutical Microbiology QC

EMMA delivers enhanced data integrity from the outset, ensuring compliance with current and future regulatory standards while providing a robust foundation for reliable and secure microbiology QC workflows.

- ✓ 21CFR part 11 compliant
- ✓ ALCOA+ principles
- ✓ 100% of the Petri dish surface imaged
- ✓ Imaging with lid on
- ✓ Barcode reader integrated
- ✓ Software designed around 4-eyes principle

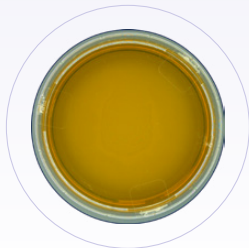
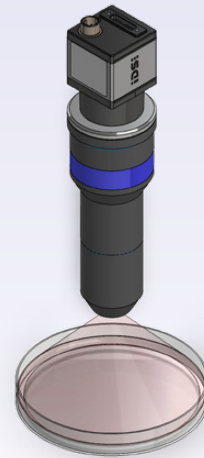


Learn more about the workflow on [microtechnix.com](https://www.microtechnix.com)



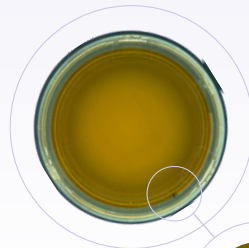
# Redefining Imaging Standards in Microbiology QC

EMMA features a patent-pending optical system that ensures 100% imaging of the Petri dish surface, including lateral walls, without removing the lid. This innovation eliminates contamination risks while delivering clear, reproducible images for AI-assisted or manual analysis.



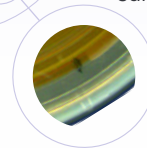
## Competitor technology

Image up to 97.5% of the Petri dish surface



## Microtechnix optical system

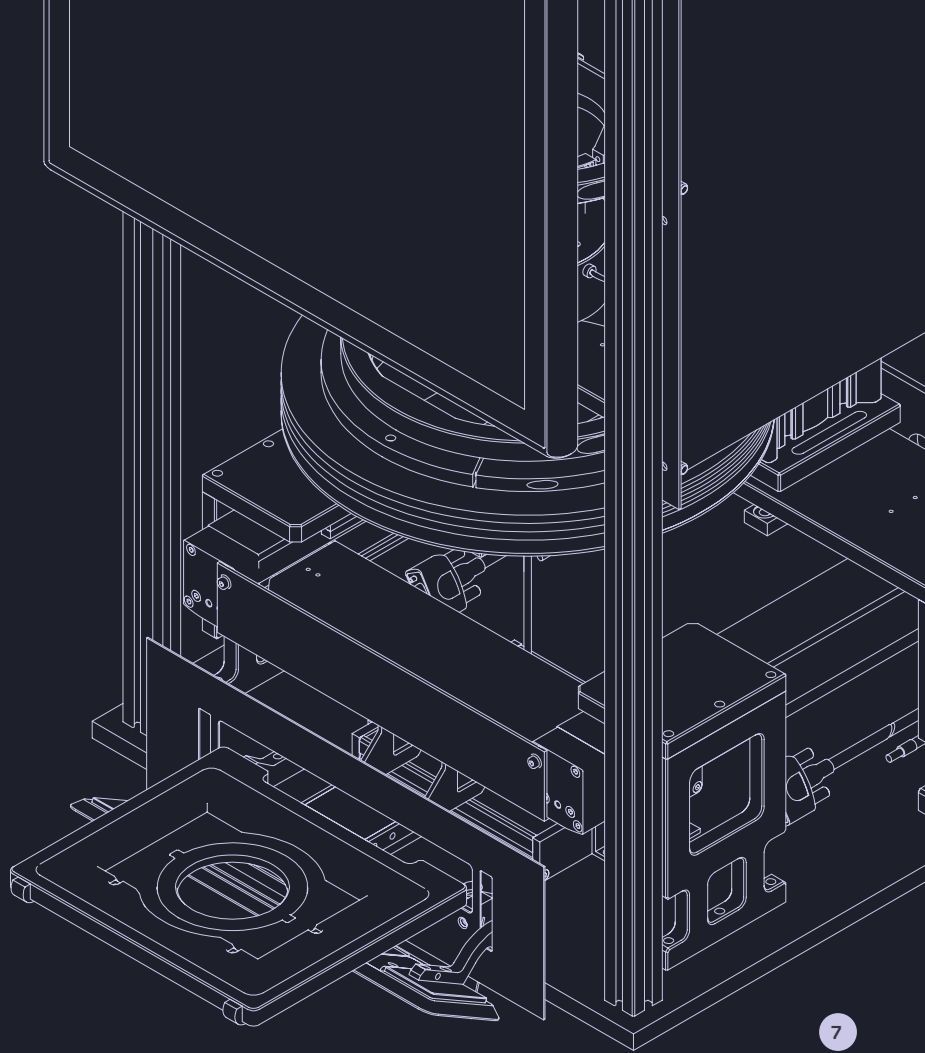
Image 100% of the Petri dish surface, including the lateral walls



Same Petri dish, different outcome.

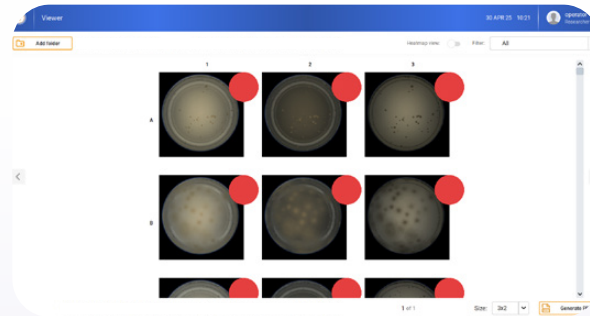
Learn more about the optical advantage on [microtechnix.com](https://www.microtechnix.com)

*Simple and*  
**robust**  
**engineering**



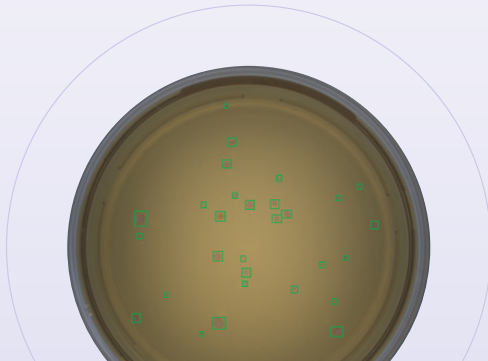
# *EMdi Software* simplifying compliance

The purpose-built, in-house developed EMdi software manages every aspect from planning your run to image acquisition and analysis. Easily set up a routine and have it analyzed by your expert. Ready to upgrade with AI? EMdi assistant and count AI-model upgrades are available to assist 1 operator to achieve the 4-eyes principle.



## Audit & validation

All software is designed with ALCOA+ principles in mind and is fully compliant with 21 CFR part 11. This ensures a full audit trail and straightforward validation process.

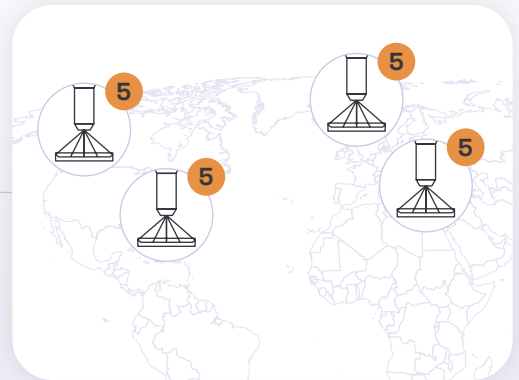
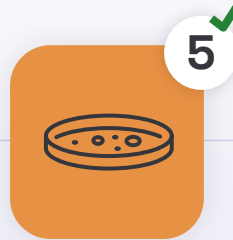


# Taking variables out of the analysis

Human eye



Imaging and vision AI



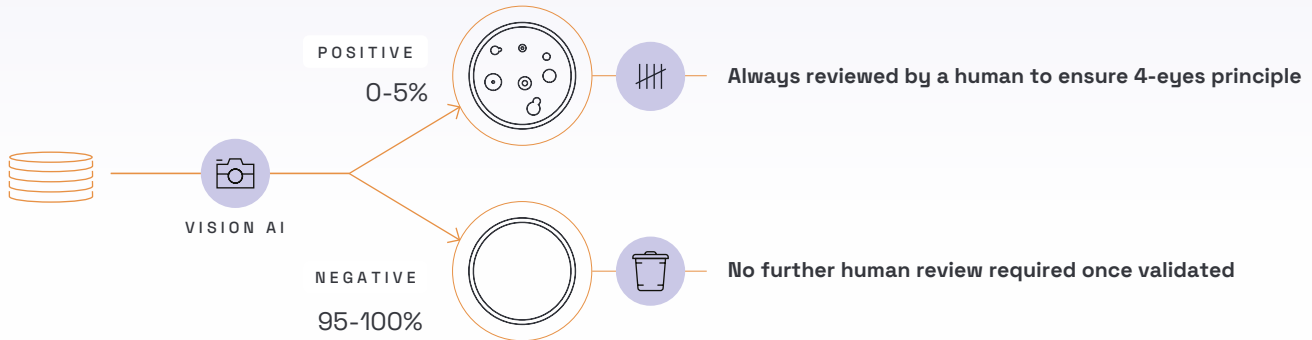
Imaging and vision AI allow for reproducible analysis and enumeration.  
Learn more about [vision AI](#).

# Rethinking Analysis in Pharmaceutical Microbiology QC

Traditional microbiology QC relies on visual inspection to assess microbial growth on agar plates — a process that's slow, subjective, and varies between operators.

EMMA uses high-quality images and vision AI to digitize & automate this task, delivering faster, more consistent results and enhanced data integrity.

**Focus where it matters** — thanks to EMMA's triaging capabilities



# *Locked-State AI*

## **Reproducible. Validated. Compliant.**

Microtechnix's AI models operate in a locked state, meaning version-controlled once validated to maintain compliance with GMP and 21 CFR Part 11 standards.

The workflows are supported by two core AI models:

- ✓ **EMdi assistant for positive/negative classification & triaging**
- ✓ **EMdi count for CFU counting**

Upon customer's request, our in-house application specialists can retrain template AI models using customer-specific data, test performance of updated models, and track historical accuracy — ensuring traceability and continuous improvement.

- ✓ **Locked-state AI for compliance**
- ✓ **Integrated with EMdi software suite**
- ✓ **Audit-ready validation & version tracking**
- ✓ **Seamless integration with LIMS**

# *From sample to report*

## Every step accounted for

## Every result, audit-ready

At Microtechnix, we believe that **data integrity** should be effortless. EMMA transforms your microbiological quality control workflow into a fully digitized, compliant process — from the moment a Petri dish is scanned, to the final validated result.



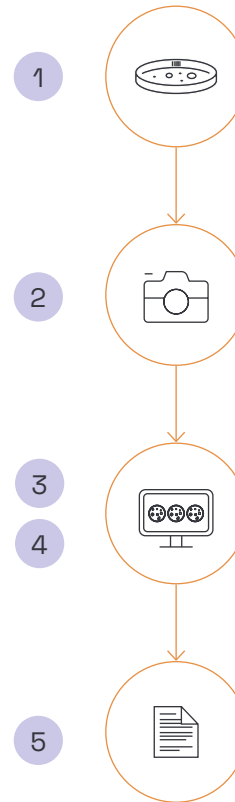
### Why It Matters

100% digital process

Compliant with 21 CFR Part 11 & ALCOA+

No handwritten records, no manual errors

Fully traceable, secure, and reviewable



1

### Sample ID

- ✓ Integrated 2D barcode scanner reads side barcodes
- ✓ Every sample is uniquely logged with time & user stamp
- ✓ Zero manual transcription = zero risk of errors

2

### Image acquisition

- ✓ 100% of the Petri dish imaged, including lateral walls
- ✓ Imaging with lid on prevents contamination
- ✓ Time-stamped, high-resolution images stored securely

3

### AI assisted or manual analysis

- ✓ Locked-state AI models perform positive/negative triaging and CFU counting
- ✓ 4-eyes principle enforces supervisor review of plates flagged positive
- ✓ All actions logged with full traceability

4

### Review & approval

- ✓ Results reviewed in the EMdi software
- ✓ User roles & permissions control access
- ✓ Change logs maintained automatically

5

### Report & Archive

- ✓ Export in .pdf, or .xml formats
- ✓ Audit trails ensure regulatory compliance (21 CFR Part 11, ALCOA+)
- ✓ Compatible with LIMS integration for streamlined reporting

# Product range

## 1 EMMA

- ✓ Manual loading
- ✓ Field upgradeable with robot



3

## EMMA HT

- ✓ Up to 200 Petri dishes
- ✓ Up to 240 plates per hour



2

## EMMA RL

- ✓ Up to 200 Petri dishes
- ✓ Up to 120 plates per hour

THROUGHPUT

	EMMA	EMMA RL	EMMA HT
Sample capacity	Single Petri dish	up to 200 Petri dishes	
Throughput	up to 100 / hour	up to 120 / hour	up to 240 / hour
Consumables	Petri dish ø 55-90 mm from any vendor – any type of medium		
Camera	5MP HD camera		
Lens	Patent-pending application specific lens		
Footprint	50 X 50 X 42 cm	50 X 50 X 140 cm	50 X 84 X 140 cm
Weight	27 kg	52 kg	79 kg
Screen	22" inch touch screen		
Data format	.jpeg, .xml		
Accessories	Robot, base plate & holder with a load capacity up to 25 Petri dishes		
Operation system	Windows 10 // 11		
Software	EMdi software suite: EMdi OS & viewer		
Warranty	1 year warranty		
Voltage and frequency	100-240Vac~/50-60Hz		
Compliance	EU Annex 11 & 21 CFR Part 11, ALCOA+ principles for data integrity		
Temperature	6-35°C		
Humidity	75% at 30°C		

# EMMA RL

EMMA RL offers a comprehensive solution to digitize and automate Environmental Monitoring. This fully integrated and automated system includes a camera, barcode reader, computer and robot, ensuring seamless operation.

Key features:

- ✓ **Process and analyze up to 120 Petri dishes per hour**
- ✓ **Perfectly fit to analyze up to 1000 Petri dishes per day**
- ✓ **Automated sorting of Petri dishes flagged positive in one stack, ready for further verification**
- ✓ **Focus on data integrity to guarantee error-proof sample identification and audit trail compliance (21 CFR Part 11 compliant)**
- ✓ **Integrated analysis tools for a streamlined workflow**
- ✓ **Ability to connect to existing Laboratory Information Management Systems (LIMS)**
- ✓ **Expanded sample capacity, enabling imaging and analysis of up to 200 Petri dishes**
- ✓ **Upgrade options include vision AI for enhanced automated analysis**



# EMMA

## Save Time & Cost

**Automating microbial QC isn't just about innovation — it's about return.** With EMMA, Microtechnix offers a scalable platform that saves labor, reduces errors, and ensures compliance — leading to a strong and measurable ROI.

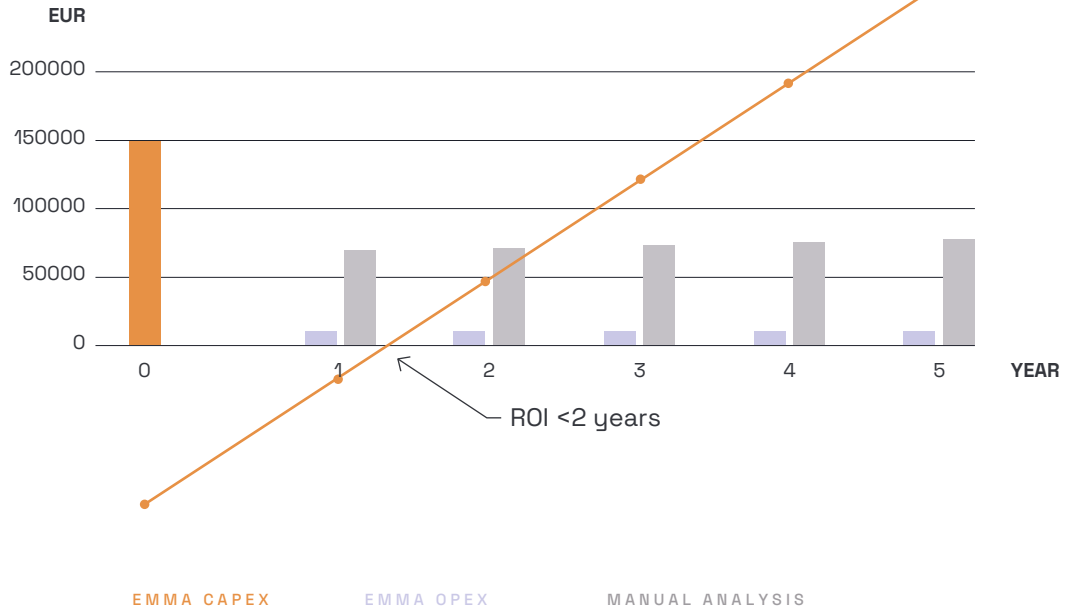
Benefit	Impact
Labor savings	Up to <u>90% less hands-on time</u>
Fewer errors	Eliminate manual transcription risks
Faster throughput	Up to <u>1000 plates/day</u> using a single EMMA RL
Compliance built-in	21 CFR Part 11 & ALCOA+ ready
Scalable automation	Match your current & future needs



Discover the  
whitepaper



Demonstrated positive ROI in less than 2 years.



# *Ensuring zero false negatives*

## Minimizing risk. Maximizing trust.

### Protocol Highlights

- 1 Calculate sample size using binomial confidence interval method
- 2 Select positive to negative ratio based on grade (i.e. 1:100 for grade A)
- 3 Document & analyze plates using EMMA workflow
- 4 Human review of results in EMdi viewer based on 4-eyes principle
- 5 Statistical analysis (FNR) based on Clopper-Pearson method (guideline & tool provided by Microtechnix)
- 6 Generate final report for PQ and regulatory discussions

### Why FNR Validation Matters

- ✓ False negatives = missed contamination
- ✓ EMMA's validation follows **USP <1223>**, **Ph. Eur. 5.1.6**, and **GMP Annex 1**

### Target FNR

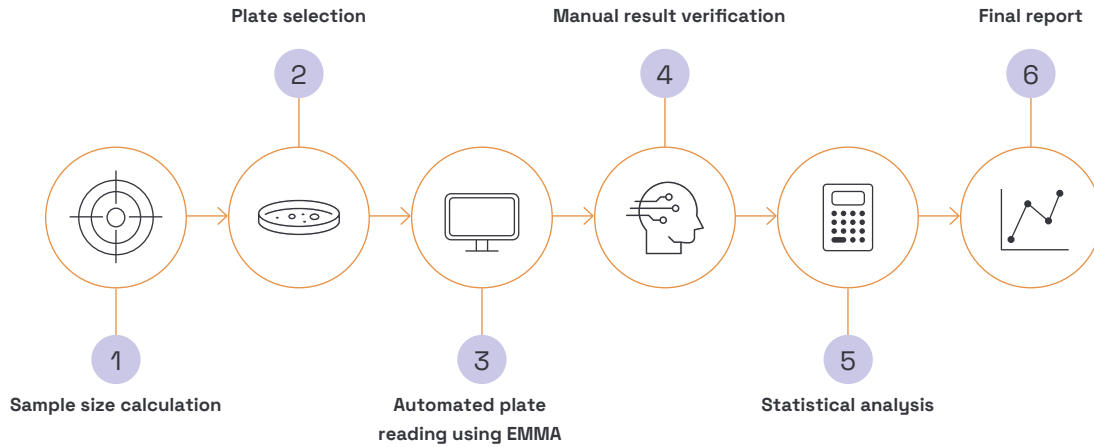
- ✓ **<0.1%** in Grade A/B
- ✓ **<1%** in Grade C/D

Achieved with **zero false negatives**.



Discover the  
whitepaper





**Validated AI. No compromise on safety.**

## *Our* mission

At Microtechnix, we transform Pharmaceutical Microbiology QC with innovative automated solutions that drive accuracy, efficiency, and reproducibility —ensuring compliance.

The logo for Microtechnix, featuring the word "Micro" in orange and "technix" in black, with a stylized orange closing parenthesis symbol to the right of the text.

Micro**technix**)

## *Our* vision

We envision a future where pharmaceutical microbiology quality control is fully digitized and automated, driven by intelligent systems that enhance precision, reproducibility, and data integrity. By revolutionizing Microbiology QC and fostering innovation, we aim to become the global benchmark for QC excellence, advancing scientific progress and contributing to the safety and sustainability of healthcare and life sciences industries.



# *Transforming* **Pharmaceutical Microbiology QC**

Ready to discover how Microtechnix can help to digitize  
and automate your Pharmaceutical Microbiology QC?

[www.microtechnix.com](http://www.microtechnix.com)

Contact us

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