

Microbial Environmental Monitoring System



# EMMA is transforming pharmaceutical microbiology QC

The Microtechix EMMA is revolutionizing the world of microbial environmental monitoring thanks to its high-end components, housed in a modular benchtop format that scales with your needs.

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 patentpending 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 and automate microbiology QC.







# 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.

# 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.





### 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? Our EMdi assistant and automation AI-model upgrades are available to assist 1 operator to achieve the 4-eyes principle.

#### **Audit and validation**

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

## Taking variables out of the analysis

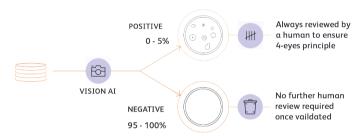


# Rethinking analysis in pharmaceutical microbiology QC

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 and 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 and 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 and 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 and 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 and 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

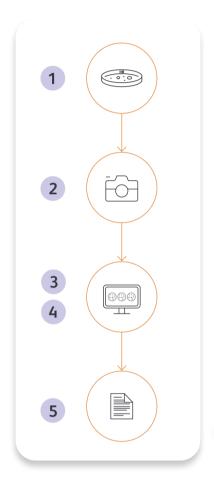
- Locked-state AI models perform positive/negative triaging and CFU counting.
- 4-eyes principle enforces supervisor review of plates flagged positive.
- All actions logged with full traceability.

#### 4. Review and approval

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

#### 5. Report and archive

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



Microtechnix **EMMA** EXPERIENCE & EXPERTISE

### **EMMA RL**

EMMA RL offers a comprehensive solution for digitizing and automating your Microbiological 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.
- Efficiently sort positive Petri dishes in one stack, ready for identification.
- 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.



### **Specifications**

	ЕММА	EMMA RL	ЕММА НТ
Sample Capacity	Single Petri dish	Up to 200 Petri dishes	
Throughput	1 plate per minute	2 plates per minute	4 plates per minute
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	.csv, .xls, .pdf, .mp4, .jpeg, .png, .bmp		
Accessories	Robot, base plate and holder with a load capacity up to 25 Petri dishes		
Operation System	Windows 10		
Software	EMdi software suite		
Warranty	1 year warranty		
Voltage and Frequency	100 - 240Vαc~ / 50 - 60Hz		
Compliance	21 CFR Part 11, ALCOA+ principles for data integrity		
Temperature	6 - 35°C		
Humidity	75% αt 30°C		

Please refer to the Technical Specification Sheet for further information

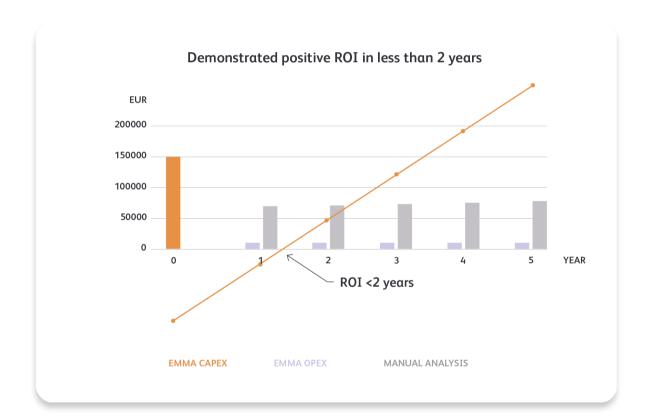
### Save time and cost

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 90% less hands-on time
Fewer Errors	Eliminate manual transcription risks
Faster Throughput	Up to 1000 plates/day using a single EMMA RL
Compliance Built-in	21 CFR Part 11 and ALCOA+ ready
Scalable Automation	Match your current and future needs







# 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 and 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 and 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

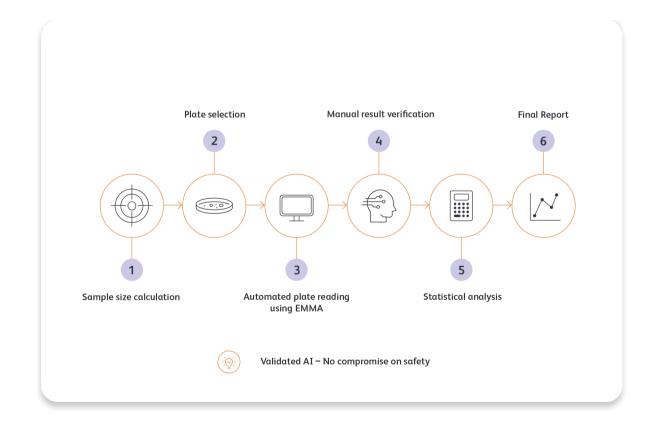
- <0.1% in Grade A/B.</li>
- <1% in Grade C/D.</p>

Achieved with zero false negatives.



Discover the whitepaper





### Service and Support

Users of our systems can benefit from our <u>comprehensive</u>, fully inclusive service and support.

We can give reassurance that if things go wrong or you need expert advice, help is only an e-mail or phone call away.

# TATERN 2023 TRADE

#### **Validation Services**

Our Validation Service enables you to implement and get maximum value from your investments as soon as possible.

We work as a partner with your Quality Manager, System Manager and users to provide a tailored Validation Plan, suited to your needs. Our Validation Specialists who have many years' of experience in GLP system validation, detailed knowledge of our systems, together with other industry standard systems to help you meet company and regulatory requirements.

### **Training**

LabLogic can provide a variety of training courses and workshops to help you get the most out of your instrument and software.

All training is performed by our expert Product and Support Specialists who have many years experience in the development and use of the instruments and software.

Certificates can be provided to complement your internal GLP training records.

USA & Canada

<u>LabLogic</u> Systems, Inc.

3901 Centerview Drive, Suite B Chantilly, VA 20151, USA

E-mail: solutions@lablogic.com Tel: +1-703-429-4209

www.lablogic.com



Europe & Worldwide

LabLogic Systems Limited

Innovation House, 6 Europa View
Sheffield, S9 1XH, UK

E-mail: solutions@lablogic.com Tel: +44 (0)114 266 7267

www.lablogic.com







LabLogic