Bringing cell imaging into validated environment with the SpectraMax® MiniMax™ 300 Imaging Cytometer and SoftMax® Pro 7.6 GxP Software

Caroline Cardonnel, Marie Pape-Bub, Ida Thaarup | Molecular Devices, LLC

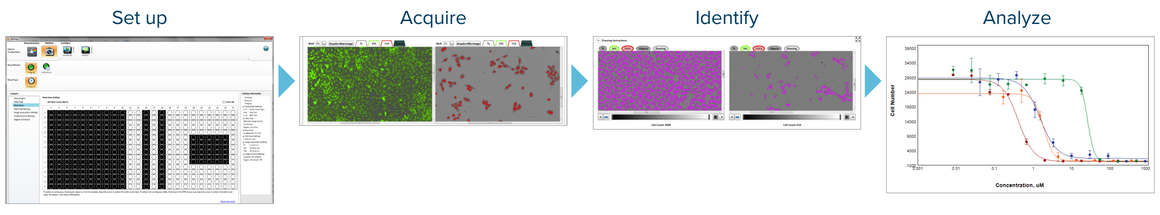
Introduction

Quality control (QC) laboratories increasingly adopt cell-based assays, which give a direct measure of biological activity and product potency. Unlike microplate readers, which measure an overall well signal, imaging systems directly visualize and quantify individual cells. They provide biological context through measurements of cell number, viability, morphology, proliferation, marker expression, receptor activation, and reporter responses. By linking quantitative results to visual evidence and the relevant cell population, imaging can improve assay interpretation, sensitivity, reproducibility, and traceability. This approach is particularly valuable for GMP/GLP potency and batch-release assays, where results must closely reflect the product's mechanism of action.

This poster highlights how the MiniMax™ 300 Imaging Cytometer combined with SoftMax Pro 7.6 GxP brings cell-based assay imaging into a validated environment, supporting data integrity and traceability in GLP/GMP workflows

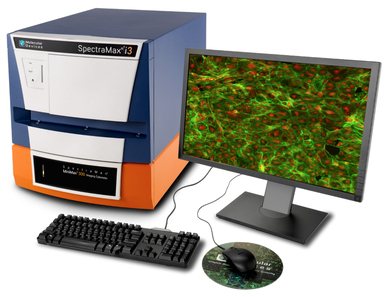
Key features

- Combine cellular imaging and microplate assays into a single workflow
- Eliminate cell staining for cell counting and confluency with our patented StainFree™ Technology
- 4 steps workflow: Set-up, Acquire, Identify and analyze.
- Supports GLP and GMP compliance



MiniMax™ 300 Imaging Cytometer is a compact microplate imaging system designed to add whole-well imaging and cell counting capabilities to a SpectraMax® i3x microplate reader. It captures brightfield and fluorescence images directly in microplates, allowing users to perform cell counting, confluency, and marker expression measurements, in a simple cellular imaging workflows.

Light source	Proprietary solid state illumination, White, 460/20 nm and 625/20 nm excitation	
Detector	1.25 megapixel, 12-bit high sensitivity CCD camera	
Emission	Brightfield; Green 541/108 nm; Red 713/123 nm	
Objective	Single 4x objective	
Autofocus	Proprietary laser scanning autofocus	
Resolution	1.9 µm x 1.9 µm pixel size	
Data acquisition and analysis software	SoftMax® Pro Software MiniMax Imaging Edition	
Imaging speed*	Acquisition	Acquisition + analysis
1 color – 96 wells	3:40	6:30
2 color – 96 wells	3:40	6:30
Specimen carriers	ANSI-SBS-conformant microplates, 96 and 384 wells	





Imaging assay types and applications for GLP and GMP labs

- **Cell proliferation:** measure the growth rate of cells in response to a drug, read by cell count and confluency, giving insight into potency and potential toxicity.
- **Cell death** (Figure 1): evaluate the ability of a drug to induce cell death, read by viable cell area, which is crucial for assessing a safety profile.
- **Cell signaling:** assess the effects of a drug on specific signaling pathways, read by marker expression, helping determine efficacy and potential side effects.

Main applications: batch release, potency, cell viability and toxicity assays, microplate reader assay normalization.

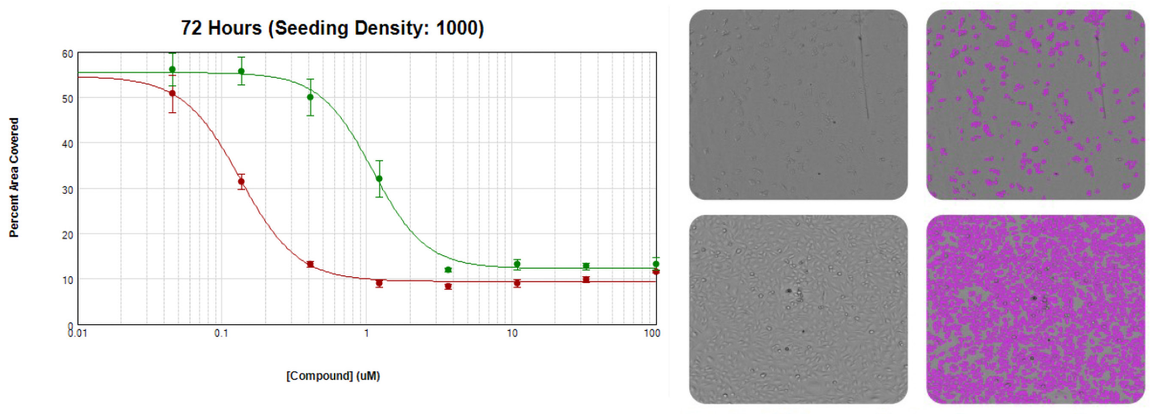


Figure 1. *Cell death assay measured as percent well area covered, using StainFree™ analysis. HeLa cells were seeded at 1,000 cells per well and treated with anisomycin or trichostatin A for 72 hours to induce apoptosis. Software segmentation settings identified cells in purple.*

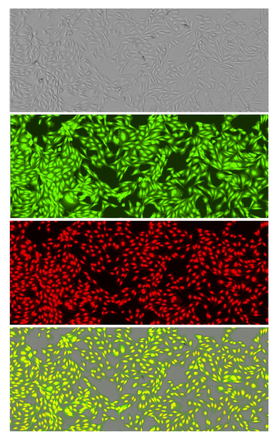
Robust image analysis with SoftMax® Pro Imaging edition

The algorithm developed for SoftMax® Pro Imaging edition combines proprietary StainFree™ cell detection, fluorescence segmentation, object classification, and machine-learning-based image analysis to provide fast, robust, and easy-to-use cellular analysis. Built on the proven MetaMorph® image-analysis engine, MiniMax™ delivers reliable cell counting, confluency, viability, and marker-expression measurements without requiring advanced imaging expertise.

Key steps for incorporating imaging systems into GLP/GMP workflows

Integrating imaging systems into GLP/GMP workflows requires:

- End-to-end workflow validation
- Control of acquisition and analysis parameters
- Algorithm performance and reproducibility
- Traceability of images, metadata, audit trails, and results
- Image review, storage, retention, and data integrity



Our GLP/GMP compliance solutions for regulated workflows

Beyond the instrument IQ, our new MiniMax™ 300 Imaging Cytometer OQ procedure (Figure 2) verifies focus, illumination, exposure, segmentation algorithms, and analysis settings. The method demonstrates consistent performance across representative samples. Raw images, processed data, metadata, audit trails, and reports remain secure and traceable in our SoftMax® Pro GxP Software. These procedures test the fluorescence and StainFree™ channels to ensure reproducibility, data integrity, and fitness for intended use in GLP/GMP environments.

Figure 2. *MiniMax™ 300 Imaging Cytometer OQ Report for Fluorescent and StainFree channel*

Conclusion

The MiniMax™ 300 Imaging Cytometer with SoftMax® Pro GxP Software brings whole-well imaging and StainFree™ cell counting into regulated cell-based assay workflows, with no standalone microscope required. Ready-to-use protocols automate acquisition, segmentation, analysis and pass/fail reporting, while secure user access, electronic records, e-signatures and audit trails preserve data integrity and traceability. Combined with the new imaging OQ procedure, qualified SpectraMax® readers and IQ/OQ services, cell-based imaging assays can be implemented and validated in GLP/GMP quality control laboratories.

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