

# Nikon Instruments, Inc.

www.microscope.healthcare.nikon.com/products/cell-screening



## Shedding a new light on regenerative medicine

**Building on a century of experience in developing advanced optical solutions, Nikon embarked on a quest in 2017 to help accelerate clinical and diagnostic imaging innovation. Through its Healthcare Business Unit, Nikon is poised to contribute to the medical and biological science fields and help raise quality of life globally.**

Since its establishment in 1917, Nikon has been at the forefront of optical and technological innovation. Today, Nikon is firmly established as a market leader in optical instrumentation and is the only microscope company to manufacture its own glass, ensuring the finest quality throughout production.

As Nikon embarks on the next 100 years of innovation, the company is committed to applying the power of optics to the development of solutions for the medical and biological science fields to improve health care and quality of life globally.

### Focus on regenerative medicine

Great expectations have been placed upon cell therapies to become effective solutions for a number of currently intractable diseases or conditions for which traditional therapies provide only partial solutions. Nikon's Healthcare Business Unit, established in 2017, prioritizes among others the development of tools for regenerative medicine solutions to rapidly improve cell culture, differentiation, and manufacture.

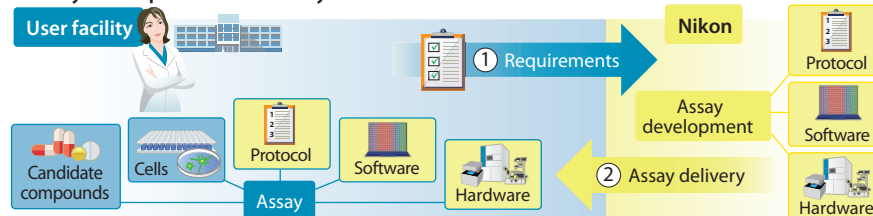
In collaboration with Lonza, Nikon has begun contract cell manufacturing and development for regenerative medicine with a wholly owned subsidiary, Nikon CeLL innovation Co., Ltd. Nikon has also partnered with Yumanity Therapeutics, Inc. to develop high-throughput assays and high-content image-analysis algorithms. Nikon has also developed a line of imaging instruments and software solutions for cell manufacturing.

### Honing the optics of cell regeneration

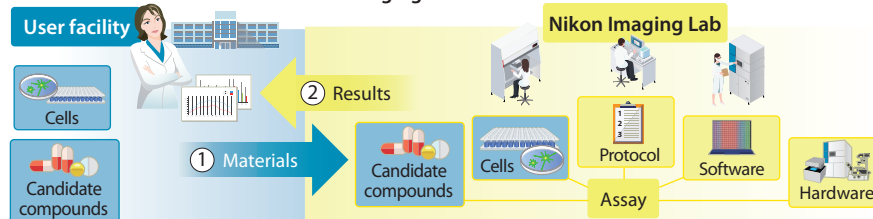
The regenerative medicine industry faces unique challenges. Cell therapies, for example, require the production of extremely large numbers of cells. Stable cell manufacture protocols are critical to achieve this, but their implementation can be quite difficult. Cells are highly sensitive to environmental changes, with even subtle shifts causing significant changes in cell health, cellular identity, and differentiation outcomes. Cellular behavior and morphology reflect these changes and thus detection of variations in parameters such as motility, growth rates, and cell shape or size is key to establishing quality assurance measures for ensuring the stable production of homogeneous cell products.

Human pluripotent stem cells can be differentiated into a variety of cell types for use as cell therapies. To achieve reliable mass production of high-quality differentiated cells, routine monitoring is essential. This is both a matter of quality control for regenerative medicine companies and a regulatory requirement, as highlighted by recommendations from the US Food and Drug Administration and

### a Assay development and delivery



### b Contract research service at Nikon Imaging Lab



**Fig. 1 | Nikon's assay development support and contract research services at a glance.**

other agencies for using quantitative morphological data in cellular identity testing.

Traditionally, much of this work has been done by humans; however, observation by humans is neither a quantitative nor precise method—it is impossible to track and record the morphology and movement of millions of cells in a culture dish by human observation.

Nikon has developed cutting edge, advanced imaging devices and artificial intelligence-enhanced, machine-learning image-analysis algorithms that solve these unique challenges.

Specifically, Nikon's toolbox includes hardware and software for in-line, nondestructive, label-free quantification of cultured cells and tissues, automated image analysis for reproducible quality control measurements, and generation of regulatory-compliant quantitative data. These tools can help determine the timing for cell passage or drug additions, predict the success of cell culture, and detect unwanted cells in culture early.

### Flexible adoption and implementation

Nikon has adopted a flexible structure for implementing its regenerative medicine capabilities (Fig. 1).

The basic approach allows customers to purchase newly released, cutting-edge imaging instrumentation such as the good manufacturing practice (GMP)-ready BioStudio-T, the modular High-Content T12-E, and the BioStation CT with corresponding image acquisition and analysis software. These solutions are provided as bundles of user-selected software and hardware modules and come with customer training and support.

Nikon also offers a comprehensive suite of contract research services through Nikon Imaging Lab, a state-of-the-art facility located in Cambridge, Massachusetts, to support the burgeoning regenerative medicine and biotech sector. At Nikon Imaging Lab, Nikon offers the expertise and equipment required to carry out simple to complex cell-based imaging assays. Customers can choose from a menu of ready-made assays or can work with Nikon application scientists to implement custom assays. The facility is equipped to handle the complete assay process—cell thawing, expansion, differentiation, drug and toxicology screening, image data acquisition, and image data analysis. This service is designed for clients that don't have the capital to invest in purchasing major instrumentation and expertise, or that need punctual support for a one-time project.

And finally, a third approach consists of a hybrid offering in which Nikon provides customized hardware and software, as well as assay-design consultation—from conception through to implementation and analysis steps, at the customer's facility.

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