



# NKCL Bio “Popularization of ‘NK Immune Cell Therapy’ System”

## Development of 'automated culture system' for NK cells with 0% contamination... Medical personnel, "Making Easy 'healing and treatment' possible"

NKCL Bio Group (CEO Shin Dong-hwa) is a bio company that continuously researches, develops, and commercializes 'immune care' products, including 'NK cell therapy' that can help improve 'immunity', which is the keyword that is focused on. Founded in 2019, NKCL Bio Group leads the 'personalized immune care' market through the expansion of its fields such as the establishment of the NKCL company-affiliated research center for the advancement of R&D and the GMP automated culture center and the commercialization of microbiome-related foods. NKCL Bio Group has secured an automated culture system under 'GMP conditions' in Hwaseong, Gyeonggi-do, and is at the forefront in this field in Korea, drawing attention from the medical science community from the beginning of its establishment. NKCL Bio Group won the grand prize in the 'Promising Bio Company Category' at the '2021 Korea Future Management Awards' hosted by the Herald Economics and the Korea Herald for two consecutive years. Although it's only been established for about two years, it has received exceptional attention, such as winning a promising company-related award

from a government agency. The founder, CEO Shin Dong-hwa, majored in business administration (Chung-Ang University). However, CEO Shin, who has been interested in sound life and disease since college, began to take an interest in stem cells-NK cells in 2008. For 13 years, he visited and studied research institutes in the United States, Japan, and Europe with invited medical scientists. Based on this, 'personalized immune care' became possible, and the automated culture system under GMP conditions has been developed to be more affordable and to a stage where healing is possible. He became a leader in this field and is recognized as a 'teacher' by medical doctors. In particular, the contribution to the formation of the 'ND Immunity Specialist' course at Yonsei University Future Education Center is drawing attention.

<Reporter Bong Doo-han / hois232@gmail.com>

NKCL Bio Group, which has the most qualified experts in Korea in the field of NK immune cell culture technology, is located in Hwaseong. CEO Shin Dong-hwa, the chief executive officer, who is an expert in this field. Many supporters say, “We participated in the launch of NKCL Bio Group because of CEO Shin’s passion for research, his honesty and transparency.” NKCL Bio Group, with CEO Shin Dong-hwa's passion as the engine,

**CEO Shin Dong-hwa, although majored in business administration is receiving attention from the medical field for 13 years of cell research**

**NK cells are sensitive to external stimuli, lowered efficiency and high cost when cultured manually**

has achieved ‘results’ that have received attention from the beginning of its establishment in ‘NK Cell Therapy (Natural Killer Cell)’ and ‘Immune Care’ products. This group is developing and producing NK cell therapeutics using its own technology. As of 2020, the company expects to grow at an average annual rate of 13% or higher in the domestic market.

**NKCL Bio is building Korea's largest sterile 'automated cell culture room' in Hwaseong**

**Progress towards the goal of simultaneous KGMP-EUGMP-cGMP certification...Blockchain, seeking to improve productivity**

In fact, the global market is expected to grow tremendously. According to Frost & Sullivan, a global market research institute, the global biopharmaceutical contract development and manufacturing (CDMO) market, which is at a size of \$13.3 billion (about 15 trillion won) in 2019, is expected to continue to grow over the next five years to \$25.3 billion (about 29 trillion won

) by 2025. Among them, the global cell and gene therapy contract development and manufacturing market, which is the main focus of NKCL Bio Group, are expected to grow at an average annual rate of 31%. NKCL Bio Group is expanding its production facilities to enter the Contract Manufacturing Organization (CMO) and Contract Development Organization (CDO) markets for advanced biopharmaceuticals.

NKCL Bio Group's internal facilities are private, but the company says it is in "100% clean condition". All processes such as incubation from the initial setting to completion are read only by automatic processing and high-tech microscope monitor zoom-in-zoom-out, which does not require human hands. The consumer (person placing the order) is also treated in the same first-last method. The interior has

the same atmosphere as the exterior of the building, and the space is made of a glass layer, enabling the viewer to realize that they have entered a 'clean world'. ‘NK cells,’ the main product, are immune cells that detect and kill viruses that can enter from the outside and malignant cells that occur in the body. T cells and other immune cells cannot recognize “tumor cells” on



▲ CEO Shin Dong-hwa. At the groundbreaking ceremony for the automated culture system, he said, “Only the company that sees the future can survive.”

their own. However, 'NK cells' have a differentiated ability to recognize and immediately eliminate cancer cells on their own. That is why all scientists of the world are paying attention to it. Immune cell

therapy increases the number of immune cells and strengthens their functions by collecting them from their own blood and culturing them in vitro. Then, the cultured immune cells are injected back into the body to treat the diseases. Because it's the body's own immune cells, there are no side effects such as rejection. Therefore, it is attracting attention as the fourth treatment for cancer.

However, NK immune cells are difficult to culture. NK immune cells are very weak to environmental stress and are difficult to culture. Therefore, the entire process of culture can only be carried out by professional research personnel who have majored in this field, such as life science. For the manual culture method, it is very

### ■ Biography of CEO Shin Dong-Hwa

- 1995 Graduated from Chung-Ang University in Business Administration
- 1995~2004 CEO of Yesung Planning Co., Ltd.
- 2004~2007 CEO of YS Enterprise Co., Ltd.
- 2007~2010 General Director of JP Systech Co., Ltd.
- 2008~Present Establishment and operation of Stem Cell Research Lab
- 2012~Present Establishment and operation of Immune Cell Lab (Currently NKCL Bio Group Research Institute)
- 2010~2014 CEO of Nestri Co., Ltd.
- 2014~2016 Director of External Relations Department of GK Global Group Co., Ltd.
- 2019~Present CEO of NKCL Bio Group.

difficult to secure high-quality manpower, and the number of cultures that can be managed per researcher is limited, so productivity is very low. In response, NKCL Bio Group secured an 'automated culture system'. Researchers have succeeded in developing a clean and scientifically automated culture system using artificial intelligence (AI). Specially programmed artificial intelligence finds the 'culture environment' optimized for NK cell culture by itself. This not only replaces the required high-quality manpower but it is also evaluated as having achieved the feat of improving production efficiency by more than 100 times. This pulled the 'future' of cancer treatment to the 'present' at an ultra-low cost.

As described above, the company's GMP automated culture system enables cell culture-reading throughout the entire process in a closed system, blocking the source of contamination. In this way, NK cells can be mass-produced. For this reason, it is evaluated that it has maximized the reduction of the procedure cost by significantly lowering the labor and production costs. This means



▲ Besides NK immune cells, we produce and supply various products that help with immunity. These products are produced under ‘clean conditions’.





## World market (commissioned) for 'NK cell therapy' that naturally kills cancer cells at 29 trillion won in 2025

Still in its beginning stage... The domestic CDMO market is expected to grow by 13% annually

that it will be possible to significantly increase the potential customers for NK immune cell therapy. In addition, NKCL Bio Group is exporting its automated culture system solution and plant to overseas markets to popularize it in the global market.

**Extremely low ability to self-generate NK cells in cancer patients, but same as a normal person in an 'automated culture system'**

**Automated culture system solution—plant overseas export, astronomical productivity can be created**

**NKCL Bio** "Recently, there has been an increase in inquiries about 'NK cell automated incubator (kit)' from hospitals and clinics.

In this case, astronomical productivity can be created.

NKCL Bio Group is constructing a 4,000 m<sup>2</sup> (approx. 1,200 pyeong) production facility at the Hwaseong Knowledge Industry Center in

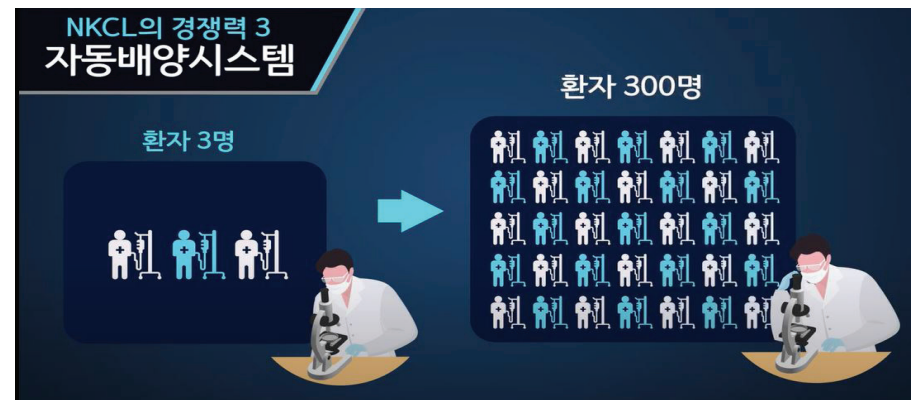
to proposing an NK cell culture medium kit (hereinafter referred to as 'NK kit') as another NK immune cell popularization solution. As the GMP automated culture system has many advantages, it requires a significant initial equipment cost. Due to the

high barriers to entry, it is difficult for small hospitals and businesses to have access to it. The NK kit is an alternative for anyone to commercialize (use) by culturing NK cells with a simple facility.

culture by simply mixing the culture medium when culturing. Everyone can easily culture NK cells with basic training. NKCL Bio Group introduces that "not only will this lead the popularization of NK immune cell culture technology, but this technology is the 'power' of differentiation." Immune cells can be cultured in normal people and patients with severe cancer. The problem with the conventional culture method was that cell culture was inconsistent and that the growth difference for each individual cell was relatively large. In particular, the proliferation of immune cells is not easy when cultured with the blood of severe cancer patients whose immune system is compromised by cancer cells. In other words, it is difficult to



▲ Dongtan Building



▲▲ Illustration of automated cell culture system and effects explanation

Gyeonggi-do, and it is expected to start operation within this year.

In particular, it is designed and is proceeding with the goal of obtaining the three certifications of KGMP EUGMP and cGMP at the same time. An automated culture system

**Equipped with advanced facilities at the headquarter R&D center in Dongtan High-tech Industrial Complex, Dongtan M Tower, 14th floor**

**Research and commercialization of 'immune care' products... Microbiome related food development results**

NKCL Bio Group explains, "The NK kit developed with the company's 'unique' technology is a standardized method with simple instructions to easily culture NK cells that are difficult to culture." With the equipment at the level of a small laboratory

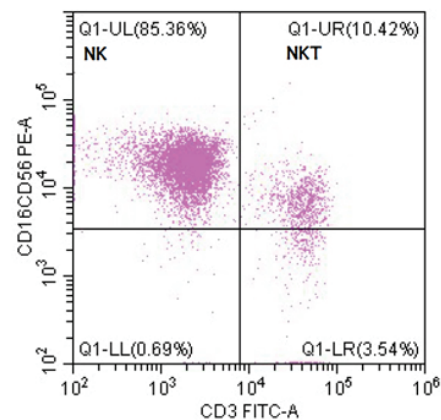
certified by GMP, the kit can be supplied safely by the NKCL Bio Group, and NK immune cell therapy products can be produced anywhere under the guidance of a doctor (according to the Advanced Regenerative Medicines Act). Securing safety expected. Complex steps can be omitted as no antibody-fixing flask is required, and it is designed to facilitate cell

increase their 'activity' to kill cancer cells. However, NKCL Bio Group found the cause of why immune cells are not activated and why cell proliferation does not occur and solved the problem.

Even in patients with severe cancer, cell culture was optimized to the same level as normal people. This company does not use feeder cells such as cell lines. Many NK cell researchers develop or explore and use various cell lines to avoid existing patents and to secure their own patents. However, if the cell line used for cell culture survives and exists in our body, it may grow into cancer. In order to remove it, 'gamma-ray treatment' is needed. In this case, the operation method becomes difficult and the unit price will inevitably increase. As such, NKCL Bio Group's cell culture is safer and simpler because it does not use feeder cells and NK cells are not affected by gamma rays.

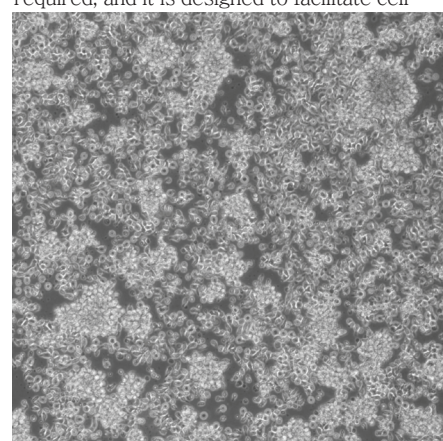
For this reason, NKCL Bio Group is evaluated to have a very bright future. The latest personalized immune care platform. It is rare to hear the phrase "the age of 120 years" beyond the 'age of 100'. In order to lead the bio-industry in the era of the 4th industrial revolution, personalized service is an essential element.

Prediction and analysis that even the medical paradigm of the future will be transformed into 'precision medicine' centering on personalized medicine are dominant. This means that it precisely proposes a customized solution in individual units according to the specific characteristics based on individual genetic information, disease information, and lifestyle information. With the keyword 'immunity', NKCL Bio Group is planning to quickly respond to the market demand and operate 'personalized immune care' through a variety of products, including immune cell therapy products. In line with the direction of these companies, NKCL Bio Group is expected to attract attention as a company that contributes to the qualitative improvement of public health in an aging society and in the immune crisis caused by COVID-19.



▲ FACS Data

Data analyzing the purity of NK cells cultured for 14 days show high purity of 85.36% of NK cells and 10.42% of NKT cells (CD16+, CD56+ cells 95.78%).



▲ Cell microscope image

It can be confirmed that the immune cells are very healthy and growing well from the image of the cells on the 8th day of cell culture.