

# BIKEN's 80-year tradition of saving lives through quality vaccines

THE BIKEN GROUP is strengthening its commitment to eradicate serious infectious diseases by developing next-generation vaccines.

The BIKEN Group, a specialty bio-pharmaceutical organization based in Osaka, Japan, is striving to meet society's demand for more effective vaccines. BIKEN researchers are encouraged to tackle difficult but vital projects, and create innovative products that enrich the marketplace. The group has further strengthened its manufacturing capability with a recent joint venture, and now is the largest supplier of vaccines in Japan.

**A unique organization**  
The Research Foundation for Microbial Diseases of Osaka University, also referred to as the BIKEN Foundation, was established on an Osaka University campus in 1934 by the bacteriologist, Tenji Taniguchi. Thanks to generous financial support from the philanthropist Gendo Yamaguchi, Taniguchi set up the foundation with a mission to free people from fear of serious infectious diseases. Since then, BIKEN has launched many vaccines in Japan and licensed their technology overseas. "Over the generations, we have embraced Dr Taniguchi's drive to save lives by making excellent vaccines," says Koichi

Yamanishi, Director General of the BIKEN Foundation. The BIKEN Foundation takes full advantage of its origin as a university start-up and maintains a strong network with infectious disease experts. The foundation works especially closely with the Research Institute for Microbial Diseases (RIMD), Osaka University, developing RIMD's basic research outcomes into practical vaccines.

**"UTILIZING THE FULL POTENTIAL OF THE BIKEN GROUP, WE WILL PROVIDE WORLD-FIRST BIOLOGICAL PHARMACEUTICALS DEVELOPED IN JAPAN."**

The BIKEN Foundation has recently established another research centre in collaboration with Osaka University to propel research and development for next-generation vaccines. In 2017, the foundation spun off its production division and formed BIKEN Co. Ltd., a joint venture with the Mitsubishi Tanabe Pharma Corporation, one of



Nucleic acid analysis of a virus at BIKEN's R&D labs.



Making an undiluted solution at BIKEN's Production Division.



Tenji Taniguchi, founder of BIKEN, at Osaka University.

Japan's major pharmaceutical corporations, in an effort to further ensure the stable supply of high-quality vaccines. This led to the formation of the BIKEN Group, which includes both the BIKEN Foundation and BIKEN Co. Ltd.

**A history of firsts**

In 1970, BIKEN obtained the government's approval to develop Japan's first freeze-dried, live, attenuated vaccine against measles. A regular vaccination programme led to the eradication of measles in Japan by 2015. The foundation also contributed to the global prevention of measles by exporting the vaccine to UNICEF and licensing the technology to Brazil and Indonesia.

In 1974, BIKEN developed the world's first varicella (chicken pox) vaccine. Its live attenuated varicella virus (Oka strain) was considered to be suitable for vaccine production against the disease by the World Health Organization (WHO).

**Looking ahead**

More than 100 researchers from Japan and abroad are working towards the creation of new vaccines at the BIKEN Foundation. They are now conducting Phase III clinical tests for a DTaP-IPV-Hib vaccine, a combination of vaccines against five infectious diseases — diphtheria, tetanus, pertussis, polio and Haemophilus influenzae type b infections. BIKEN plans to

add more vaccines in the one formulation to reduce the number of injections children have to endure. Yamanishi says their most challenging project is the development of a nasally administered inactivated influenza virus vaccine. Conventional influenza vaccine injections induce production of antibodies in the blood, which prevent disease onset and lessen the severity of flu symptoms. The new vaccine, to be sprayed on nasal mucous membranes, could prevent infection by inducing neutralizing antibodies out of the membranes and blocking entry of the virus — making it more effective in preventing disease onset than conventional

influenza vaccines. Researchers are now preparing to launch Phase III clinical tests. BIKEN researchers are also working towards a novel pneumococcal vaccine. The current vaccine is serotype-dependent, but the number of pneumococcal strains with serotypes not covered by the current vaccine are increasing. BIKEN's vaccine contains pneumococcal surface protein A (PspA), an antigen which would be common to all pneumococcus. The vaccine is expected to cover 96% of clinical isolates of the bacteria, which would make it the world's most effective pneumococcal vaccine. The organization is also looking into the development of vaccines for Hand, Foot

and Mouth Disease (HFMD), and Zika. These projects are supported by the Japan Agency for Medical Research and Development, the public institute that oversees and funds the nation's medical research. A year after the formation of the BIKEN Group, Yamanishi says it is accelerating its efforts to fight infectious diseases. BIKEN Co. Ltd. has integrated the foundation's manufacturing technologies with Mitsubishi Tanabe Pharma's expertise in production and quality-control management, and is expanding production capabilities and introducing advanced IT systems. The group is also planning to introduce new businesses such as *in-vitro*

diagnostic agents for infectious disease, while expanding international distribution routes for BIKEN high quality vaccines and strengthening international collaborations with immunology and infectious disease researchers. "Utilizing the full potential of the BIKEN Group, we will provide world-first biological pharmaceuticals developed in Japan," says Yamanishi, "and by providing excellent clinical testing services, we hope to establish a solid position as a specialty bio-pharmaceutical organization." ■

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