MINIMIZING ANIMAL USE AND IMPROVING REPRODUCIBILITY OF WHOLE-CELL VACCINE TESTING

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INTERNATIONAL ASSESSMENT OF THE PSPT IN MICE TO REPLACE THE INTRACEREBRAL-CHALLENGE MOUSE PROTECTION TEST (MPT) FOR WHOLE-CELL PERTUSSIS (WP)

Developing Countries Vaccine Manufacturers Network (DCVMN), Hyderabad, India

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INDUSTRY NEED

Regulatory approval and release of whole-cell vaccines, including cellular pertussis vaccines, requires additional testing for potency—the ability of the vaccine to stimulate antibody production in the body. Cellular vaccine potency is typically tested in animals using a protocol that has not changed since the 1950s. This method has high variability, is time consuming, and causes significant distress to the animals. In recent years, there has been a drive to find more humane approaches to evaluate cellular vaccines. Ideally, testing should also be standardized to improve reproducibility across different vaccine manufacturers.

SOLUTION

An ELISA-based technology to test the potency of cellular pertussis vaccines had been developed decades ago but was abandoned as countries moved toward the use of acellular pertussis vaccines. However, cellular pertussis vaccines continue to be used by most developing countries, with hundreds of millions of doses produced by various manufacturers globally. Combined with the push to reduce animal testing, scientists within the Developing Countries Vaccine Manufacturers Network (DCVMN) took another look at the ELISA-based technology.

DCVMN invited vaccine manufacturers and national control laboratories to form a global consortium to develop the ELISA-based Pertussis Serological Potency Test (PSPT) technology. With PSPT, mice are vaccinated, but blood samples are collected to test vaccine potency, eliminating the need for pertussis challenge. In addition, PSPT takes only 3-4 hours and uses a standardized procedure that reduces variability and allows batch-to-batch comparisons to evaluate consistency. At monthly workshops, industry partners provided feedback to DCVMN on the PSPT technology and protocols, and shared insights into logistical considerations, such as test feasibility in low-resource settings. The PSPT technology, reagents, and protocol were then deployed to 10 different laboratories in India, Indonesia, and Thailand, for initial feasibility testing.

OUTCOME

Once the first round of testing was completed, a technical workshop was held where all partners shared their experiences with the PSPT technology and DCVMN provided technical support for optimizing the protocol. Several of the partners are currently conducting a second round of testing and validation of PSPT with their manufacturing systems. All protocols have been made available at the DCVNM website. The global partnership allowed industry to contribute to the development of and gain familiarity with PSPT and establish valuable ongoing collaborations to minimize animal testing.

> *"PSPT minimizes animal use and distress while improving reproducibility and decreasing the time and cost of cellular pertussis vaccine testing."*

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