



Enabling Vaccine Equitable Access Through

Manufacturing Innovations

WHO/MPP mRNA Technology Transfer Programme, 1 Nov 2023

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About Us

Hilleman Laboratories is an equal joint-venture partnership formed between Merck Sharp & Dohme Corp. (MSD), a global research-driven pharmaceutical company and Wellcome Trust, a global charitable foundation dedicated to supporting science and solving urgent health challenges.



Our Mission

We are committed to developing



Deliver impact to 100 million people globally



affordable

Affordable by UNICEF and governments in low- and middle-income countries



vaccines in LMICs

With strong focus on Africa, Asia and Latin America



in a safe, effective, novel

Develop vaccines using existing and novel platform technologies



and sustainable

Achieve operational sustainability within next 5-7 years



manner.





Hilleman has created a legacy of research excellence in the first decade and is expanding its capabilities & global footprint in its next stage of growth.

Development of flagship product, HillChol®

developing a high impact

cholera vaccine

MSD & Wellcome Trust open R&D facility in Jamia Hamdard University, New Delhi, India Cholera vaccine proceeds to Phase II trials, with two other assets in development **Expansion to Singapore & construction of Hilleman's first GMP manufacturing plant**

Hilleman expands global footprint with its new global headquarters in Singapore

Expected completion of GMP pilot plant



Hilleman partners with Bharat Biotech for development and manufacturing of the oral cholera vaccine (Hillchol®) Inauguration of R&D Labs and groundbreaking of pilot GMP plant in Singapore

Hilleman launches first ever training programme on technology transfer for DCVMN*

*Developing Countries Vaccine Manufacturers Network



Hilleman's value proposition lies in de-risking the product development process and supporting delivery through its strong network of partners.

Expertise in process
development, formulation
science, preclinical R&D, as
well as GMP manufacturing,
provides the full suite of
translational capabilities

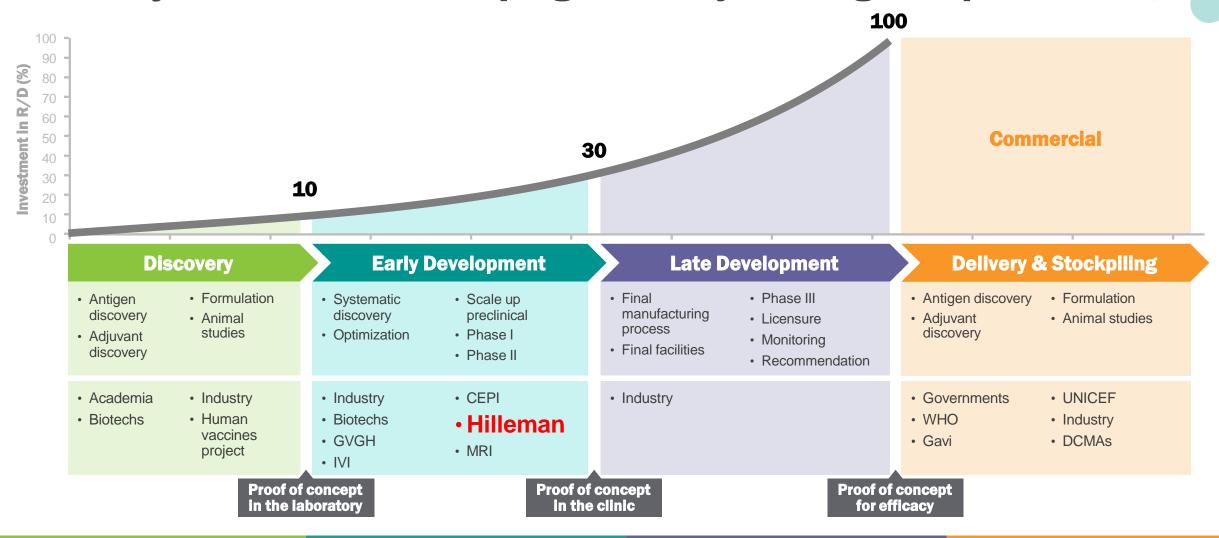
Strong partnerships with funders and global health organizations (incl. Bill and Melinda Gates Foundation & Temasek) to drive large scale delivery



Workforce development, industry exposure and training programs targeting vaccine manufacturers in low and middle-class countries to develop local manufacturing capabilities



Our objective is to de-risk a programme by working with partners.





To date, Hilleman has built a portfolio of advanced product candidates for global health.

Cholera Vaccine (HillChol®)

A best-in-class vaccine developed as a single strain, single dose liquid oral delivery licensed to Bharat Biotech (India).

Phase III trials have concluded, with licensure pending.

2 MenACWYX

A pentavalent meningitis vaccine with broadest coverage against the main circulating vaccine strains that cause infection and disease, with several granted patents in developed and developing countries.

ERVEBO®

(Ebola Zaire)

2nd Generation

A second-generation vaccine with an improved thermostability profile (4–8°C) compared to the current ERVEBO® (-80°C), with the aim of reducing COGS and increasing production volumes to provide a wider, more equitable and affordable access.

4 rHSA

Optimized platform based on *P. pastoris* for an alternative mode to produce recombinant human serum albumin for use as an excipient.









PLATFORMS FOR VACCINE DEVELOPMENT

Hilleman R&D portfolio is driven by diverse platform technologies.

We have made great strides in moving beyond legacy portfolio (of whole cell and conjugate vaccines for enteric diseases) to various modalities for platform development, and to develop accessible and affordable solutions to control the impact of infections.

VACCINES VIRAL VECTOR NUCLEIC ACID SUBUNIT Optimize for effective Conjugate • DNA Recombinant protein • mRNA yield at acceptable COGS in production at scale for traditional vectors and to develop for novel vectors **circRNA** rHSA VSV MeV (excipient) **LPS** Conjugate

MONOCLONAL ANTIBODIES



Opportunity to work with partners



We are your key development partner to take assets from early discovery, through process and product development up to Phase 2 clinical trials and pilot manufacturing.

CMC and Preclinical R&D

- Antigen research and identification
- Proof-of-concept validation
- Product development: Process, analytical and formulation development
- Toxicity, immunogenicity and reactogenicity studies
- Safety & efficacy in vivo
- Phase I: Safety in human
- Phase II: Dosing & safety





- Technology transfer from R&D to manufacturing
- Adaptation of new manufacturing condition
- Antigen production



- Delivery system establishment
- · Vaccines formulation development
- Manufacturing for safety studies



- Upscale manufacturing GMP
- GMP grade product
- Equipment qualification
- Critical analytical assay validation



- Fill & Finish
- Full equipment qualification
- Full analytical assay validation
- Established manufacturing process



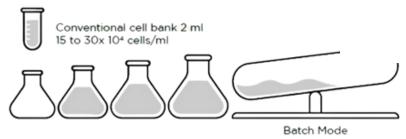
Hilleman's full suite of translational capabilities enable end-to-end product development.

Scale Up

Through our twin engines of development, Hilleman's core capabilities of CMC and preclinical R&D along with our GMP facility provide the unique value proposition of taking assets from early discovery, through to process and product development up to Phase 2 clinical trials and pilot manufacturing,

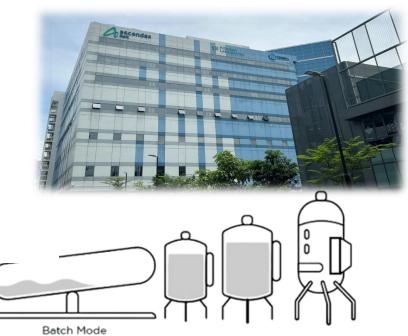
R&D Laboratory for CMC and Preclinical





 Upstream and downstream process development, drug product development, formulation and analytical development for vaccines and biologics

GMP Facility for pilot-scale manufacturing



- 2 Drug Substance suites which can be adapted for mRNA
- 1 pilot-scale Drug Product Formulation and Fill & Finish bench-scale lyophilisation suite







TRAINING AND CAPACITY BUILDING

Technology Transfer Management

Designing Technology Transfer strategies to meet program objectives for Biopharmaceutical and Vaccine manufacturing

Preparing technical and validation documents, memorandum, protocols, reports and summaries for regulatory agency submissions.



Using statistics to analyze data and trends arising from the pharmaceutical manufacturing operations of CMOs.

Support investigations to analyze and troubleshoot deviations in the pharmaceutical manufacturing process.

Liaising with third-party contractors to oversee process technology transfer for clinical vaccine manufacturing to external manufacturers (CMOs).



Singapore Ecosystem





















Hilleman is engaged with Singapore Government:

- Pandemic Preparedness Programme (PREPARE)
- ACES will produce pandemic vaccines for national needs.
- Talent development subsidy and workforce support schemes

Singapore offers strong network of enablers for Hilleman:

- World-class regulatory authority
- Economic development grants
- Wide network of research collaborators
- Rich ecosystem of partners and suppliers



As a key player in the vaccine ecosystem, we drive capability building through training and manpower initiatives to facilitate global access and vaccine equity.



Supported by the Gates Foundation, this is a 2-week programme for DCVMN member companies, offering essential professional exposure and guidance on technical mastery which are crucial during process optimization, development, and transfer.



This is a 12-month internship programme in partnership with Kenya Medical Research Institute (KEMRI) providing 360-degree experience and training in vaccine R&D and GMP manufacturing, intended to develop and expose the African workforce to CMC and GMP activities to build up manufacturing capabilities on the African continent.



A Singapore government-supported initiative, this is a 12-month on-the-job training placement designed to equip biomedical research and academic professionals with the skillset and understanding of best practices for the pharmaceuticals and biotechnology industry, to build a pool of industry-ready talent in the local ecosystem.



Hilleman-DCVMN Training Programme in Technology Transfer: Participating Companies (2022-2023)





THANK YOU

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