

# PSPT Project's Outcomes

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DCVMN

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PSPT Final Meeting



# Introduction

## Whole-cell Pertussis Potency Test

The current pertussis potency test for whole-cell vaccine (wP) is based on the intracerebral mouse protection test as described by Kendrick (1947) or Mouse Protection Test (MPT).

The Kendrick test (KT) is an assay designed to estimate the potency of wP containing vaccines on the basis of their ability to protect mice against intra-cerebral challenge with virulent *Bordetella pertussis* (strain n.18323).

The potency is expressed in International Units (IU) calculated by comparing the effective dose of the test vaccine to the reference vaccine.

# Introduction

## Pertussis Serological Potency Test – History of the Assay

- PSPT described for the first time in 1994 (van der Ark) and assessed in a 2 phase study supported by WHO in 2000 (van der Ark)
  - PSPT is more reproducible while the welfare of the animals would be less compromised and numbers of animals can be reduced by 25%
- Study by European Centre for the Validation of Alternative Methods (ECVAM) in 2008:
  - PSPT-whole-Cell-ELISA (PSPT-wC-ELISA) is a promising approach for batch release potency testing of wP vaccines for which consistency in production has already been demonstrated by the MPT. The study found a good correlation between the potencies estimated by the MPT and the PSPT-wC-ELISA.
- International Collaborative Study promoted by EDQM Biological Standardization Program (BSP-104) aimed to evaluate the transferability and robustness of the guinea pig PSPT selected in the 2008 study and also including the mouse PSPT (data not published)

# Introduction

## DCVMN Pertussis Serological Potency Test Project

The DCVMN Pertussis Serological Potency Test (PSPT) Project was designed as an international **assessment** of a serological assay based on the humoral antibody response (by ELISA) in serum of mice (ms) vaccinated with wP-containing vaccines (final batches).

Funded by



In-kind contribution

DCVMN and PSPT  
Consortium Members

# Objectives of the Project

## DCVMN Pertussis Serological Potency Test Project

1. Produce and characterize the assay-critical reagent.
2. Assess the PSPT as a serological method to determine the potency of the wP vaccine as final lot test: the assay is fit-for-purpose and it is able to discriminate between potent and sub-potent lots.
3. Support manufacturers and national control laboratories to gain trust in new assay and plan full validation study.
  - a) Further product specific validation would lead to local and international regulatory acceptance of the assay
  - b) Assay's implementation will refine animal use (intra-cerebral challenge vs immunization and bleeding), reduce testing repeating and therefore the product final cost.

# PSPT Consortium Members

## Manufacturers and NCLs

### *Manufacturers*



### *National Control Laboratories*







# SERUM INSTITUTE OF INDIA PVT. LTD.



**Dr. Sunil Gairola:**

(Executive Director, PSPT Steering Group member)

Planning, Execution & overall project approval.

**Dr. Yojana Shinde:**

(Deputy Director)

Overall PSPT project supervision.

From Left to Right : (Dr. Arvind, Mr. Anand, Dr. Sunil, Dr. Yojana, Mr. Ritesh)

- 1) **Mr. Anand kumar:** Planning & Execution of KT study
- 2) **Dr. Arvind Ghule** : Planning & Execution of PSPT *in vivo/ in vitro* study
- 3) **Mr. Ritesh Karegaonkar:** ELISA analysis

## Organization Description

- Established during the 'Swadeshi Movement' of India, Biological E. Limited (BE) started during a time when the nation sought access to critical healthcare products. Founded and led by Dr. DVK Raju, Biological E. Limited commenced its operations in 1953 as a biological products company manufacturing liver extracts and anti-coagulants.
- With an objective of transitioning from treating diseases to preventing them, Biological E. Limited launched its Biotechnology Division (now Vaccines and Biologics Division) and commenced large-scale production of DPT vaccines as early as 1962.
- Biological E. Limited continues to evolve as an organisation and currently has four strategic business units: Branded Formulations, Speciality Generic Injectables, Synthetic Biology and Vaccines and Biologics.

## Name and Roles of the Team

Name	Role
K.Srikanth (From left 1 <sup>st</sup> person)	Randomization & arrangement of Animals
S.Ashok (From left 2 <sup>nd</sup> person)	Bleeding & Sera separation
M.Mahesh (From left 3 <sup>rd</sup> person)	Bleeding & Sera separation
D.V.Rakesh (From left 4 <sup>th</sup> person)	Planning, calculations & Result comparisons)
Dr.Pradip Kumar Das (From left 5 <sup>th</sup> person)	Planning & Scientific In-charge for PSPT studies
Dr. Swapnil (From left 6 <sup>th</sup> person) Dr. Naveen (From left 8 <sup>th</sup> person)	Animal health certification, Postmortem & ELISA part
B.Venu gopal (From left 7 <sup>th</sup> person)	Randomization & Immunization to the animals

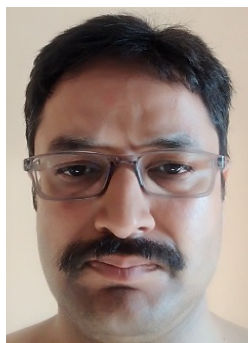




## TEAM MEMBERS WITH FUNCTIONS:



**Mr. Gopal Singh (Approver) Associate Vice President  
Head of Department (Quality Control)**



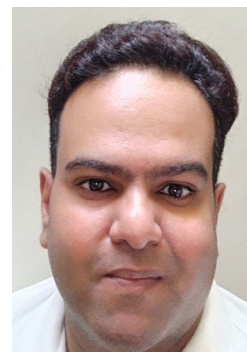
**Mr. Gurbaksh Singh  
(Reviewer)  
Senior Manager QC**



**Dr. Brunda Ganneru  
(Reviewer)  
Senior Manager QC**



**Mr. Ganesh Dubey  
(Supervisor)  
Manager QC**



**Dr. Tarun  
(Analyst)  
Executive QC**



**Ms. Neha Kumari  
(Analyst)  
Trainee QC**



## Details of Organization :

Panacea Biotech Limited, VFP-Baddi, Solan (H.P.)-173205, India

## Details of Core Team :

- *Mr. Deepak Mahajan -GM, QA*
- *Dr. Maya Ramdas- DGM, QC*
- *Mr. Yashpal Kaushik- GM, QC*
- *Dr. Bonny Sharma- Manager, Animal House*
- *Ms. Rashmi Saini- Manager, QC*



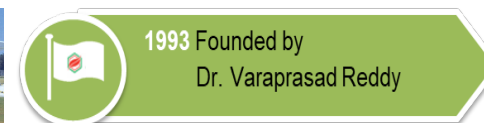
Deepak Mahajan,



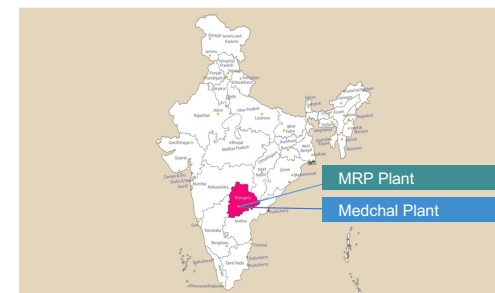
Maya Ramdas, Bonny Sharma, Yashpal Kaushik, Rashmi Saini



# Sanofi Healthcare India Private Limited



- ⇒ Shantha Biotech was the first Indian company to develop, manufacture and market a recombinant human healthcare product in India
- ⇒ Spread across 22 acres (Medchal) and 40 acres (MRP) area
- ⇒ Acquired by Sanofi in 2009 & re-named it as Sanofi Healthcare India Private Limited (SHIPL) in 2020



## Product Portfolio



## R&D-MTECH-CMC Team, SHIPL

Sreenivasulu Reddy. B (AnSci)  
Surender Reddy. B (AnSci)  
Sunil Kumar. D (AnSci)  
Srikanth. K (AnSci)  
Devi Sravani. K (AnSci)  
Prasanna Kumar. K (Projects)

## Pipeline Products



## Hepatitis A

## QC Team, SHIPL

Sarvesh. T (In Vivo)  
Veerababu. K (In Vivo)  
Shiva Krishna. Y (In Vivo)



CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

CENTRAL DRUGS LABORATORY, KASAULI



## TEAM CDL

**Dr. Arun Bhardwaj**



**Mr. Sushil Kumar Sahu**



**Dr. Vivek Bansal**



**Miss Suchita Sharma**







**Name of the company** : PT Bio Farma (Persero)  
**Head of institution** : Honesti Basyir  
**Country** : Indonesia

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### Overview of the company

Bio Farma focuses on research, development, production, marketing and distribution of biological and pharmaceutical products both nationally and globally.

Playing an important role to establish a healthy nation in which its existence would be maintained for generations to come. With our philosophy of being “Dedicated to improve Quality of Life”.

### PSPT Project Team Bacterial Vaccine Quality Control Department



**Irma Riyanti**



**Erti Resnawati**



**Dewi Dahlia Y**



# NQCLDF OF INDONESIA

Is a laboratory under the  
INDONESIAN FDA which is in  
charge of technical policy making,  
implementation, monitoring,  
evaluation, and reporting the  
testing and method development  
to ensure the quality of drugs and  
food pre and post market.  
As a part of NRAs, we responsible  
for laboratory access & testing  
and lot release function for  
vaccine products

## THE TEAM OF PSPT PROJECT

Anissa Wari Murti  
Supervisor

Zulfa Noerhidayati  
Analyst

Ratih Pujilestari  
Reviewer



Keti Yuliani  
Analyst

Dewi Sulanjari  
Section Head

E Ika Prawahju  
Project Leader

M Erdiansyah  
Analyst

# BULBIO NCIPD – ORGANIZATION AND TEAM



## ■ Organization

- BB-NCIPD Ltd. is a trade company, 100% state-owned, headed by the Ministry of Health, with more than 140 years of history
- More than 500 products for the prophylaxis, diagnosis and treatment of the infectious diseases
- BB-NCIPD Ltd. is prequalified by WHO as a supplier for UNICEF and PAHO and the vaccines produced are exported in more than 140 countries in the world
- Vaccines: BCG, Tetatox (Tetanus vacc.), Diftet and Tetadif (Diphtheria and Tetanus vacc.), DTP

## ■ PSPT Team

- Pavel – Head of QC
- Saveta – Head of R&D, Team Lead
- Viktor – Biologist

# Institute of Biological Products (IBP), Department of Medical Sciences, Thailand

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- IBP is the National Control Laboratory for Biological Products, mainly responsible for
  - quality control and assuring the quality of biological products used in the country,
  - preparing of national standard for quality control of biological products,
  - testing researching and developing on knowledge and technology of biological product laboratory,
  - developing and standardizing laboratory testing system for vaccines and other biological products used for control, prevention and treatment of human diseases.



# สถาบันชีววัตถุ INSTITUTE OF BIOLOGICAL PRODUCTS



# PSPT Project

## Steering Group



Christina von Hunolstein  
Istituto Superiore di Sanità, Italy



Arjen Sloots  
Intravacc, The Netherland



Tim Schofield  
CMC Science, USA



# PSPT Project

## Steering Group



Sunil Gairola  
Serum Institute of India, India



Irma Riyanti  
BioFarma, Indonesia



Valentina Salvati  
Istituto Superiore di Sanità, Italy

# PSPT Project

## Steering Group



Pavlinka Stoyanova  
Bulgarian Drug Agency (BDA), Bulgaria



Ute Roskopf  
World Health Organization, Switzerland



Coenraad Hendriksen  
Emeritus Professor, The Netherland

# PSPT Project

## DCVMN



Laura Viviani



Sivashen Cunden



Sonia Pagliusi



Perna Kumar

Thank you to NIIMBL Team: Namrata Raman, James Saylor, Peggy Thomas  
Thank to Bill & Melinda Gates Foundation: Gautam Sanyal

# Thank you!

For more information

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