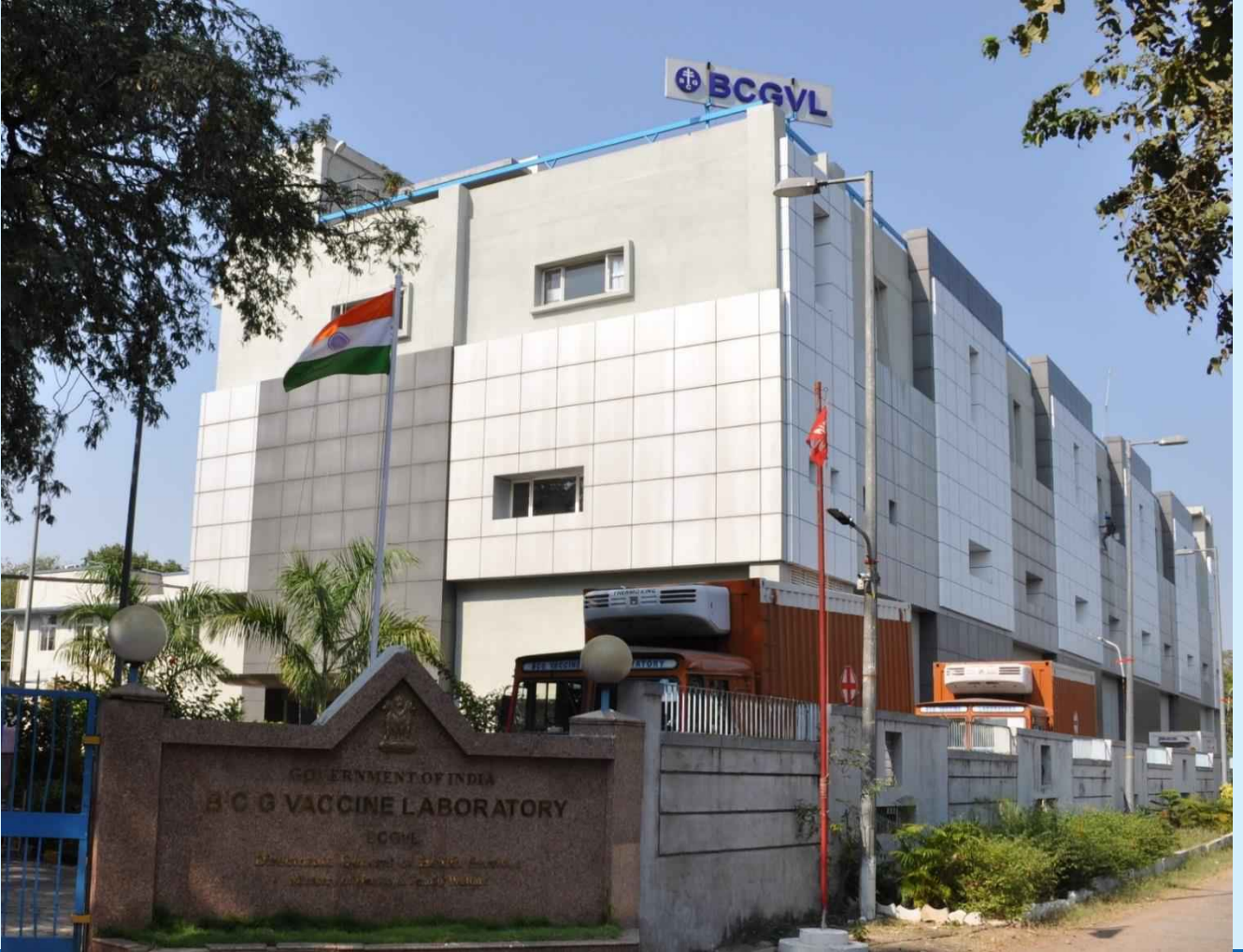


பிசிஜி தடுப்பூசி ஆய்வகம், சென்னை  
बीसीजी वैक्सीन प्रयोगशाला, चेन्नई  
BCG Vaccine Laboratory, Chennai



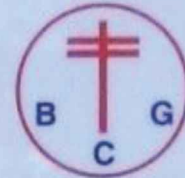
## cGMP Compliant Vaccine Manufacturing facility



75  
Azadi Ka  
Amrit Mahotsav

Annual Report  
2021 -2022

## Quality Statement



# BCG VACCINE LABORATORY

GUINDY, CHENNAI - 600032.

## QUALITY STATEMENT

BCG Vaccine Laboratory will continuously and consistently thrive to produce BCG vaccine, both, in quality and quantity as required for immunization of children against tuberculosis, with compliance of all relevant national regulations associated with vaccine manufacture.

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## डॉ. नवीन कुमार गुप्ता, एम.डी.

एम.बी.बी.एस. (यूसीएमएस, दिल्ली), एम.डी. सूक्ष्मजीवविज्ञान (एमएमसी, दिल्ली)  
पूर्व अध्येता संक्रामक रोग (पीडीएचएनएच, मुंबई)  
विशेषज्ञता: सूक्ष्मजीवविज्ञान, संक्रामक रोग, पशुजन्यरोग, वैक्सीनॉलजी

### Dr. NAVEEN KUMAR GUPTA, M.D.

MBBS (UCMS, Delhi), MD Microbiology (MAMC, Delhi)  
Ex-Fellow Infectious Diseases (PDHNP, Mumbai)  
Expertise : Microbiology, Infectious Diseases, Zoonoses, Vaccinology



## निदेशक

बी.सी.जी. वैक्सीन प्रयोगशाला  
भारत सरकार  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
स्वास्थ्य सेवा महानिदेशालय

### DIRECTOR

### BCG VACCINE LABORATORY

Government of India  
Ministry of Health & Family Welfare  
Directorate General of Health Services

Ex-Head, Centre for Arboviral & Zoonotic Diseases, National Centres for Disease Control, Delhi - 110 054

Ex-Head, NSEC, RRC, DR Lab, DPT Vaccine, Central Research Institute, Kasauli, Himachal Pradesh

## Director's Message

Greetings from BCG Vaccine Laboratory, Chennai

I assumed charge as Director of BCGVL on 19<sup>th</sup> January 2021. It gives me an immense pleasure in bringing out the Annual Report of BCGVL for the year 2021-22.

The production of commercial batches from the cGMP compliant facility was initiated in December 2019 and BCGVL has supplied 170 lakh doses to 15 consignees all over India from July 2020 to March 2021 for Universal Immunisation Programme (UIP) for the Financial Year 2020-21. For the Financial Year 2021-22, BCGVL has supplied 196.9 lakh doses to 24 consignees all over India till 31.03.2022 for UIP.

I take this opportunity to acknowledge the co-operation, hard work and diligence of all the members of BCGVL family and extend my thanks to Directorate General Health Services and Ministry of Health and Family Welfare for their continued support, guidance and encouragement to make BCGVL as current Good Manufacturing Practices (cGMP) compliant state of art facility for production of BCG vaccine at par with National and International Vaccine production Institutes in terms of quality by design and technology with World Class Quality Control and Quality Assurance protocols. It is also an opportunity for me to lead this premier organization by ensuring vaccine production and supply to make Universal Immunisation Programme a great success in India.

*Naveen*  
18/6/22

Dr.Naveen Kumar Gupta  
Director, BCGVL



## PREFACE

BCG Vaccine Laboratory, Chennai is a sub-ordinate office of the Directorate General of Health Services (DGHS) under the Ministry of Health and Family Welfare, Government of India. It was established on 1st May, 1948 with the assistance of Staten's Serum Institute (SSI), Copenhagen, Denmark.

The mandates of this Laboratory are:

To manufacture and supply of freeze dried BCG Vaccine to Universal Immunization Programme (UIP) of the Government of India for the control of Childhood Tuberculosis.

The BCG-DANISH-1331 seed strain, which is being used at BCGVL, was initially obtained from Staten's Serum Institute (SSI) Copenhagen, Denmark through World Health Organization (WHO) for production of liquid BCG Vaccine. Until the year 1973, liquid form of BCG vaccine was manufactured at BCGVL. Later this lab has switched over to freeze dried form in ampoules. Subsequently, the production of BCG vaccine was changed from ampoules to vials as 10 doses/vial from 2000-2001 onwards. This Laboratory has also been involved in manufacturing of BCG Cancer Immuno-therapeutic (40 mg/ml) for use in Urinary bladder cancer therapy since 1993.

## LIST OF STAFF

Sl.No	Designation	Name (Shri/Smt)
1	Director	Dr.Naveen Kumar Gupta
2	Consultant (Micro)	Dr.B.Sekar
3	Chief Medical Officer (SAG)	Dr. Hassan Thuddathifanuge
	<b>GROUP-B (Gazetted)</b>	
4	Veterinarian	Dr. S.Anand
	Administrative Officer	A.Krishna Kumar
5	<b>Group-B (Non-Gazetted)</b>	
6	E&MSupervisor	R.Anandan Padvi Shirish Bapu
7	Asst. Technical Officer	K.Ekambaram M.R.Jayanthi
8	Junior Statistical Officer	S.Andrew
	<b>GROUP-C</b>	
9	Office Superintendent	V.Indra
10	Animal Supervisor	B.Ananthi
11	Technical Supervisor	R. Balaje M.G.Rajasekhar A.Revathi P. Sasikala K.Raji S.Sudhendhira Devi D.Hema V.Nalina Jancy
12	Scientific Assistant	S.Rajalakshmi Md.Ayoob T.S.Karthigai S.Malathy M.Pushparani G.Ravisankar S.Harini Priyaadarshini
13	Senior Lab. Assistant	P.Saravana Kumar A.Sheshalakshmi V.Balakrishnan K.Gunasekaran
14	Laboratory Assistant	A.Titus SengolRaj M.Krishnan C.K.Venkatesan M.P.Natarajan A.Arulmadhan

Sl.No	Designation	Name (Shri/Smt)
15	Technician	R.Narayanan D.Selvam
16	Mechanic	K.K.Joseph L.Kathirvel M.Suresh V.R.Jagadish Suri J.Dhandapani A.Murali
17	Assistant Mechanic	S.Mohan
18	Upper Division Clerk	G.Vijay T.Vairavel M.Jayashankar D.Joycemani
19	Storekeeper	M.K. Gurumurthy
20	Lower Division Clerk	R.Gopi T.Babu
21	Motor Driver	L.Agasthiyar B.Sathiyadass
22	Carpenter	J.Ciril Raj
23	Lab. Attendant	M.Madhavan B. Kumar A.S.Khumar R.Sampath A.Suriyakala V.Kathiravan L.Chithra E.Senthil Kumar K.Babu V. Kennedy R.Madanagopal D.B.Sase Kumar M. Samy Kumar J. Mahalakshmi Kumar Natwar Singh M. Elumalai K. Selvaraghu R.Panchavarnam T.VenkatesaLal Bahadur V.Kannan
24	Multi-Tasking Staff	K.Umar Ali B. Jayakumar G. Vidya Bharathi



## List of Committees

### 1. Departmental Screening Committee

S.No	List of Officers/ Officials	Designation
1	Dr Hassan Thuddathifamuge, CMO(SAG)	Chairman
2	Dr S Anand, Veterinarian	Member
3	Shri A Krishna Kumar, AO	Member

### 2. RR committee for Group C posts

S.No	List of Officers/ Officials	Designation
1	Dr Hassan Thuddathifamuge, CMO(SAG)	Chairman
2	Dr S Anand, Veterinarian	Member
3	Shri A Krishna Kumar, AO	Member
4	Shri R Anandan, EMS	Member
5	Shri Padvi Shirish Babu, EMS	Member
6	Shri K Ekambaram, ATO	Member
7	Shri R Balaje, TS	Member
8	Smt V Indra, Office Superintendant	Member
9	Shri G Vijay, UDC	Member
10	Shri P Chandrasekaran, Lab Assistant	Member

### 3. RR committee for Group A & B posts

S.No	List of Officers/ Officials	Designation
1	Dr B Sekar, Consultant	Chairman
2	Dr Hassan Thuddathifamuge, CMO(SAG)	Member
3	Dr S Anand, Veterinarian	Member
4	Shri A Krishna Kumar, AO	Member

### 4. Purchase committee

S.No	List of Officers/ Officials	Designation
1	Dr Hassan Thuddathifamuge, CMO(SAG)	Chairman
2	Dr S Anand, Veterinarian	Member/ Co - Chairman
3	Shri A Krishna Kumar, AO	Member
4	Shri R Anandan, EMS or Shri K Ekambaram, ATO	Member
5	Shri M.K Gurumurthy, Store Keeper or Shri T Vairavel, UDC	Member

### 5. Preventive Vigilance Committee

S.No	List of Officers/ Officials	Designation
1	Shri A Krishna Kumar, AO	Member
2	Smt V Indra, Office Superintendant	Member
3	Shri G Vijay, UDC	Member
4	Shri M Jayshankar, UDC	Member

## 6. Estate Committee

S.No	List of Officers/ Officials	Designation
1	Dr B Sekar, Consultant	Chairman
2	Dr S Anand, Veterinarian	Member
3	Shri A Krishna Kumar, AO	Member
4	Smt V Indra, Office Superintendant	Member

## 7. Technical Committee

S.No	List of Officers/ Officials	Designation
1	Dr B Sekar, Consultant	Chairman
2	Dr S Anand, Veterinarian	Member
3	Shri R Anandan, EMS	Member
4	Shri Ekambaram, ATO	Member
5	Smt M R Jayanthi, ATO	Member
6	Shri S. Andrew, JSO	Member
7	Shri R Balaje, TS	Member

## 8. Complaints committee for prevention of sexual harassment of working women at workplace

S.No	List of Officers/ Officials	Designation
1	Dr S Amudhavalli, Dy Director, KIPM&R	Chairperson
2	Dr S Anand, Veterinarian	Member
3	Shri A Krishna Kumar, AO	Member
4	Smt V Indra, Office Superintendant	Member
5	Smt M R Jayanthi, Assistant Technical Officer	Member
6	Smt A Revathi, Technical Supervisor	Member
7	Ms D Joyce Mani, UDC	Member

## 9. Civil/ Electrical Committee

S.No	List of Officers/ Officials	Designation
1	Dr TF Hassan, CMO(SAG)	Chairman
2	Dr S Anand, Veterinarian	Member
3	Shri A Krishna Kumar, AO	Member
4	Shri R Anandan, EMS	Member
5	Shri Ekambaram, ATO	Member
6	Shri R Balaje, TS	Member

**10. Cadre Review Committee**

S.No	List of Officers/ Officials	Designation
1	Dr B Sekar, Consultant	Chairman
2	Dr TF Hassan, CMO(SAG)	Member
3	Dr S Anand, Veterinarian	Member
4	Shri A Krishna Kumar, AO	Member Secretary
5	Shri K Ekambaram, ATO	Member
6	Shri R Balaje, TS	Member
7	Shri V Kennedy, Laboratory Peon	Nominated members by Office Council (Staff Side)
8	Shri Padvi Shirish Babu, EMS	

**11. Condemnation Committee**

S.No	List of Officers/ Officials	Designation
1	Shri A Krishna Kumar, AO	Chairman
2	Shri R Anandan, EMS	Member
3	Shri K Ekambaram, ATO	Member
4	Shri R Narayanan, Technician	Member
5	Shri R Balaje, TS	Member
6	Shri M K Gurumurthy, Store Keeper	Member

**12. Transport Committee**

S.No	List of Officers/ Officials	Designation
1	Shri R Anandan, EMS	Chairman
2	Shri D Selvam, Technician	Member
3	Shri M Suresh	Member
4	Shri L Agasthiyar/Shri B Sathiyadoss, Motor Driver	Member

**13. Annual Report Committee**

S.No	List of Officers/ Officials	Designation
1	Dr TF Hassan, CMO(SAG)	Chairman
2	Dr S Anand, Veterinarian	Member
3	ShriS Andrew, JSO	Member
4	Shri R Balaje, TS	Member

## FOUNDERS OF BCG VACCINE



**Dr. Albert Calmette**

**1863-1933**



**Dr. Camille Guérin**

**1872-1961**

### *History of BCG Vaccine*

In 1900 Albert Calmette and Camille Guérin began their research for an antituberculosis vaccine at the Pasteur Institute in Lille. They cultivated tubercle bacilli on a glycerin and potato medium but found it difficult to produce a homogeneous suspension of the bacilli. In an attempt to counteract their tendency to clump they tried the effect of adding ox bile to the medium and, to their surprise, they noted that subculture led to a lowering of the virulence of the organism. It was this fortuitous observation that led them to undertake their long term project of producing a vaccine from this attenuated tubercle bacillus.

In 1908, starting with a virulent bovine strain of tubercle bacillus supplied by Nocard (originally isolated by him in 1902 from the udder of a tuberculous cow), they cultured it on their bile, glycerine and potato medium and then proceeded to subculture at roughly three weekly intervals. By 1913 they were prepared to initiate a vaccination trial in cattle which was interrupted by outbreak of World War I. Subculturing was continued throughout the German occupation of Lille, despite the greatly increased cost of potatoes and the difficulty of obtaining suitable ox bile from the abattoir. Yet, they managed to obtain this by grace of the veterinary surgeons of the German occupying force. By 1919, after about 230 subcultures carried out during the previous 11 years, they had a tubercle bacillus which failed to produce progressive tuberculosis when injected into guinea pigs, rabbits, cattle, or horses. At Guérin's suggestion, they named it Bacille Bilie Calmette-Guérin; later they omitted "Bilie" and so BCG was born.

BCGVL History Source : <https://www.ncbi.nlm.nih.gov>

## Brief History of BCGVL

### Pioneers

1	Dr.Paul Lind	Statens Serum Institute Copenhagen, Denmark,Consultant
2	Dr.K.S.Ranganathan	Director
3	Shri A.V.Oommen	Assistant Bacteriologist
4	Shri Mohan Rao	Laboratory Assistant
5	Shri P.K.Mukundan	Laboratory Assistant
6	Shri A.Subramani	Laboratory Peon
7	Shri James Dorairaj	Laboratory Peon
8	Kum. Pramila	Lower Division Clerk

### Important Milestones

1948	Laboratory for production of BCG Vaccine was built by Government of India at King Institute, Guindy, Madras, with assistance from UNICEF and a center for vaccination was also opened
1972	BCG vaccine was supplied in ampoules in liquid form.
1973	Introduced production of BCG Vaccine Freeze Dried form (50 doses/ampoule)
1982	Introduced BCG Vaccine in 20 doses/ampoule
1995	Prepared the Manufacturers working seed lot
2001	Changed BCG Vaccine from ampoules to vials.
2019	Initiated manufacturing of Commercial batches of BCG Vaccine in new cGMP facility.
2020	Initiated the supply of BCG Vaccine from new cGMP facility to Universal Immunization Programme, Government of India.



**List of Directors of BCGVL**

Sl.No.	Name	From	To
1.	Dr.K.S.Ranganathan	01.05.48	02.06.57
2.	Dr.C.B.D'silva	03.06.59	28.10.66
3.	Dr.J.C.Suri	28.07.67	26.06.71
4.	Dr.K.P.Rao	10.09.71	30.01.82
5.	Dr.S.Basu	10.11.82	31.05.93
6.	Dr.M. Jayasheela	30.06.93	06.11.98
7.	Dr.N. Elangeswaran	11.11.98	31.07.08
8.	Dr.C.H.D. Vinodkumar (I/C)	31.07.08	26.07.09
9.	Dr. Usha Soren Singh	27.07.09	30.04.12
10.	Dr. H.G. Bramhne	24.05.12	27.07.18
11.	Dr. B.Sekar	04.08.18	04.03.20
12.	Dr.T.F.Hassan (Addl Charge)	11.03.20	16.08.20
13.	Dr.V.K.Chadha (Addl Charge)	17.08.20	27.09.20 (FN)
14.	Dr.S.Uma Shankar (Addl Charge)	27.09.20 (AN)	18.01.2021
15.	Dr.Naveen Kumar Gupta	19.01.21	Present

## **Establishment of cGMP facility for Manufacturing BCG Vaccine**

- ★ As part of revival project a new cGMP facility for manufacturing BCG Vaccine was made and handed over in March 2016 through M/s HLL (Project management consultant) at the sanctioned project cost of Rupees 64.70 crores.
- ★ BCGVL undertaken production of trial batch and successfully completed consistency batch production of BCG Vaccine in June 2018.
- ★ Joint inspection by Regulatory Authorities for the grant of manufacture and sale license was carried out in the month of September 2018.
- ★ Manufacture and sale Licence (Commercial Licence) was granted in October 2019.
- ★ Manufacturing of Commercial batches of BCG Vaccine was initiated in Dec 2019.
- ★ BCGVL initiated the supply of BCG Vaccine to Universal Immunization Programme, Government of India in the month of July 2020 as committed.
- ★ BCGVL had committed to supply 170.0 lakh doses for FY 2020 -21. Out of which BCGVL successfully completed supply of 161.45 lakh doses (95%) to 15 consignees spread over 9 states within the time schedule in the midst of prevailing COVID situation for the Financial year 2020-21.
- ★ Supply of 8.55 (5%) Lakhs doses were deferred on the request of the consignee and the same was supplied in August 2021.
- ★ For the FY 2021-22, BCGVL has committed to supply 270 lakh doses to Universal Immunization Programme, Government of India. 196.9 lakh doses were supplied and the remaining to be supplied by June 2022 as per the revised consignee list.

## Administration Section

### List of Staff in Administration and Accounts Section

S.NO	NAME (Sri/Smt)	DESIGNATION
1	A. Krishna Kumar	AO
2	V. Indra	OS
3	G. Vijay	UDC
4	M. Jayasankar	UDC
5	D. Joycemani	UDC
6	R. Gopi	LDC
7	T. Babu	LDC
8	L. Agasthiyar	MOTOR DRIVER
9	B. Sathiyadoss	MOTOR DRIVER
10	G. Vidya Bharathi	MTS

### Court Cases

Number of cases handled in CAT, Chennai	13
Number of cases handled in High Court of Madras	07
Total	20
Less: Number of cases settled during 01.04.2021 to 31.03.2022	01 ( High Court of Madras)
Total Number of cases pending as on 31.03.2022	19 (13 in CAT + 6 in HC)

### List of Minor works carried out by CPWD and their estimates for the period from 31.03.2021 to 31.03.2022

Sl.No	Minor Works	Estimate
1	Maintenance of Electrical Installations etc in BCG Staff Quarters	Rs. 14,94,972/
2	Providing Aluminum partition cabin inside the Lyo Technical area in BCGVL office	Rs. 1,83,000/
3	Renovation of Type V (13/1) quarters Civil Works	Rs.21,29,700
4	Day today maintenance & annual repair works of civil nature in BCGVL office	Rs. 6,13,700

### Budget (BE and RE) as on 31.03.2020 and 31.03.2021

As On	B.E.	R.E.
31.03.2020	210,300,000	210,600,000
31.03.2021	205,700,000	234,900,000

### Revenue generated by supply of vaccine to various consignees

★ Doses Supplied: 19,69,000 vials X 10 doses = 196.90 lakh doses

Revenue Generated in FY 2021-22

★ 196,90,000 (Dose supplied) X Rs.5.89 (price per dose) = Rs.11,59,74,100/

## PRODUCTION SECTION

### Facility Description

The manufacturing block is an independent cGMP facility dedicated only for manufacturing of BCG Vaccine. The block consists of ground plus two floors, in which the upstream process is done in the first floor (Media preparation, Culture propagation, Harvesting and Final bulk preparation), downstream process in the ground floor (Containerization, Vial inspection and labeling). The required classification is maintained by the HVAC system controlled by BMS.

All the critical process of manufacturing are carried out in the Biosafety level 2 area (Grade A) with background of Grade B classification. Starting from seed Revival to preparation of final bulk is to be undertaken in the first floor of the cGMP compliant manufacturing facility. The production facility is well equipped with all essential machine /equipment. The equipment are validated as per Master Validation Plan. The manufacturing process is undertaken as per the Master Formula Record following the required protocols and SOP's. Every stage of the production is recorded in the Batch Manufacturing Record.

The upstream process comprises of Material arranging & sterilization, Media preparation, Propagation, Harvesting and preparation of Final bulk. The upstream facility has dedicated glassware washing and garment washing in first floor backside. In media preparation the following media are prepared.

#### Growth Media

1. Sauton potato
2. Sauton medium

#### Buffer

1. Phosphate Buffer

#### Stabilizer

1. 1.5% Mono sodium glutamate

## UPSTREAM PROCESS

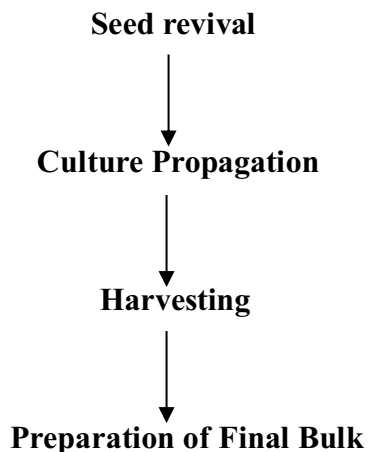
**Seed revival:** The BCG Seed lot MWSL (Danish1331) is revived in sauton potato medium. The inoculated tubes are incubated at 37 °C for 21 days.

**Propagation:** Production involves three stages of subculture. The revived culture is transferred to sauton potato medium incubated at 37 °C for 14 days, then to sauton liquid medium (100 ml) in conical flask, incubated at 37 °C for 7 days and then to sauton liquid medium (200 ml) in tuberculin flask, incubated at 37 °C for 7 days.

**Harvesting** After the incubation period, the culture grown in tuberculin flask are harvested using Birkaugh's apparatus, the wet cake is weighed, homogenized using BCG Mill. The cake is diluted using mono sodium glutamate 1.5% and made to 40mg/ml suspension. The individual culture suspension is aspirated and stored at -28°C. This is intermediate bulk. The in process sterility on the intermediate bulk is performed.

**Final Bulk:** The suspension passing the in-process sterility is pooled and diluted to 10mg/ml using stabilizer 1.5% w/v mono sodium glutamate. This is the final bulk which is given to filling section for containerization.

## Flow chart of Upstream Process



## Training/workshop/Seminar/Conference undergone from 31.03.2021 to 31.03.2022

Production department SOP Oral training for General, Operation, Cleaning & Calibration procedure given to all the staff of the production department.

## Activities performed from April 2021 to March 2022 in production department.

- Seed revival was performed four times on 19/05/2021, 09/08/2021, 01/11/2021 & 27.01.2022.
- Total number of subculture made was 104
- Total number of Harvesting made was 58
- Total volume of 40 mg/ml suspension made was 1,71,754 litres
- Total number of pooling made was 58
- Total volume of 10mg/ml suspension given to containerisation was 5,54,420 litres
- Total volume of Sauton media prepared was 701 litres
- Total volume of Mono sodium L glutamate prepared was 710 litres
- Total volume of phosphate buffer prepared was 295 litres



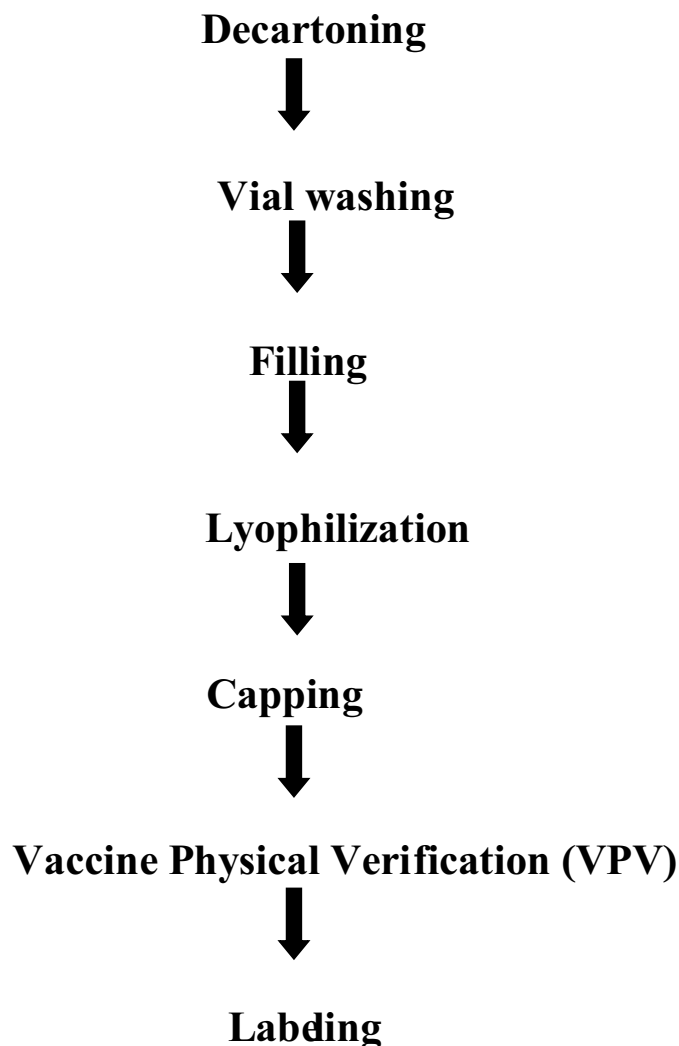
**List of Staff in Production and Containerization**

S.NO	NAME(Sri./Smt.)	DESIGNATION
1	K. Ekambaram	A.T.O
2	P. Sasikala	T.S
3	K. Raji	T.S
4	S. Sudhendiradevi	T.S
5	V. Nalina Jancy	T.S
6	S. Rajalakshmi	SCI.ASSISTANT
7	M. Pushparani	SCI.ASSISTANT
8	G. Ravishankar	SCI.ASSISTANT
9	Harini Priyadharshini	SCI.ASSISTANT
10	K. Gunasekaran	S.L.A
11	A.Titus Sengolraj	LAB.ASSISTANT
12	M. P. Natarajan	LAB.ASSISTANT
13	A. Arulmadhan	LAB.ASSISTANT
14	P. Chandrasekaran	LAB.ASSISTANT
15	L. Chithra	LAB.ATTENDANT
16	V. Kennedy	LAB.ATTENDANT
17	R. Madhanagopal	LAB.ATTENDANT
18	D. B. Sasekumar	LAB.ATTENDANT
19	M. Elumalai	LAB.ATTENDANT
20	V. Kannan	LAB.ATTENDANT

## CONTAINERIZATION SECTION

Downstream block is dedicated for the filling of final lots. The GMP facility is about 36,928.51 square feet of functional area with modular panel walls and HVAC system to facilitate clean room environment for the production which encompasses the compliance with schedule M and World Health Organization (WHO). The following functional areas are Vial washing area, Filling area, Capping area, Sterilization area, Vaccine Physical Verification area and Labeling area. The visual inspection of the vials will be carried out with the help of Semi automated vial inspection machine. The inspected vials will be stored in cold storage area.

### FLOW CHART



### DOWNSTREAM PROCESS

#### Online Vial Washing and Depyrogenation

- Required quantity of 2R amber vials are decartoned at the day of vial washing.
- Decartoned vials are arranged in the vial washing machine conveyor for vial washing by using SS trays.
- Inner and outer surface of vials blow by compressed air.
- Inner and outer surface of vials washing by recycled WFI (Water for injection).
- Inner and outer surface of vials washing by fresh WFI.

- Inner and outer surface of vials blow by compressed air.
- Washed vials are arranged in tunnel conveyer and enter in to the Depyrogenation tunnel.
- Vials are depyrogenated at 290°C by depyrogenated tunnel.

## Online Filling

- The final bulk is received from culture section.
- Manifold assemble in online filling machine.
- Sterilized rubber wads have been loaded to hooper.
- Depyrogenated vials are automatically filled and half Stoppered with sterile rubber wads under hanging HEPA filter automatically in the filling station.
- The Half Stoppered vials are collected in SS trays and it is fenced by SS frames and it's loaded in mobile LAF (Laminar air flow chamber) and transferred for loading into lyophilizer.
- After completion of filling the manifold and buffer vessel are disconnected and loaded in decontamination autoclave.

## Online Capping

- Sterile aluminum flip off seals are loaded in hooper.
- Fully Stoppered lyophilized vials are unloaded from lyophilizer.
- Vials are transferred to capping area through mobile LAF and arranged in feeding turn table.
- Vial capping is carried out over the fully stoppered vials with sterile aluminum flip off seals in the vial capping machine under hanging HEPA filter. The capped vials are collected in plastic crates and stored in cold room at -28° C.

## Vaccine Physical Verification

- Examine the vials by visual inspection machine, defective vials are picked and dropped in the rejection bin, thereby passing good vials through the conveyor which are collected in crates.
- Cracked vials, broken vials, empty, sticky, liquid vials, defective capping, low and high volume vials, dust or foreign particles in the vials are rejected, decontaminated and segregated for disposal.

## Labeling and VVM

- Vials are taken from cold room after receiving order from QA for labeling.
- Vials are arranged in SS trays and dried to remove moisture in outside of the vials.
- Respective batch details was uploaded in labeling machine and vials are labeled.

**Doses of BCG Vaccine Produced during the Year 2021-2022**

S.NO.	MONTH	LOT NO.	DOSES IN LAKHS
1.	APRIL 2021	LO75-LO81 (7 lots)	26.7
2.	MAY 2021	LO82-L086 (5 lots)	18.9
3.	JUNE 2021	LO87-LO94 (8 lots)	30.5
4.	JULY 2021	LO95-L101 (7 lots)	26.8
5.	AUGUST 2021	L102-L110 (9 lots)	34.3
6.	SEPTEMBER 2021	L111-L118 (8 lots)	30.1
7.	OCTOBER 2021	L119-L125 (7 lots)	26.7
8.	NOVEMBER 2021	L126-L128 (3 lots)	11.5
9.	DECEMBER 2021	L129	3.8

## PACKING SECTION

List of Staff

S.NO	NAME(Sri./Smt.)	DESIGNATION
1	M.R. Jayanthi	A.T.O
2	MD. Ayooob	SCI.ASSISTANT
3	A. Sheshalakshmi	S.L.A
4	V. Balakrishnan	S.L.A
5	R. Sampath	LAB.ATTENDANT
6	K. Selvaraghu	LAB.ATTENDANT
7	J. Dhandapani	MECHANIC
8	Murali	MECHANIC
9	V.R. Jagadish Suri	MECHANIC
10	J. Cirilraj	CARPENTER
11	K. Umarali	MTS

## Activities Performed

Packed and supplied -- 205.45 Lac Doses to consignees throughout the country by refrigerated truck (8.55 Lakh Doses for the financial year 2020 -2021 and 196.9 Lakh Doses for the year 2021 2022)

## 2. Training

Induction training given to newly appointed contract staff on packing and supply activities and SOP's of the section.

## 3. Specific Achievement

Expandable Polystyrene container was included in the major carton packing material itself as per EPW 2008 Packing Specifications.

Major corrugated boxes have been redesigned so as to accommodate 2000 vials per box instead of 600 vials per box.

Secondary Packing materials such as Inner partition and Minor carton boxes have also been redesigned.

The final Packing is done in such a way that the Consignee can store the vaccine in minor cartons easily in the cold storage without the major carton. During distribution the Vaccine can be transferred from cold storage into the respective major box which has thermocol box inside it.

This method of Packing is of great space saving idea. The utility of existing cold storage space of BCGVL also considerably improved and it also facilitates Vaccine storage at centres to store more quantity of Vaccine. Also, this enabled the more quantity of transportation by refrigerated truck.

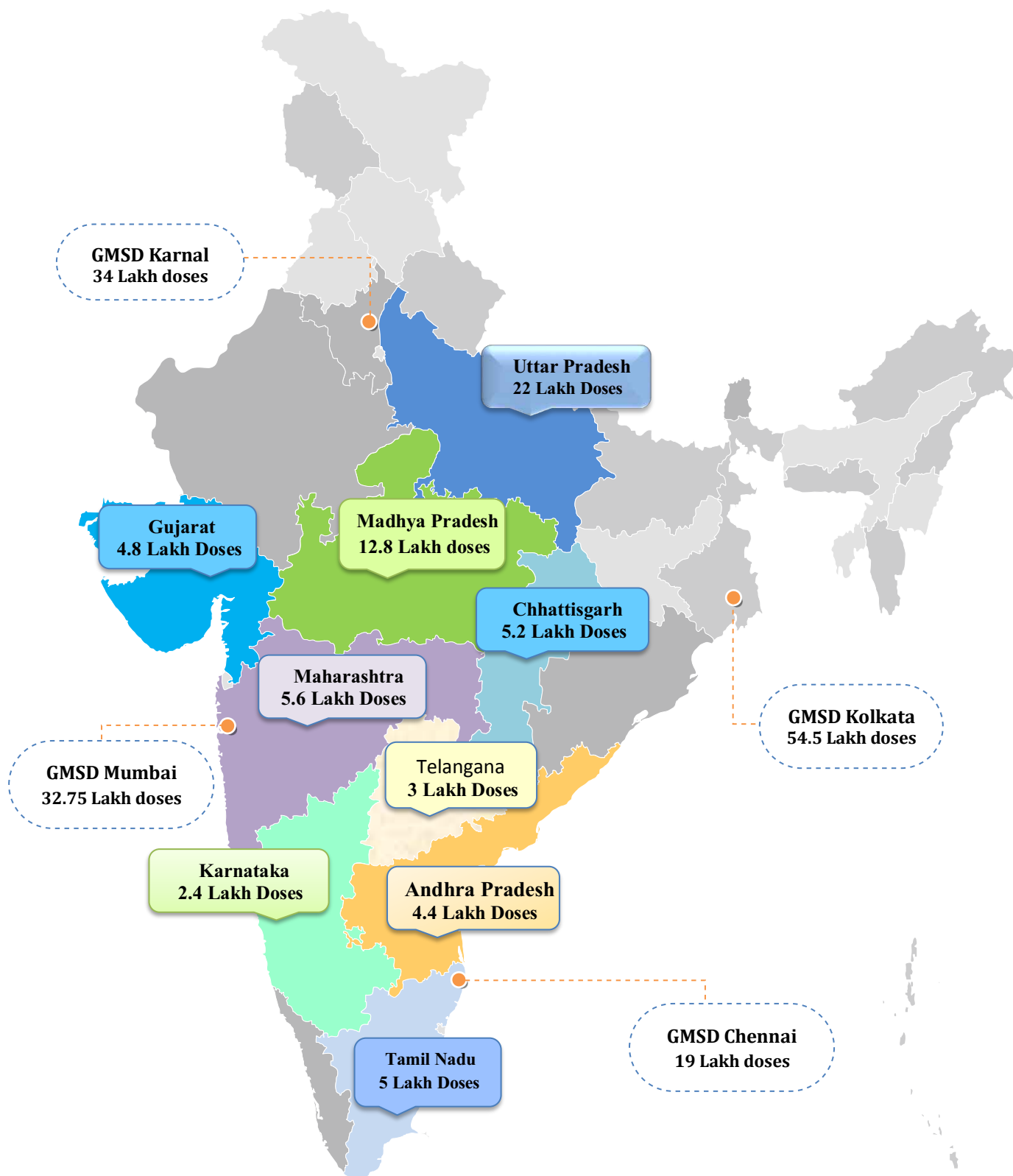


## SUPPLY SECTION

205.45 Lakh doses have been supplied for the Financial Year 2021-22. The details of the consignees and the doses supplied are tabulated as follows:

S.NO.	CONSIGNEE	TOTAL DOSES SUPPLIED
1	GMSD, Chennai	19.0
2	GMSD, Kolkata	54.5
3	GMSD, Karnal	34.0
4	GMSD, Mumbai	32.75 (7.75 lakh doses previous FYsupply)
5	DPH, Chennai	5.0
6	Rajkot, Gujarat	0.4
7	Vadodara, Gujarat	0.8
8	Surat, Gujarat	0.8
9	Gandhinagar, Gujarat	2.8 (0.8 lakh doses previous FY supply)
10	Bhopal, Madhya Pradesh	1.2
11	Indore, Madhya Pradesh	4.0
12	Jabalpur, Madhya Pradesh	5.0
13	Gwalior, Madhya Pradesh	2.6
14	Jhansi, Uttar Pradesh	3.0
15	Agra, Uttar Pradesh	4.0
16	Kanpur, Uttar Pradesh	3.0
17	Lucknow, Uttar Pradesh	4.0
18	Varanasi, Uttar Pradesh	8.0
19	Raipur, Chhattisgarh	5.2
20	Pune, Maharastra	5.6
21	Gannavaram, Andhra Pradesh	4.4
22	Hyderabad, Telangana	3.0
23	Banglore, Karnataka	1.4
24	Belguam, Karnataka	1.0
Total Vaccine doses supplied in FY 2021-22		205.45 lakh doses (196.9 lakh doses for FY 21-22 & 8.55 lakh doses for FY 20-21)

## GMSD and State-wise supply of BCG Vaccine in FY 2021-22



## WAREHOUSE SECTION

List of Staff

S.NO	NAME (Sri/Smt)	DESIGNATION
1	T. Vairavel	UDC
2	M. K. Gurumurthy	STORE KEEPER
3	E. Senthilkumar	LAB.ATTENDANT

**Functions of the Warehouse Section**

The warehouse section procures raw materials, chemicals, equipment, spares, stationery, consumables, clean room materials and furniture. Floating of tenders for procurement, preparation of ranking, conducting technical committee / purchase committee meetings are being performed by the warehouse section. Condemnation of obsolete items. It performs inventory management through online and processes bills for payment on time.

**Activities performed**

1. Purchase, Storage and issue of Chemicals, Raw Materials, Packing Materials, Sticker Labels, Animal Feed, Bedding Material for Lab Animals, Maintenance spares, Consumables and Stationeries with proper documentation.
2. Orders placed through GeM for Annual Requirement of Computer Cartridges and Stationery/Consumables, Air Conditioners, Maintenance Spares such as Cable, LED Street Lights, LED Tube Lights, Battery, etc.
3. Installation of RMG 11 KVA at BCGVL.
4. Procurement of VVM Stickers from M/s. Temptime Corporation, USA and Rubber wads from M/s. West Pharma, Singapore through LC.
5. Printing of Adhesive Tapes with BCGVL Logo
6. Number of Maintenance Contracts awarded :  
Total Annual Maintenance Contracts awarded Equipment 16 + Deployment of Security  
Out of 16 AMCs, GeM Portal- 04 (Computers, Rodent Control, Air conditioners, Hiring of Vehicle)  
Comprehensive Maintenance Contract – 07  
Operations and Maintenance - 04
7. Procurement of Staff Car through GeM
8. Total value of Orders placed through - GeM portal : Rs.50,00,000/  
{Goods - Rs. 31,00,000/- & Service- Rs. 19,30,000/-}
9. Number of Bills processed- 727

## QUALITY ASSURANCE SECTION

List of Staff

S.NO	NAME (Sri/Smt)	DESIGNATION
1	S. Andrew	JSO
2	R. Balaje	T.S
3	M.G. Rajasekhar	T.S
4	S. Malathi	SCI.ASSISTANT
5	P. Saravanakumar	SENIOR.LAB.ASST
6	M. Krishnan	LAB.ASSISTANT
7	R. Panchavarnam	LAB.ATTDT

Quality assurance drafts quality assurance policies and procedures. It plans, conducts and monitors the testing and inspection of materials and products to ensure required product quality.

**Functions of the Section**

It is responsible for the management of documents, SOPs and other protocols. It takes action to investigate complaints and monitors corrective and preventive actions. It supervises validation and calibration of all equipment and instruments. It documents internal audits and monitors risk management activities. It analyses data to identify areas for improvements in the quality system. It monitors temperature maintenance of deep freezers, cold storages and incubators through data logger system. It conducts and organizes training to meet quality standards.

**Inspection of BCG Vaccine Lots**

S.NO	Particulars	No of Occasions
1.	Sample Draw	08 Occasions
2.	Cold room inspection	06 Occasions

**Purchase of VVM roll from USA**

S.NO	Date of Receipt	Quantity
1.	20-Dec-21	22,00,000

**Annual Medical Check-up****Chest X-Ray: For all BCGVL Staff**

- FY 21-22 : 02-Mar-21 to 17-Mar-21

**Standard Operating Procedures**

Section	Total No. of SOPs	Revised in 2021-22	New SOPs in 2021-22
Quality Assurance	55	7	2
Quality Control	75	16	5
Production	43	0	0
Containerization	17	0	1
Laboratory Animal House	19	0	0
Labelling and Packing	13	2	2
Electrical and Maintenance	55	0	0
Warehouse	12	0	1
Total SOPs	289	25	11

**Trainings conducted****One day visit of PG Medical Students from Kings Institute of Preventive Medicine.**

Sl.No	Date	Medical College	No. of students
1	17.09.2021	Thanjavur Medical College	2
2	18.11.2021	Chengelpet Medical College & Melmaruvathur Adhiparasakthi Institute of Medical Sciences	4
3	02.03.2022	Mohan Kumara mangalam Medical College, Salem	4

## List of Equipment procured

Equipment	Quantity
UPS – 3KVA	2
UPS – 2KVA	2

## Details of vaccine produced and supplied

Produced	Supplied
239 lac doses (L067-L129)	205.45 lac doses

## List of Equipment available

S. No.	Equipment	Nos.
1.	HP computer (Windows10) exclusively for data logging with software	1
2.	HP computer (Windows 10) i-7 Processor	1
3.	Acer computer (Windows 7) i- 5 Processor	2
4.	Acer Veriton (Windows 10) i-7 Processor	2
5.	HCL computer (Windows 7) i-3 Processor	1
6.	Server- HP Proliant 350 Gen 10, 2TB Hard disk	1
7.	Toshiba E-Studio 2010 AC photo copier	1
8.	X-Rite Spectro Densitometer	1
9.	Zebra GC420 barcode printer	1
10.	HP laser jet pro printers	2
11.	Canon laser jet colour printer	1
12.	Deep Freezer Sub Zero-( 80 ) Horizontal	1
13.	Deep Freezer Sub Zero-( 80 ) Vertical	1
14.	Deep Freezer Ferminator-( 20 ) chest type	1
15.	Voltas (-20 )	1
16.	Refrigerator LG	1
17.	High frequency vacuum tester	1
18.	Anemometer	1
19.	Non-viable particle counter LASAIR III	1
20.	Non-viable particle counter MetOne	1
21.	Water dispenser Blue star	1

## QUALITY CONTROL SECTION

List of Staff

S.NO		DESIGNATION
1	A. Revathi	T.S
2	D. Hema	T.S
3	T.S. Karthigai	SCI.ASSISTANT
4	C.K.Venkatesan	LAB.ASSISTANT
5	A. Suriyakala	LAB.ASSISTANT
6	V. Kathiravan	LAB.ATTENDANT
7	J. Mahalakshmi	LAB.ATTENDANT
8	M. Samy Kumar	LAB.ATTENDANT

## Activities performed from 31.3.2021 to 31.03.2022

Sl No	Activities	No. of test / Batches
1	<b>Testing of BCG vaccine for batch release</b> <b>The Following tests has been completed for 61 batches</b> a) Identity test b) Sterility test c) Optical Density d) Viability for Bulk e) Thermal stability f) Absence of virulent Mycobacteria g) Excessive Dermal Reactivity h) Water content	549 Tests 305 Tests 61 Batches 61 Batches 122 Times 61 Batches 15 Batches 61 Batches
2	<b>Environmental Monitoring Programme and Personal Monitoring Programme</b> <b>Environmental &amp; Personnel Monitoring were performed and 585 tests reported</b>	
3	<b>Raw material testing</b> a) Water testing Routine Physiochemical tests Fortnightly test were performed and reported.(Physiochemical& Microbiology tests)  b) Primary packaging material 1) 2R Vials 2) Rubber wads 3) Al. Flip offs c) Diluents	Daily 25 tests      13 Batches 07 Batches 04 Batches 37 Batches
4	<b>GrowthPromotion Test for SCDA,FTM &amp; SCDM</b>	58 tests
5	<b>PCR – Test for BCG strain (DANISH 1331) using the RD gene system was performed during this period</b>	10 tests



**Training conducted from 31.3.2021 to 31.03.2022**

In-house Oral & Hands on training sessions given to all and for newly appointed staff on nearly 100 SOP's..

**Future plan**

1. A proposal and plan for establishment of new Microbiology lab facility has been duly forwarded
2. Water testing to be carried out-in house in future for Heavy metals and Nitrates.
3. Testing of Rubber wads as per regulatory guidelines some of the test to be outsourced
  - a) Identification
  - b) Biological test to be outsourced

**List of Equipment procured**

Equipment	Quantity
Refrigerator (Celfrost)	1
Conductivity meter (Labman)	1
Air sampler (Himedia)	4

**Specific achievements for the period from 31.3.2021 to 31.03.2022**

1. Investigation was carried out for the environmental monitoring programme during every activity. The microorganisms were isolated, identified by culture characteristics and biochemical testing.
2. Polymerase Chain reaction (PCR) for BCG using the RD gene system was previously established, further using a single step crude DNA isolation protocol in place of one day protocol for DNA isolation, additionally a colony PCR method was performed which will further improvise the PCR technique.

## List of the Equipment available

Equipment	Types of Equipment	Room Name
Decontamination Autoclave	Process	Washing area / QC-02
Vacuum Cleaner	Moveable	Clean corridor
Autoclave Sterilization	Process	Media preparation / QC-04
Dry Heat Sterilizer	Process	Media preparation / QC-04
Temperature indicator		
Electronic Weighing Balance	Lab	Media preparation / QC-04
Analytical Weighing Balance	Lab	Instrumentation / QC-25
Analytical Weighing Balance	Lab	Instrumentation / QC-25
SS Fumigator	Lab	QC Clean rooms
Motorized stirrer	Lab	Media preparation / QC-04
Laminar Air Flow	Clean Room	Viability room / QC-15
Laminar Air Flow	Clean Room	Viability room / QC-15
Laminar AirFlow	Clean Room	Sterility room / QC-16
Laminar Air Flow	Clean Room	Water testing / QC-26
Bio – Safety Cabinet	Lab	Microbiology Lab/QC-24
Static Pass Box	Clean Room	Autoclave Unloading area-Sterility area
Dynamic Pass box	Clean Room	Washing- Media preparation
Dynamic Pass Box	Clean Room	Clean corridor- Sterility room
Dynamic Pass box	Clean Room	Incubator room- Viability room
Dynamic Pass box	Clean Room	QCT- Clean corridor
Incubator	Storage	Incubator room- QC-19
Incubator	Storage	Documentation/ QC-23
Incubator	Storage	Microbiology Lab/QC-24
Incubator	Storage	Microbiology Lab/QC-24
Incubator	Storage	Microbiology Lab/QC-24
Inspissator	Storage	Inspissator room / QC-20
Water Bath (Electrical)	Lab	Microbiology Lab/QC-24
WaterBath (Electrical)	Lab	Media preparation / QC-04
Fluorescent Microscope	Lab	Microbiology Lab/QC-24
Light Microscope	Lab	Microbiology Lab/QC-24
Light Microscope	Lab	Microbiology Lab/QC-24

Digital Colony Counter	Lab	Microbiology Lab/QC-24
Bioluminocense(Bioluminometer)	Lab	Instrumentation / QC-25
Hot Air Oven	Lab	Microbiology Lab/QC-24
HPLC	Lab	Instrumentation / QC-25
Sonicator	Lab	Instrumentation / QC-25
TOC Analyser	Lab	Instrumentation / QC-25
KF Tritinoplus	Lab	Instrumentation / QC-25
KF Thermoprep	Lab	Instrumentation / QC-25
UV -Vis Spectrophotometer	Lab	Instrumentation / QC-25
Vortex Mixer	Lab	Microbiology Lab/QC-24
pH – Meter	Lab	Water testing / QC-26
pH – Meter	Lab	Media preparation / QC-04
Deep Freezer (100L)	Lab	Microbiology Lab/QC-24
Refrigerator	Lab	Cooling zone / QC-14
Refrigerator	Lab	Cooling zone / QC-15
Refrigerator	Lab	Microbiology Lab/QC-24
Heating Block (Dry Heat Bath)	Lab	Microbiology Lab/QC-24
Temperature indicator		
Cold Room	Storage	Buffer room / QC-07
Temperature indicator		
Refrigerated Centrifuge	Lab	Microbiology Lab/QC-24
Gel Doc system	Lab	Instrumentation / QC-25
Bio Spectrometer	Lab	Instrumentation / QC-25
Agarose Gel Electrophoresis Apparatus	Lab	Instrumentation / QC-25
PCR	Lab	Water testing / QC-26
Conductivity meter	Lab	Water testing / QC-26
Air sampler	Process	Clean rooms
Vacuum Cleaner	Process	Clean rooms
Micro oven	Lab	Water testing / QC-26
Walk-in incubator	Storage	Walk - in incubator room / QC-23

## LABORATORY ANIMAL HOUSE

The laboratory animal house (LAH) facility at BCGVL is a standalone building located inside the premises and markedly distant from the production and other ancillary facilities. The institute is registered with CPCSEA wide Reg.no358/GO/ReRcBi/S/2001/CPCSEA from 19.01.2001 and subsequently renewed its registration, current renewal is valid till 23/08/2026. The animal house is maintained in accordance with the CPCSEA guidelines which are subjected to annual inspection by the respective authorities.

### Routine Performance during the year 2021-22

The laboratory animal house (LAH) facility comprises of Breeding animal house at first floor and Experimental animal house at ground floor. The activities at the breeding animal house include breeding and waning of guinea pigs which is planned to meet the supply of animals for the testing requirement of the production. The activity at experimental animal house involves testing the vaccine for potency and safety in accordance with IP guidelines 2018.

The institute successfully renewed its registration with CPCSEA for a further period of 5 years from 24.08.2021. The IAEC (Institutional Animal Ethics Committee) reconstituted with new members and approved by the CPCSEA monitors the care, welfare, usage of animals and ethical guidelines are strictly adhered with.

Both LAH are maintained with adequate animal and veterinary care 24x7 including holiday and weekend by assigning staff on duty. Exceptional work delivered by the staff of LAH during the lock down implemented as a measure to contain spread of Covid-19 pandemic. IAEC members appreciated LAH staff for their commitment.

The LAH currently houses about 300 breeders of Dunkin Hartley breed of guinea pigs, in deep litter system.

### Staff on Roll as on 31.03.2022

Sl. No	Name	Designation
1	Dr. Anand S	Veterinarian
3	Mrs. B. Anandhi	Animal Supervisor
4	Mr. M. Madhavan	Laboratory Attendant
5	Mr. B. Kumar	
6	Mr. A.S. Kumar	
7	Mr. K. Babu	
8	Mr. Kumar Natwar Singh	
9	Mr. T. Venkatesa Lal Bahadur	
10	Mr. B. Jayakumar	MTS

**Animal stock and usage**

<b>Guinea pigs</b>	<b>2020-21</b>	<b>2021-22</b>
<b>Animal Stock( as on 31st March)</b>	<b>477</b>	<b>716</b>
<b>Births</b>	<b>877</b>	<b>995</b>
<b>Receipts</b>	<b>290</b>	<b>0</b>
<b>Used for Testing</b>	<b>576</b>	<b>426</b>
<b>No of batches tested</b>	<b>96</b>	<b>73</b>

**Meetings/ Inspection conducted**

<b>Name</b>	<b>Duration</b>	<b>Participants</b>
<b>1st IAEC meeting</b>	<b>25.09.2021</b>	<b>CPCSEA nominee and IAEC members</b>
<b>Joint inspection</b>	<b>5<sup>th</sup> -7<sup>th</sup> Oct 2021</b>	<b>State and National regulatory authority</b>
<b>2nd IAEC meeting (Online)</b>	<b>23.02.2022</b>	<b>CPCSEA nominee and IAEC members</b>

**Equipment/ Materials acquired:**

1. Solid floor cages Conventional wire mesh cages in experimental animal house replaced with solid floor polypropylene cages.
2. Proposal for Modification of Breeding Animal House: Under pipeline.

**ENGINEERING AND MAINTENANCE SECTION****List of Staff**

S.NO	NAME (Sri. / Smt.)	DESIGNATION
1	R. Anandan	EMS
2	Padvi Shirish Bapu	EMS
3	R. Narayanan	TECHNICIAN
4	D. Selvam	TECHNICIAN
5	K. K. Joseph	MECHANIC
6	Suresh	MECHANIC
7	L. Kathirvel	MECHANIC
8	S. Mohan	ASST.MECHANIC

**Regular Works**

1. Regular production activities done.
2. Regular maintenance of equipment done.
3. Successfully renewed TNPCB license.
4. Successfully renewed fire license.
5. Successfully renewed IBR Boiler, fire order
6. Successfully renewed electrical safety license (central electrical authority)

**Special Work**

1. Double pole system (11KV) converted to ring main gear (RMG). Successfully installed RMG in BCGVL electrical substation.
2. New building Cladding cleaning work done.
3. BCGVL logo fabricated and fixed.
4. Approach road of BCGVL was cleaned and saplings laid work done.
5. Motorvehicle /cycle shed renovated.
6. Parking area made for BCGVL visitors at the entrance of the campus.

**Future Plans**

1. To install underground Diesel tank.
2. To procure and install stand by Boiler.
3. To procure and install stand by Air compressor

## IBR BOILER (Forbes Marshall)

IBR Boiler (Forbes Marshall) 1.5 Ton capacity: 1 no.

The steam produced by this IBR boiler is being utilised,

- To Produce Pure Steam from Pure Steam Plant for Autoclaves, Sanitation of PW,WFI Vial Washing and Lyophilizer
- To Maintain WFI Hot mode, temperature more than 80°C

## AIR COMPRESSOR (Ingersoll Rand)

Air Compressor (Ingersoll Rand) 8.6 bar capacity:1 no.

This Air Compressor is used to supply dirt free and moisture free air to different pneumatic control valve of the entire facility. This will be in operation continuously round the clock to cater the above.

The list of equipment which requires Air are as follows.

- Water Plant Systems
- Steam Sterilizer
- Dry Heat Sterilizer
- Vial on line Washing and Filling Machine,
- Lyophilizer
- Bio Waste Plant
- Labelling Machine

## ETP/STP (Effluent Treatment Plant/Sewage Treatment Plant)

ETP with Capacity 15 KLD and STP with Capacity-10 KLD

The ETP Plant is operated to treat the effluents and to reclaim the water from the in process water outlets. This process is done by aerating the effluent chamber with fresh air. The treated water is being used for green belt area.

The STP Plant is operated to treat sewage water of BCGVL. This process is done by aerating the sewage chamber with fresh air. The aerobic bacteria survive and decompose the raw sewage and gets deposited

## Water Plants

The following methods are used to treat water which are used at BCGVL.

The following stages of purification being carried out in the water plant at BCGVL.

- Multi Grade Filter Its used to remove large particles of molecules

- **Ultra-Filter-** Its used to remove total suspended solids and silica
- **Softener Plant** It is used to reduce the hardness (Ca & Mg)
- **Reversed Osmosis Plant**to reduce the TDS and conductivity
- **Electro Di Ionisation** to control the conductivity and pH < 7.0
- **Pure Water MCDP & WFI** Used to produce Media Preparation etc.
- **Pure Steam Generation Plant**It caters to sterilizers and Lyophilizers.
- **WFI Generation Plant**-It caters vial washing and used in some of the production processes.

## Power Generator

The following powers installation are installed in BCGVL substation

- 1025 KVA RMG power supply.
- 600 KVA gensets 2 nos
- 380 KVA gensets 1 no.

During TNEB Power failure or shut down, the above Generator will be operated.

## HVAC System (Heat Ventilation Air-Conditioning)

The Chiller Plant, Brine Chiller Plant and HVAC system controlled and monitored using Building Management System in new facility.

Chiller Plant is used to cool water in the water chiller plants. Then this chilled water will be circulated to AHU/ HVAC system.

AIR HANDLING UNIT(AHU) is one of the most important equipment in HVAC (heating, ventilation, and airconditioning) system in BCGVL new facility for providing both heating and cooling for multiple rooms.

In BCGVL 16 nos of Air Handling Units are in use,

Out of which Treated Fresh Air units are 3 nos and Ventilated Unit System are 4nos.

Brine Chiller Plant is used cool the Brine solution and this chilled brine solution is circulated in AHU which will maintain the temperature in clean cold room. This cold rooms is being used to store in process goods at a controlled temperature.



## List of Equipment

### In Seed Revival, Sub-Culture, Harvesting and Media Preparation

Sl.No.	Name of the Equipment	Sl.No.	Name of the Equipment
1.	Incubator	12.	Media dispenser
2.	Dynamic pass box	13.	pH meter
3.	Bio safety cabinet	14.	Garment cubicle (Dynamic)
4.	Electronic Weighing balance	15.	Deep freezer
5.	Dispensing booth	16.	Peristaltic pump
6.	BCG Mill	17.	Floor Mount Passbox (Dynamic)
7.	Autoclave	18.	Garment Cubical(static)
8.	Hanging LAF	19.	Viable Air sampler
9.	Refrigerator	20.	Computer with Printer
10.	Media preparation vessel	21.	Vacuum Cleaner
11.	CIP- trolley		

### In Preparation and arrangement

S.No.	Name of the Equipment	S.No.	Name of the Equipment
1.	Autoclave(Material sterilization)	6.	Garment cubical (static)
2.	Dry Heat Sterilizer	7.	Vacuum cleaner
3.	Autoclave(Decontamination)	8.	Computer with printer
4.	Garment washing machine	9.	Pass box(Dynamic)
5.	Garment Drier Machine	10.	Pass box(Static)

### Containerization

S.No	Equipment Name	Equipment Code
1	Online filling machine & half stoppering	CN31FM01
2	Online vial capping machine	CN31VC01
3	Mobile LAF	CN31MF01, CN31MF02, CN31MF03 & CN33MF04
4	Dynamic garment cubical	CN28GC02 => ICTL/HLL/DGC/003/1314
5	Dynamic garment cubical	CN27GC01 =>ICTL/HLL/DGC/004/1314
6	Decontamination Autoclave	CN24AU01
7	Garment Washing	CN25GW01
8	Dynamic pass box	CN24DP01

9	Static pass box	ICTL/HLL/SPB/104/1314
10	Dry heat sterilizer	CN23DH01
11	Bung processor cum sterilizer	CN23BS01
12	Floor mountdynamic pass box	CN22FP02 => ICTL/HLL/DPB/105/1314
13	Online vial washing & depyrogenation	CN17WD01
14	Floor mount pass box	CN01FP01
15	Dynamic garment cubical	ICTL/HHL/SGC/005/1314
16	Dynamic garment cubical	ICTL/HHL/SGC/006/1314
17	Dynamicgarment cubical	ICTL/HLL/SGC/020/1314

## WAREHOUSE

S.No.	Name of the Equipment
1	Electronic Weighing Balance
2	Dispensing Booth
3	Sampling Booth

## QUALITY ASSURANCE

S.No.	Name of the Equipment
1	Deep freezer
2	Particle counter (Lasair III )
3	Particle counter (Metone)

## QUALITY CONTROL

S.No.	Name of the Equipment
1	Autoclave
2	Dry Heat Sterilization
3	pH Meter
4	Conductivity meter
5	Electronic Weighing Balance
6	Refrigerator
7	Laminar Air Flow
8	Incubator
9	Fluorescent Microscope
10	Deep Freezer

## MAINTENANCE/UTILITY

S.No.	Name of the Equipment	
1	Boiler	Chiller Plant II
2	Diesel Generator Set	Filter Cleaning Machine
3	Air Compressor	Building Management System
4	Fire pump	Sewage Treatment plant
5	Filter Cleaning Machine	Effluent Treatment Plant
6	Building management System	Brine Chiller Plant I

## WATER SYSTEM

S.No.	Name of the Equipment	
1	Pre-treatment system	Pure Steam Generation Plant
2	RO Water System	WFI Generation Plant
3	Purified water Generation System	WFI Storage & Distribution
4	Purified Water Storage & Distribution	



RMG





**Lyophilizer technical area**



**Water Plant**



**Diesel Generator with 600KVA capacity**



**1025 kVA Electrical Distribution station**





**Transformer**



**IBR Boiler with capacity 1.5 tonne**



**Effluent Treatment Plant (15KLD capacity) and Sewage Treatment Plant (4KLD capacity)**  
**List of Staff Superannuated/Voluntarily retired/ deceased from 31.03.2021 to 31.03.2022**

**List of Staff Superannuated**

Sl.No	Name	Designation	Date of Superannuation
1	V.Nanthan	MTS	30.04.2021
2	V. Palanivel	Technician	31.05.2021
3	A.Kalyani	Assistant Technical Officer	30.11.2021
4	M.Amaithimalai	Lab Attendant	31.12.2021

**Deceased Staff**

Sl.No	Name	Designation	Date
1	M.Rathi	MTS	10.10.2021

**BCGVL Residential Quarters**

BCGVL residential quarters is located on the other campus in the Sardar patel road. The campus has facilities such as playground, open stage and designated play area for Children. The campus also houses CGHS dispensary for Guindy area with Allopathy and Ayurvedha units.

**Total Quarters – 131**

Sl No	Type	No of Quarters	Occupied
1	I	55	41
2.	II	44	37
3	III	22	13
4	IV	8	3
5	V	2	1
	<b>Total</b>	<b>131</b>	<b>95</b>



## Events & Gallery

### 1. BCGVL Raising Day Celebration on 01.05.2021



## 2. Independence Day Celebration on 15.08.2021







**3. Institutional Animal Ethics Committee Meeting held on 25.09.2021**





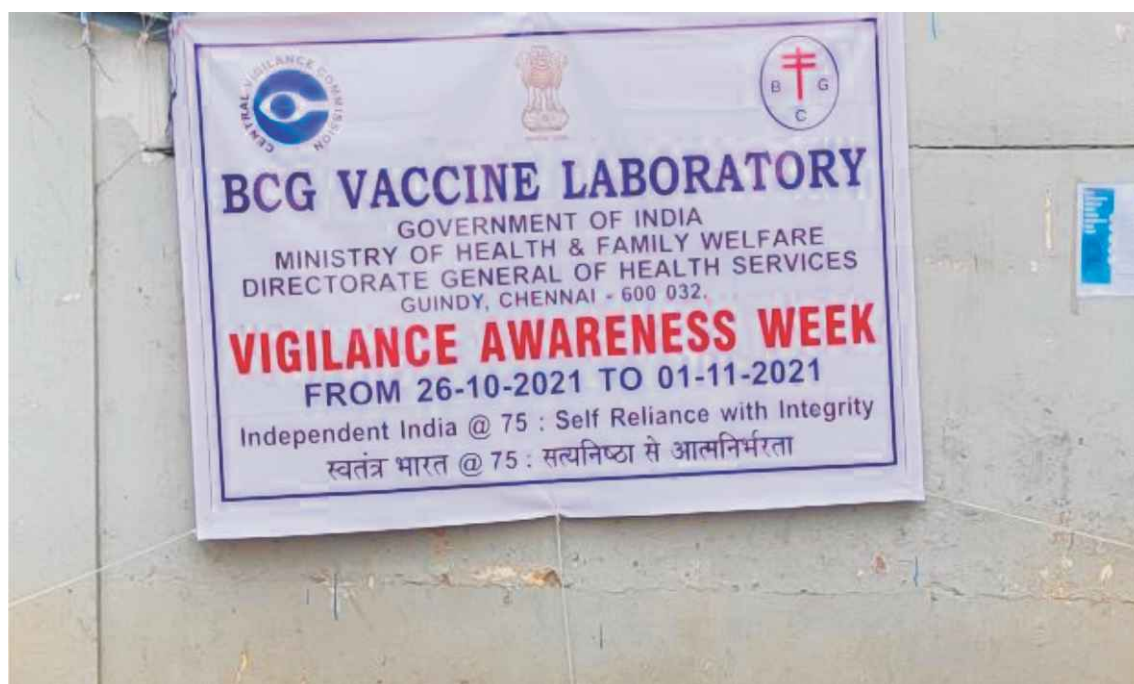
**4. Gandhi Jayanthi was observed on 02.10.2021**







## 5. Vigilance Awareness week from 26.10.2021 to 01.11.2021





**6. Republic Day Celebration on 26.01.2022**





**7. Women's Day celebration on 08.03.2022**









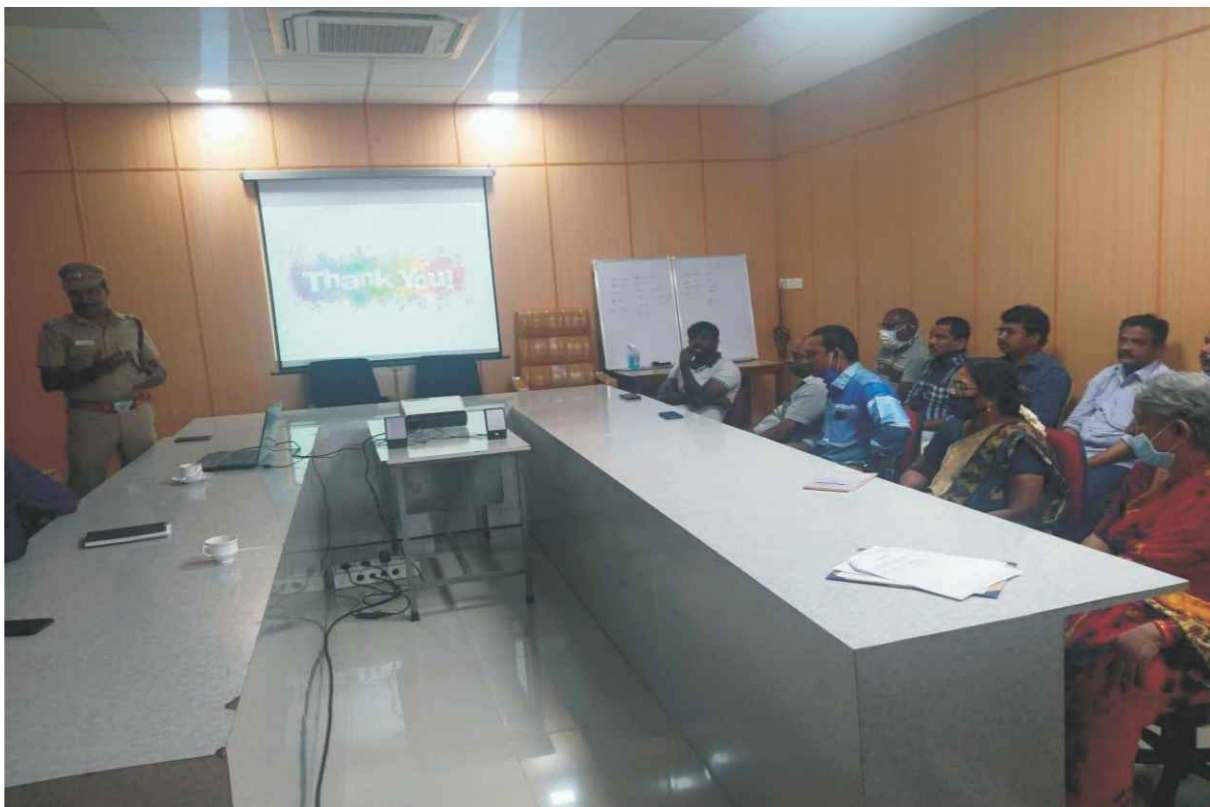
## 8. Swachh Abhiyan





**9. Fire and Safety drill conducted by Tamil Nadu Fire and Rescue Services**









**BCGVL CAMPUS IN 1992**



### **BCG Vaccine Laboratory**

Directorate General of Health Services  
Ministry of Health and Family Welfare  
Government of India

No.110, 33 Feet Road, Mount Road  
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