



பிசிலி தடுப்புச் சூய்வகம், சென்னை  
बीसीजி वैक्सीन प्रयोगशाला, चेन्नई  
BCG Vaccine Laboratory, Chennai

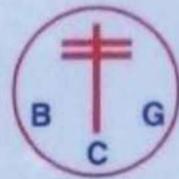


## cGMP Compliant Vaccine Manufacturing facility



Annual Report 2022 - 2023

## 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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# BCG VACCINE LABORATORY, CHENNAI



**डॉ. नवीन कुमार गुप्ता, एम.डी.**

एम.बी.बी.एस. (प्रूसीएमएस, दिल्ली), एम.डी. मूल्यजीवविज्ञान (एमएमयो, दिल्ली)

पूर्व अध्येता संकामक रोग (पीडीएचएनएच, मुम्बई)

विशेषज्ञता: मूल्यजीवविज्ञान, संकामक रोग, पशुजन्यरोग, वैक्सीनोलॉजी

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

MBBS (UCMS, Delhi), MD Microbiology (MAMC, Delhi)

Ex-Fellow Infectious Diseases (PDHNH, Mumbai)

Expertise : Microbiology, Infectious Diseases, Zoonoses, Vaccinology

## निदेशक

वी.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 19th, January 2021, it gives me an immense pleasure in bringing out the annual report of BCGVL for the year 2022-23.

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 Immunization Programme (UIP). For the Financial Year 2021-22, BCGVL has supplied 196.9 lakh doses to 24 consignees all over India. For the Financial Year 2022-23, BCGVL has supplied 177.1 lakh doses of BCG vaccine to 15 consignees all over India to UIP.

A new cold room for storage of BCG vaccine has been constructed and RMG has been installed in BCGVL. Animal house upgradation has been initiated by CPWD which is likely to be completed in Financial Year 2023-24.

It gives me immense pleasure to say that a new location for BCG Vaccine production has been identified at Tambaram site in Chennai for upscaling the vaccine production and supply in India.

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 & 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 & International Vaccine production Institutes in terms of quality by design and technology with World Class Quality Control & 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.

*25/4/23*

Dr. Naveen Kumar Gupta  
Director, BCGVL

सं. 110, 33 फुट रोड, माउंट रोड, गिन्डी, चेन्ऩै - 600 032.  
No.110, 33 Feet Road, Mount Road, Guindy, Chennai - 600 032.  
फोन / Phone : 044 - 2250 0476 / 2250 1906 (D)



## 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
	<b>Group-B (Non-Gazetted)</b>	
5	E&M Supervisor	R. Anandan Padvi Shirish Bapu
6	Asst. Technical Officer	K. Ekambaram M.R. Jayanthi
7	Junior Statistical Officer	S. Andrew
	<b>GROUP-C</b>	
8	Office Superintendent	V. Indra
9	Animal Supervisor	B. Ananthi
10	Technical Supervisor	R. Balaje M.G. Rajasekhar A. Revathi P. Sasikala K. Raji S. Sudhendhira Devi D. Hema V. Nalina Jancy
11	Scientific Assistant	S. Rajalakshmi T.S. Karthigai G. Ravisankar S. Harini Priyaadarshini P. Saravana Kumar A. Sheshalakshmi M.P. Natarajan K. Gunasekaran
12	Senior Lab. Assistant	A. Titus Sengol Raj M. Krishnan
13	Laboratory Assistant	C.K.Venkatesan A. Arulmadhan P. Chandrasekaran V. Kathiravan L. Chithra T. Venkatesa Lal Bahadur

Sl.No	Designation	Name (Shri/Smt)
14	Technician	R. Narayanan D. Selvam
15	Mechanic	K.K. Joseph L. Kathirvel M. Suresh V.R. Jagadish Suri J. Dhandapani A. Murali
16	Assistant Mechanic	S. Mohan
17	Upper Division Clerk	G.Vijay T.Vairavel M. Jayashankar D. Joycemani
18	Storekeeper	M.K. Gurumurthy
19	Lower Division Clerk	R. Gopi T. Babu
20	Motor Driver	L. Agasthiyar B. Sathiyadass
21	Carpenter	J. Ciril Raj
22	Lab. Attendant	M. Madhavan B. Kumar A.S. Khumar R. Sampath A. Suriyakala 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 V. Kannan
23	Multi-Tasking Staff	K. Umar Ali B. Jayakumar G.Vidya Bharathi V. Neelambari Shankar Lal Meena

## List of Committees

### 1. Departmental Screening Committee

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

### 2. RR committee for Group C posts

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

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

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

### 4. Purchase committee

S.No	List of Officers/ Officials	Designation
1	<b>Dr. Hassan Thuddathifanuge, CMO(SAG)</b>	<b>Chairman</b>
2	<b>Dr S. Amuthavalli, Deputy Director, KIPMR</b>	<b>Member</b>
3	<b>Smt. Soniya Vijayanandan, TO, NSTI</b>	<b>Member</b>
4	<b>Dr. S. Anand, Veterinarian</b>	<b>Member</b>
5	<b>Shri R. Anandan, EMS</b>	<b>Member</b>
6	<b>Shri M.K. Gurumurthy, Store Keeper</b>	<b>Member</b>
7	<b>Shri. M. Jayasankar, UDC</b>	<b>Member</b>

### 5. Preventive Vigilance Committee

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

# BCG VACCINE LABORATORY, CHENNAI

## 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 Superintendent	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 Superintendent	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. T.F. 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	<b>Dr. B. Sekar, Consultant</b>	<b>Chairman</b>
2	<b>Dr. Hassan Thuddathifanuge, CMO(SAG)</b>	<b>Member</b>
3	<b>Dr. S. Anand, Veterinarian</b>	<b>Member</b>
4	<b>Shri A. Krishna Kumar, AO</b>	<b>Member Secretary</b>
5	<b>Shri K. Ekambararam, ATO</b>	<b>Member</b>
6	<b>Shri R. Balaje, TS</b>	<b>Member</b>
7	<b>Shri V. Kennedy, Laboratory Peon</b>	<b>Nominated members by Office Council (Staff Side)</b>
8	<b>Shri Padvi Shirish Babu, EMS</b>	

**11. Condemnation Committee**

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

**12. Transport Committee**

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

**13. Annual Report Committee**

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

## 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 Bilié Calmette-Guerin; later they omitted "Bilié" and so BCG was born.

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

## Brief History of BCGVL

### Pioneers

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

### 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.	<b>Dr.K.S.Ranganathan</b>	<b>01.05.48</b>	<b>02.06.57</b>
2.	<b>Dr.C.B.D'silva</b>	<b>03.06.59</b>	<b>28.10.66</b>
3.	<b>Dr.J.C.Suri</b>	<b>28.07.67</b>	<b>26.06.71</b>
4.	<b>Dr.K.P.Rao</b>	<b>10.09.71</b>	<b>30.01.82</b>
5.	<b>Dr.S.Basu</b>	<b>10.11.82</b>	<b>31.05.93</b>
6.	<b>Dr.M. Jayasheela</b>	<b>30.06.93</b>	<b>06.11.98</b>
7.	<b>Dr.N. Elangeswaran</b>	<b>11.11.98</b>	<b>31.07.08</b>
8.	<b>Dr.C.H.D. Vinodkumar (I/C)</b>	<b>31.07.08</b>	<b>26.07.09</b>
9.	<b>Dr. Usha Soren Singh</b>	<b>27.07.09</b>	<b>30.04.12</b>
10.	<b>Dr. H.G. Bramhne</b>	<b>24.05.12</b>	<b>27.07.18</b>
11.	<b>Dr. B.Sekar</b>	<b>04.08.18</b>	<b>04.03.20</b>
12.	<b>Dr.T.F.Hassan (Addl Charge)</b>	<b>11.03.20</b>	<b>16.08.20</b>
13.	<b>Dr.V.K.Chadha (Addl Charge)</b>	<b>17.08.20</b>	<b>27.09.20 (FN)</b>
14.	<b>Dr.S.Uma Shankar (Addl Charge)</b>	<b>27.09.20 (AN)</b>	<b>18.01.21</b>
15.	<b>Dr.Naveen Kumar Gupta</b>	<b>19.01.21</b>	<b>Till date</b>

## **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	V. Indra	OS
2	G. Vijay	UDC
3	M. Jayasankar	UDC
4	D. Joyceman	UDC
5	R. Gopi	LDC
6	T. Babu	LDC
7	L. Agasthiyar	MOTOR DRIVER
8	B. Sathyadoss	MOTOR DRIVER
9	G. Vidya Bharathi	MTS
10	V. Neelambari	MTS

**Court Cases**

Number of cases handled in CAT, Chennai	13
Number of cases handled in High Court of Madras	08
Total	21
Less: Number of cases settled during 01.04.2022 to 31.03.2023	07 ( 3 in CAT and 4 High Court of Madras)
Total Number of cases pending as on 31.03.2023	14

**List of Minor works carried out by CPWD and their estimates for the period from 01.04.2022 to 31.03.2023**

Sl.No	Minor Works	Estimate
1	Renovation of type V Qtrs in BCGVL	Rs. 3,57,271 (revalidated)
2	Cleaning of UG Sump and Over head water storage tanks in BCGVL office premises	Rs. 76,000/-
3	Construction of one additional cold storage room in BCGVL office premises	Rs. 38,81,900/-
4	Construction of damaged compound wall in BCGVL office premises	Rs. 10,98,500/-
4	Upgradation of Animal House (First Floor) at BCGVL office premises	Rs. 30,00,000/- (First Instalment)
4	Maintenance of Electrical Installations etc. BCG Staff Quarters	Rs. 14,71,392/-

**Budget as on 31.03.2023**

As On	B.E.	R.E.
31.03.2023	305,900,000	279,000,000

## PRODUCTION SECTION

### Facility Description

The manufacturing block is 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 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 sautonpotato medium. The inoculated tubes are incubated at 37 °C for 21 days.

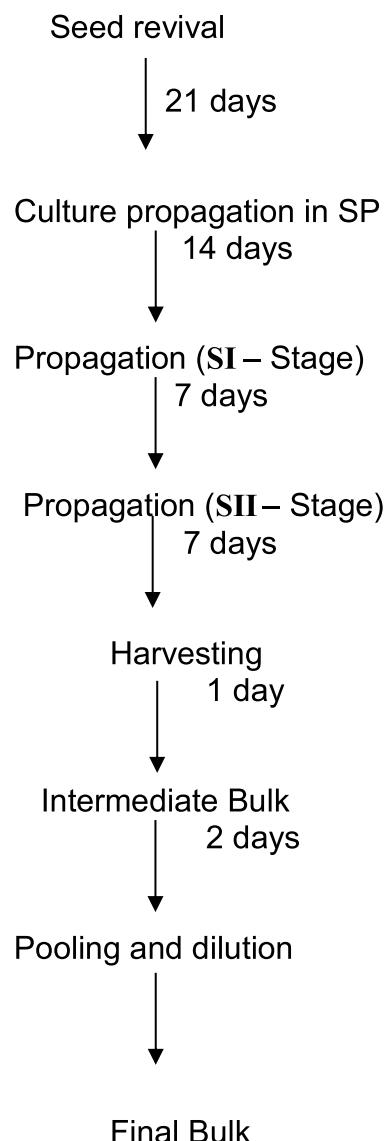
**Propagation:** Production involves three stages of subculture. The revived culture is transferred to sauton potato medium incubated at 37 °C for 14 days, then to satouon liquid medium (100 ml) in conical flask, incubated at 37 °C for 7 days and then to sauton liquid medium (200 ml) in tuberculinflask,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

**Harvesting:** After the incubation period, the culture grown in tuberculin flask are harvested using Birkhaugh'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 inprocess sterility on the intermediate bulk is performed.

# BCG VACCINE LABORATORY, CHENNAI

**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 undergone from April 2022 to March 2023**

### Hands on training

- Propagation of BCG culture (SP3 to SP4, SP3 to SP3SI, SP3SI to SP3SII).
- BCG Culture Grinding.

**Activities performed from April 2022 to March 2023 in production department**

- Seed revival was performed three times on 21/04/2022, 13/07/2022, 05/10/2022 and one revival proposed on 01/03/2023.
- Total number of subculture done 60 and 1 subculture will be carried out on 24/03/2023.
- Total number of Harvesting done 20.
- Total volume of suspension made 74,988 ml (40 mg/ml).
- Total number of Pooling made 28.
- Total volume of suspension given to containerization was 2,60,410 ml (10mg/ml).
- Total volume of Sauton media prepared 420 liters and 5 liters will be prepared on 22.03.2023 .
- Total volume of Mono Sodium L Glutamate prepared was 387 liters.
- Total volume of Phosphate buffer prepared was 155 liters.
- Total volume of Soya bean Casein Digest Medium prepared was 103.25 liters for Media Filling .

**List of the Equipment and Instruments available inthe department as on March 2023  
(Front side)**

S.No	Name of the Equipments and Instruments
1.	Bio safety cabinet
2.	Incubator
3.	Autoclave
4.	Media & Buffer Preparation Vessel
5.	CIP – trolley
6.	Media dispenser
7.	Deep freezer
8.	Refrigerator
9.	Electronic Weighing balance
10.	Standard weighing sets
11.	pH meter
12.	BCG Mill
13.	Peristaltic pump
14.	Viable Air sampler
15.	Easy pet 3 (Electronic pipette controller)

16.	Garment cubicle (Dynamic)
17.	Garment Cubical(static)
18.	Computer with Printer
19.	Clean room Vacuum Cleaner
20.	Hanging Laminar Air Flow
21.	Dispensing booth
22.	Floor Mount Pass box (Dynamic)
23.	Dynamic pass box

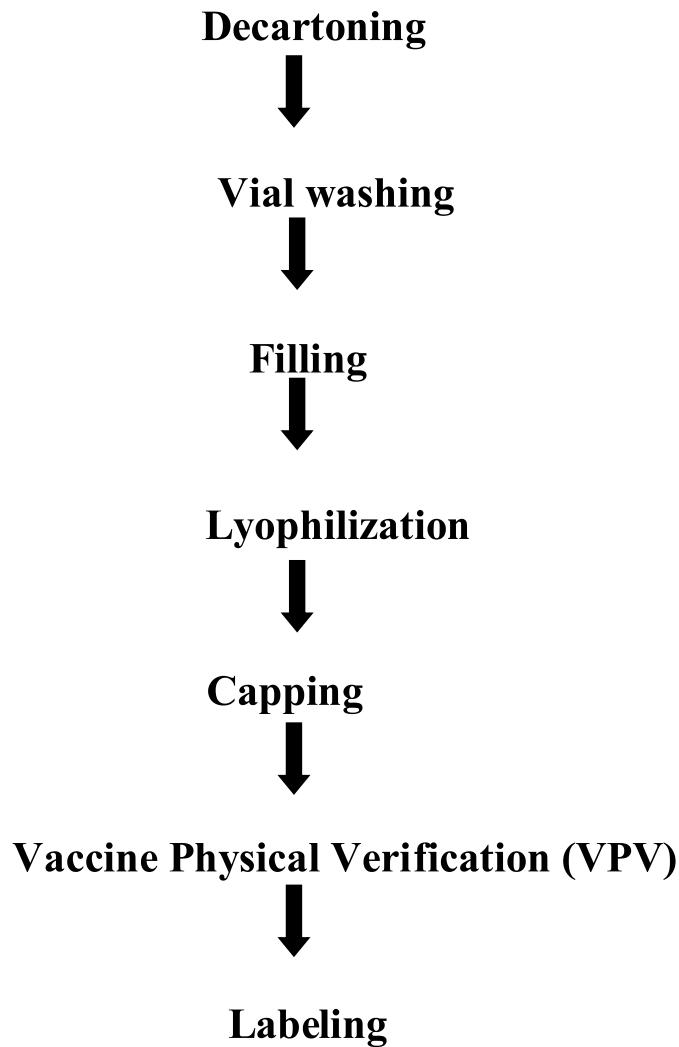
**List of the Equipment and Instruments available in the department  
as on March 2023 (Back side)**

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

## 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 encompass 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



### DOWNTREAM 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 conveyer 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.
- Depyrogenatedvials 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 aluminumflip 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 aluminumflip 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 - 2 to -8° 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 2022-2023**

S.NO.	MONTH	LOT NO.	DOSES IN LAKHS
1.	September 2022	L-133 to L-142 (10 lots)	38.77
2.	October 2022	L-143 to L-151 (9 lots)	35.25
3.	January 2023	L152 (1 lot)	3.87
4.	February 2023	L-153 to L-160 (8 lots)	31.3

**PACKING SECTION**

The number of doses packed for supply during the Financial Year 2022 - 23 are as follows:

**May 2022**

Jhansi	-	1.6 Lakh Doses
Agra	-	2.0 Lakh Doses
GMSD Karnal	-	20.0 Lakh Doses
Lucknow	-	2.0 Lakh Doses
Kanpur	-	1.5 Lakh Doses
Varanasi	-	4.0 Lakh Doses
GMSD Chennai	-	5.0 Lakh Doses

Vaccine Packed for Supply in May 2022 - 36.1 Lakh Doses

**June 2022**

**GMSD Chennai - 10.0 Lakh Doses**

Vaccine Packed for Supply in June 2022 - 10.0 Lakh Doses

## August 2022

<b>DPH - Chennai</b>	-	<b>1.0 Lakh Doses</b>
<b>Bangalore</b>	-	<b>1.5 Lakh Doses</b>
<b>Pune</b>	-	<b>6.5 Lakh Doses</b>
<b>Jhansi</b>	-	<b>2.0 Lakh Doses</b>
<b>Agra</b>	-	<b>2.5 Lakh Doses</b>
<b>Lucknow</b>	-	<b>2.5 Lakh Doses</b>
<b>Kanpur</b>	-	<b>2.0 Lakh Doses</b>
<b>Varanasi</b>	-	<b>4.5 Lakh Doses</b>
<b>Raipur</b>	-	<b>2.0 Lakh Doses</b>
<b>Hyderabad</b>	-	<b>1.0 Lakh Doses</b>
<b>Gannavaram</b>	-	<b>1.5 Lakh Doses</b>

**Vaccine Packed for Supply in August 2022 27.0 Lakh Doses**

## November 2022

<b>GMSD Chennai</b>	-	<b>4.5 Lakh Doses</b>
<b>GMSD Mumbai</b>	-	<b>8.5 Lakh Doses</b>
<b>GMSD Karnal</b>	-	<b>11.0 Lakh Doses</b>
<b>GMSD Kolkata</b>	-	<b>14.0 Lakh Doses</b>

**Vaccine Packed for Supply in November 2022-38.0 Lakh Doses**

## February 2023

<b>GMSD Chennai</b>	-	<b>6.0 Lakh Doses</b>
<b>GMSD Mumbai</b>	-	<b>11.0 Lakh Doses</b>
<b>GMSD Karnal</b>	-	<b>20.0 Lakh Doses</b>

**Total No. of Vaccine Supplied in February 2023 - 37.0 Lakh Doses**

## **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.

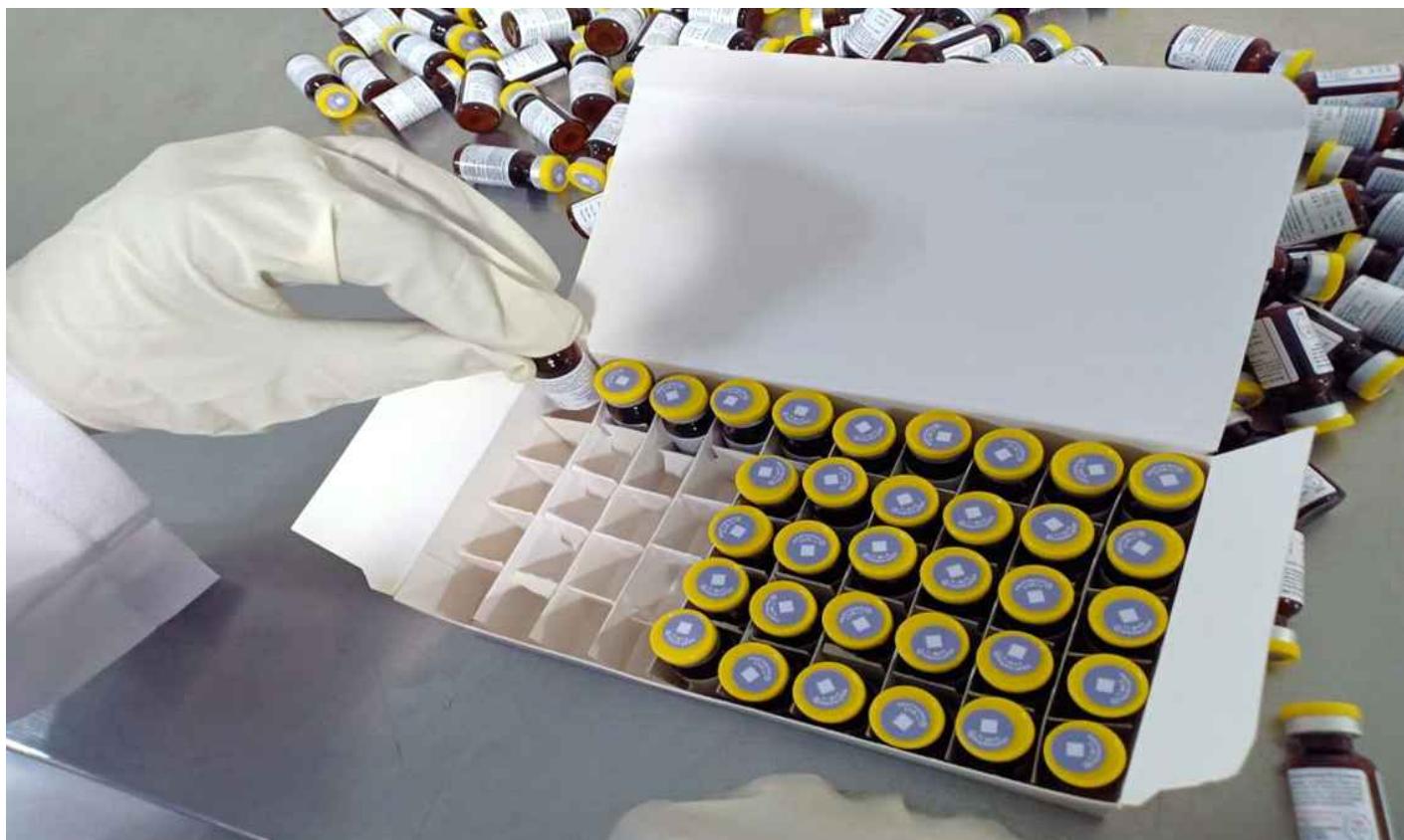
Secondary Packing materials such as Inner partition and Minor carton boxes have also been redesigned.

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.



# BCG VACCINE LABORATORY, CHENNAI



**SUPPLY SECTION**

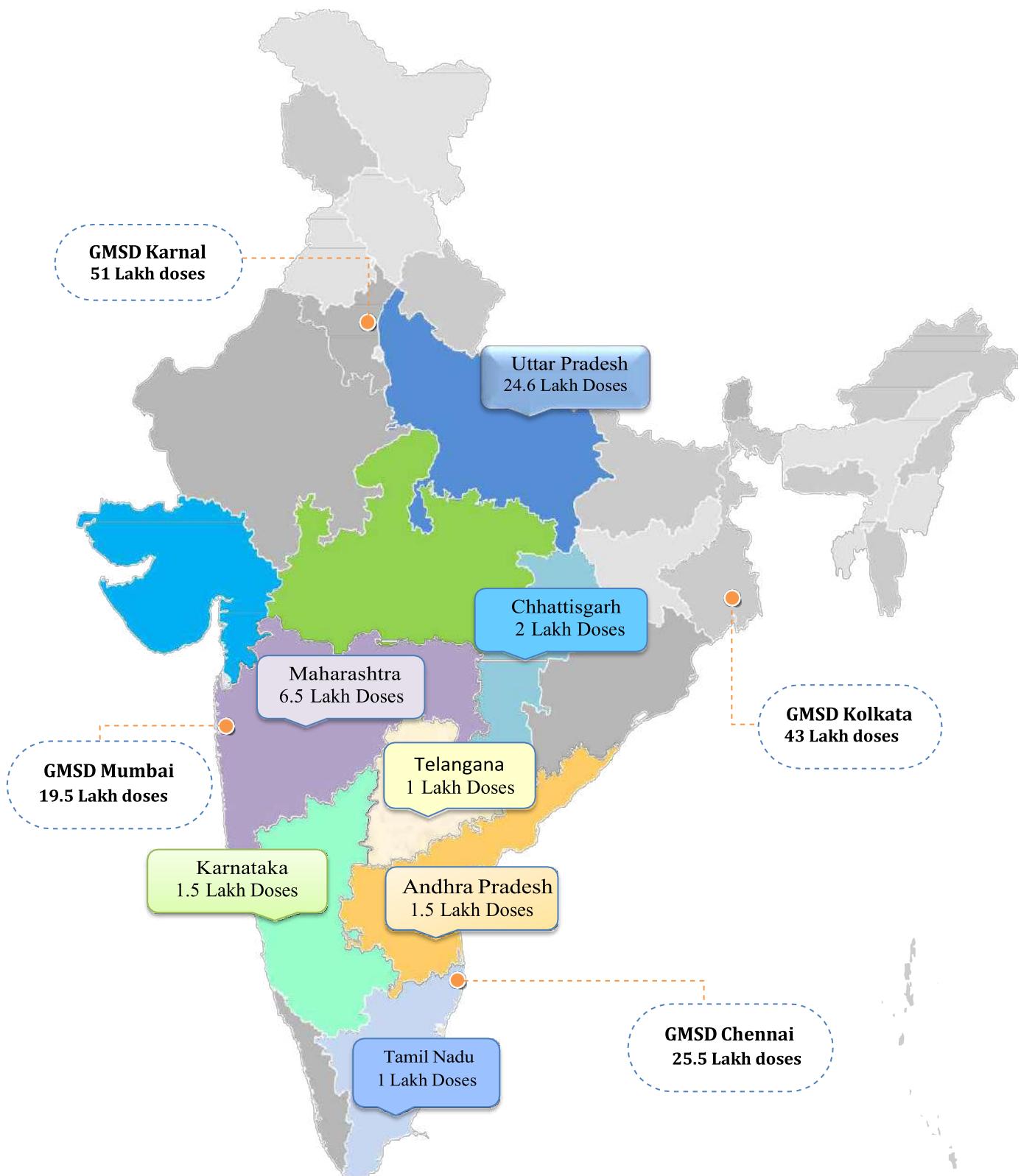
S.NO.	CONSIGNEE	TOTAL DOSES SUPPLIED
1.	GMSD, Chennai	25.5
2.	GMSD, Kolkata	43
3.	GMSD, Karnal	51
4.	GMSD, Mumbai	19.5
5.	DPH, Chennai	1.0
6.	Jhansi,UttarPradesh	3.6
7.	Agra,UttarPradesh	4.5
8.	Kanpur, UttarPradesh	3.5
9.	Lucknow, UttarPradesh	4.5
10.	Varanasi, UttarPradesh	8.5
11.	Pune, Maharastra	6.5
12.	Gannavaram,Andhra Pradesh	1.5
13.	Hyderabad, Telangana	1.0
14.	Banglore, Karnataka	1.5
15.	Raipur, Chhattisgarh	2.0
Total Vaccine doses supplied in FY 2022-23		177.1 lakh doses (104 lakh doses for FY 2022-23 and 73.1 lakh doses for FY 2021-22)

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

★ Doses Supplied:17,71,000 vials X 10 doses = 177.1 lakh doses  
**Revenue Generated in FY 2022-23**

★ 177,10,000 (Doses supplied)X Rs.6.51 (price per dose) = Rs.11,52,92,100/

## GMSD and State-wise supply of BCG Vaccine in FY 2022-23



## WAREHOUSE SECTION

### 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 through CPP Portal & Limited Tender, 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

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.

1. Orders placed through GeM for Annual Requirement of Computer Cartridges and Stationery/Consumables, Maintenance Spares such as Cable, LED Street Lights, LED Tube Lights, Battery, Computers, Microscopes, Weighing Balance, Air Sampler, Drying Machine, RO Water System, etc.
2. PROCUREMENT THROUGH L/C Process :
  - VVM Stickers from M/s. Temptime Corporation, USA-22 Lakhs
3. Number of Maintenance Contracts awarded :

Sl. No.	Nature of Contract	No. Awarded
1.	Annual Maintenance Contract	17
2.	Comprehensive Maintenance Contract	07
3	Operation & Maintenance Contract	04
4.	Maintenance Contracts through GeM Portal (a) Air Conditioners (b) Computers (c) Rodent Control	04

4. Total No. of orders placed through GeM portal:

	2021-22	2022-23
No. of Orders placed	88	146
Goods	31,00,000/-	Rs. 55,01,689/-
Services	19,30,000/-	Rs. 52,89,630/-

5. No. of Bills processed - 566

## **QUALITY ASSURANCE SECTION**

**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.**

### **Activities Performed**

1. **Calibration of Instruments and HEPA Filter validation of Classified Clean room Facility was undertaken through external agencies.**
2. **Periodical Validation of sterilizing Equipments (Autoclaves, Dry Heat Sterilizers and Online Tunnel for vial Depyrogenation was validated with Biological Indicators and BET challenge.**
3. **BCG vaccine with its diluent for 28 Batches are sent to CDL for testing and Release.**
4. **BCGVL produced and Supplied 104 Lakh Doses for the UIP.**
5. **Critical Raw materials and Rubber stoppers are outsourced for testing its suitability.**
6. **BCG Vaccine Sample draw and Cold storage Inspection for supply upon release by the Joint Director, DPH & Immunization was coordinated and undertaken on five occasions.**
7. **Inspection notes of eight No's to the allotted consignees are processed and issued to respective consignees.**
8. **Verified the suitability of certain materials purchased and the same certified.**
9. **Involved in the procurement of items on Market survey, technical committee and generated the comparison statement and the report submitted for the procurement process.**
10. **Interaction with the internal Departments in the process of production activities and utilities management.**

## QUALITY CONTROL SECTION

Sl. No	Activities	No of tests/batches
1.	<b>Testing of BCG vaccine for Batch release</b> The following tests has been completed for 32 batches a) Identity test b) Sterility test c) Optical Density d) Viability for Bulk e) Viability for Lot & Thermal Stability f) Absence of virulent Mycobacteria g) Excessive Dermal Reactivity h) Water content i) Retention sample with Diluent	254 Tests 182 Tests 32 Batches 32 Batches 67 Test 32 Batches 10 Batches 32 Batches 23 Batches
2.	<b>Operation of Autoclave for decontamination</b> <b>Operation of Autoclave for Sterilization (Media &amp; Materials)</b> <b>Operation of Double door Hot air oven for Sterilization</b>	139 cycles 332 cycles 155 cycles
3.	<b>Environmental &amp; Personnel Monitoring programme</b> a) Performed during every activity A,B,C b) Performed at rest A,B,C,D c) D Area	386 Tests Before start of process Monthly once
4.	<b>Raw material testing</b> a) Water testing Routine Physiochemical & Microbiology tests TOC & ENDOTOXIN tests b) Primary packaging material (For every lot) 1) 2R Vials 2) Rubber wads 3) Al. Flip offs c) Diluents (For every lot)	Daily Fortnightly 10 Batches 09 Batches 04 Batches 04 Batches
5.	<b>Suitability of culture media</b> <b>Growth Promotion Test for SCDA,SDA, FTM &amp; SCDM</b>	82 Times
6.	<b>Process Validation</b> PCR– Test for BCG strain (DANISH 1331) using the RD gene system was performed during this period	07 Times
7.	<b>Stability Studies</b> Routine Stability studies conducted for 3 consecutive batches L133, L134, L135 for Identification , Sterility,Viability & Watercontent parameters	Every 3 months

## Media Preparation

- SOYA, FTM, L.J.MEDIA , SAUTON, D'SAUTON , N'SALINE 9%, 10 % TWEEN 80
- Microbiological Media, Selective Media and Biochemical Media
- Processing of validation samples-Autoclave & DHS
- Washing of Glasswares and Garments.
- Operation, Calibration and maintenance of instruments
- Safe disposal of waste and expired/ absolutely materials.

Training conducted from 31.3.2022 to 31.03.2023

- Regular sessions of Oral & Hands-on training sessions given to all and for newly appointed staff
- Documentation and reporting.

## Future plan

1. To initiate testing of Rubber wads as per regulatory guidelines. Some of the tests to be outsourced
  - a) Identification b) Biological test to be outsourced
2. A proposal and plan for establishment of new Microbiology lab and washing facility is under consideration.
3. To evaluate residual moisture content in the product after lyophilisation process in individual vials, the test procedure to be upgraded from titrometric method to coulometric method.

### A. List of equipment procured during the period of 31.3.2022 to 31.03.2023

Sl.No.	Equipment	Nos
1	Microscope	1
2	Pipette controller	1
3.	Pen Type pH Meter	1
4.	KF Coulometer	1

### B. Specific achievement, if any for the period from 31.3.2022 to 31.03.2023

- Investigation was carried out for the environmental monitoring programme during every activity. The microorganisms were isolated, identified by culture characteristics and biochemical testing.
- 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.

### C. Additional information, if any

- Pre-treatment and PW water were tested (Microbiological tests-Specific pathogen identified with the available facility and sent to National Institute of Epidemiology for further identification at species level using VITEK test.

**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 CSEA wide reg no 358/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 CCSEA guidelines which are subjected to annual inspection by the respective authorities.

**Routine Performance during the Year 2022-23**

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 weaning 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 LAH currently houses about 300 breeders of Dunkin Hartley breed of guinea pigs, in deep litter system. The Experimental animal house has capacity to house 108 batches of testing animals at once.

**Staff On Roll as on 31.03.2023**

Sl. No	Name	Designation
1	Dr. Anand S	Veterinarian
2	Mrs. B. Anandhi	Animal Supervisor
3	Mr. T. Venkatesa Lal Bahadur	Laboratory Assistant
4	Mr. M. Madhavan	
5	Mr. B. Kumar	
6	Mr. A.S. Kumar	
7	Mr. K. Babu	
8	Mr. Kumar Natwar Singh	
9	Mr. B. Jayakumar	MTS
01	Mr. Shankar T	TA Grade III (Contract)
11	Mr. Akash S	TA Grade III (Contract)

**Animal Stock and Usage**

Guinea pigs	2021-22	2022-23
Animal Stock ( as on 31 <sup>st</sup> March)	716	490
Births	995	307
Receipts	0	0
Used for Testing	426	252
No of batches tested	73	42

**Conferences/Seminars/Trainings/Visit attended**

1. 10<sup>th</sup> International Conference of Laboratory Animal Scientists' Association (LASA), India, on "Animal Models for One Health Programme Challenges and Future Perspectives" jointly organized by the National Institute of Animal Biotechnology (NIAB), National Animal Resource Facility for Biomedical Research (NARFBR) and LASA India in Hyderabad during 3rd & 4th June 2022 at NAARM, Hyderabad attended by Dr. Anand S, Veterinarian.

2. Seminar on "Nutritional models and Ethics for Laboratory Animals used in Biomedical Research" organized by the Department of Animal Nutrition, Veterinary College and Research Institute, Tamil Nadu Veterinary and Animal Sciences University, Namakkal in association with Laboratory Animal Scientists Association of India (LASA India) on 12.08.2022 attended by Dr. Anand S, Veterinarian.
3. "Defining Ethics and Welfare in Preclinical Research & Workshop on Preparing B- Forms and the Conduct of IAEC" DEW 2022 Division of Laboratory Animal Science, Biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences & Technology, Poojappura, Thiruvananthapuram 695012, Kerala, at Achutha Menon Center Auditorium held on the 14th and 15th of November attended by Dr. Anand S, Veterinarian.

## Meetings/ Inspection conducted

Name	Duration	Participants
3 <sup>rd</sup> IAEC meeting	26.11.2022	IAEC members
Annual inspection	31.12.2022	CCSEA Main nominee
2 <sup>nd</sup> IAEC meeting (Online)	25.03.2023	IAEC members

## Equipment's / Materials acquired

1. Electronic animal weighing balance (2 nos) with animal mode procured through GeM.
2. Refrigerator procured through GeM.
3. Personal Computer and table procured through GeM



**Members of IAEC as on 31.03.2023**

Name of the IAEC member	Designation in IAEC	Member profile
<b>Dr. B. Sekar,</b> Consultant ( Micro), BCG Vaccine Laboratory, Guindy Chennai-32	Biological scientist (Chairperson)	Internal member & Institute recommended and accepted by CCSEA
<b>Dr. T.F. Hassan,</b> Chief Medical Officer( SAG), BCG Vaccine Laboratory, Guindy Chennai-32	Scientist from different biological discipline	Internal member & Institute recommended and accepted by CCSEA
<b>Dr Anand S</b> Veterinarian, BCG Vaccine Laboratory, Guindy Chennai-32	Veterinarian (Member Secretary)	Internal member & Institute recommended and accepted by CCSEA
<b>Dr .R. Balaje,</b> Technical Supervisor, BCG Vaccine Laboratory, Guindy Chennai-32	Scientist from different biological discipline	Internal member & Institute recommended and accepted by CCSEA
<b>Smt .D. Hema,</b> Technical Supervisor, BCG Vaccine Laboratory, Guindy Chennai-32	Scientist In-charge of Animal house facility	Internal member & Institute recommended and accepted by CCSEA
<b>Dr R. Ananda Raja,</b> Senior Scientist, ICAR – Central Institute of Brackishwater Aquaculture, 75, Santhome High Road, R. A. puram, Chennai 600028	Main Nominee	External member & Nominated by CCSEA
<b>Dr A. Gopinathan,</b> Assistant Professor & Head, Dept of Animal Genetics and Breeding, Veterinary College Research Institute, Udumalpet	Link Nominee	External member & Nominated by CCSEA
<b>Dr A. Muthuvel,</b> Assistant Professor National Institute of Siddha, Dept of AYUSH, Tambaram Sanitorium, Chennai-47	Scientist from outside the Institute	External member & Nominated by CCSEA
<b>Dr R. Aruna Devi,</b> Research officer, Captain srinivasa Murti Drug Research Institute for Ayurveda, Dept of AYUSH, Chennai,Tamil Nadu	Socially Aware Nominee	External member & Nominated by CCSEA

## CCSEA Annual Inspection of LAH on 31.12.2022 by Main Nominee



## **ENGINEERING AND MAINTENANCE SECTION**

- Engineering Section office is situated in the ground floor of the main building of BCGVL. The workshop for Engineering Section situated opposite to the Animal House.
- All the record works, planning of preventive maintenance activities and maintenance work are carried out in the Engineering Section office. Minor repair works are being carried out in the workshop area.
- The operation / preventive maintenance / breakdown maintenance of the following equipments are carried out by the Engineering section.

SI.No.	NAME OF THE EQUIPMENTS
	Pre-Treatment System
	RO system
	Purified Water Generation System
	Purified Water Storage & Distribution
	Pure Steam Generation Plant
	WFI Generation Plant
	WFI Storage & Distribution
2.	Air Compressor
3.	Boiler Plant (Indian Boiler Regulations [ IBR ] )
4.	Fire Fighting Room
5.	Electrical HT / LTinstallations
	Chiller Plants
	Brine Chiller Plant
	Air Handling Units (AHU)
	Treated Fresh Air units(TFA)
	Ventilation Unit System (VUS)
	Cold Rooms
	Filter Cleaning Machine
	Effluent Treatment Plant (ETP)
	Sewage Treatment Plant (STP)
8.	Online Vial Washing & Depyrogenation
9.	Online Vial Filling & Half Stoppering machine
10.	Lyophilizer
11.	Vial capping machine

- Apart from the above, preventive maintenance / breakdown maintenance of all the equipment machineries are carried out by the Engineering Department. The names of the equipment are as follows:

SL. NO.	NAME OF THE EQUIPMENT
1.	<b>Static Pass box / Dynamic Pass box</b>
2.	<b>Garment cubicle</b>
3.	<b>Bio-Safety Cabinet</b>
4.	<b>Auto clave</b>
5.	<b>Dry Heat Sterilizer (DHS)</b>
6.	<b>Dispensing booth</b>
7.	<b>Incubator</b>
8.	<b>Media Preparation</b>
9.	<b>Media Dispenser</b>
10.	<b>Refrigerator</b>
11.	<b>Deep Freezer</b>
12.	<b>Garment washing machine</b>
13.	<b>Clean room vacuum cleaner</b>
14.	<b>Mobile Gen Set</b>
15.	<b>Diesel Generator Set</b>
16.	<b>Peristaltic pump</b>
17.	<b>Data Logger</b>
18.	<b>On Line Particle Counter</b>
19.	<b>Garment Cubicle</b>
20.	<b>Laminar air flow</b>
21.	<b>Ceiling Laminar flow</b>
22.	<b>Mobile Laminar flow</b>
23.	<b>Vial inspection &amp; Coding Machine</b>
24.	<b>Vial Labeling Machine</b>
25.	<b>VVM Applicator</b>
26.	<b>Bio waste Inactivation plant</b>

- Apart from the preventive maintenance activities, the Engineering section officials are engaged 24 x 7 basis for the monitor / rectification work of critical equipment like Cold Rooms, Incubator, Boiler, HVAC systems, which are in operation continuously throughout the year.

- The duties of the Engineering Officials are planned in such a way that, to address the issues in the critical equipment during out of office hours / holidays also etc. This will ensure the uninterrupted operation of the critical utilities.

## 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. Motor vehicle /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

## 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.	<b>Incubator</b>	12.	<b>Media dispenser</b>
2.	<b>Dynamic passbox</b>	13.	<b>pH meter</b>
3.	<b>Bio safety cabinet</b>	14.	<b>Garment cubicle (Dynamic)</b>
4.	<b>Electronic Weighing balance</b>	15.	<b>Deep freezer</b>
5.	<b>Dispensing booth</b>	16.	<b>Peristaltic pump</b>
6.	<b>BCG Mill</b>	17.	<b>Floor Mount Passbox (Dynamic)</b>
7.	<b>Auto clave</b>	18.	<b>Garment Cubical (static)</b>
8.	<b>Hanging LAF</b>	19.	<b>Viable Air sampler</b>
9.	<b>Refrigerator</b>	20.	<b>Computer with Printer</b>
10.	<b>Media preparation vessel</b>	21.	<b>Vacuum Cleaner</b>
11.	<b>CIP-trolley</b>		

### In Preparation and arrangement

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

### Containerization

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

9	Staticpassbox	ICTL/HLL/SPB/104/1314
10	Dryheatsterilizer	CN23DH01
11	Bungprocessorcumsterilizer	CN23BS01
12	Floormountdynamicpassbox	CN22FP02=>ICTL/HLL/DPB/105/1314
13	Onlinevialwashing& depyrogenation	CN17WD01
14	Floormountpassbox	CN01FP01
15	Dynamicgarmentcubical	ICTL/HHL/SGC/005/1314
16	Dynamicgarmentcubical	ICTL/HHL/SGC/006/1314
17	Dynamicgarmentcubical	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	Viable Air Sampler
2	Particle counter (Lasair III)	Data Logger
3	Particle counter (Metone)	Electronic Weighing Balance

### **QUALITY CONTROL**

S.No.	Name of the Equipment	
1	Autoclave	Centrifuge
2	Dry Heat Sterilization	Light Microscope
3	pH Meter	Biolumino meter
4	Conductivity meter	HPLC
5	Electronic Weighing Balance	Sonicator
6	Refrigerator	TOC Analyser
7	Laminar Air Flow	Karl Fischer
8	Incubator	Spectrophoto meter
9	Fluorescent Microscope	Vortex Mixer
10	Deep Freezer	Stability Chamber

**MAINTENANCE / UTILITY**

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

**WATER SYSTEM**

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

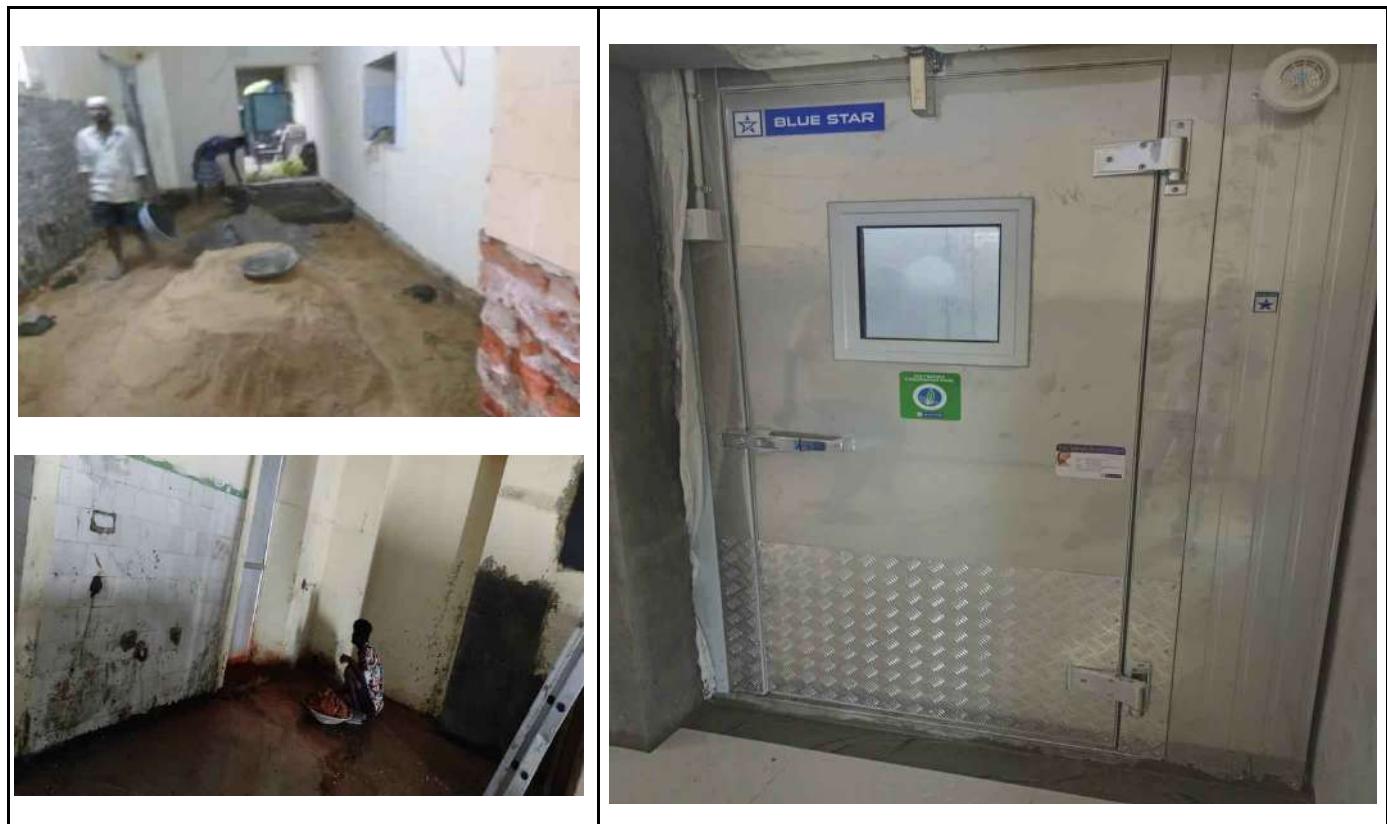
## Conversion from Double Pole System to Ring Main Gear (RMG)

BEFORE (DOUBLE POLE STRUCTURE)	AFTER (Ring Main Gear (RMG))
	

## Construction of Compound wall (part of the area at BCGVL premises)



## COLD ROOM



## GARDEN





**Metro Water Meter**

BEFORE	AFTER
	
	
	

## Steam line laid at Main Building (Quality Control Department and Animal House)



## Speed Bread Pad Arrangements

BEFORE	AFTER
	

## BCG Staff Quarters (vacant land)

BEFORE	AFTER
	
	

**List of Staff Superannuated/Voluntarily retired from 01.04.2022 to 31.03.2023**

Sl.No	Name	Designation	Date
1	M.Pushparani	Scientific Assistant	30.04.2022
2	Md. Ayoob	Scientific Assistant	31.05.2022
3	S.Malathi	Scientific Assistant	31.05.2022
4	V.Balakrishnan	Scientific Assistant	30.11.2022
5	A.Krishnakumar	Administrative Officer	30.11.2022
6	Dr.B.Sekar	Consultant (Micro)	31.03.2023

**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 and Gallery**

### **1. Visit of DGHS to BCGVL on 01.05.2022**



### **2. Gandhi Jayanthi on 02.10.2022**





### 3. Pongal Celebration on 13.01.2023





#### 4. Visit by Central team of Experts to BCGVL on 31.03.2023





BCGV L TEAM as on 31.03.2023



MAIN BUILDING ENTRANCE IN 2006



### BCG Vaccine Laboratory

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

No.110, 33 Feet Road, Mount Road  
Guindy, Chennai - 600 032

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