



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



**cGMP Compliant Vaccine Manufacturing facility**



**Annual Report 2023 - 2024**

## 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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## DIRECTOR'S MESSAGE



**डॉ. नवीन कुमार गुप्ता, एम.डी.**

एम.बी.बी.एस. (पुणे/एम्एम, दिल्ली), एम.डी. वृक्षजीवविज्ञान (एमएमसी, दिल्ली)  
पूर्व अध्यक्ष संक्रमक रोग (पीडीएसएलएल, मुंबई)  
विशेषज्ञता: वृक्षजीवविज्ञान, संक्रमक रोग, पशुजन्यरोग, वैक्सीनोसर्ज

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

MBBS (UCMS, Delhi), MD Microbiology (MAMC, Delhi)  
Ex-Fellow Infectious Diseases (PDHNS, 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

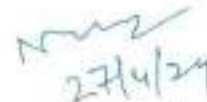
Greetings from BCG Vaccine Laboratory, Chennai.

I assumed charge as Director of BCGVL on 19th, January 2021, it gives me an immense pleasure in bringing out the Annual Report of BCGVL for the year 2023-24.

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). During the Financial Year 2021-22, BCGVL has supplied 270 lakh doses to 24 consignees all over India. In the Financial Year 2022-23, BCGVL has supplied 148 lakh doses of BCG vaccine to consignees all over India to UIP. In the FY 2023-24, BCGVL has supplied 201 lakh doses to GMSD Mumbai, GMSD Chennai, GMSD Karnal and GMSD Kolkata.

New upgraded website of BCGVL, Chennai was launched on 1<sup>st</sup> May 2023. A new walk-in 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 (FY) 2024-25. Repair and maintenance of BCG Staff Quarters is also initiated for FY 2024-25.

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.

  
Dr. Naveen Kumar Gupta  
Director, BCGVL

सं. 110, 33 फुट रोड, माउंट रोड, गिन्दी, चेन्नै - 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 mandate of this Laboratory is:

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.

## Staff Details as on 31.03.2024

Sl.No	Designation	Name (Shri/Smt)
1	Director	Dr. Naveen Kumar Gupta
2	Non-Teaching Specialist Grade II	Dr. D.Senthil Pragash
3	Assistant Director (Non-Medical)	Dr. Vedhagiri Kumaresan
	Group-B (Gazetted)	
4	Veterinarian	Dr. S. Anand
5	Supply Officer	T.Immanuel Gladston
	Group-B (Non-Gazetted)	
6	E & M Supervisor	R. Anandan Padvi Shirish Bapu
7	Asst. Technical Officer	K. Ekambaram M.R. Jayanthi
8	Junior Statistical Officer	S. Andrew
9	Store Officer	A.F. Shahul Hameed
	Group - C	
10	Animal Supervisor	B. Ananthi
11	Technical Supervisor	Dr. R. Balaje M.G. Rajasekhar A. Revathi P. Sasikala K. Raji S. Sudhendhira Devi D. Hema V. Nalina Jancy
12	Scientific Assistant	S.Rajalakshmi T.S.Karthigai G.Ravisankar S.Harini Priyaadarshini P.Saravana Kumar M.P.Natarajan K.Gunasekaran A.TitusSengol Raj
13	Senior Lab. Assistant	M.Krishnan C.K.Venkatesan A. Arulmadhan
14	Laboratory Assistant	P.Chandrasekaran V.Kathiravan L.Chithra T.VenkatesaLal Bahadur E.Senthil Kumar R.Madhanagopal

Sl.No	Designation	Name (Shri/Smt)
15	Technician	R.Narayanan D.Selvam K.K.Joseph T.Sathish
16	Mechanic	L.Kathirvel M.Suresh V.R.Jagadishsuri J.Dhandapani
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 K.Babu D.B.Sase Kumar M. Samy Kumar J. Mahalakshmi Kumar Natwar Singh M. Elumalai K. Selvaraghu R.Panchavarnam V.Kannan
24	Multi-Tasking Staff	K.Umar Ali B.Jayakumar Shankar Lal Meena Shyamsundar Tiwary G.N.Dhivakaran S.L. Indhumol



## List of Committees

### 1. Departmental Screening Committee

S.No	List of Officers/ Officials	Designation
1	Dr. S Anand, Veterinarian	Chairman
2	Shri R Anandan, EMS	Member
3	Shri K Ekambaram, ATO	Member
4	Smt M R Jayanthi, ATO	Member

### 2. Technical Committee

S.No	List of Officers/ Officials	Designation
1	Shri K Ekambaram, ATO	Chairman
2	Smt M R Jayanthi, ATO	Member
3	Shri Padvi Shirish Bapu, EMS	Member
4	Shri S Andrew, JSO	Member
5	Dr. R Balaje, TS	Member

### 3. Purchase committee

S.No	List of Officers/ Officials	Designation
1	Dr.D. Senthil Pragash	Chairman
2	Dr S.Amuthavalli, Deputy Director, KIPMR	Member
3	Smt. Soniya Vijayanandan, TO, NSTI	Member
4	Dr S Anand, Veterinarian	Member
5	Shri R Anandan, EMS	Member
6	Shri A.F.Shahul Hameed, Store Officer	Member

### 4. 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

## 5. IAEC Committee

IAEC Committee	Designation in IAEC	Member profile
Dr. Anand .S, Veterinarian BCG Vaccine Laboratory, Guindy, Chennai-32	Veterinarian (Chairperson)	Internal member
Dr .R. Balaje, Technical Supervisor BCG Vaccine Laboratory, Guindy, Chennai-32	Scientist from different biological discipline (Member Secretary)	Internal member
Smt .D. Hema, Technical Supervisor , BCG Vaccine Laboratory, Guindy, Chennai-32	Scientist In-charge of Animal house facility	Internal member
Mrs S. Sudhendiradevi Technical Supervisor BCG Vaccine Laboratory, Guindy, Chennai-32	Scientist from different biological discipline	Internal member
Mr P. Saravana kumar, Scientific Assistant BCG Vaccine Laboratory, Guindy, Chennai-32	Biological scientist	Internal member
Dr R. Ananda Raja, Principal Scientist, ICAR – Central Institute of Brackishwater Aquaculture, 75, Santhome High Road, R. A. puram, Chennai- 28	Main Nominee	External member nominated by CCSEA
Dr A. Gopinathan, Professor & Head, Dept of Animal Genetics and Breeding, Veterinary College Research Institute, Udumalpet	Link Nominee	External member nominated by CCSEA
Dr A. Muthuvel, Assistant Professor National Institute of Siddha, Dept of AYUSH, Tambaram Sanitorium, Chennai -47	Scientist from outside the Institute	External member nominated by CCSEA
Dr R. Aruna Devi, Research officer, Captain srinivasa Murti Drug Research Institute for Ayurveda, Dept of AYUSH, Chennai,Tamil Nadu	Socially Aware Nominee	External member nominated by CCSEA

## 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 at the time of establishment of BCGVL

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 opened as well.
- 1972** BCG vaccine was supplied in ampoules in liquid form.
- 1973** Production of BCG Vaccine Freeze Dried form (50 doses/ampoule) was introduced
- 1982** Introduced BCG Vaccine in 20 doses/ampoule
- 1995** Manufacturers working seed lot was prepared.
- 2001** BCG Vaccine production was shifted from ampoules to vials.
- 2016** As part of revival project a new cGMP facility for manufacturing BCG Vaccine was made through M/s HLL (Project management consultant) at the sanctioned project cost of Rupees 64.70 crores and handed over in March 2016.
- 2017-18** cGMP facility validation (IQ, OQ and PQ) and process validation was completed. Further, production of trial batches and consistency batches for the manufacturing of BCG Vaccine have been completed successfully.
- 2019** Manufacturing of Commercial batches of BCG Vaccine in new cGMP facility was initiated.
- 2020** Supply of BCG Vaccine from new cGMP facility to Universal Immunization Programme, Government of India was started.

## 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)	18.01.21
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 supplied 170 lakh doses to UIP during FY 2020-21 despite the COVID pandemic.
- ★ BCGVL supplied 270 lakh doses to UIP during FY 2021-22 despite the COVID pandemic.
- ★ BCGVL supplied 148 lakh doses to UIP during FY 2022-23.
- ★ BCGVL supplied 201 lakh doses to UIP during FY 2023-24

## ADMINISTRATION SECTION



### List Of Staff In Administration And Accounts Section

S. No.	NAME (Sri/Smt)	DESIGNATION
1	G. Vijay	Upper Division Clerk
2	M. Jayasankar	Upper Division Clerk
3	D. Joycemani	Upper Division Clerk
4	R. Gopi	Lower Division Clerk
5	T. Babu	Lower Division Clerk
6	Shyamsundar Tiwary	Multi-Tasking Staff
7	G.N.Dhivakaran	Multi-Tasking Staff
8	S.L. Indhumol	Multi-Tasking Staff

### Court Cases

Number of cases handled in CAT, Chennai	11
Number of cases handled in High Court of Madras	04
Total	15
Less : Number of cases order pronounced during 01.04.2023 to 31.03.2024	03 (High Court of Madras)
Total Number of cases pending as on 31.03.2024	12

List of Civil / Electrical Works carried out by CPWD and LOA issued during the period from 01.04.2023 to 31.03.2024

Sl.No	Name of the Works	LOA issued in Rs.
1	Day to Day Maintenance and Annual Repair works of civil nature in Non-Residential Building of BCGVL, Chennai	Rs. 21,04,500/-
2	Upgradation of Animal House (First Floor) at BCGVL office premises	Rs. 74,94,770/- (Revalidated)
3	Maintenance of Electrical Installations etc. in Residential Building of BCGVL at BCG Staff Quarters, Chennai	Rs. 15,54,978/-
4	Day to Day Maintenance and Annual Repair works of civil nature in Residential Building of BCGVL at BCG Staff Quarters, Chennai	Rs. 5,00,000/- (First Phase)

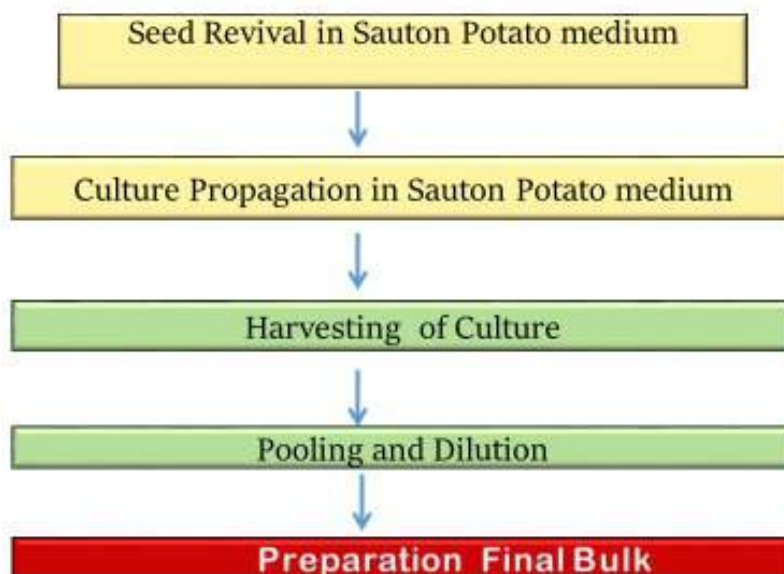
Budget for FY 2023-24

As On	B.E.	R.E.
FY 2023-24	33.71 Crores	31.44 Crores

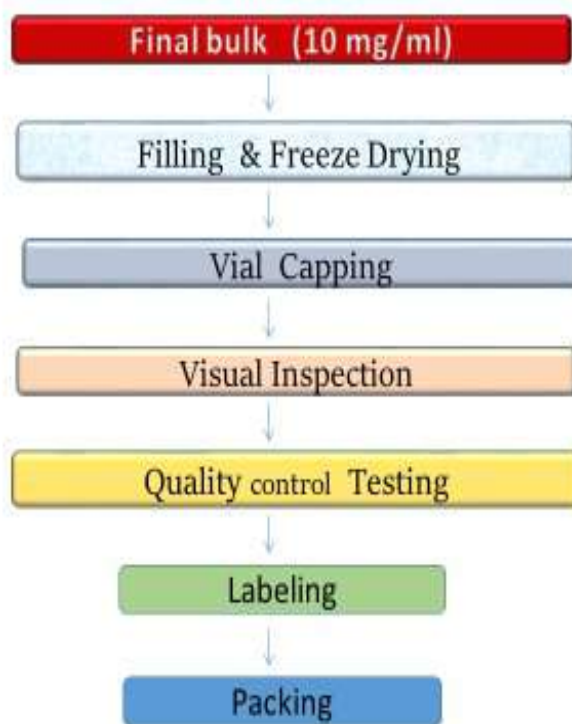
## PRODUCTION SECTION



### Manufacturing Process – Up Stream



## Manufacturing Process - Downstream



### Activities performed from April 2023 to March 2024 in production department

- Seed revival was performed four times on 24/05/2023, 16/08/2023, 08/11/2023 & 06/03/2024.
- Total volume of Sauton media prepared 800 liters.
- Total number of subculture done 100.
- Total number of Harvesting done 67.
- Total volume of suspension made 2,20,215 ml (40 mg/ml).
- Total number of Pooling made 59.
- Total volume of suspension given to containerization was 5,54,070 ml(10mg/ml).
- Total volume of Mono Sodium L Glutamate prepared was 787 liters.
- Total volume of Phosphate buffer prepared was 370 liters.
- Total volume of Soya bean Casein Digest Medium prepared was 66 liters for Media Filling.



# BCG VACCINE LABORATORY, CHENNAI

## Core List of the Equipment and Instruments available in the department for production (Upstream Activities)

S.No	Name of the Equipment 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 for preparative purpose

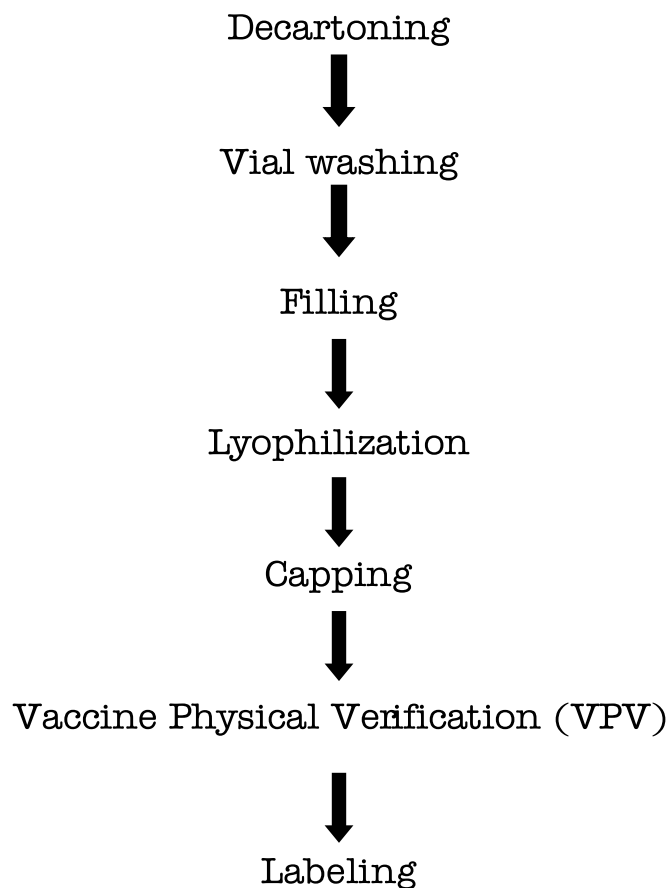
S.No	Name of the Equipment and Instruments
1	Autoclave (Material sterilization)
2	Dry Heat Sterilizer
3	Autoclave(Decontamination)
4	Garment washing machine
5	Garment Drier Machine
6	Garment cubicle (static)
7	Vacuum cleaner
8	Computer with printer
9	Pass box(Dynamic)
10	Pass box(Static)

## 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



## 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 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.
- 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.

### Lyophilization

- Half stoppered vials are loaded in lyophilizer and the temperature is reduced to -400 C within a period of 3 hours. During this process, the product is converted from liquid form to frozen form. The product is kept at this temperature for one hour. After this, the lyophilization process is started to remove the moisture in the product without disturbing the physical and chemical characteristics.
- Before increasing the temperature, the pressure inside the lyophilizer is reduced to 100 micro torr at a prescribed rate to convert the moisture in the product to water vapour and the water vapour gets migrated to the condenser (trap). During this process, moisture content in the product is reduced to 3%. Hence, the shelf life of the product is increased to two years.

### 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 2 to 8° c.

## DOWNSTREAM PROCESS

## 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.

## Containerization Section Regular Staff

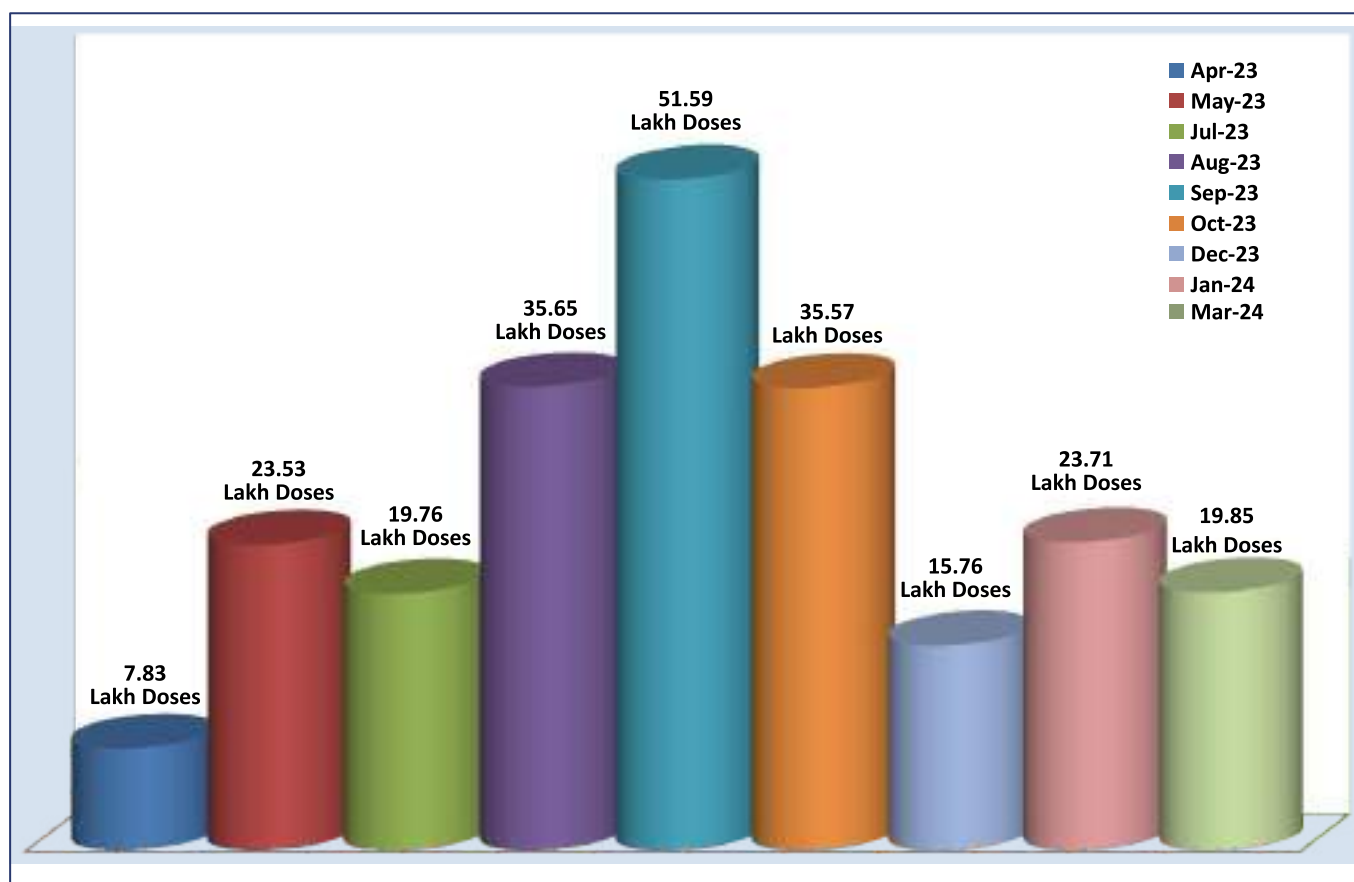
S. No.	Name Of The Staff	Post
1.	K. Ekambaram	Assistant Technical Officer
2.	P. Sasikala	Technical Supervisor
3.	S. Sudhendra Devi	Technical Supervisor
4.	S. Harini Priyaadarshini	Scientific Assistant
5.	G. Ravisankar	Scientific Assistant
6.	K. Gunasekaran	Scientific Assistant
7.	A. Arul Madhan	Senior Laboratory Assistant
8.	P. Chandrasekaran	Laboratory Assistant
9.	R. Madhanagopal	Laboratory Assistant
10.	A.S. Kumar	Laboratory Assistant
11.	V. Kannan	Laboratory Assistant
12.	J. Dhandapani	Mechanic
13.	J. Ciril Raj	Carpenter
14.	K.Selva Raghu	Laboratory Attendant

## Containerization Section Contractual Staff

S. No.	Name Of The Staff	Post
1.	R.Parthiban	Technical Assistant Grade II
2.	C.David Bagyaraj	Technical Assistant Grade II
3.	K.Ajith	Technical Assistant Grade II
4.	J.Gnanaprakash	Technical Assistant Grade II
5.	K.Karthik	Technical Assistant Grade II
6.	N.Divyamahalakshmi	Technical Assistant Grade I
7.	S.Swetha	Technical Assistant Grade II
8.	N.Nareshbabu	Technical Assistant Grade III
9.	S.Karthick	Technical Assistant Grade III

S. No.	Month & Year	Lot Numbers	Doses Produced in Lakhs
1.	April 2023	L 161 to L 162	7.83
2.	May 2023	L 163 to L 168	23.53
3.	July 2023	L 169 to L 173	19.76
4.	August 2023	L 174 to L 182	35.65
5.	September 2023	L 183 to L 195	51.59
6.	October 2023	L 196 to L 204	35.57
7.	December 2023	L 205 to L 208	15.76
8.	January 2024	L 209 to L 214	23.71
9.	March 2024	L 215 to L 219	19.85
Total		L 161 to L 219	233.25

## Bcg Vaccine Doses Produced During The Year 2023-2024





## Containerization Equipment List

S. No.	Equipment
1.	Vial washing & Depyrogenation Tunnel (IMA Life)
2.	Online filling machine & Half stoppering (IMA Life)
3.	Vial capping machine (IMA Life)
4.	Mobile LAF (Dyna)
5.	Dry heat sterilizer (Metal Chem industries)
6.	Bung processor cum sterilizer (Metal Chem industries)
7.	Decontamination autoclave (Metal Chem industries)
8.	Vial inspection machine (Fabtech technologies)
9.	VVM Applicator (Maharshi)
10.	Vial labeling machine (NKP Pharma)
11.	Dynamic garment cubical (Dyna)
12.	Dynamic garment cubical (Dyna)
13.	Garment Washing (Lucky engineering works, Bosch)
14.	Dynamic pass box (IClean)
15.	Static pass box (IClean)
16.	Floor mount Dynamic pass box (IClean)
17.	Floor mount pass box (IClean)
18.	Dynamic garment cubical (IClean)
19.	Dynamic garment cubical (IClean)
20.	Dynamic garment cubical (IClean)
21.	Garment dryer (IFB, Bosch)
22.	Weighing balance (Shimadzu)
23.	LAF (Dyna)

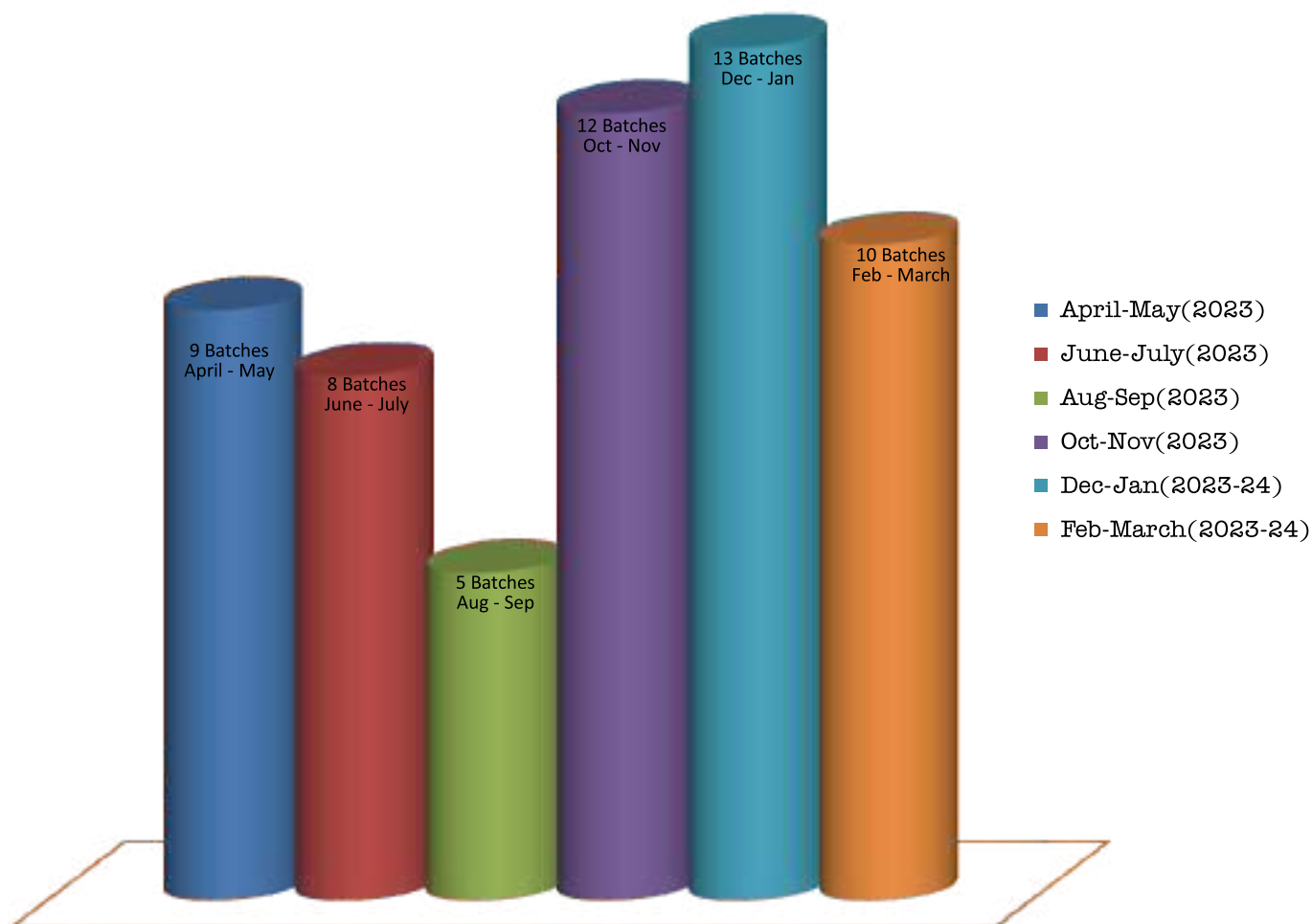
## PACKING AND SUPPLY SECTION



- IPQC released and labelled Batches of vials are packed into respective Batches in minor cartons of 50 vials each and kept in a pack of 20 minor cartons to make 1000 vials/pack and stored in cold room at 2-8°C for CDL release to supply.
- In total 57 Batches consisting of 2209000 vials were packed in minor cartons.
- Upon release and Inspection, for supply to allotted consignees 2000 vials along with cold gel packs were packed in EPS box with outer corrugated major box and the diluent of respective Batches are arranged as per packing note and verified for dispatch.
- The consignment of Vaccine and its diluent allocated for the consignee is loaded in the refrigerated truck maintained at 2-8°C on the day of dispatch.

S.No.	Period	No. of batches	Total vials packed for supply
1.	April 2023	7	267750
2.	May 2023	2	77350
3.	June 2023	5	192400
4.	July 2023	3	115150
5.	August 2023	NIL	NIL
6.	September 2023	5	194250
7.	October 2023	4	156100
8.	November 2023	8	310600
9.	December 2023	6	233850
10.	January 2024	7	272050
11.	February 2024	6	234400
12.	March 2024	4	155100
	<b>Total</b>	<b>57</b>	<b>2209000</b>

## TOTAL NUMBER OF BATCHES PACKED FOR FY 2023 - 2024

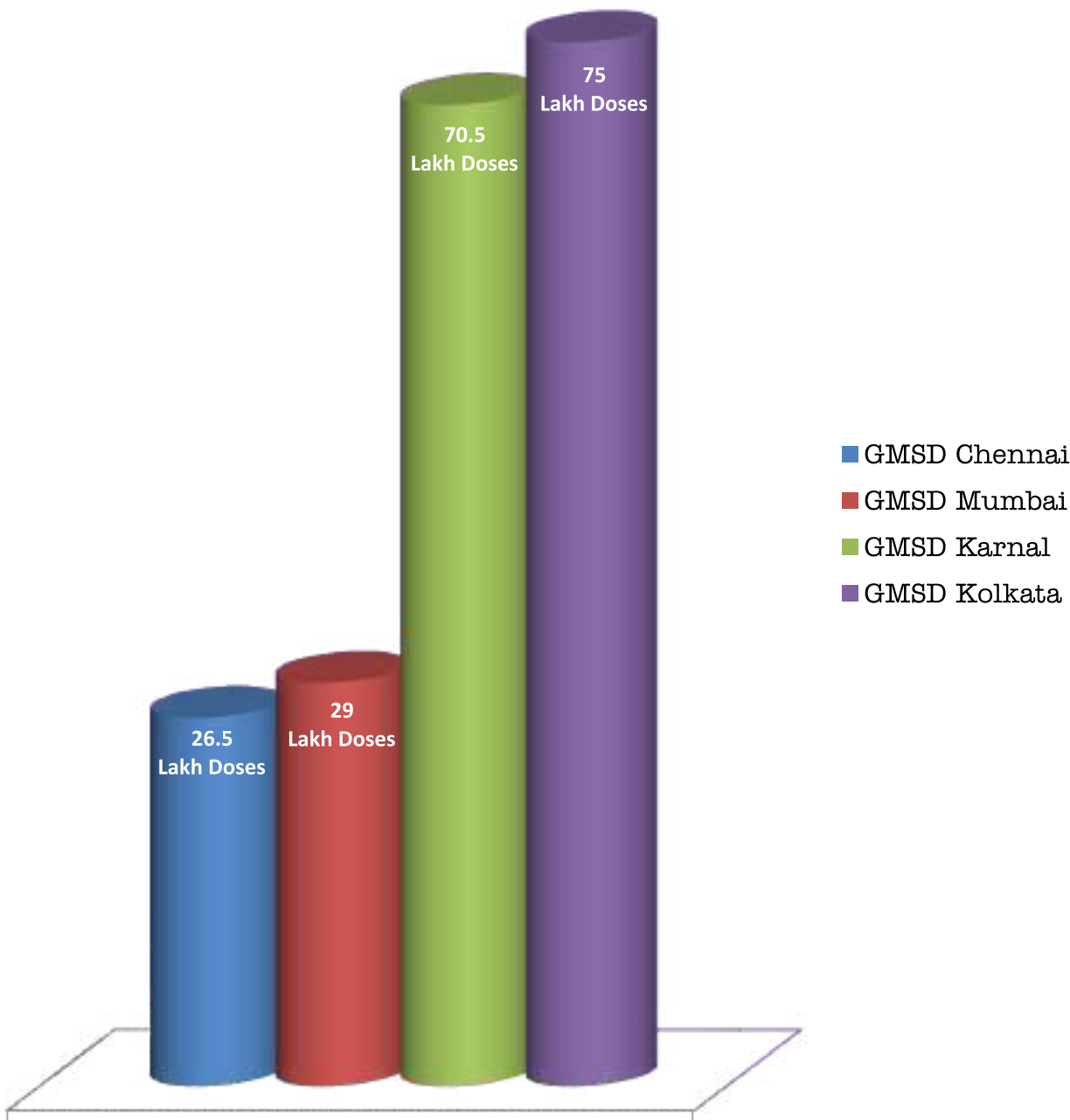




## SUPPLY SECTION

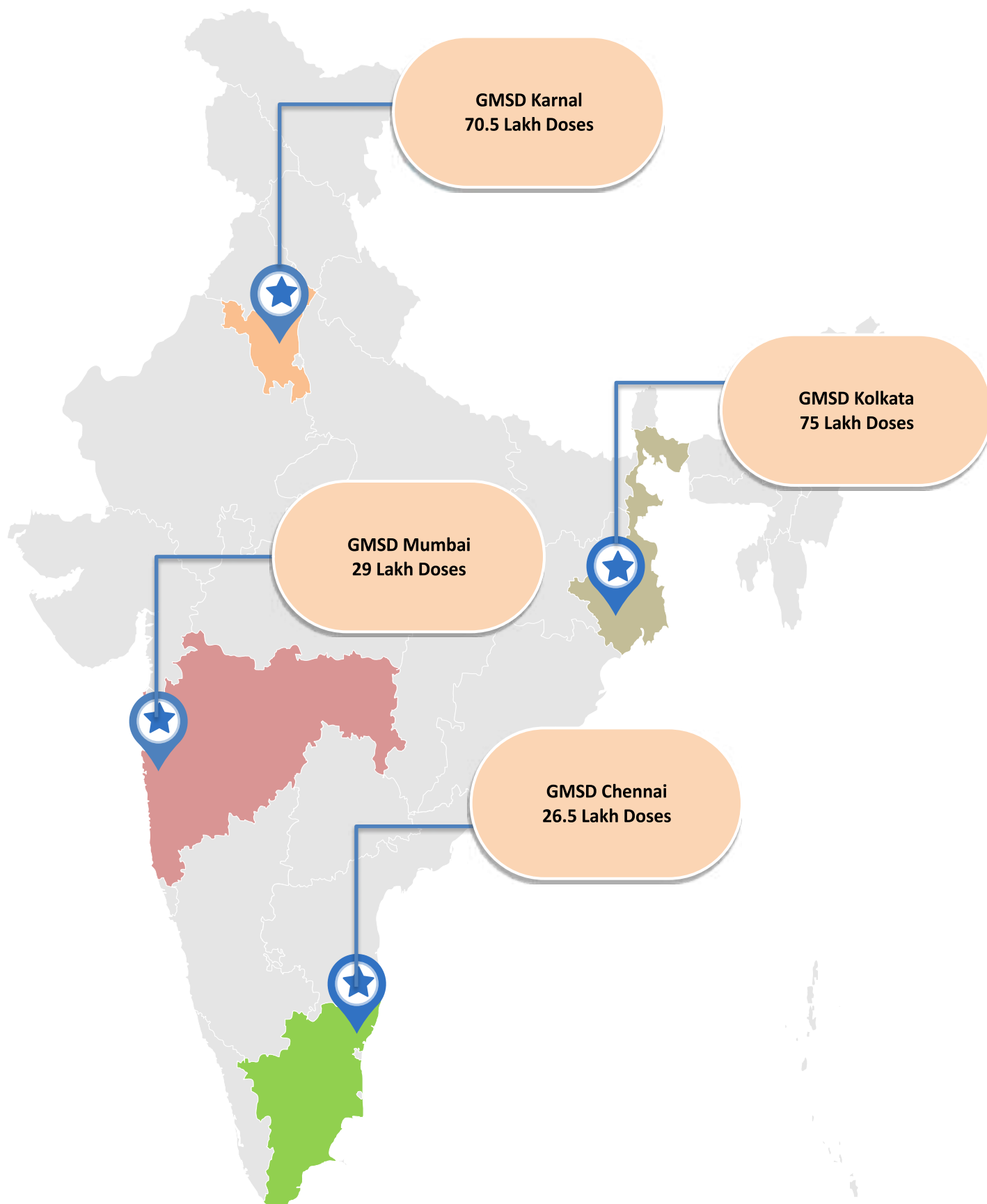
S.NO.	CONSIGNEE	TOTAL DOSES SUPPLIED
1	GMSD, Chennai	26.5 Lakh
2	GMSD, Mumbai	29 Lakh
3	GMSD, Karnal	70.5Lakh
4	GMSD, Kolkata	75 Lakh
Total Vaccine doses supplied in FY 2023-2024		201 lakh doses (128 lakh doses for FY 23-24 and 73 lakh doses for FY 22-23)

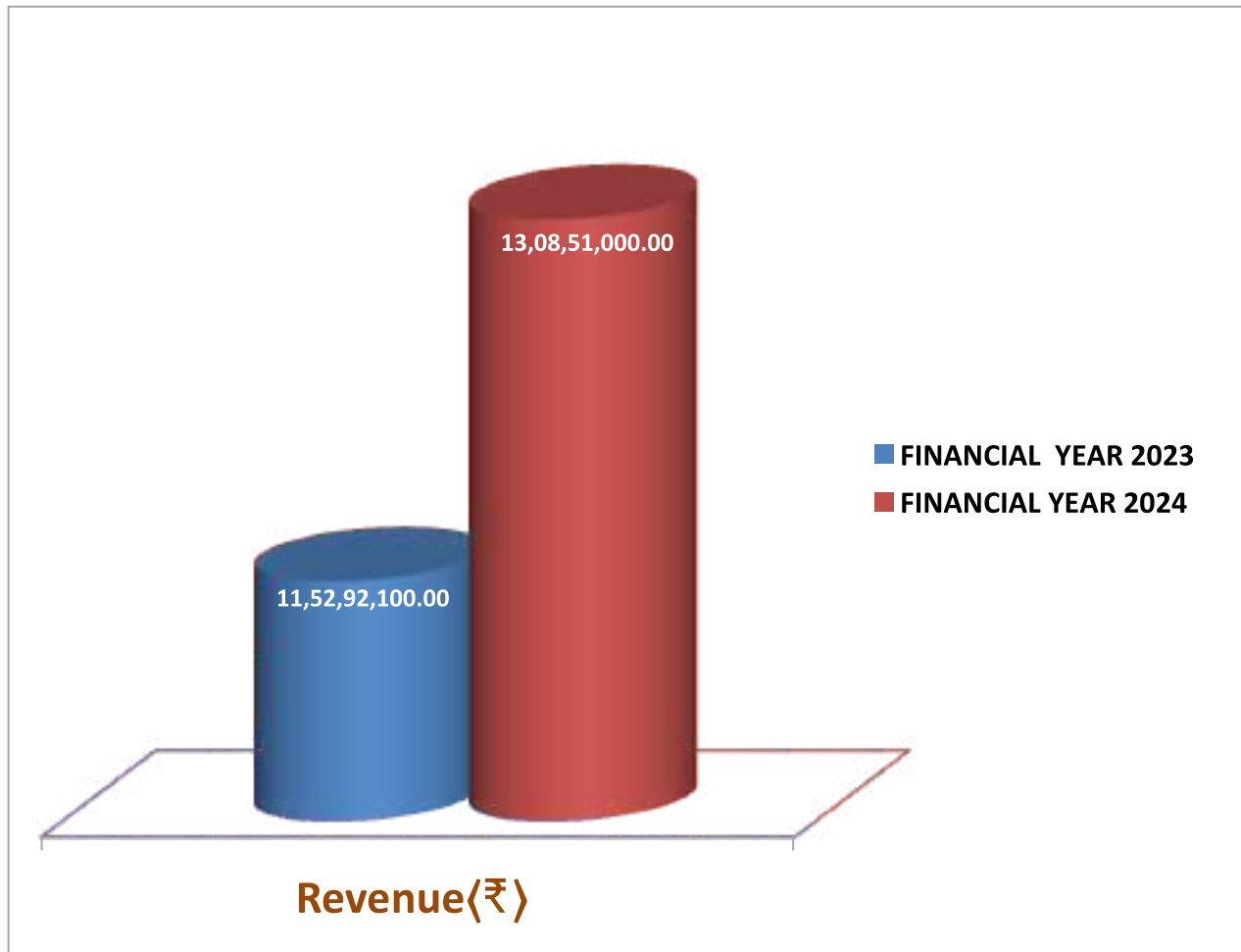
SUPPLY STATUS OF BCG VACCINE IN FY 2023-2024





## GMSD Supply Of BCG Vaccine For FY 2023-2024





Revenue Generated by supply of vaccine to various consignees

- ★ Doses Supplied: 20,10,000 Vials X 10 doses = 201 lakh doses
- ★ Revenue Generated in FY 2023 - 2024
- ★ 2,01,00,000 (Doses supplied) X Rs.6.51 (price per dose) = Rs 13,08,51,000/

## 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.

### STAFF DETAILS

Sl. No.	Name	Designation
	S/Shri/Smt.	
1.	A.F. Shahul Hameed	Store Officer
2.	T. Vairavel	UDC
3.	M.K. Gurumurthy	Storekeeper
4.	E. Senthil Kumar	Lab Assistant
5.	Shankar Lal Meena	MTS

### ACTIVITIES

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 - 29 Lakhs

## 3. Number of Maintenance Contracts awarded :

Sl. No.	Nature of Contract	No. Awarded
1.	Annual Maintenance Contract	12
2.	Comprehensive Maintenance Contract	04
3	Operation & Maintenance Contract	04
4.	Maintenance Contracts through GeM Portal	04
	(a) Air Conditioners	
	(b) Computers	
	(c) Rodent Control	
	(d) Deployment of Security Guards	

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

	2021 - 22	2022 - 23	2023 - 24
No. of Orders placed	88	146	454
Goods	31,00,000/-	Rs. 55,01,689/-	Rs. 76,88,417/-
Services	19,30,000/-	Rs. 52,89,630/-	Rs. 93,32,209/-
TOTAL	Rs.50,30,000/-	Rs.1,07,91,319/-	Rs.1,70,20,626/-

## 5. No. of Bills processed - 797

## 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 46 Batches are sent to CDL for testing and Release.
4. BCGVL produced and Supplied 201 Lakh Doses for the UIP.
5. BCG Vaccine Sample draw and Cold storage Inspection for supply upon release by the Joint Director, DPH & Immunization was coordinated.
6. Inspection notes of fourteen No's to the allotted consignees are processed and issued to respective consignees.
7. Verified the suitability of certain materials purchased and the same certified.
8. Involved in the procurement of items on Market survey, technical committee and generated the comparison statement and the report submitted for the procurement process.
9. Interaction with the internal Departments in the process of production activities and utilities management.

S.No	Name of the Equipment	
1	Deep freezer	Viable Air Sampler
2	Particle Counter (LasairIII)	Data Logger
3	Particle Counter (Metone)	Electronic Weighing Balance



## QUALITY CONTROL



The activities are given below:

Sl.No	Topic	Activities
1.	Activities performed from 01.04.2023 to 31.03.2024	<p>1. Testing of BCG vaccine The Following tests has been completed for 58 Batches</p> <ul style="list-style-type: none"> <li>a) Identity test (Seed Lot, Individual suspension, Final Bulk, Final Lot, labeled vials)</li> <li>b) Sterility test (Seed Lot, Individual suspension, Final Bulk, Final Lot)</li> <li>c) Optical Density (For Every Final Bulk)</li> <li>d) Viability for Every Bulk</li> <li>e) Viability for Lot &amp; Thermal Stability for Every Final Lot</li> <li>f) Absence of Virulent Mycobacteria (For Every Final Bulk)</li> <li>g) Excessive Dermal Reactivity (For FIVE Consecutive batches from Seed Lot)</li> <li>h) Water content for Every Final Lot</li> </ul> <p>2. Environmental and Personnel Monitoring were performed and reported. (At rest and during every operation for all sections)</p> <p>3. Raw material testing</p> <ul style="list-style-type: none"> <li>a) Water testing- Raw water, Pre- treatment MGF, UF, Softner, RO I RO II EDI SMBS , PW and WFI Daily Routine Physiochemical &amp; Microbiology tests</li> <li>b) Primary packaging material</li> </ul>

		1) 2R Vials 2) Rubber wads 3) Al. Flip offs c) Diluents  4. Growth Promotion Test for SCDA,SDA, FTM & SCDM  5. PCR – Test for BCG strain (DANISH 1331) using the RD gene system was performed during this period.  6. Stability study (Real time study) for 3 consecutive batches  L133, L134, L135 Identity, Sterility, Viability & Water Content  7. Media Fill - 4 times  8. Retention sample with Diluent received from Packing for Every Final Lot
2	Training conducted from 01.04.2023 to 31.03.2024	Oral and Hands - on training sessions given to all and for newly appointed staff
3	Future plan	1. Testing of Rubber wads as per regulatory guidelines some of the test to be outsourced a) Identification b) Biological test to be outsourced
4	Brief write up on New facility created	A proposal and plan for establishment of new Microbiology lab and washing facility has been duly forwarded.
5	List of equipment procured during the period of 01.04.2023 to 31.03.2024	1. Hot Air Oven 2. Cell frost (Refrigerator) 3. Emergency Lamp 3 Nos. 4. Autoclave 5. Air blower (BOSCH) 6. Washing machine Drier (BOSCH) 2 Nos.

Sl.No	List of Equipment
1.	Decontamination Autoclave
2.	Vacuum Cleaner
3.	Autoclave Sterilization
4.	Dry Heat Sterilizer
5.	Electronic Weighing Balance
6.	Analytical Weighing Balance
7.	Dry Fogger
8.	Decontamination Autoclave

9.	Vacuum Cleaner
10.	Autoclave Sterilization
11.	Dry Heat Sterilizer
12.	Electronic Weighing Balance
13.	Analytical Weighing Balance
14.	Dry Fogger
15.	SS Fumigator
16.	Motorized stirrer
17.	Laminar Air Flow
18.	Bio- Safety Cabinet
19.	Static Pass Box
20.	Dynamic pass box
21.	Incubator
22.	Water Bath (Electrical)
23.	Inspissator
24.	Air Conditioner
25.	Air sampler
26.	Fluorescent Microscope
27.	Light Microscope
28.	Micro oven
29.	Digital Colony Counter
30.	Bioluminocense (Bioluminometer)
31.	Hot Air Oven
32.	HPLC
33.	Sonicator
34.	TOC Analyzer
35.	KF Coluometer
36.	KF Thermoprep
37.	UV - Vis Spectrophotometer
38.	Vortex Mixer
39.	pH - Meter
40.	Drier machine
41.	Deep Freezer
42.	Refrigerator
43.	Walk in incubator
44.	Stability chamber
45.	Heating Block (Dry Heat Bath)
46.	Cold Room
47.	Refrigerated Centrifuge
48.	Gel Doc system
49.	Bio Spectrometer
50.	Agarose Gel electrophoresis Apparatus
51.	PCR
52.	Conductivity meter

## 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 CCSEA wide registration 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: 2023 - 24

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 31.03.2024

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	Laboratory Attendant
5	Mr. B. Kumar	
6	Mr. K. Babu	
7	Mr. Kumar Natwar Singh	
8	Mr. B. Jayakumar	MTS
9	Mr. S. Vignesh	TA Grade III (Contract)
10	Mr. Shankar T	

Animal stock and usage

Guinea pigs	2022 - 23	2023 - 24
Animal Stock( as on 31 <sup>st</sup> March)	490	364
Births	307	393
Receipts	0	150
Used for Testing	252	480
No of batches tested	42	80

Conferences/Seminars/Trainings/Visit attended

1. 5-day training on Laboratory Animal Management for Animal Attendants from 24th to 28th April 2023 conducted by Laboratory Animal Medicine unit, Centre for Animal Health Studies, Tamilnadu Veterinary And Animal Sciences University, Chennai 600 051 attended by Mrs B. Ananthi - Animal supervisor, Mr M. Madhavan, and Mr A. S. Kumar – Laboratory Attendant.,
2. 11th International Conference of Laboratory Animal Scientists' Association (LASA), India, on "Advancement of 3R's in Biomedical research, Laboratory Animal Welfare: International perspectives" and preconference workshop organized by the LASA India in Hyderabad during 6th, 7th and 8th 3rd & 4th November 2023 at JN Tata Auditorium, National Science Complex, Indian Institute of Science, Bangalore attended by Dr. Anand S, Veterinarian.

Meetings/ Inspection conducted

Name	Duration	Participants
5 <sup>th</sup> IAEC meeting	23.12.2023	IAEC members
Annual inspection	17.02.2024	CCSEA Main nominee

Equipment / Materials acquired:

1. Work initiated for renovation and upgradation of First floor of Laboratory Animal House through CPWD.



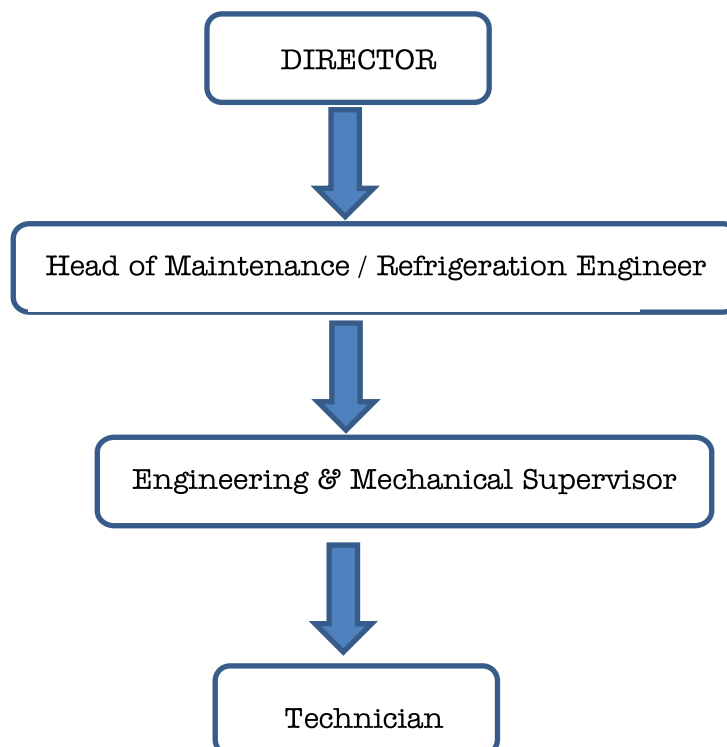
## ENGINEERING AND MAINTENANCE SECTION



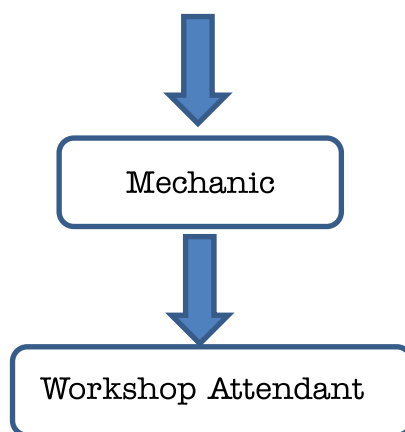
- Engineering & Maintenance Section is situated in the ground floor of the main building of BCGVL and the Engineering Workshop is situated opposite to the Animal House Section.

### Organogram of Engineering & Maintenance Section

The Organogram of Engineering & Maintenance Section







Apart from the above, Operation & Maintenance Officials are working on annual contract basis for running utilities such as Boiler, Air Compressor, Water Plant System, ETP/STP, Electrical Substation & HVAC System on 24 X 7 basis under the supervision of Engineering & Maintenance Section.

## Major Works of Engineering & Maintenance Section in BCGVL

- A. Preventive Maintenance.
- B. Breakdown Maintenance.
- C. Operation & Maintenance of Utility.
  - 1) Building Management System.
  - 2) HVAC System
    - ❖ Air Cooled Chiller & Brine Chiller.
    - ❖ Air Handling Unit (AHU).
    - ❖ Ventilation Unit System (VUS).
    - ❖ Treated Fresh Air Unit (TFA).
  - 3) IBR Boiler.
  - 4) Air Compressor.
  - 5) Electrical Substation.
  - 6) Water Treatment Plant.
    - ❖ Pre-Treatment System.
    - ❖ RO system.
    - ❖ Purified Water Generation System
    - ❖ Purified Water Storage & Distribution
    - ❖ Pure Steam Generation Plant.
    - ❖ WFI Generation Plant
    - ❖ WFI Storage & Distribution
  - 7) Effluent Treatment Plant (ETP).

- 8) Sewage Treatment Plant (STP).
- 9) Fire Pumps (Diesel, Electrical & Jockey Pump).
- 10) Diesel Generator.

D. Operation of Important Machineries used for vaccine production.

- 1) Online Vial Washing & Depyrogenation tunnel.
- 2) Online Filling & Half Stoppering Machine.
- 3) Lyophilizer
- 4) Labelling Machine.

E. Renewal of various licences such as Fire licence, TNPCB, IBR Boiler and Electrical Safety.

F. Co-ordination with outsourcing agencies for validation of Equipment

## Preventive / Breakdown Maintenance

- Preventive Maintenance has been carried out on Quarterly basis as per the Schedule received from Quality Assurance Section and documents (i.e., Checklist & History Card) are being maintained by Engineering & Maintenance Section.
- Preventive / Breakdown Maintenance is carried out by Engineering & Maintenance Section for the following equipment listed below :

S.No	Name of the Equipment
1)	Pass Box (Dynamic / Static)
2)	Garment Cubicle
3)	Bio Safety Cabinet
4)	Autoclave / Decontamination Autoclave
5)	Dry Heat Sterilizer
6)	Dispensing Booth
7)	Laminar Air Flow (Hanging / Mobile)
8)	Incubator
9)	Media Preparation
10)	CIP Trolley
11)	Deep Freezer
12)	Refrigerator
13)	Garment Washing / Drying Machine
14)	BCG Mill
15)	Water Plant
16)	HVAC System ( Chiller, AHU, VUS, TFA)
17)	Building Management System (BMS)
18)	Filter Cleaning Machine
19)	Diesel Generator Set
20)	IBR Boiler
21)	ETP / STP
22)	Air Compressor
23)	Fire Pump
24)	Mobile Generator Set

25)	Bung Processor cum Sterilizer
26)	Physical Verification Machine
27)	Vial Labelling Machine
28)	VVM Applicator
29)	Vial Washing & Depyrogenation Tunnel
30)	Filling & Half Stoppering Machine
31)	Vial Capping Machine
32)	Lyophilizer
33)	Bio Waste Inactivation Tank
34)	Bio Waste Collection Tank
35)	Cold Room
36)	Elevator (Material \ Personnel)

## Operation & Maintenance of Utility:



Fig : Building Management Sysytem (BMS)



Fig : Air Cooled Chiller



Fig : Brine Chiller



Fig : Air Handling Unit (AHU)



Fig : IBR Boiler



Fig : Electrical Substation





Fig : Air Compressor



Fig : Effluent Treatment Plant (ETP)



Fig : Sewage Treatment Plant (STP)



Fig : Water Treatment Plant



Fig : Diesel Generator (600 KVA)



Fig : Diesel Generator (380 KVA)

## Major Activities Done By Engineering & Maintenance Section During FY 2023 - 24

- New RO Plant Installed at Main Building for providing drinking water to BCGVL Officials.
- New Refrigerated truck was bought from Government Medical Store Depot Chennai and the process of Registration, National & State Permit was carried out by Engineering & Maintenance Section.
- Office Room facility for Animal House Section.
- Conversion of Main Building Vial Washing Area into temporary Washing Area of Animal House Section due to renovation of Animal House Building.
- Conversion of Main Building Sterilization Section into temporary Breeding Area of Animal House Section due to renovation of Animal House Building.
- Flooring Work in Engineering Workshop.
- Co-ordination with CPWD for renovation works of Animal House Section.



Fig : Installation of RO Plant in Main Building of BCGVL





Fig : New Refrigerated Truck for supplying BCG Vaccine to various GMSD across India

## Equipment in cGMP Facility







## Transport

BCG Vaccines are being supplied to various GMSDs (i.e, GMSD Mumbai, GMSD Karnal, GMSD Kolkata & GMSD Chennai) through refrigerated trucks of BCGVL.

The transport details of BCG Vaccines to various GMSDs during FY 2023-24 is as follows:

Vehicle No	Date		Kilometres Covered	Place of Supply	Quantity (in Lakh Doses)
	From	To			
TN04 AY 3492	26-10-2023	26-10-2023	25	GMSD Chennai	4.0
	28-10-2023	12-11-2023	6015	GMSD Kolkata	7.0
				GMSD Karnal	23.5
	22-01-2024	22-01-2024	25	GMSD Chennai	7.16
	02-02-2024	14-02-2024	5344	GMSD Mumbai	16.0
				GMSD Kolkata	14.0
	23-02-2024	07-03-2024	4961	GMSD Karnal	29.0
TN19 D 3546	07-03-2024	07-03-2024	25	GMSD Chennai	7.84
	21-03-2024	01-04-2024	3544	GMSD Kolkata	25.0
	06-04-2023	16-04-2023	3452	GMSD Kolkata	29.0
	24-04-2023	24-04-2023	25	GMSD Chennai	7.5
	14-08-2023	28-08-2023	3544	GMSD Mumbai	13.0
				GMSD Karnal	18.0

## LIST OF RETIRED STAFF FOR THE PERIOD FROM 01.04.2023 TO 31.03.2024

S.No.	Name (S/Shri/Smt.) & Designation	Date of Retirement
1.	A.Sheshalakshmi, Scientific Assistant	30.04.2023
2.	V.Indra, Office Superintendent	31.05.2023
3.	A.Murali, Mechanic	31.05.2023
4.	Dr. Hassan Thuddathifanuge, CMO(SAG)	31.08.2023
5.	V.Kennedy, Laboratory Attendant	31.12.2023



## Events and Gallery

### 1. BCGVL 75th Raising Day Celebration held on 01.05.2023











## 2. Independence Day celebration in BCGVL campus on 15.08.2023





## 3. Independence day celebration in BCG Staff Quarters on 15.08.2023



4. Gandhi Jayanthi on 02.10.2023



5. Swachhata Campaign during 01.10.2023 to 31.10.2023









**BEFORE**



**AFTER**



**BEFORE**



**AFTER**



6. Women's day Sapling Plantation Drive



## 7. Pongal Celebration in BCGVL Campus





### 8. Five days training on Laboratory Animal Management for Animal Attendants from 24th to 28th April 2023 at TANUVAS



### 9. Annual Inspection of Animal House by CCSEA Main Nominee



10. Ayud Pooja in BCGVL



11. Function at Voluntary Health Services on 14.06.2023.







Officers and Section Heads in BCGVL, Chennai



BCGVL Staff Union





**BCGVL TEAM AS ON 31.03.2024**





### **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

Email: [bcgvl.tnchn@nic.in](mailto:bcgvl.tnchn@nic.in) / Website: [www.dirbcglab.gov.in](http://www.dirbcglab.gov.in)  
044- 2250 0476

