

# Regional Workshop on lot release of COVID-19 vaccines

Kasauli, India, 10–14 October 2022  
Report of the Workshop



REGIONAL OFFICE FOR

**World Health  
Organization**  
**South-East Asia**



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## List of abbreviations and acronyms

AEFI	adverse events following immunization
CDL	Central Drugs Laboratory (Kasauli, India)
COVID-19	novel coronavirus disease
CMC	chemistry, manufacturing and control
CQA	critical quality attribute
GBT	Global Benchmarking Tool
GLO	Global Learning Opportunities
GMP	good manufacturing practice
ISS	Immunization System Strengthening
IVD	Immunization and Vaccine Development
LNS	Laboratory Networks and Services
mRNA	messenger-ribonucleic acid
NCL	national control laboratory
NIBSC	National Institute for Biological Standards and Control
NRA	national regulatory authority
QMS	quality management system
SEARN	South-East Asian Regulatory Network
SOP	standard operating procedure
TGA	Therapeutic Goods Administration
WCO	WHO country office
WHO	World Health Organization

## Executive summary

A five-day regional workshop on “Lot release of COVID-19 vaccines” was conducted in Kasauli, India from 10 to 14 October 2022 by the Communicable Diseases Department – Immunization and Vaccine Development (IVD) of the WHO Regional Office for South-East Asia in coordination with the Central Drugs Laboratory (CDL) for vaccine testing in India. It had participants from national control laboratories (NCLs)/national regulatory authorities (NRAs)/ministries of health of Bangladesh, Bhutan, India, Indonesia, Maldives, Nepal, Sri Lanka, Thailand and WHO Country Office Nepal. Experts from the Therapeutic Goods Administration (TGA), WHO headquarters and WHO Country Office Bangladesh attended the workshop virtually.

During the working group’s meeting of the South-East Asian Regulatory Network (SEARN) in January 2022, participating NRAs had requested support on COVID-19 vaccines. Three main needs were highlighted:

- the need to discuss regulatory hot topics related to COVID-19 (such as how to transition from emergency use authorizations to full marketing authorizations);
- the need to advocate integration of adverse events following immunization (AEFI) into the vigilance system; and
- the need for capacity-building through training of laboratory technical staff in testing and lot release of COVID-19-related products (e.g. mRNA platforms or diagnostics).

The WHO Regional Office for South-East Asia (Health System Development [HSD] and IVD) is conducting a series of meetings, trainings and workshops for regulation of all COVID-19-related medicinal products including vaccines and in vitro diagnostics to address the above needs. This regional lot release workshop was part of this larger programme of activities, which aimed to address the third need for capacity-building of laboratory technical staff.

The objectives of the workshop were:

- to strengthen capabilities of NCL and NRA staff to carry out independent lot release of COVID-19 vaccines when the vaccine has full marketing authorization in the country
- to efficiently review the lot summary protocols of all types of COVID-19 vaccines
- to deliberate on policies and approaches in the Region for testing and lot release of COVID-19 vaccines
- to prepare a plan for participation in international harmonization exercises for testing of COVID-19 vaccines and a roadmap for regional NCLs surrogacy plan for vaccine testing
- to explore the possibilities of developing regional working reference standards for certain COVID-19 vaccines for laboratory access of locally produced vaccines.

The five-day workshop had four technical sessions with presentations, discussions and group exercises and hands-on laboratory sessions and a field visit. The technical sessions had discussions on the progress made in COVID-19 Vaccine Deployment and Regulation and Linkages with Regional Vaccine Implementation Plan 2022–2026; WHO



lot release guidelines and lessons learnt from the pandemic and modules on lot release management, NRA indicators and lot release procedure; summary lot protocol for COVID-19 vaccines and global experience sharing by TGA on lot release processes; and testing of imported and indigenously manufactured COVID-19 vaccines. The workshop had laboratory sessions on COVID-19 vaccines/conventional technologies at the CDL to better explain the laboratory access regulatory function to the participants. The participants were also taken on a field visit for sample collection, shipment preparation and tracking.

The final day of the workshop involved “report making for lot release finalization” incorporating case studies of lot release and test certificates. This was followed by a “course overview and follow-up actions”, which included future workshops and proposed trainings. The participating NRAs/NCLs were requested to share certain experiential information with WHO for analysis and publication. The closing session of the workshop featured a post-workshop questionnaire and course evaluation.



## 1. Background

Lot release of vaccines by, as a minimum, review of a summary protocol and access to a laboratory are two of the essential functions of a national regulatory authority (NRA) for assuring the quality of vaccines used in the immunization programme as defined by WHO. Lot release is the process of evaluating each individual lot of a licensed product before giving approval for its release into the market. This process is carried out for vaccines and other biologicals in most countries. General practices of release involve the review of manufacturer's production data and quality control test results (product summary protocol) by the NRAs and national control laboratories (NCLs). This may or may not be supplemented by laboratory testing by the NCL, or by an agency or contracted laboratory performing tests for the NRA.

The past two years have seen an unprecedented approach to vaccine development and manufacturing in the global efforts against the COVID-19 pandemic. Despite the huge scientific and regulatory achievements and significant investment to accelerate vaccine availability, it is essential that quality, efficacy and safety measures are not compromised. Vaccines undergo rigorous regulatory approval procedures, which include an obligation for compliance with good manufacturing practices (GMP), testing and lot release. Vaccine lot or batch release by NRAs/NCLs is thus essential to monitoring critical quality attributes (CQAs) and ensuring that high-quality and well-characterized vaccine products are manufactured consistently. The regulatory functions of lot release and laboratory access are a critical part of the regulatory oversight by NRAs.

The Central Drugs Laboratory (CDL), Kasauli, India has been a centre of excellence for vaccine testing and lot release. It has also been a WHO Global Learning Opportunities (GLO) training centre for lot release and has conducted many regional and global workshops for this NRA function. It has successfully developed capabilities to test and release most of the COVID-19 vaccines including a novel technology platform. After the notable accomplishment in testing and releasing billions of doses of COVID-19 for national and international use, the CDL could share this experience with other Member States of the South-East (SE) Asia Region.

## 2. Objectives of the workshop

The main objective of the workshop was to improve capacity of NRAs and NCLs in the Region in lot release of COVID-19 vaccines.

The key objectives of the workshop were:

- to strengthen capabilities of NCL and NRA staff in the SE Asia Region to carry out independent lot release of COVID-19 vaccines when the vaccine has full marketing authorization in the country;
- to review the lot summary protocols of all types of COVID-19 vaccines;
- to bring clarity on policies and approaches in the SE Asia Region for testing and lot release of COVID-19 vaccines;

- to prepare a plan for participation in international harmonization exercises for testing of COVID-19 vaccines and develop a roadmap for a surrogacy plan for vaccine testing for NCLs in the SE Asia Region; and
- to explore the possibilities of developing regional working reference standards for certain COVID-19 vaccines for laboratory access of locally produced vaccines.

Overall, it also deepened the theoretical and practical concepts and prepared staff from manufacturing countries for a future hands-on training workshop for learning scientific concepts and knowledge for lot release of COVID-19 vaccines.

### 3. Organization of the workshop

The five-day workshop was organized by the Communicable Diseases Department – Immunization and Vaccine Development (IVD) of the WHO Regional Office for South-East Asia in coordination with the CDL Kasauli, who were also the main trainers and facilitators. The technical staff (directors, scientists, drug inspectors and officers) of NRAs/NCLs/ministries of health of the Region (eight from the SE Asia Region: Bangladesh, Bhutan, India, Indonesia, Maldives, Nepal, Sri Lanka and Thailand) physically participated in this workshop. Experts from the Therapeutic Goods Administration (TGA) Australia and WHO headquarters joined the workshop virtually to train the participants during the technical sessions. Focal points from WHO Country Office Nepal and Bangladesh also attended the workshop, physically and virtually, respectively (Annex 4: List of participants).

The workshop was organized on “Lot release of COVID-19 vaccines” that had four technical sessions involving presentations, discussions and group exercises and hands-on laboratory sessions and a field visit, over the five days of the workshop (Annex 1: Agenda of the workshop).

The technical sessions included:

- Progress in COVID-19 Vaccine Deployment and Regulation and Linkages with Regional Vaccine Implementation Plan 2022–2026
- WHO lot release guidelines and lessons learnt from the pandemic
- Global experience in COVID-19 vaccines lot release, testing and the role of the Laboratory Networks and Services (LNS) team
- Lot release – administration and quality management
- NRA indicators and lot release procedure
- Summary lot protocol – overview and COVID-19 vaccines
- Overview of TGA lot release processes and lot release and testing of imported COVID-19 vaccines
- Lot release and testing of indigenously manufactured vaccines in Australia including for COVID-19 and influenza

Laboratory sessions on COVID-19 vaccines/conventional technologies were held at the CDL Kasauli for better explaining the laboratory access regulatory function to the participants. The following tests were demonstrated for the participating groups:

- Test for virus content by infectivity assay in COVID-19 vaccines
- Test for identity of Corona spike protein in COVID-19 vaccines
- Spectrophotometric analysis for determination of adenovirus particle concentration and DNA–protein ratio
- Estimation of endotoxin content by the limulus amebocyte lysate (LAL) assay (Gel Clot method).

This was followed by analyses of the test results and discussion on the queries. The participants were also taken on a field visit for sample collection, shipment preparation and tracking. The workshop included pre- and post-workshop questionnaires, course evaluation and distribution of course certificates.

Various sessions of the workshop were chaired jointly by IVD and CDL Kasauli. Secretarial support was provided by IVD at the WHO Regional Office for SE Asia.

All the technical sessions were physically conducted in the conference room of Kasauli Resorts, Kasauli, India, except the technical sessions involving experts from the TGA and WHO headquarters, which were made live through a virtual meeting platform; the links had been shared with all relevant partners and stakeholders before the meeting.

## 4. Proceedings of the workshop

### *Pre-workshop preparatory activities*

To ensure a productive workshop and based on past experiences, all Member States and the representing participants were provided with key pre-workshop documents through respective WHO country offices. These included:

- (1) Administrative information note
- (2) Confidentiality undertaking

Dr Suman Rijal, Director, Communicable Disease Surveillance (CDS) and Dr Sunil Bahl, Coordinator – COVAX and IVD, actively supervised the preparation of the workshop including the meeting of the Planning Committee and finalization of the agenda and the budget.

A list of stationery and laboratory items was prepared and then procured as prerequisites for the workshop. Various charts related to the technical sessions were prepared for the participants by experts from the CDL (Annex 2: Charts on lot release).

### *Opening session*

The workshop was opened by Dr Jayantha Liyanage, WHO Regional Advisor – Immunization System Strengthening (ISS) and inaugurated by Mr Sushil Kumar Sahu, Director, CDL Kasauli, by lighting the lamp. Dr Jayantha Liyanage welcomed all the participants and explained the objectives of the workshop. Mr Sushil Kumar Sahu also gave his opening remarks. This was followed by introduction of the participants and administrative announcements by Dr Anil Chawla, Consultant, Regional Office for SE Asia and details of the week-long programme of the course by Ms Sameera Rawat, CDL Kasauli. All the attendees posed for a group photograph.

### **Technical sessions**

The technical sessions covered various activities to meet the objectives of the workshop. The workshop had four technical sessions involving presentations, discussions and group exercises and hands-on laboratory sessions and a field visit. The first technical session on Day 1 focused on introductory aspects including the progress made in COVID-19 Vaccine Deployment and Regulation and Linkages with Regional Vaccine Implementation Plan 2022–2026, WHO lot release guidelines and lessons Learnt from the pandemic, introduction of the CDL Kasauli, global experience in COVID-19 vaccines lot release, testing and the role of the LNS team and activity chart and the day's programme. Following the pre-course questionnaire, the second technical session was on "Lot release management" and presented two modules: Module 1 – Administration and Quality Management, and Module 2 – Administration and Quality Management. For these interactive sessions the participants were divided into four groups of two countries each. The session concluded with an evaluation of the day. The third technical session on Day 2 of the workshop focused on the NRA indicators and lot release procedure. This session had two modules: Module 3 – Fundamentals of Vaccine Manufacturing and Vaccine Lot Release and Laboratory Access – NRA indicators, functionality and benchmarking along with a group exercise, and Module 4 – Summary Lot Protocol – Overview and Summary Lot Protocol for Covid-19 Vaccine. Day 3 of the workshop began with the fourth technical session on "Global experience sharing by TGA". This included an overview of TGA lot release processes, lot release and testing of imported COVID-19 vaccines and lot release and testing of indigenously manufactured vaccines in Australia including COVID-19 and influenza. The second half of the day held "Laboratory sessions on COVID-19 vaccines/conventional technologies" at the CDL to better explain the laboratory access regulatory function to the participants. This had demonstration of general tests, tests on inactivated COVID-19 vaccine and adenovirus-based vaccine. Day 4 of the workshop continued with the "Laboratory Session on Novel COVID-19 Vaccines" and a field visit for sample collection, shipment preparation and tracking. The final day of the workshop started with a session on "Report making for lot release finalization". This session had case studies of lot release and test certificates.

### **Workshop evaluation**

Questionnaires were provided to the participants both before and after the course to evaluate various aspects of the workshop. A group performance matrix was created (Annex 3: Evaluation of the workshop). The participants expressed satisfaction with most aspects of the workshop. They also recommended some actions and proposed follow-up training and workshops.

### **Closing session**

The workshop concluded with the post-workshop questionnaire, course evaluation, follow-up actions and distribution of certificates. The participating NRAs/NCLs were also requested to share certain experiential information with WHO for analysis and publication.

## 5. Technical sessions

The technical sessions had various presentations in the following areas:

- Progress in the COVID-19 Vaccine Deployment and Regulation and Linkages with Regional Vaccine Implementation Plan 2022–2026 with an emphasis on the Global Covid-19 Vaccination Strategy in a Changing World and Recommendations of SE Asia Region Immunization Technical Advisory Group on strengthening vaccine regulation capacity
- WHO lot release guidelines and lessons learnt – The presentation focused on WHO standards for vaccine and other biologicals, regulatory functions, WHO policy for vaccine lot release, key issues and challenges in WHO Guidelines for vaccine lot release of COVID-19 vaccines and the way forward
- Global experience in COVID-19 vaccines lot release, testing and the role of the LNS team – The presentation gave details of the WHO LNS and NNB overviews, WHO independent vaccine testing programme, test programme development, WHO test programme, impact of the network, WHO network of NCLS for biologicals, share lot release data and best practices, WHO-EUL – evaluation procedure, post-EUL procedure, WHO COVID-19 EUL products, global regulatory environment, specific challenges in lot release testing; the WHO central approach to addressing this challenge; reliance and how it is promoted and how to optimize the vaccine regulatory process
- Administration and quality management system (QMS) of lot release – The presentation trained the participants on quality management and how to improve it; organization structure, policies and tools for lot release; quality audit and review; process of lot release in pre-analytical, analytical and post-analytical stages
- Vaccine basics – The presentations explained the different types of vaccines, the vaccine production process and testing required at different stages of production. Production and testing of six different types of vaccines were explained through flow-charts
- Summary lot protocol – The presentations gave an overview on how to review a summary lot protocol along with checklists and specifically explained how to review the summary lot protocol of different COVID-19 vaccines
- Vaccine lot release and laboratory testing: indicators, functionality and benchmarking – The presentation explained the WHA Resolution 67.20, WHO Five-step capacity-building model for NRAs, benchmarking process, Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of vaccines; laboratory testing function and indicators; lot release function, challenges in lot release testing; and the WHO approach to address the challenges
- Overview of TGA lot release – The presentation explained the Australian risk context; process of batch release by TGA and that for COVID-19 vaccines in Australia; how to decide which vaccines to test; challenges and learnings during the pandemic

- Batch release of COVID-19 vaccine (Vaxzervria) – The presentation gave details of the TGA batch release process and requirements of Vaxzervria, potential challenges and risks; batch release summary; what was done before and after release and new developments in the process
- Influenza batch release testing approach – The presentation focused on the risk-based sampling approach, TGA's Influenza Batch Release Programme, influenza testing strategy and factors influencing sampling.

All the presentations made during the workshop were provided to the participants in a pen drive and are available on request from the WHO Regional Office for SE Asia.

## **6. Laboratory sessions on COVID-19 vaccines/conventional technologies**

To train the participants on laboratory access, a two-day “Laboratory session” was conducted on 12–13 October 2022. The session began with a visit to the CDL from the areas of sample receipt and sample distribution to its various units, namely the Bacterial Unit, Viral Unit, Antisera Unit, Sterility Unit, Instrumentation and Analytical Lab and Animal house.

Experts from CDL informed the participants about the quality management system and final lot testing of COVID-19 vaccines being performed at the CDL Kasauli. They also answered participants' queries. The laboratory session was effective in terms of the hands-on training on COVID-19 vaccine testing. The following tests were demonstrated for the participant groups:

- (1) Test for virus content by infectivity assay in COVID-19 vaccines
- (2) Test for identity of Corona spike protein in COVID-19 vaccines
- (3) Spectrophotometric analysis for determination of adenovirus particle concentration and DNA–protein ratio
- (4) Estimation of endotoxin content by LAL assay (Gel Clot method).

This was followed by analyses of the test results and discussions on the queries. This interactive hands-on experimental training was facilitated as part of the laboratory session, to carry out experiments on the “Final lot of COVID-19 vaccine”, using modern scientific tools and techniques.

## **7. Field visit for sample shipment preparation and tracking**

The four participant groups were assigned the mock exercise for “Sample shipment preparation and tracking” on 13 October 2022. Vaccine samples were collected at the Health Centre of Dharampur, District Solan (Himachal Pradesh). Each group collected vaccine samples, filled the sample collection form at the site, prepared the sample for shipment; and each vaccine carrier container was inserted with a data logger for temperature evaluation and tracking. On 14 October 2022, the temperature data logger was decoded for temperature response of each vaccine carrier container and the results were interpreted.



This mock exercise was conducted to ensure safe storage, transportation and delivery of vaccine doses with proper arrangements to enable a smooth delivery system.

In addition, a vaccine manufacturer (M/s Vaccigen) was visited for a firsthand experience.

## **8. Follow-up actions and recommendations**

At the conclusion of the workshop, the following recommendations and action points were proposed by NRA/NCL teams for “Laboratory access and lot release”:

- Conduct intradepartmental trainings/workshops for colleagues and NCL technicians
- Send proof of information sharing and at least one day self-training to WHO
- Collect data for lot release; analyse and share them with WHO within one month (Annex 5: Draft assimilation paper)
- Identify in-country training needs and workshop requirements; discuss with WHO and send the requirement to WHO country office
- Collect data on individual country strength and send them to WHO; attempt online test for GBT tools and qualify as an expert accessor.
- The following future trainings and workshops were proposed by the teams:
- Hands-on training and proficiency studies for producing countries NCLs/NRAS for COVID-19 vaccines at TGA Australia/PEI Germany/NIBSC London in agreement with and schedule provided by the host organization
- Provide CVs of candidates
- Support for NCLs surrogacy and adoptions (regional or intercountry)
- India, Indonesia and Thailand to give list of NRAs
- Countries adopt reliance mechanisms in their legal framework– internal discussion by each NRA/NCL
- Workshop in consultations with vaccines developers and manufacturers
- Developing regional reference preparations (mRNA and adenovirus vector)
- Regional workshop for vaccine evaluators and regulatory inspectors.

## Annex 1 Agenda

Day 1: Monday 10 October 22	
	Facilitator
<b>Opening session</b>	
Welcome and Objectives of the Meeting	Dr Jayantha Liyanage, WHO SEARO
Opening remarks	Dr Sushil Sahu, Director CDL Kasauli
Introduction of Participants and Administrative Announcement	Dr Anil Chawla, WHO SEARO
Weekly Programme	Dr Anil Chawla, WHO SEARO Ms Sameera Rawat, CDL Kasauli
<b>Technical Session 1 – Introduction</b>	
Progress in COVID-19 Vaccine Deployment and Regulation and Linkages with Regional Vaccine Implementation Plan 2022-2026	Dr Jayantha Liyanage, WHO SEARO
WHO Lot Release Guidelines and lesson Learnt from Pandemic	Dr Anil Chawla, WHO SEARO
Introduction of Central Drugs Laboratory (CDL), Kasauli	CDL Kasauli
Activity Chart and Today's Program	Ms Sameera Rawat, CDL Kasauli
Global Experience in COVID-19 Vaccines Lot Release, Testing and role of LNS Team	Dr Gaby Vercauteren WHO/HQ
<b>Technical Session 2 – Lot release management</b>	
Pre-course Questionnaire	Ms Suchita Sharma and Ms Seema Sood, CDL Kasauli
Module 1- Administration and Quality Management (4 groups of 2 countries each)	Ms Seema Sood, CDL Kasauli
Module 2 – Administration and Quality Management (4 groups of 2 countries each)	Ms Seema Sood, CDL Kasauli
Evaluation of the day	Group chairpersons/ facilitators

<b>Day 2: Tuesday 11 October 22 (Venue: Conference Room, Kasauli Resort)</b>	
<b>Technical Session 3 – NRA Indicators and Lot Release Procedure</b>	
	<b>Facilitator</b>
Module 3 – Fundamentals of Vaccine Manufacturing	Mr Devender Barthwal, CDL Kasauli
Vaccine Lot Release and Laboratory Access- NRA Indicators, functionality and benchmarking	Mohamed Refaat Abdelfattah WHO/HQ
Group Exercise	Participants
Module 4 – Summary Lot Protocol - Overview	Mr Sumir Rai Bhalla, CDL Kasauli
Module 4 – Summary Lot Protocol for Covid-19 Vaccine	Mr Devender Kumar ,CDL Kasauli
Evaluation of the day	Participants

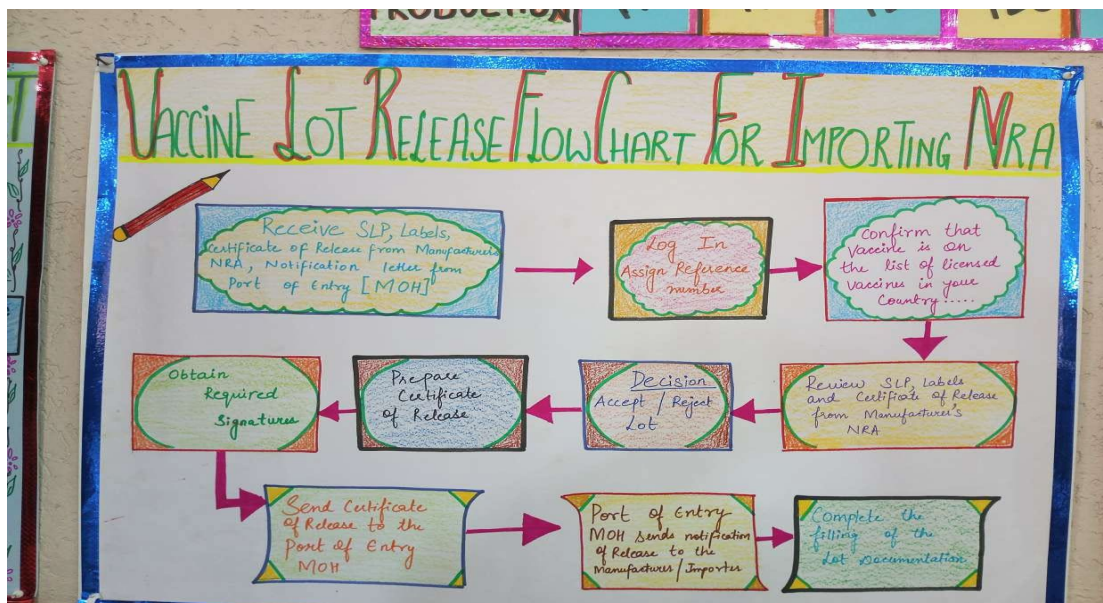
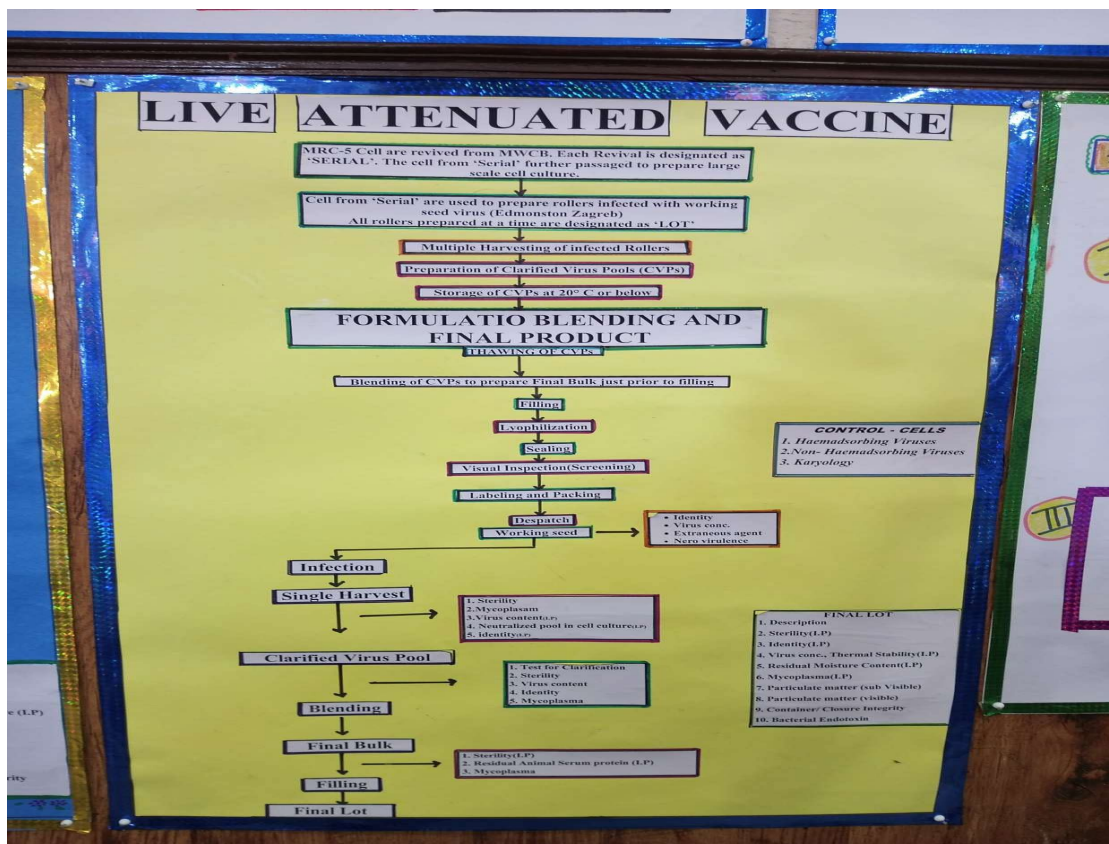
<b>Day 3: Wednesday 12 October 22 (Venue: Conference Room, Kasauli Resort)</b>	
<b>Technical Session 4 – Global Experience Sharing</b>	
	<b>Facilitator</b>
Overview of TGA lot release processes and Lot Release and Testing of imported COVID-19 Vaccines	Dr Scott Craig, TGA
Lot Release and Testing of Indigenously manufacturers vaccine in Australia including COVID and influenza	Dr Vidyani Manatunga and Dr Pearl Bamford, TGA
Travel to CDL Labs	
<b>Laboratory Sessions 1 – COVID-19 Vaccines/Conventional Technologies (Venue: CDL Laboratory)</b>	
Lab Access 1 – Inactivated Covid-19 Vaccine	Mr Devender Kumar and Mrs. Sameera Rawat, CDL Kasauli
Travel to Kasauli Resort	
Lab Access – Demonstration of General Tests	CDL staff and participants
Inactivated Covid-19 Vaccine and Lab Access 2 – Adeno Virus Based Vaccine	Mr Devender Kumar and Mrs. Sameera Rawat, CDL Kasauli
Lab Access 2 – Adeno Virus Based Vaccine (Cont.)	Mr Devender Kumar and Mrs. Sameera Rawat, CDL Kasauli
Lab Access 2 – Adeno Virus Based Vaccine (Cont.)	Mr Devender Kumar and Mrs. Sameera Rawat, CDL Kasauli
Evaluation of the day	

<b>Day 4: Thursday 13 October 22</b>	
<b>Laboratory Session 2 – Novel COVID-19 Vaccines</b>	
	<b>Facilitator</b>
Travel to CDL Labs	
Lab Access 3 – Covid-19 Vaccines	Ms Suchita Sharma and Mr Jaswinder Singh, CDL Kasauli
Lab Access 3 – Covid-19 Vaccines (Cont.)	Ms Suchita Sharma and Mr Jaswinder Singh, CDL Kasauli
Field Visit for Sample Collection, Shipment Preparation and Tracking	Participants

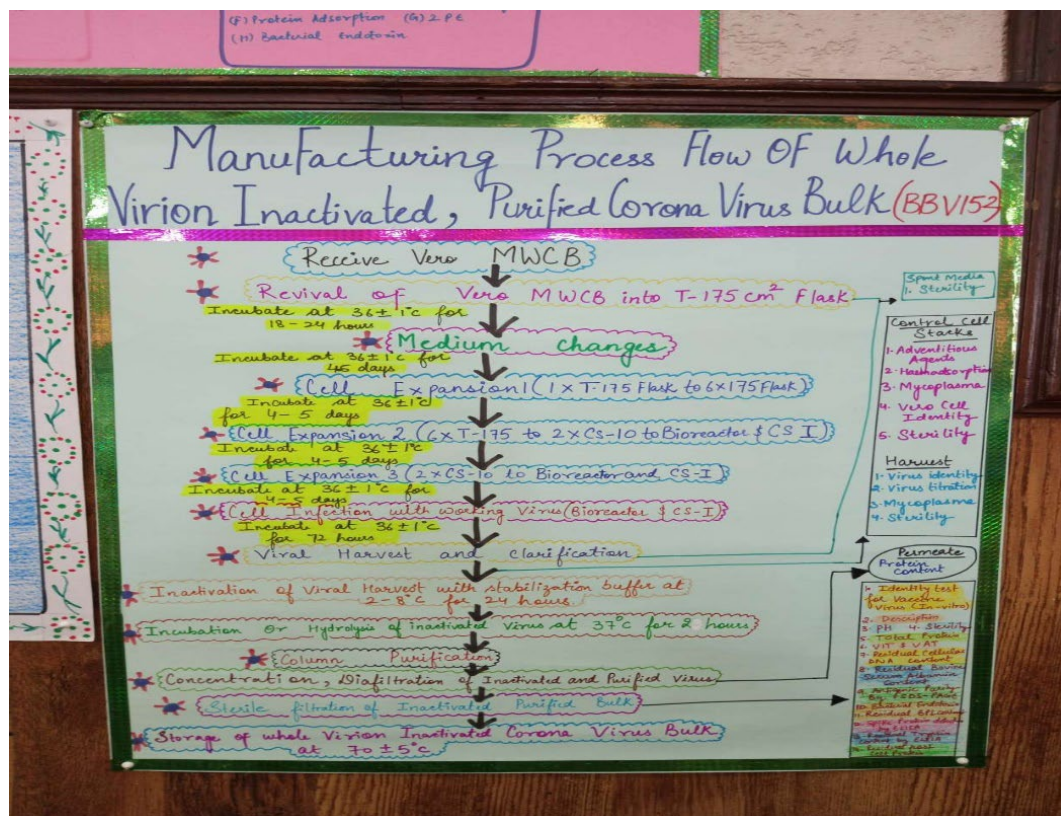
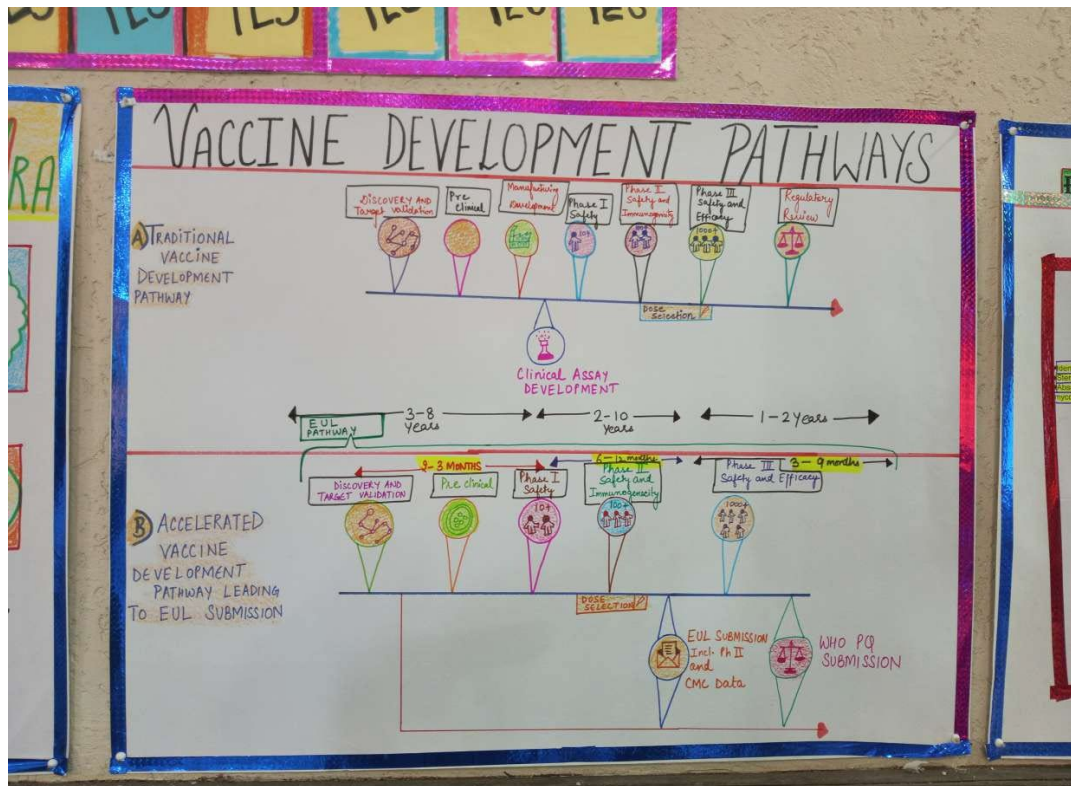
<b>Day 5: Friday 14 October 22 (Venue: Conference Room Kasauli Resort)</b>	
<b>Report Making Session – Lot Release Finalization</b>	
	<b>Facilitator</b>
Case Study 1 of Lot Release	CDL Kasauli
Case Study 1 of Lot Release...cont.	CDL Kasauli
Case Study 2 of Test Certificates	CDL Kasauli
Course Overview and Follow up Actions	CDL Kasauli / WHO SEARO
Post Workshop Questionnaire & Evaluation of the course	Participants
Certificates & closure	

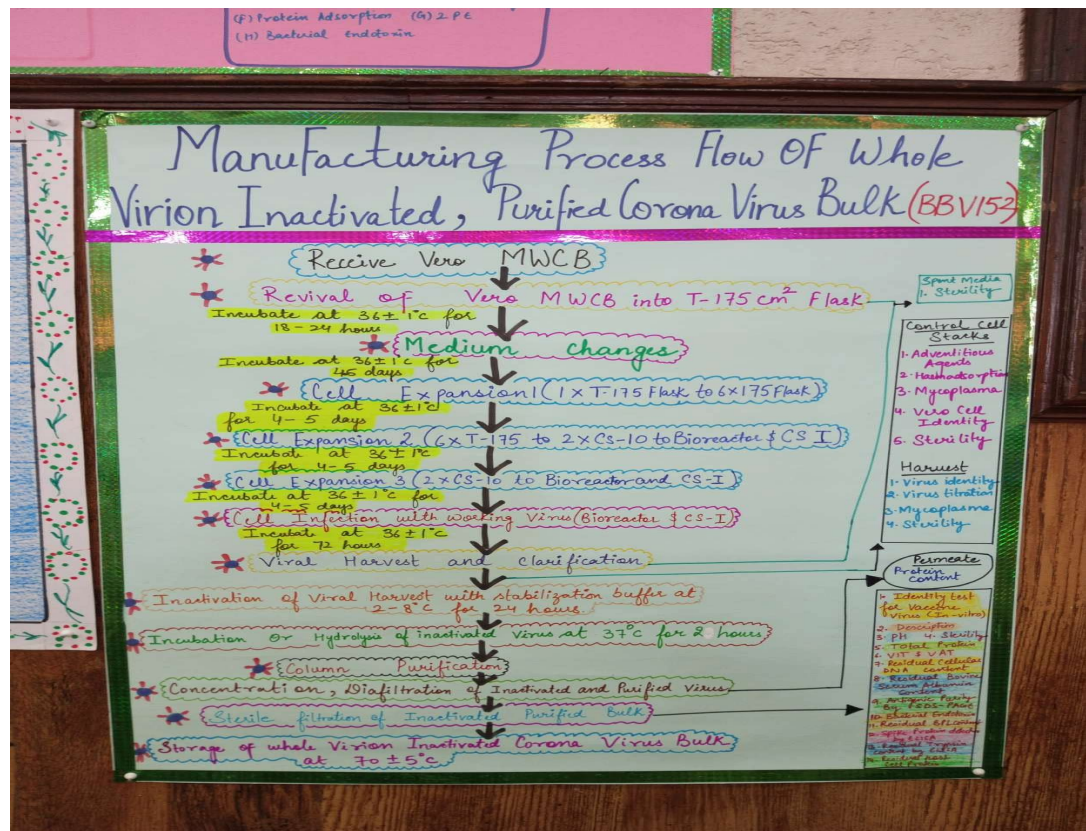
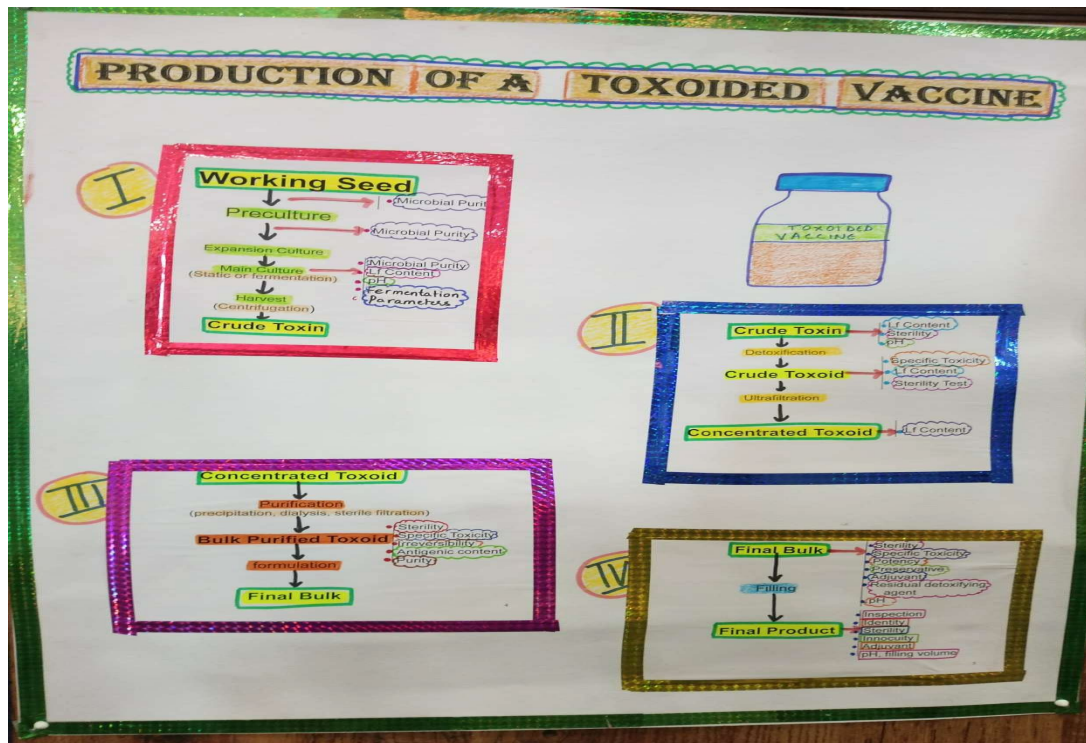
## Annex 2

## Poster Sessions on Lot Release of COVID-19 Vaccines

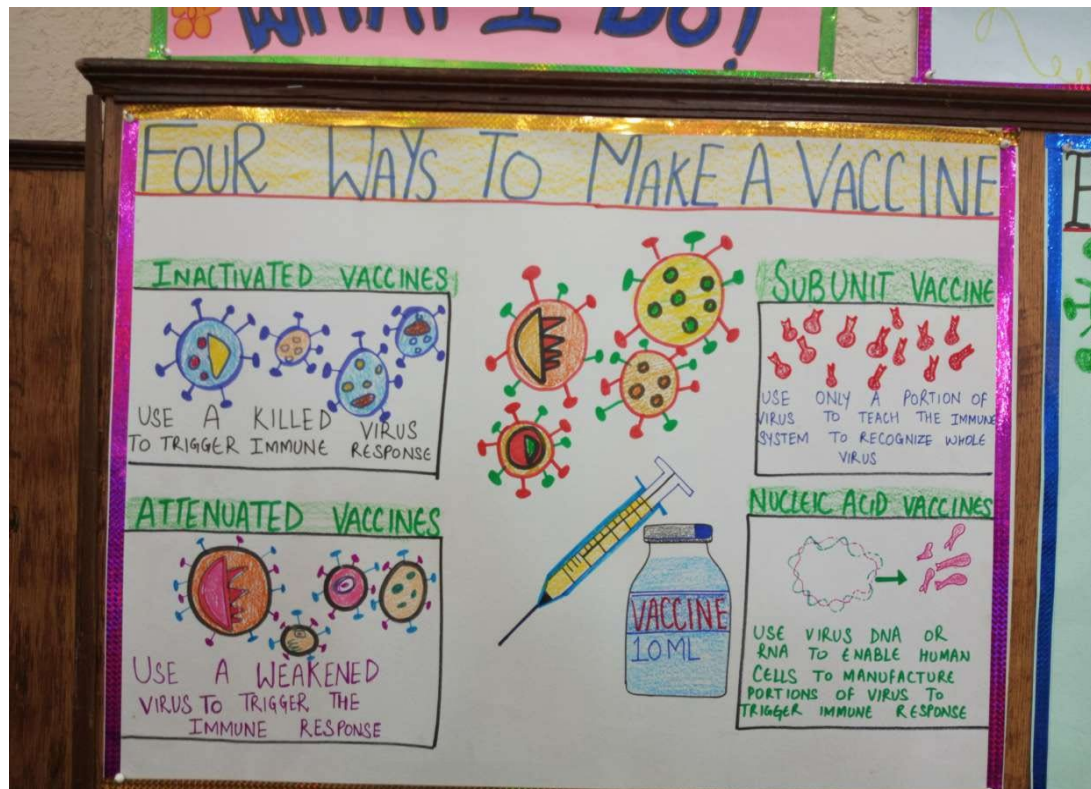






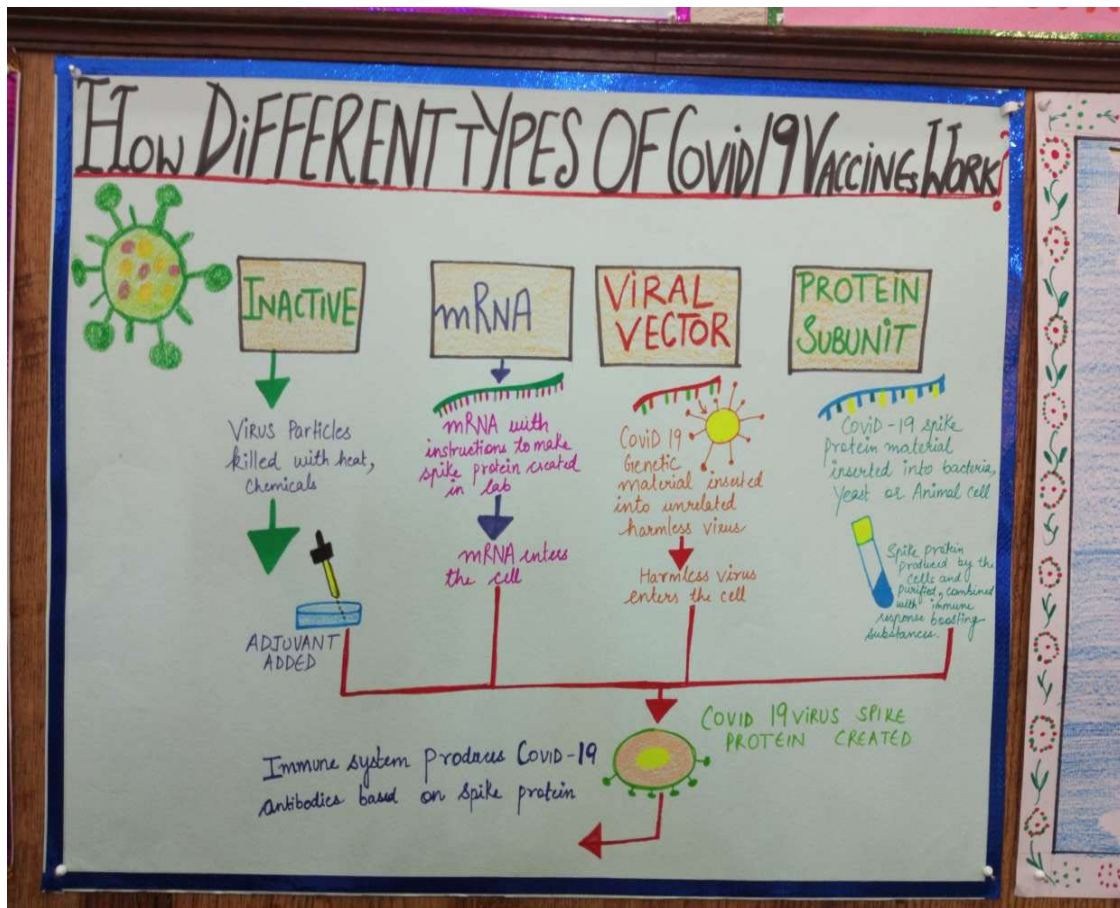






TYPES OF VACCINES					
	DNA and RNA	LIVE ATTENUATED	SUB-UNIT VACCINES	IN-ACTIVATED VACCINE	VIRAL VECTOR
HOW IT FUNCTIONS	TARGET THE VIRAL PROTEIN BY RECOGNITION THE IMMUNE SYSTEM	WEAKENED THE VIRAL ACTIVITY BY THE ACTUAL VIRUS	SUB-UNIT VACCINE IS CAPABLE OF THE PROTEIN OF THE VIRUS, BUT NOT THE WHOLE VIRUS	DIRECT PROTEIN OR PROTEIN SUB-UNIT TO RECOGNITION THE IMMUNE SYSTEM	THE VIRUS USED AS A VECTOR TO DELIVER A SMALL PORTION OF THE VIRUS
ADVANTAGES	THE CONCEPT EASY TO DESIGN	THEY CAN BE GIVEN AT THE COMMUNITY LEVEL AND DO NOT NEED TO BE GIVEN IN A CLINICAL SETTING	IT'S EASY TO PRODUCE AND STORE AND IT'S EASY TO TRANSPORT	IT MAY BE EASY TO DEVELOP	THE VIRUS IS EASY TO RECOGNITION THE IMMUNE SYSTEM TO HAVE EFFECT
DISADVANTAGES	HAY APPLIED BEFORE (CURRENTLY NO DISADVANTAGES AVAILABLE)	THEY CAN BE GIVEN TO ALL AGES, MAY BE GIVE BY COMBINATION AND COMBINATION SYSTEM	THEY CAN BE GIVEN TO ALL AGES, MAY BE GIVE BY COMBINATION AND COMBINATION SYSTEM	IT MAY BE EASY TO DEVELOP	THE VIRUS IS EASY TO RECOGNITION THE IMMUNE SYSTEM TO HAVE EFFECT
EXISTING EXAMPLE	NONE	MEASLES, MUMPS, RUBELLA, CHICKEN POX	HEPATITIS B, HPV, PERTUSSIS	POLIO	EBOLA
GROUP TESTING APPROACHES FOR COVID-19	MODERATE (RISK) SUPPLYING	MODERATE (RISK) SUPPLYING	MODERATE (RISK) SUPPLYING	MODERATE (RISK) SUPPLYING	MODERATE (RISK) SUPPLYING





## Annex 3

### Evaluation of the workshop

#### Pre-course group performance matrix

PRE- QUESTIONNARE																	
GROUP PERFORMANCE MATRIX																	
S.NO.	MODULES	QUES. NO.	NO. OF THE PARTICIPANTS														%
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	AGE
1	LOT RELEASE	1															53,84%
		2															100%
		3															100%
2	QUALITY	4															69,23%
	MANAGEMENT	5															84,61%
		6															76,92%
3	VACCINE BASICS	7															84,61%
		8															100%
		9															61,53%
		10															100%
4	SUMMARY LOT	11															53,84%
	PROTOCOL	12															92,30%
		13															69,23%
		14															69,23%
5	COVID VACCINE	15															84,61%
		16															53,84%
		17															84,61%
		18															61,53%
6	TRENDING	19															84,61%
		20															76,92%
		21															100%
7	LAB ACCESS	22															92,30%
		23															92,30%
		24															76,92%

#### Post-course group performance matrix

POST- QUESTIONNARE																	
GROUP PERFORMANCE MATRIX																	
S.NO.	MODULES	QUES. NO.	NO. OF THE PARTICIPANTS														%
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	AGE
1	LOT RELEASE	1															62,50%
		2															100%
		3															100%
2	QUALITY	4															93,75%
	MANAGEMENT	5															81,25%
		6															87,50%
3	VACCINE BASICS	7															100%
		8															100%
		9															87,50%
		10															100%
4	SUMMARY LOT	11															100%
	PROTOCOL	12															87,50%
		13															81,25%
		14															87,50%
5	COVID VACCINE	15															93,75%
		16															87,50%
		17															81,25%
		18															87,50%
6	TRENDING	19															100%
		20															93,75%
		21															100%
7	LAB ACCESS	22															93,75%
		23															93,75%
		24															100%

## Annex 4

### List of participants

#### Ministry of Health

##### Bangladesh

Ms Chittra Sarkar  
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## **Annex 5**

### **Assimilation paper**

#### **Assimilation and use of learnings from Regional Workshop on lot release of COVID-19 vaccines for continuous improvement of in-country lot release system**

##### **Summary**

A regional workshop on Lot Release of COVID-19 Vaccines was conducted in Kasauli, India on 10–14 October 2022. This document guides the participant NRAs/NCLs on how to use this training and tools effectively for lot release of COVID-19 vaccines or pandemic vaccines. It also guides on how to collate data generated from past and future lot releases, analyse it and share the data with WHO for further analysis.

As NRAs/NCLs have learnt during the workshop that independent quality testing of samples from vaccine lots is part of quality assurance, especially to ensure the consistency of production lot by lot. Effective national lot release system that ensures the quality of each lot of vaccine before it is on the market is important because vaccines are intended for healthy people. In order to respond more quickly to public health crises such as the COVID-19 pandemic, the NRAs/NCLs should implement accelerated national lot release for rapid vaccination in their respective countries.

For the accelerated system, improvement should be made in terms of timing of application for lot release and required documents. In addition, the processing period should be shortened, and sampling method and test items should be streamlined. Thorough preparation for accelerated lot release should be developed by establishing test methods for a new platform in advance as was presented by TGA, Australia. Data should be generated by each NRA/NCL on how many lots and million doses were released over a duration such as weekly or monthly basis. Lesson learnt and how continuous improvement system was implemented should be also highlighted. How the expedited lot release system contributed to roll-out and deployment of COVID-19 vaccines should be also deliberated in each analysis.

##### **Content-wise requirements**

##### **Introduction**

Each country should describe when the pandemic hit it and how it affected the country over a period of time. NRA/NCL should detail about vaccine availability, procurement or production scenario for itself. The NCL or NRA should describe about available production technologies and how government and regulatory authorities facilitated development and manufacturing of COVID-19 vaccines. NCL/NRA should collate data on how many candidate vaccines were explored and how many candidates were successful in getting emergency use authorizations.

## Pre-lot release activities

Each NCL should tabulate the number of meetings and interactions conducted with manufacturers and importers. NCL should mention the period in which it started developing new QMS, SOPs and other regulatory documents to ready itself for future lot release and testing activities. It should mention if these new documents were discussed with manufacturers or importers before implementation.

## Finalized lot release and testing system for implementation

Each NCL should list the name of finalised systems and documents for Lot Release and Testing along with their date of implementation. It may provide the copy of documents for WHO comments. The flow chart of submission and decision making should be also provided. How these documents were shared with manufacturers and importers. The strategies such as parallel testing etc should be described.

How testing methods were developed and qualified should be also described in the documents, along with how the NCL participated in lot testing and lot release for clinical trials batches.

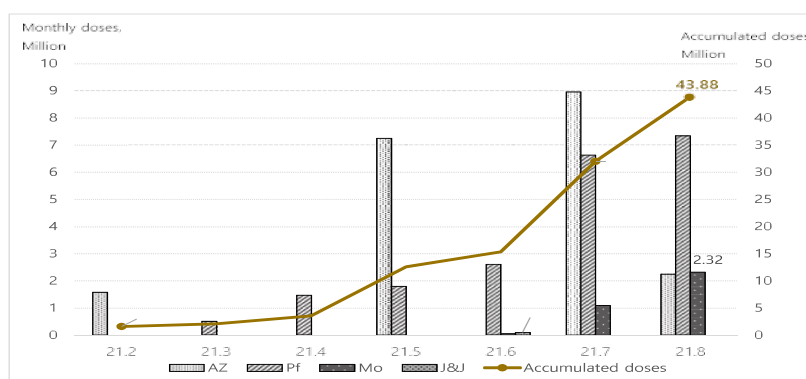
## Results and data requirements

Month wise number of batches submitted for lot release should be provided along with manufacturer's name. Number of doses per batch should be provided. What was the decision on testing along with its basis should be provided. What kind of tests were conducted on each tested batch should be provided. How much time was taken for testing each batch along with time taken for testing and release of each batch should be provided. If any test was repeated and its resolution should be provided. Number of passed and lot release batches per month should be provided. (Along with total so far)

Trend analysis of each test result in comparison with manufacturer's result should be provided. Potency results should be certainly included in this analysis. Data like endotoxin value, host cell DNA should be also included wherever applicable.

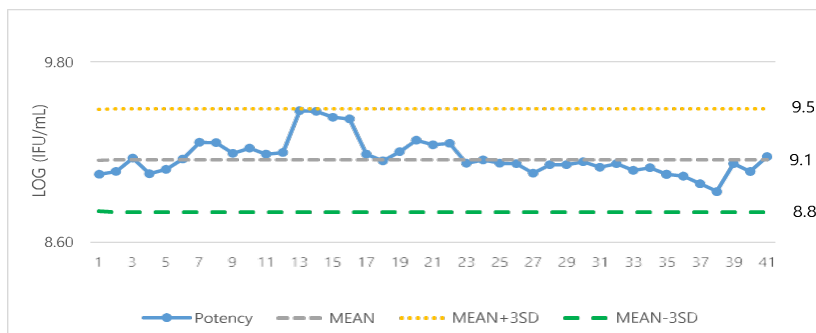
## Examples

**Fig. 1. Status of national lot release for COVID-19 vaccines.**



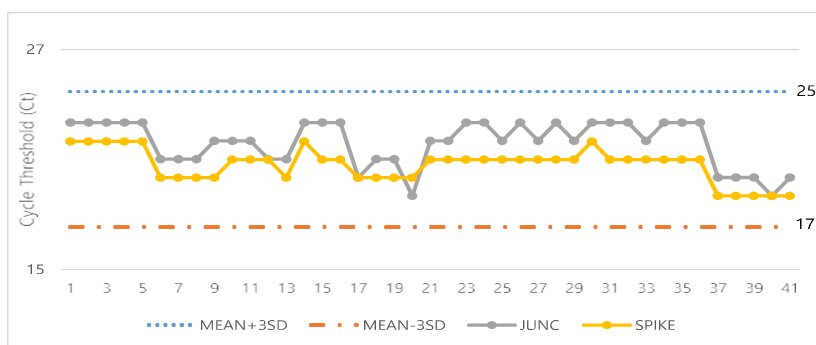
Starting with 1.57 million doses of AstraZeneca Vaxzervria (AZ) in February 2021, a total of 43.88 million doses, including Pfizer (Pf), Janssen (J&J) and Moderna (Mo) vaccines, were released by August 2021. The monthly bar graph shows the released doses of each product, and the line graph shows the accumulated doses of COVID-19 vaccines in a country.

**Fig 2. Trend analysis on potency test for national lot release of Vaccine A.**



In the infectious titre test, the value was converted to log and the mean results was 9.1 log IFU/mL on average from February to August in 2021. It was confirmed that the value for 41 lots was within the MEAN $\pm$ 3SD range (8.8–9.5 log IFU/mL).

**Fig. 3. Trend analysis on identity test for national lot release of AstraZeneca COVID-19 Vaccine Injection.**



In the identity test for AZ, the area where vector and inserted gene is connected (JUNC) and inserted gene (SPIKE) were checked by RT-PCR. When the negative Ct value is over 30 or determinants, the identity test results of total 41 lots showed 22 and 21 Ct (Cycle Threshold) on average for each JUNC and SPIKE gene. All result mean value is 21 Ct and SD (standard deviation) is 1.2. All results of identity test were within the range of MEAN $\pm$ 3SD (17–25 Ct).

**Table 1: Processing period for COVID-19 vaccines.**

Vaccine name	Processing period on Average (Calendar day)	Lots released	Volume released (10,000 doses)
AstraZeneca	–	41	2001
Pfizer	–	30	2030
Janssen	–	1	10
Moderna	–	7	347
COVID-19	8	79	4388

**Table 2: Whole test items and major test items for COVID-19 vaccines.**

Test item		Adenovirus-vectored vaccine		mRNA vaccine	
		Whole items tested	Major items tested	Whole items tested	Major items tested
General test	Appearance	O	O	O	O
	<b>Volume of injection in container</b>	O	–	O	–
Product-specific test	pH	O	–	O	–
	<b>Content</b>	O	–	O	–
	<b>Identity</b>	O	O	O	O
	<b>Potency</b>	O	O	O	O
	<b>Purity</b>	O	–	O	O
Safety test	<b>Sterility</b>	O	–	O	–
	<b>Endotoxin</b>	O	–	O	–

### **Challenges, lessons learnt and proposed solution**

The document should brief major challenges and lesson learnt during the journey. It should also high light various other external agencies involved in the journey and how these agencies supported NCLs to overcome these challenges. How NCL/ NRA's continuous improvement plan was revised based on these learning and challenges should be detailed.

### **Use of information and publication of data**

The data shall be analysed and collated by WHO. The information shall be converted into useful tools to support NRA in laboratory access and lot release function strengthening. A research paper shall be also drafted and published in reputed journal. The contributing NRAs/NCLs shall be co-author in this publication.





The Regional Workshop on lot release of COVID-19 vaccines was held in Kasauli, India, on 10–14 October 2022, and organized by the IVD Department at the WHO Regional Office in coordination with CDL Kasauli, India.

Vaccine manufacturers are obliged to undertake a wide range of quality, safety and efficacy tests of the components used in manufacturing, and the final formulated vaccine product, as a condition of regulatory approval. Full lot release and laboratory access should be managed by trained staff of NRAs/NCLs to execute this important regulatory function.

This report enumerates the proceedings of the Regional Workshop and provides an overview of the action points and recommendations

