

# Building a world class vaccine manufacturing plant in Bangladesh: Challenges and Opportunities



**Abdul Muktadir**

Secretary General

Bangladesh Association  
of Pharmaceutical Industries

# Incepta Vaccine Ltd

---



## **Abdul Muktadir**

**Managing Director  
Incepta Vaccine Ltd**

**B. Pharm (Hons), M. Pharm from University of Dhaka  
M.S. in Industrial Pharmacy, Long Island University, USA**

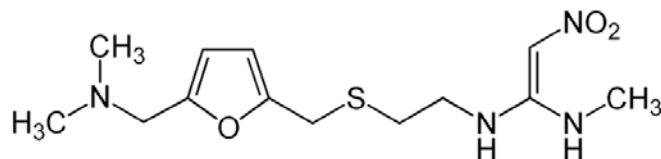
Research experience on –

1. Anti-tumor antibiotic, University of Dhaka & IPGMR (BSMMU)
2. Dosage Form Design, Long Island University, USA
3. Special research interest on Aerosol, Nanotechnology, Sustain release drug, Lyophilyzation, Design of Pharmaceutical Factory

# What is a pharmaceutical product?

Pharmaceutical products are usually small chemical compounds which have been developed into a dosage form according to route of administration intended for use in -

- Diagnosis,
- Treatment, or
- Prevention of disease





# Incepta Pharmaceutical Ltd

Dhaka, Bangladesh

A private limited company having about 5,000 employees which produces such pharmaceutical products



# GMP approval from various Authorities



UK MHRA GMP certificate



European GMP certificate



Turkey GMP certificate



Kenya GMP certificate



Ethiopia GMP certificate



Uganda GMP certificate



D R Congo GMP certificate



Yemen GMP certificate



Sudan GMP certificate



UK MHRA GMP



Turkey GMP



# Fact Sheet: Incepta Pharmaceuticals Ltd

- Year of Establishment : 1999
- Year of Business Operation : 2000
- Turnover : ~120 million USD
- Exporting to : 47 countries



# What is a Vaccine?



A vaccine is a biological preparation that improves immunity to a particular disease. A vaccine typically contains -

- Weakened or killed forms of the disease-causing microorganism,
- Its toxins or
- One of its surface proteins
- Others

# Difference between Vaccine & Pharma products in technology

<b>Pharmaceutical products</b>	<b>vaccines</b>
<ul style="list-style-type: none"><li>▶ Small chemical molecules</li><li>▶ Heat stable (more or less)</li><li>▶ Can be processed by terminal sterilization</li></ul>	<ul style="list-style-type: none"><li>▶ Large protein molecules</li><li>▶ Heat labile</li><li>▶ Can not be processed by terminal sterilization</li></ul>



# Similarities between Vaccine & Pharma products in technology

- There are some similarity in manufacturing process with pharmaceutical injectable products
- Injectable products which are produced in aseptic filling process requires similar stringent environmental control, i.e class A
- Also, gowning requirement, microbiological testing etc. are somewhat similar



# Incepta Vaccine Ltd



**INNOVATIVE CONCEPT INTO PRACTICE**

# Incepta Vaccine Ltd

- For catering global need and that of Bangladesh, Human vaccine division “INCEPTA VACCINE LIMITED” emerged.
- It will provide vaccine to vast majority of population at an affordable cost.
- It has state of art facility fully compliant with WHO-GMP & International Standard
- It is a self sufficient unit with its own dedicated technical manpower, utilities and Animal house.



# Incepta Vaccine Ltd has state of the art facility with following areas:



- Research and Development Block
- Antigen Production Block
- Fill Finish Block
- Microbiology Lab
- Chemistry Lab
- Animal House
- Day Store
- Dispensing Area
- Clean Utility Area
- Packing and Storage Area
- Ancillary Utilities Area
- Laundry
- Stability Area & Retained Sample Area
- Central Ware House and Central Power Plant

# Vaccine Production Requires

- Lab for viral & bacterial vaccine development
- Pilot scale GMP facility
- Antigen manufacturing
- Fill Finish





# Research and Development Block



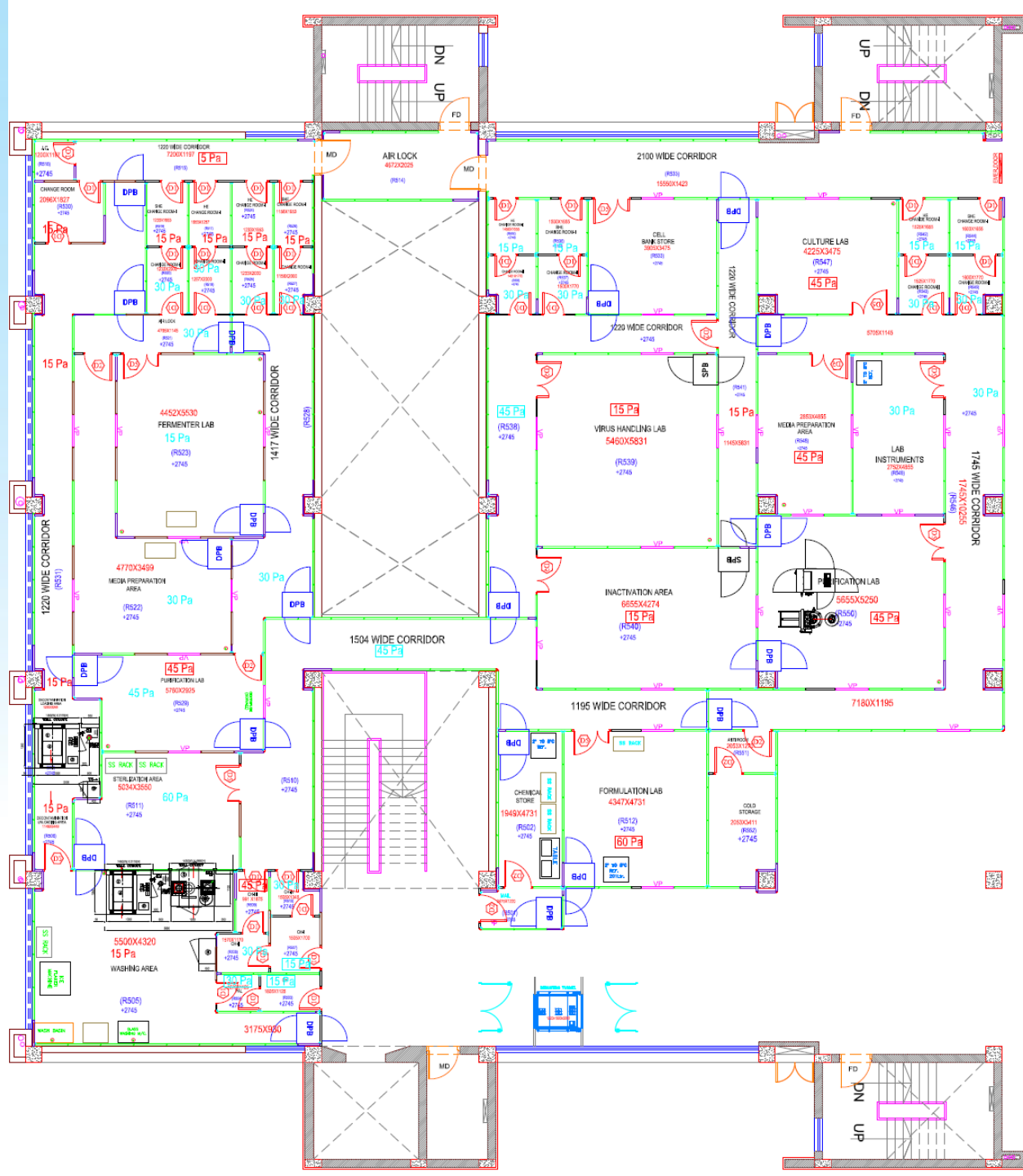
# Lab & Pilot scale GMP Facility

- Fully equipped with production and QC
- Cell Culture for Viral Vaccine
- Fermentors for Recombinant & Bacterial vaccines





# Lay out of R & D Area



# Vaccine R & D

---





# Cell Culture Lab



# Inverted Microscope











# Viral Particle analyzer (q-viro-X)

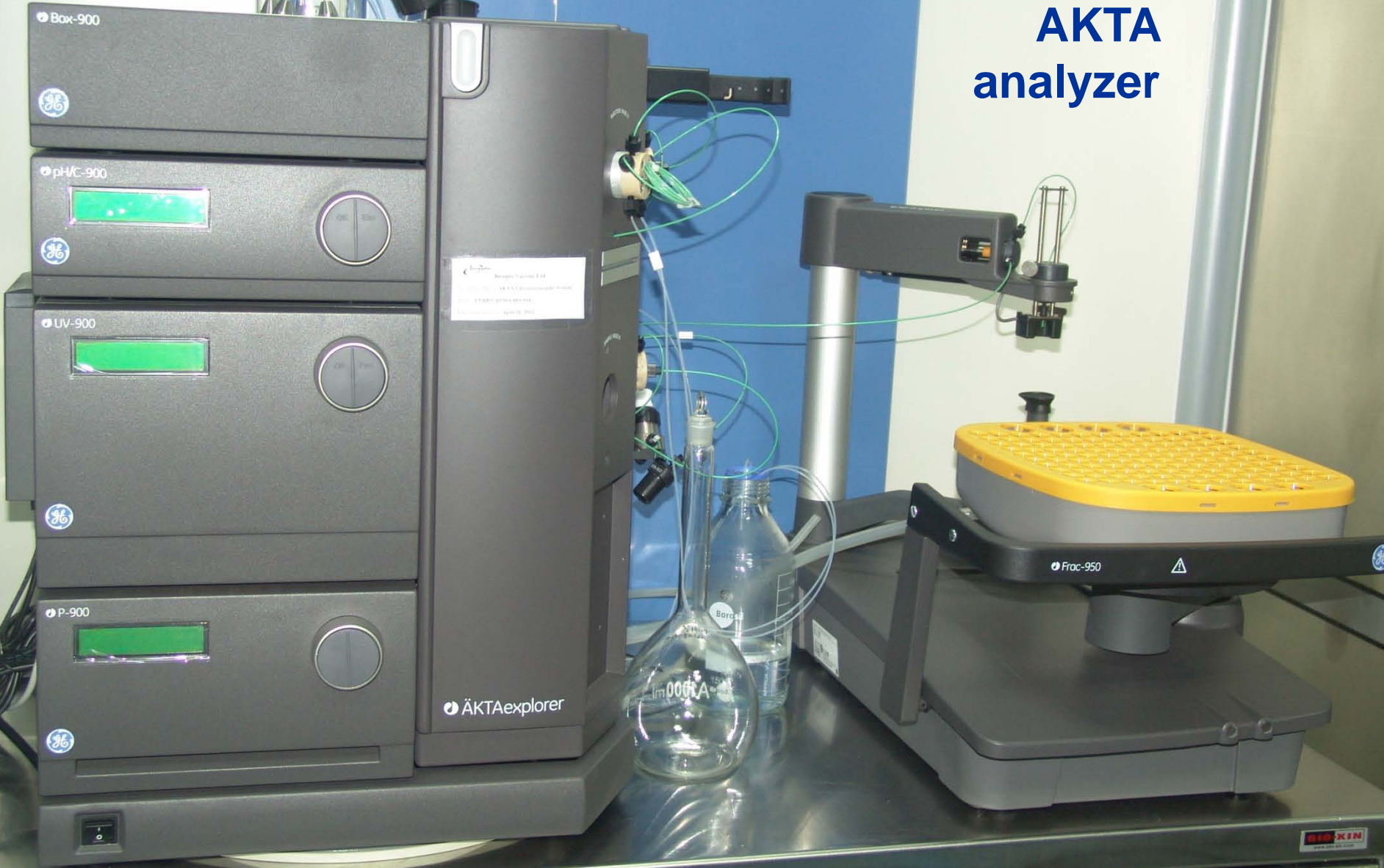




# Mammalian Cell Culture bioreactor



# AKTA analyzer





# Gel Doc XR+

## (Gel Electrophoresis)





# Bacteria Handling Lab



# Fermentation



# Centrifuge & Purification







**Spectrophotometer**



**Tangential Forward Flow (TFF) system for Filtration of Protein**





# Antigen Production Block

# Antigen Production

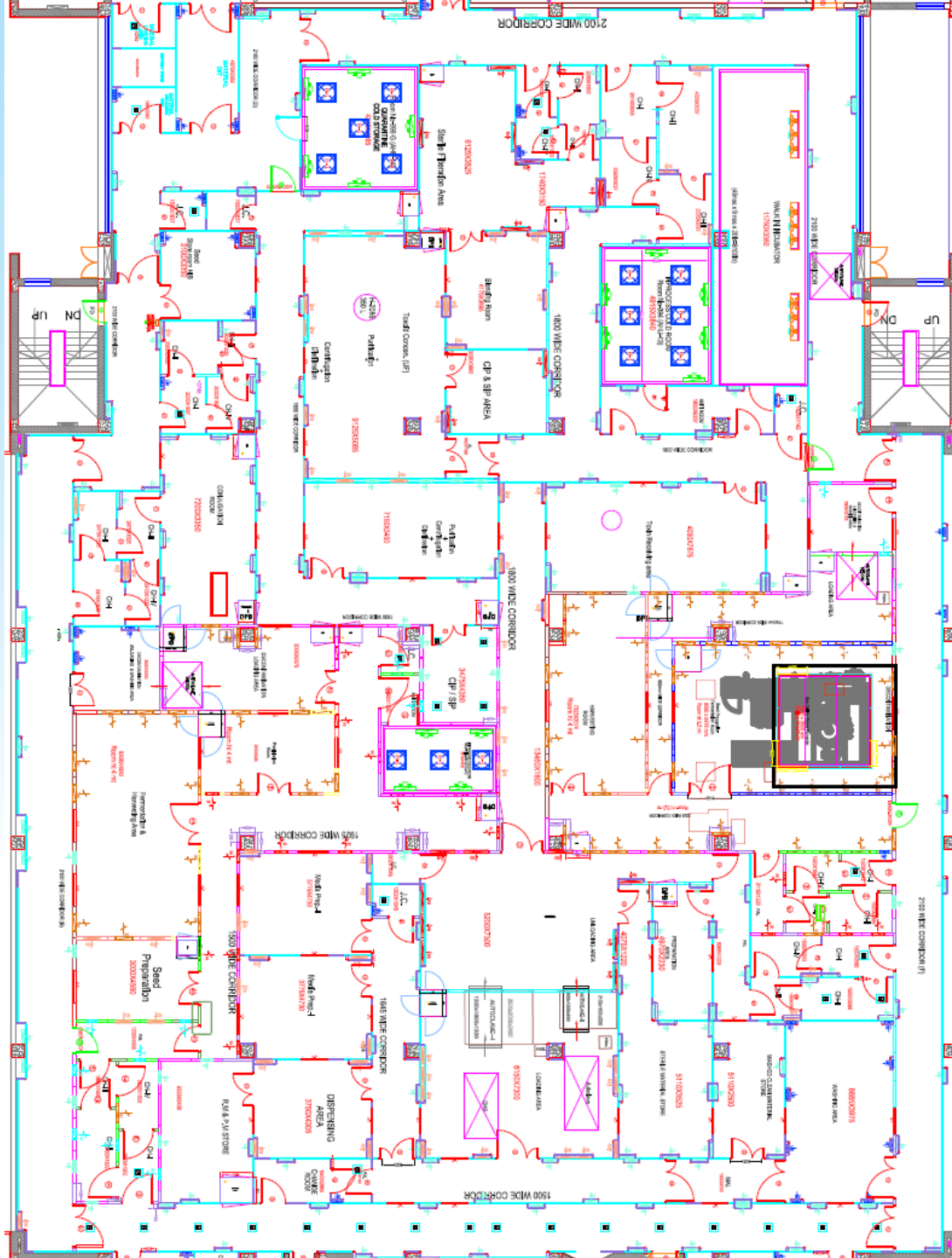
- Bacterial Line with 1500 L Fermentor
- Bacterial Line with 750 L Fermentor
- Viral Line with 450 L Bio-reactor
- Each Line is equipped with individual down-stream process



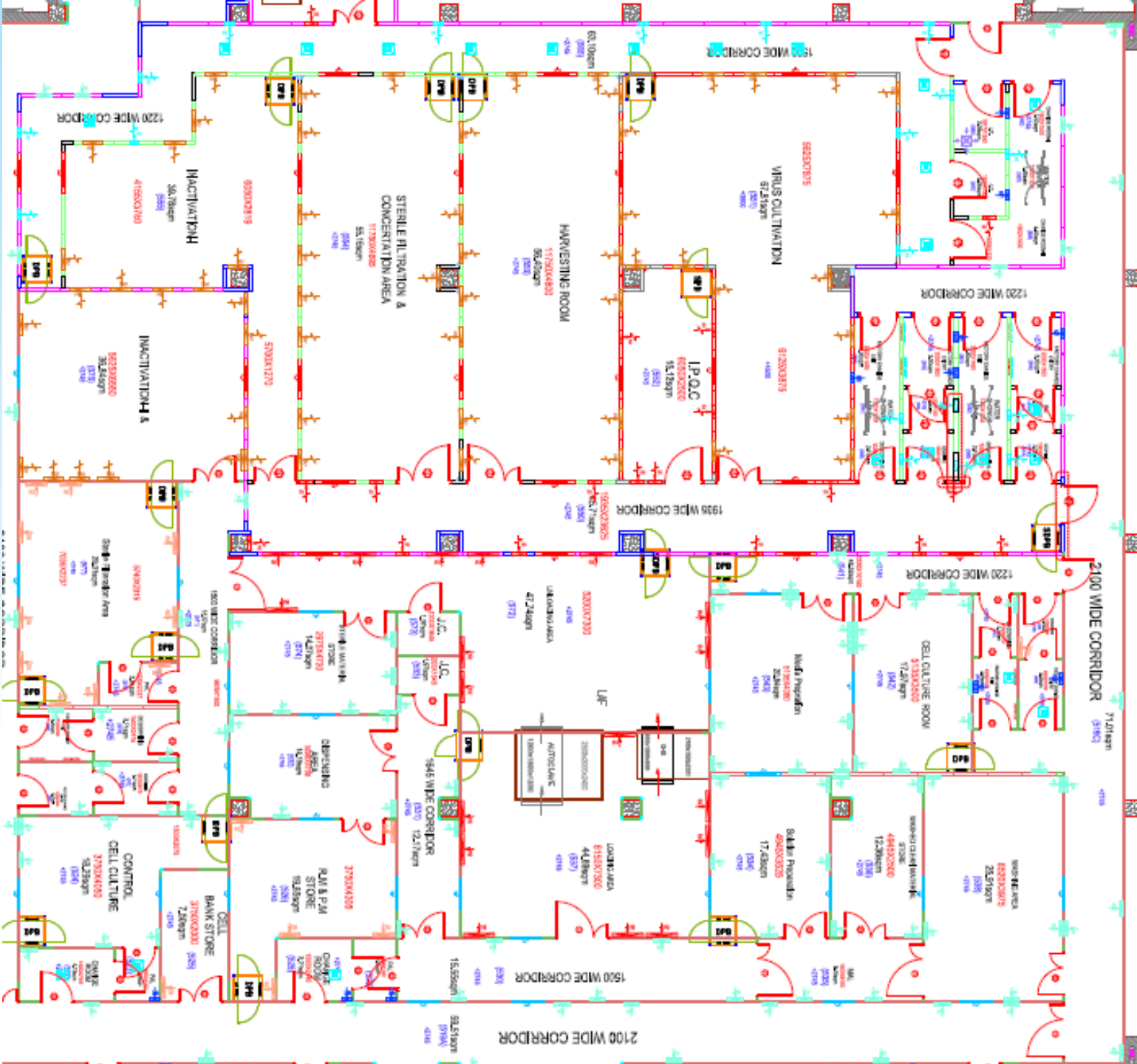
# Challenges

- Lack of Trained Manpower
- Highly Expensive
- Long development process
- Cumbersome approval process
- Cumbersome public purchase process

# Lay-out of Antigen (Bacterial)



# Lay-out of Antigen (Viral)





# Fermentor for Antigen production (for Bacterial line)

*Under construction*



# Fermentor for Antigen production (for Rabies)

*Under construction*







# Fill Finish Block

# Incepta Vaccine Ltd - Capacity

- Incepta Vaccine Ltd can produce any dose size from 0.1ml to 15 ml, with 4 different products simultaneously and has capacity to fill more than **2,40,000 ampoules** and **3,60,000 vials** per day.



# Incepta Vaccine Ltd - Capacity

The yearly capacity is **180 million** vials and ampoules.

	Capacity / Hour	Capacity / Day	Capacity / Year
Vials	18,000	360,000	108,000,000
Ampoules	12,000	240,000	72,000,000
<b>Total capacity per year</b>			<b>180,000,000</b>

# Fill & Finish

For fill & finish Incepta vaccine Ltd has 4 manufacturing lines which contains -

- Washing line
- Lyophilization line
- Filling line
- Packaging line

# Incepta Vaccine Ltd – **Filling Lines**



- Four German filling lines have been provided, independent of each other so that four different products can be manufactured simultaneously.
- Each area has been provided with dedicated HVAC system to prevent cross contamination.
- All the filling area rooms are provided with terminal HEPA filters, with required air changes so as to create Class A, B, C & D environment, as the requirement of GMP.

# Incepta Vaccine Ltd – **Filling Lines**

- Each filling line is provided with a sterilizing autoclave and decontamination autoclave.
- Each line is connected to independent visual inspection and labeling machine so as to prevent the chances of cross contamination.





# Incepta Vaccine Ltd – **Process**



- The antigens are processed aseptically to produce the final liquid bulk which is then filled into individual vials or ampoules.
- The filling is done as required and vials are stoppered and sealed automatically and passed to visual inspection and labeling Area.
- Once the QC and QA have released the batch, the material is sent to central depot for further distribution.

## Incepta Vaccine Ltd – **Packing Area**



- Big packing area, covering around 9,000 square feet.
- Material air lock. Provided with Access control.
- Day cold room with 5 – 3°C temperature is provided so as to maintain cold chain during Packing.

# Incepta Vaccine Ltd – **Storage**



- Two  $-20^{\circ}\text{C}$  cold rooms are provided to store finished products and Bulk separately.
- Three  $5\text{ } 3^{\circ}\text{C}$  cold rooms are provided. One for storage of bulk and two for finished product.
- All the cold rooms have 5 temperature sensors and two sensors for Data loggers, so as to monitor Cold chain every minute through wireless receivers.
- Total Capacity to store 500 million doses at  $2^{\circ}\text{C} - 8^{\circ}\text{C}$  is available.

# Incepta Vaccine Ltd – **Quality Control**

Quality control is done in 3 steps:

- Microbiology
- Chemical Lab, and
- Animal Tests



# Incepta Vaccine Ltd – **Microbiology**



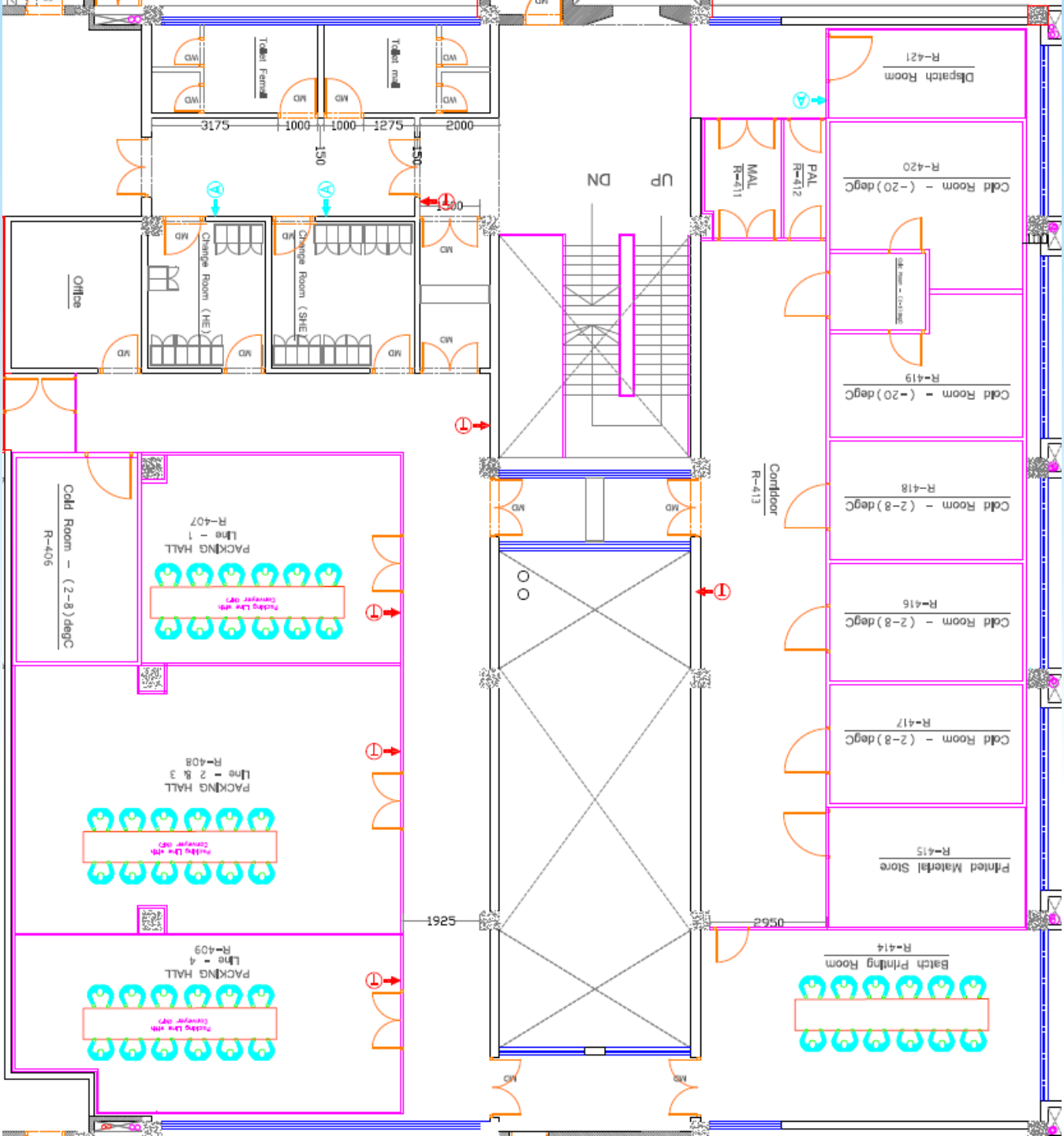
- Divided in Infectious and Non-Infectious Area
- This Microbiology area is dedicated for Sterility testing, Endotoxin testing, Bio-burden testing, cell culture testing and all other microbiological testing.



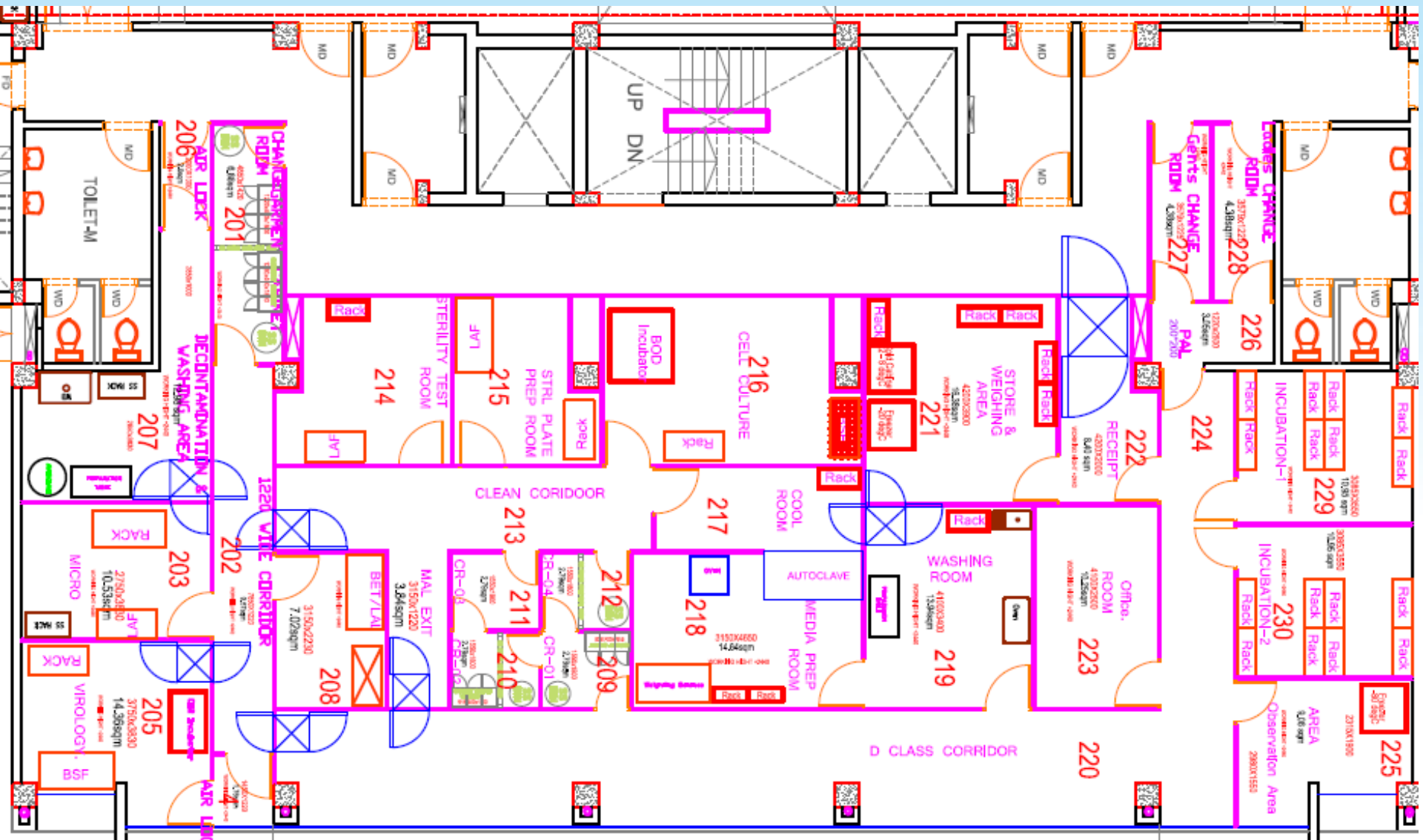
# Lay-out of Fill Finish Production Area



# Lay-out of Packaging Area



# Lay out of Micro-biology area





**Production area**





**Ampoule washing machine, Germany**



**Vial washing machine, Germany**



**Vial washing machine, Germany**



**Rabies filling machine, Germany**





**Rabies lyophilizer machine**



**Vial filling machine, Germany**



**Vial sealing machine, Germany**





**Ampoule filling machine, Germany**





**Dry heat sterilizer, Italy**



**Roll label machine**

# Fill Finish Facility, Challenges

- Requires processing of Heat Labile substances
- Aseptic Procedure
- Does not allow long room temperature exposure
- Some products require Lyophilization

## Fill Finish Facility, Challenges (Cont.)

- Small Fill volume requires Precision filling 0.01 ml level
- Huge quantity of WFI
- Class 100, 10,000, Clean Room
- Highly Expensive





## Animal House

- Largest lab animal house in Bangladesh covering around 24,000 square feet area.







# Animal House



***Rabbit***



***Guinea pig***




# Incepta Vaccine Ltd – **Animal House**

- The Animals are provided with 12 hour day light and 12 hour dark cycle and are maintained at comfortable temperature at 23 ± 2 C and Relative Humidity at 50%.
- All area are supplied with dedicated HVAC system to prevent cross contamination.
- Bio safety level 3 standard lab for testing various vaccines which involve challenge with infectious organisms.
- Can hold 6 various species of lab animals without any cross contamination.






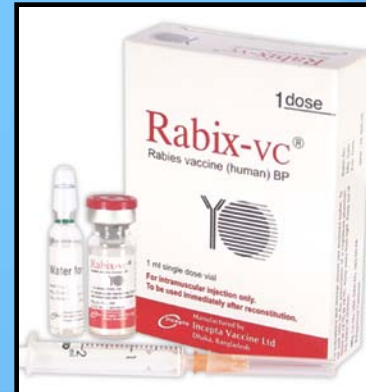
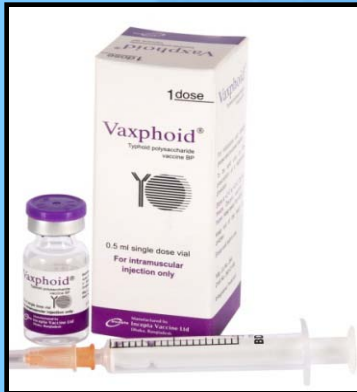
- Incepta Vaccine Ltd has already launched 4 vaccines:

  
**Vaxphoid<sup>®</sup>**  
Typhoid polysaccharide vaccine BP

  
*Incepta introduces*  
**Vaxitet<sup>®</sup>**  
Adsorbed Tetanus vaccine BP

  
**Rabix-vc<sup>®</sup>**  
Rabies vaccine (human) BP

  
**Hepa-B<sup>®</sup>**  
Hepatitis B vaccine (rDNA) BP



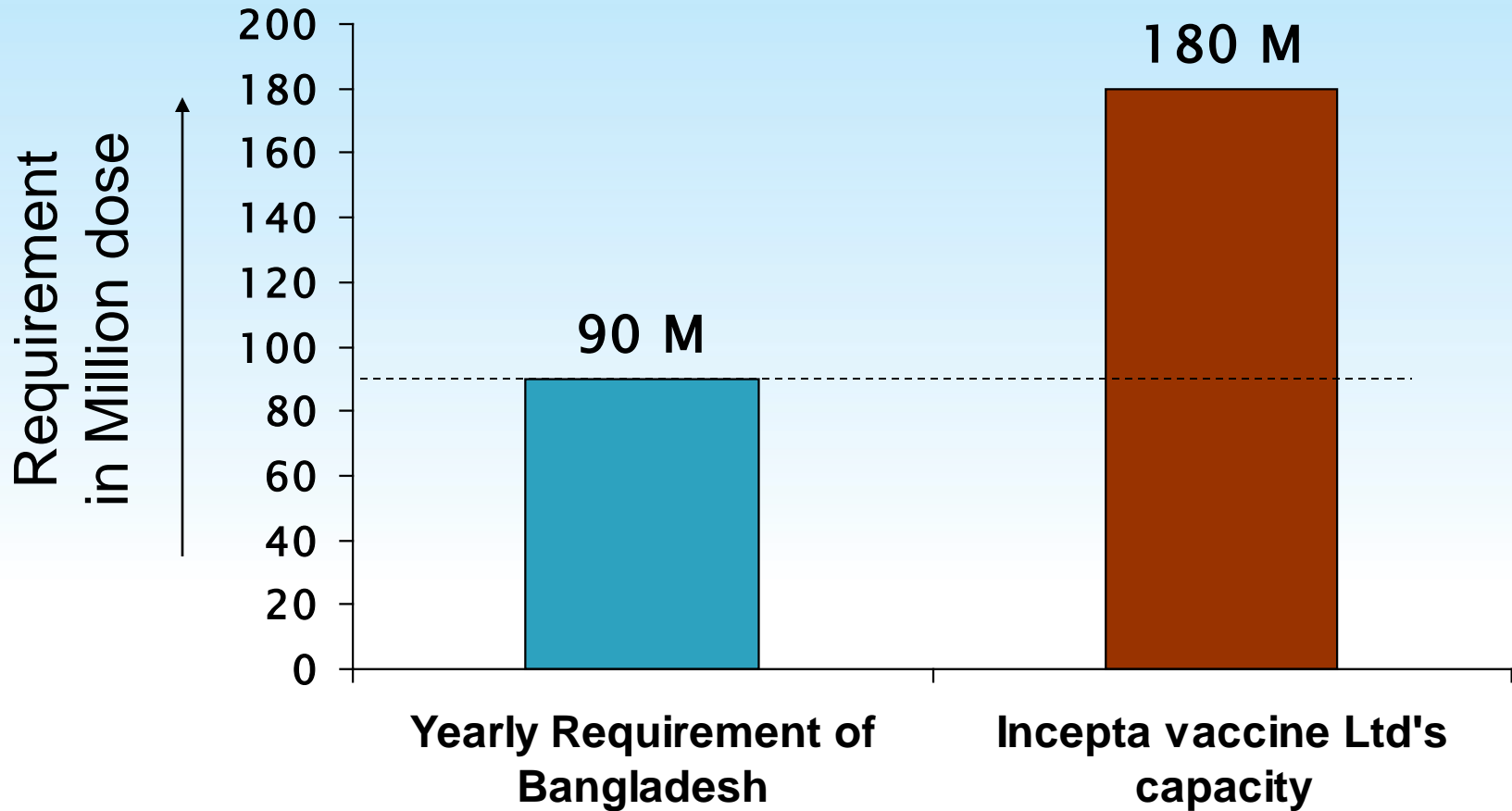
# A number of exciting vaccines are in pipeline:

1. Tetanus immunoglobulin
2. Haemophilus influenzae b (HIB)
3. Meningococcal
4. Measles & Rubella
5. Polio
6. Pentavalent (DPT,HIB,HB)



DPT: Diphtheria, Pertussis, Tetanus  
HIB: Haemophilus influenzae b  
HB: Hepatitis B

# Incepta Vaccine Ltd can become a global supplier of high quality vaccine



**Incepta Vaccine Ltd is  
poised to supply world class  
vaccine at affordable price**





# Thank You

