Mohammad Mainul Ahasan
Head, Research and Development Department

WHO mRNA Technology Transfer Programme Face-to-Face meeting, 17-21 April 2023, Cape Town, South Africa
INCEPTA PHARMACEUTICALS LTD

Established in 1999

Started operation in Jan 2000
INCEPTA PHARMACEUTICALS LTD

MISSION
Provide quality healthcare products and services for the benefit of humanity in the best possible way through innovation and diversification

VISION
To become a trusted healthcare company to ensure better health for everyone, everywhere

$529

Revenue

1300+
Products

255
First ever products

2nd
Rank

2
Manufacturing site

10,000+
Employees

“INNOVATIVE CONCEPT INTO PRACTICE”
MANUFACTURING CAPABILITY

- Tablet
- Capsule
- Liquid
- Powder for suspension
- Injections
- Ointment/cream/gel/solution
- Granules in sachets
- Nasal sprays & drops

- Lyophilized injections
- Eye drops
- Large volume injections
- Nebulizer solutions
- Dry powder inhaler
- Pre-filled syringes
- Natural and herbal products
- Veterinary products

Vaccines
Biotech products
Launched 255 generic for the first time in Bangladesh

Brought lyophilization technology for the first time in Bangladesh

First company to manufacture Insulin locally

First company to manufacture Human vaccine locally

First company to manufacture Animal vaccine locally

First local company to export in western regulated market (UK)

First company in Bangladesh with capability to produce vaccine and biosimilar from scratch
GLOBAL REACH

6 Continents
89 Countries
300+ Generics
INCEPTA VACCINE LTD

First vaccine manufacturing company in Bangladesh established in 2011

State-of-art facility compliant with WHO GMP requirements with dedicated manpower

Provide vaccine to a vast majority of population at an affordable cost
TECHNOLOGY PLATFORM

ANTIGEN PRODUCTION

3 DS production suites
- Microbial, recombinant and native strain (bacterial & yeast)
- Mammalian cell culture based
- Conjugate vaccine

PRODUCT TESTING

Quality control
- Chemical testing
- Microbiology, virology & animal testing

FILL AND FINISH

4 DP filling suites
- Lyophilized product
- Liquid vial/ampoule product
- Pre-fill syringed product
DS PRODUCTION CAPACITY

**DS SUITE 1**
- Cell culture based vaccine
- 75L and 450 SS bioreactors suitable for suspension and micro-carrier based culture
- Scale-X fixed bed bioreactor

**DS SUITE 2**
- Conventional bacterial vaccine
- 150L & 1500L SS fermenter

**DS SUITE 3**
- Recombinant/subunit vaccine
- 75L & 750L SS fermenter
FOUR FILLING LINES

- Line 1 for vial filling equipped with lyophilizer
- Line 2 for ampoule filling
- Line 3 for vial filling with PFS machine
- Line 4 for vial filling

DOSE SIZE

- 0.1ml to 20ml

FILLING CAPACITY

- Single dose: 180M per year
- Multi dose: 1B per year
RESEARCH AND DEVELOPMENT CAPACITY

R&D SUITE
- Cell culture based vaccine development lab
- Bacterial vaccine development lab
- Molecular biology lab
- Conjugation lab
- QC analytics development lab

VIRAL LAB
- Roller bottle, cell factory and bioreactors ranging from 5L to 19L
- Scale-X fixed bed bioreactor

BACTERIAL LAB
- Fermenters ranging from 5L to 19L
- Modern purification tools
**PRODUCT PORTFOLIO**

- **Products obtained licensure**
  - Meningococcal polysaccharide vaccine
  - Recombinant hepatitis B vaccine
  - Oral cholera vaccine
  - Inactivated rabies vaccine (Scale-X platform)

- **Products under clinical development**
  - Typhoid conjugate vaccine (licensure Q4 2023)
  - SARS-CoV2 protein subunit vaccine (discontinued after PCT)
PRODUCT PORTFOLIO

**Fill finish vaccines**
- Tetanus toxoid
- Typhoid polysaccharide
- Influenza
- Rubella
- Hepatitis A
- HPV
- Varicella

**Fill finish immunoglobulins**
- Tetanus (human and equine)
- Rabies
- Human normal Ig
- Snake venom
PRODUCT PORTFOLIO

Products in pipeline

- HPV L1 VLP (yeast)
- Rotavirus VP8 protein subunit vaccine (yeast)
- Zoster vaccine recombinant (yeast)
- Pneumococcal conjugate vaccine
- Meningococcal conjugate vaccine
- Measles rubella live attenuated vaccine
- CRM197 (E. coli)
Current R&D lab re-purposed for short term
- New R&D lab dedicated for mRNA by Q4 2023
- Design and develop plasmid DNA (SARS-CoV2 spike/RBD and rabies Gp)
- IVT reaction optimization, purification and expression confirmation in vitro
- Partnership with Imperial College London
- T7 RNA polymerase production (clone developed at Imperial College London)
- Thermostable formulation development
- Rotavirus, HPV, flu, Nipah virus etc.
- WHO/MPP/Afrigen

- Imperial College London
  - Prof. Robin Shattock
  - Prof. Karen Polizzi
  - Prof. Cleo Kontoravdi

- University of Leeds
  - Prof. Nicola Stonehouse