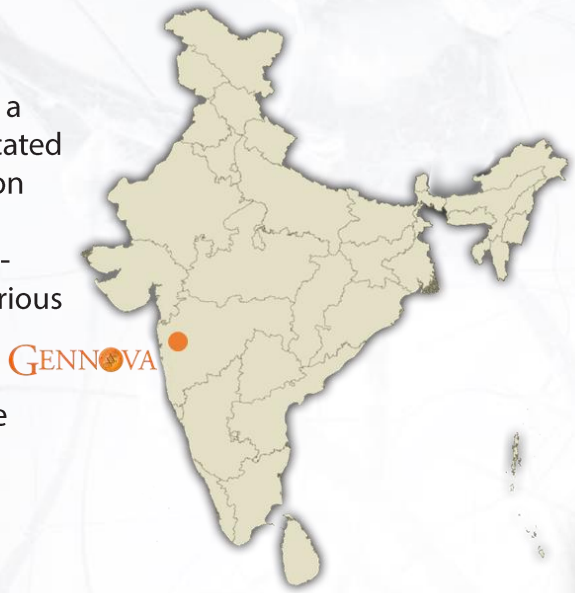

GENNOVA
Transforming
Healthcare
with cutting edge innovation

Overview

Company Overview

Gennova Biopharmaceuticals Limited, established in 2006, is a biotechnology company dedicated to the development, production and commercialization of bio-therapeutics to address life-threatening diseases across various indications.

We are transforming healthcare through innovation in bio-manufacturing processes.



Our Innovation

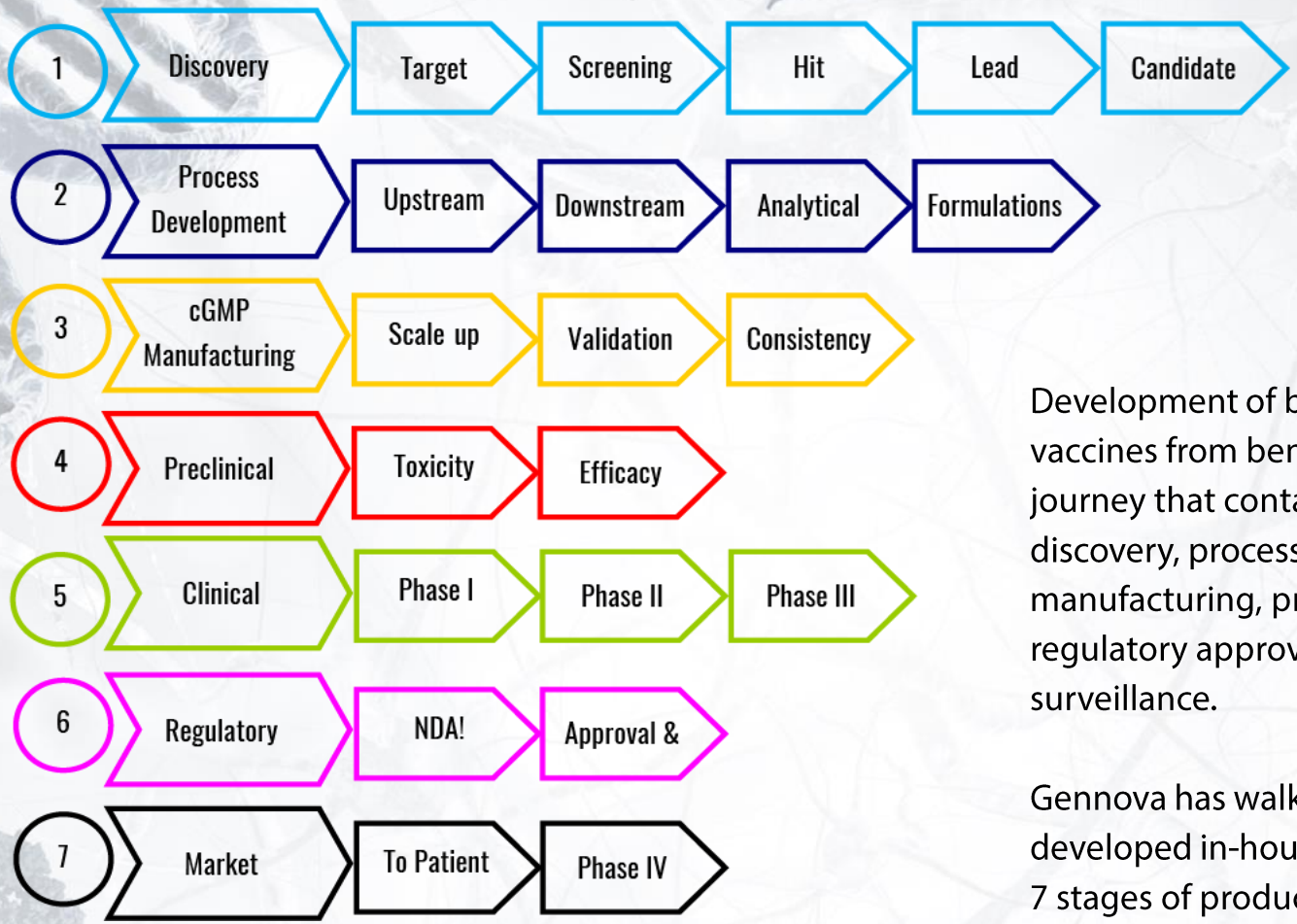
Gennova's innovation platform is based on two basic principles

- Developing next generation manufacturing technologies for bio-therapeutic productions
- Parallel innovating tools to reach to patients

Bringing these two innovations together today we are transforming healthcare

Products in Market

Bench to Bedside

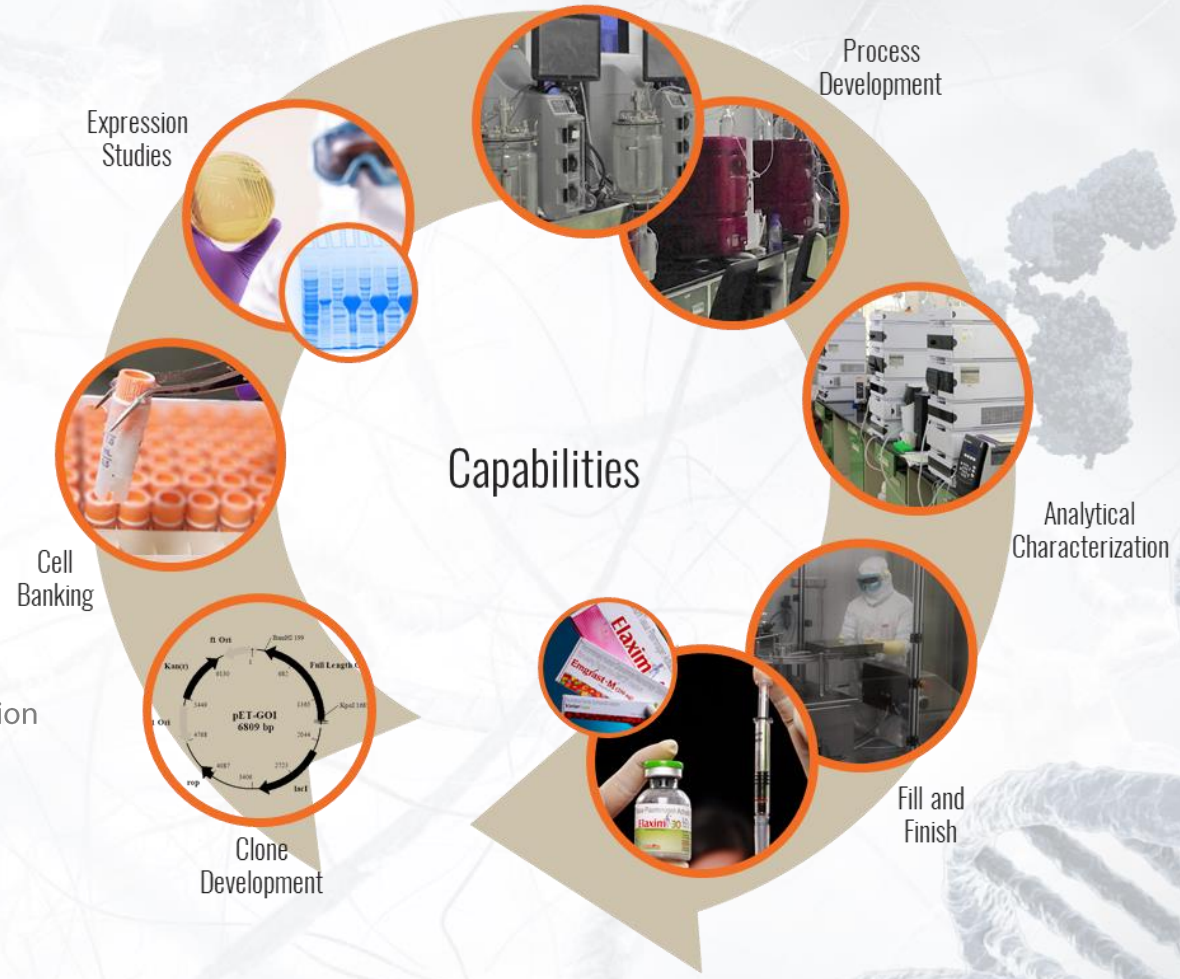


Development of bio-therapeutic and vaccines from bench to market is a long journey that contains several steps, like discovery, process development, manufacturing, pre-clinical, clinical, regulatory approvals and post-marketing surveillance.

Gennova has walked on this path and developed in-house capabilities across these 7 stages of product development – taking SEVEN products from bench to bedside.

Experience

- Intellectual property
- R & D Capabilities
  - Innovation across Bio-manufacturing processes
  - Upstream & Downstream processing
  - AI based systems
  - Cell & Molecular Biology
  - Antibody Discovery – Phage display library
- Manufacturing
  - Bulk and Drug Products
- Fill & Finish
  - Vial/PFS,
  - Liquid/Lyophilized
- Quality Systems
  - Method development & Validation
  - Training
- Clinical Trial
- Regulatory Affairs
- Marketing



PDL with NBM

Gennova's state of the art Research and Development (R & D) facility — **Vaccine Formulation Centre and Research Laboratory**, recognized by Department of Scientific and Industrial Research (**DSIR**) & that has a lab space of over **44,000 sq. ft.**, fills in the huge gap in the **availability of resources** (instruments, equipment and manpower) through its **Product Development Program** (PDP). This program uses diverse production **platforms** (**Microbial & Mammalian**) in combination with modern-day **technologies**, like **PEGylation & mRNA technology,** which can develop the processes from **cell banking to cGMP pilot manufacturing**, with validation of all developed methods (in-process, analytical etc.). This makes it suitable for required **technology transfer** for manufacturing of **clinical studies**.

Under the National Biopharmaceutical Mission (**NBM***), Gennova is creating a shared **Process Development Laboratory** (PDL) facility to **enable** ease of bench to bed side transition from taking a product at the **proof-of-concept stage to Phase III CT material production** and assist in **preparing regulatory documentations** for submission.

*An initiative of Biotechnology Industry Research Assistance Council (BIRAC), Department of Biotechnology, Ministry of Science and Technology, Govt. of India

Process & Product Development

Scope of work at PDL

- Proof of concept establishment,
- Process development,
- Analytical method development & validation
- Production of
  - biologics - enzymes, protein based reagents, therapeutics
  - GLP grade Preclinical Toxicity study material
  - Phase I clinical grade cGMP material

Process & Product Development

Cell line development

- Microbial
- Mammalian (Transient)
- Yeast (Transient and Stable)

Downstream capabilities

- Purification capacity from 1ml to 1L.
- Protein purification from soluble, insoluble (IBs), & secretory fraction.
- Purified proteins can be used directly for in vitro and in vivo studies.

Formulation capabilities

- Liquid drug product formulation
- Lyophilized drug product formulation

Upstream Process Development

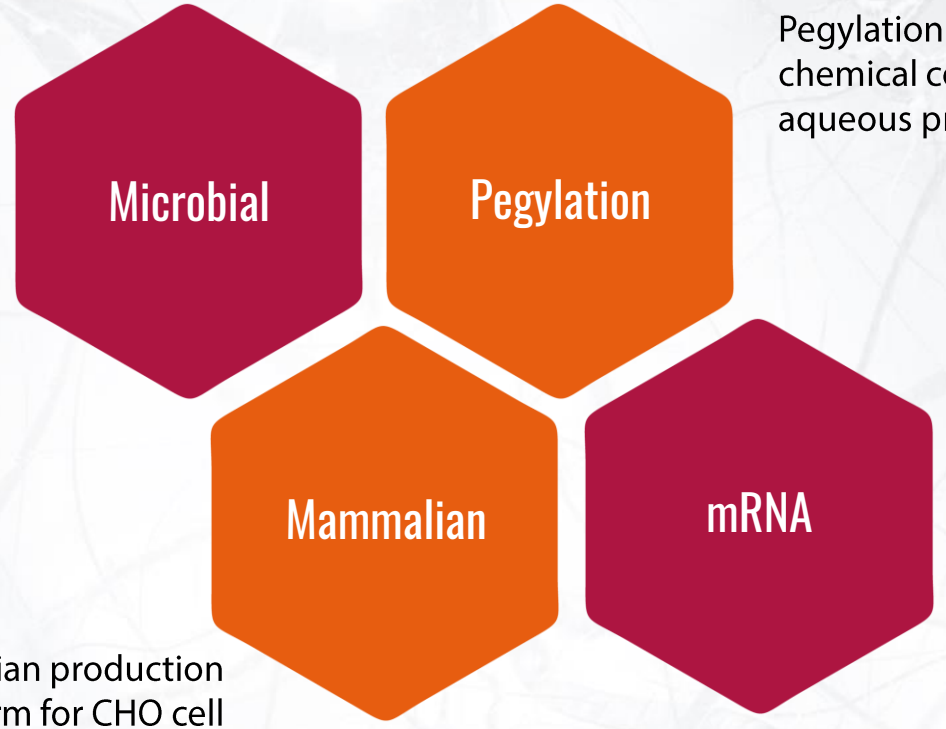
- **Microbial:** 1LX6 reactors for optimization, 5LX3 reactors for consistency and 30LX1 reactor scale up.
- **Mammalian:** 5LX2 reactors for feasibility, consistency & material generation and 50L-100X1 reactor for scale up

Analytical capabilities

- IPQC
- Drug substance and drug product characterization
- Methods development, qualification and validation
- Stability

Platform Technologies

Microbial fermentation technology for E.coli and other bacterial based products



Pegylation as well as various chemical conjugation using aqueous protein chemistry

Mammalian production platform for CHO cell based production of biotherapeutics.

mRNA technology for development of vaccine candidates and personalized medicine in oncology

Product Development Program

To participate in the product development program please contact
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www.gennova.bio/pdl

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