



Introduction



Your Collaborative Partner in
Process Development and GMP Manufacturing for
Vaccines and Biologics/Bio-therapeutics

+91-40-23480049
corporate@yapanbio.com
www.yapanbio.com



About Yapan Bio

- Biotechnology company serving the Custom Development and Manufacturing (CDMO) market for Vaccines and Biologics/Bio-therapeutics
- Process Development, Characterization and Phase I/II GMP Manufacturing
- Facilities for high containment products (BSL-2+)
- Customer and Quality Focused
- Team with proven track record and execution skills
- Based in Genome Valley, Hyderabad (India)
 - Major hub for the Biotechnology industry (Vaccines and Biologics)

Services Offered: Process Development, Characterization and GMP Manufacturing

Vaccines:

- Recombinant Vaccines (Protein antigens, Virus Like Particles, Nano-Particles etc.)
- RNA/DNA Vaccines
- Whole Cell and Live (attenuated) Vaccines

Biologics/Bio-therapeutics:

- Gene Therapy
 - Oncolytic Viruses
 - Vectors (Viral, Non-viral Plasmid, Naked DNA) etc.
- Monoclonal Antibodies
- Therapeutic proteins and other complex biologics

Cloning and Cell line development via experienced Third-Party Partners

Services Offered



Process Development

- Optimization and scale-up for high product titer, stability and consistent manufacturing output;
- Upstream and Downstream Development
 - Upstream manufacturing technologies and strategies know-how (eg. Bioreactors / fermenters, disposable systems, fed-batch, perfusion, expression kinetics)
 - Downstream product harvest, recovery and purification methods such Centrifugation, tangential flow filtration (UF/DF), Depth filtration, Chromatography
- Assay development and qualification
- Stability studies



Process Characterization

- Establishment and qualification of small-scale model for different unit operations for the process;
- Classification of Process Parameters and Product Quality Attributes-Critical, Major, Minor;
- Design of Experiments (DoE) to establish the appropriate Ranges for the Process Parameters and Product Quality Attributes;
- Execution of experiments and generation of data/reports to support regulatory filings

Services Offered



GMP Manufacturing

- Cell and Virus seed banking
- Rocker, Stirred Tank and Adherent Cell Bioreactors
- Up to 200L Stirred bioreactor scale
- Utilization of single-use (disposable) technologies
- Two separate suites
 - Non-infectious organisms
 - Infectious organisms (BSL-2+)
- Fill/Finish on site - Aseptic formulation/fill/finish (Liquid in Vials).

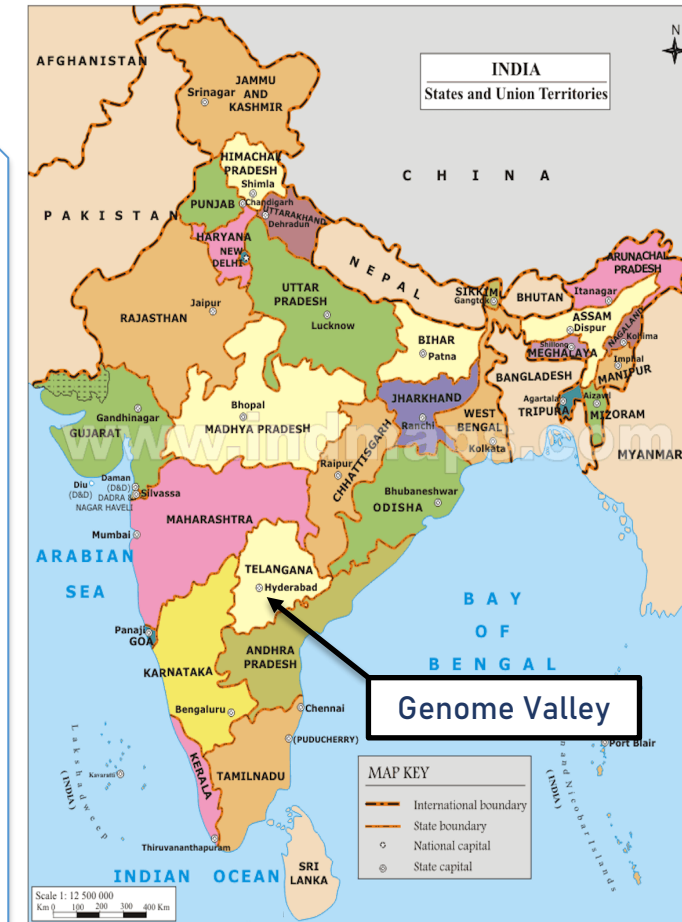


Additional Support Offered

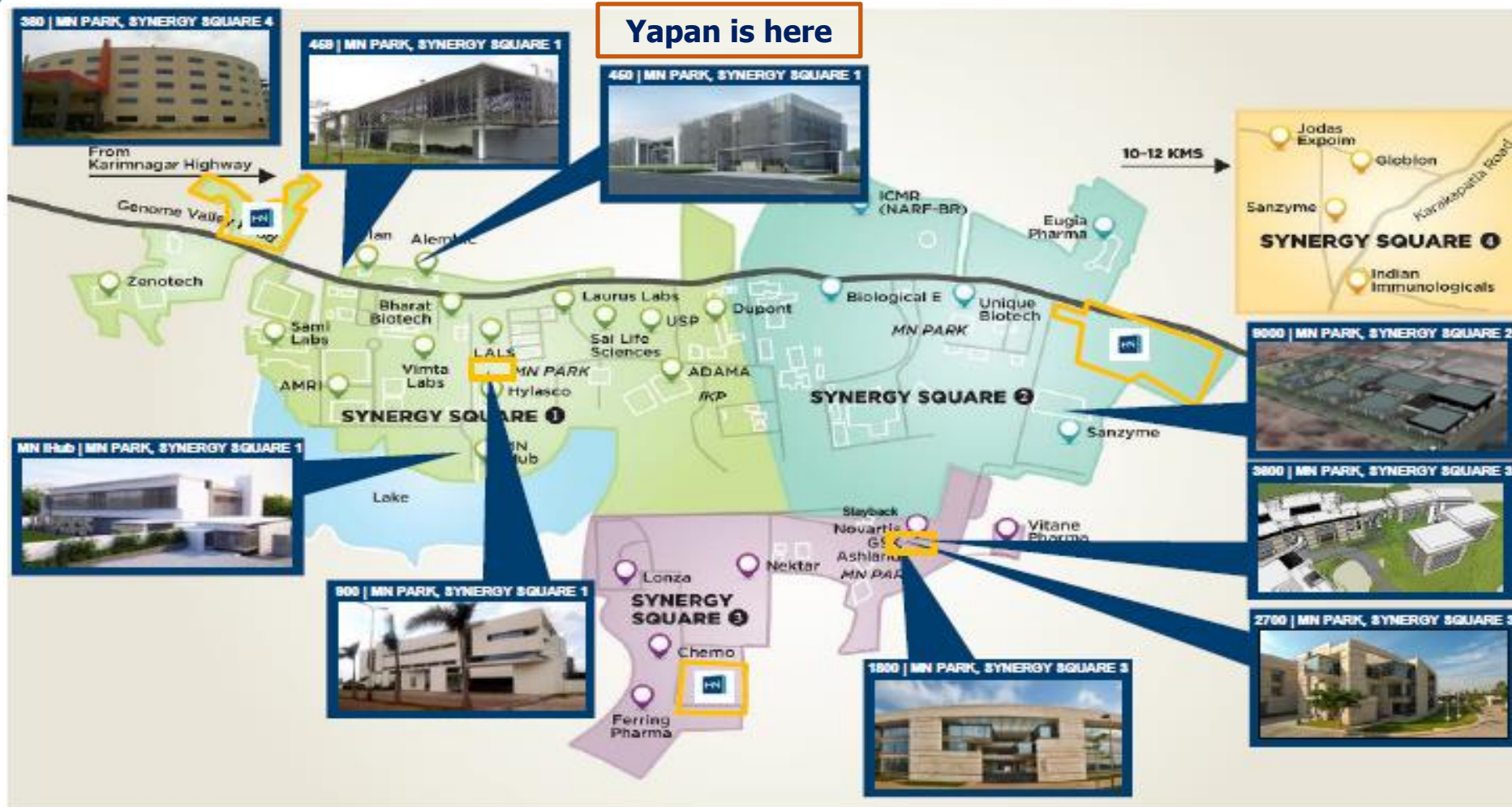
- Third Party CRO management for outsourced activities and testing:
 - Cloning and Cell line development
 - Cell line and Virus bank characterization
 - Release testing; safety, identity, strength, quality, purity
 - Work with client QP to ensure compliance with EU/EMEA
- Short-term product storage;
- Product supply/distribution to study sites;
- Client support in regulatory filings and meetings with government agencies (USFDA, EMEA, etc.).

Located at Genome Valley, Hyderabad, India

- India's 1st state-of-the-art systematically developed R&D and clean manufacturing cluster
- 25 km radius designated as "Pollution Free Zone"
- >200 companies, with more than 50 global majors
- >10,000 scientific & technical work force
- Specialised Life science Environments: Biologics, Vaccine Development and Manufacturing, Vivariums, Polyhouse, Pilot plants and Production
- Three of India's largest vaccine manufacturers accounting for the bulk of drugs- Bharat Biotech, Biological E and Indian Immunologicals



Genome Valley: Life Sciences Capital of India



Facility Design: Salient Features



Designed as per the:

- Global cGMP expectations/guidelines
- Multi-product processing
- Appropriate Biosafety and cleanliness classification
- Appropriate safety and waste handling



With segregation between:

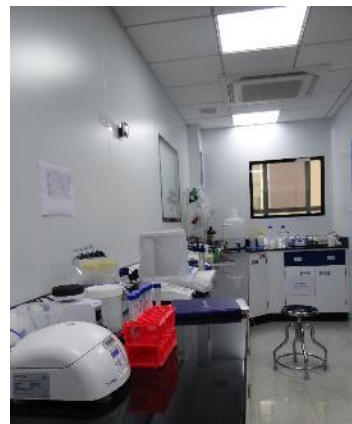
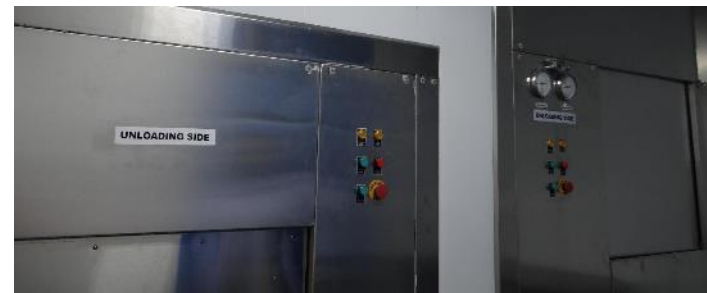
- Organisms, products and/or technologies
- Processing steps (e.g. upstream & downstream operations)
- Components or equipment at different stages of cleanliness



Utilizing adoption of:

- Modular construction
- Use of disposables (Single use)
- Unidirectional-flow to the extent possible

Facilities and Equipment



Summary: Yapan Bio Advantage

- Integrated services from early-stage process development & scale-up to process characterization and GMP manufacturing for Clinical Studies
- Niche capabilities: Custom Development and Manufacturing for high containment requirement products (BSL-2+ containment)
- Result Oriented: Customization and flexibility is key
- Global quality standards: Documentary/data support for regulatory filings
- Flexible partnership structure: Milestone or FTE based collaboration (depending on the project/scope)
- Team with extensive experience: Strong expertise and credibility in developing vaccines and biologics from early stages to commercial scale GMP manufacturing
- Capabilities to support broad spectrum of cell-culture/viral and microbial based systems
- Potential for expansion for later stage manufacturing

“The Company To Watch Out For”

4th Annual Asia-Pacific Bioprocessing Excellence Awards 2020 (Singapore)



"10 Most Promising Biotechnology Companies 2020"

Silicon India Magazine, Special Issue on Biotechnology - October 2020

siliconIndia 10 MOST PROMISING
BIOTECHNOLOGY
COMPANIES - 2020

Yapan Bio: A Collaborative Partner for Vaccines and Biologics/Bio-therapeutics Process Development and Manufacturing

The biotechnology sector in India has perceived rapid development in the recent years and stands to be a preferred destination for biopharmaceuticals to manoeuvre and innovate effective services and products. The prodigious and diverse complexion of the industry has stimulated the interest of many highbrows who decided to turn the window of opportunity this space extends. The founders of Yapan Bio, Atin Tomar and Nirav Desai, comprehended the prospering potential, scope and the demand of the biotechnology-based services and products and settled on the plan of laying the cornerstone of Yapan Bio. The core purpose of establishing this firm is to serve the expeditious inflating custom process development and manufacturing market concerning the Vaccines and Biologics/Bio-therapeutics. "Our niche ability lies in the customized, flexible and integrated solutions for the successful development and manufacturing of high potential biotechnology based products like vaccines (Recombinant Vaccines including Protein antigens, Virus Like Particles, Nano-Particles; RNA/DNA Vaccines and others) and Biologics/Biotherapeutics (Gene Therapy -



Atin Tomar, Co-Founder & CEO
Nirav Desai, Co-Founder & CEO

that manoeuvres in the niche and high potential areas of Vaccines and Gene Therapy. Yapan Bio pioneers in strategizing and executing the entire product development pathway required for successful development and manufacturing of innovative and novel products. Yapan Bio provides robust process development, appropriate scale-up and complaint GMP manufacturing of vaccines and biologics/bio-therapeutics for human clinical trials across the world.

Considering its true form, the company has moulded a team of highly experienced experts who hold remarkable credentials in the research, development, and manufacturing of biotechnology products, among other disciplines. Apart from just formulating innovative approaches, the team supports its partners to craft pertinent development plans and documentations for developing novel products as per global quality and regulatory expectations. Established just a year ago, Yapan Bio has created a niche for itself in the ecosystem. Despite of being in an advancing stage, the company has embarked on the development of a novel recombinant vaccine for a US based innovative biotechnology company. In the first financial year, it did witness a remunerative revenue growth, with a positive EBITDA. "The advancement of Yapan Bio is a product of unique synchronization and the hard work of our team in the denouement of the vision of our company. We are recognized as 100 percent Export Oriented Unit (EOU), MSME and Start-up by the Department for Promotion of Industry and Internal Trade. We strongly support Make-in-India and India as prime destination for services and manufacturing of biotechnology-based products. Contemplating over the overwhelming increase in the demand of our development and manufacturing capabilities, we aspire to steer our operations in devising additional capacity and capabilities for development of innovative products that suits the needs of global biotechnology/biopharma companies," states Nirav Co-Founder & COO. Yapan Bio was recognized as "The Company To Watch Out For" at the 4th Annual Asia-Pacific Bioprocessing Excellence Awards 2020 (Singapore).

The company displays every sign of future potential where it intends to expand its capacities and capabilities in different verticals so as to seize constructive opportunities that will eventually spike up its overall growth. ■



Yapan Bio stands out to be the only biotech firm that manoeuvres in the niche and high potential areas of Vaccines and Gene Therapy based product development and manufacturing

Oncolytic Viruses; Vectors - Viral, Non-viral Plasmid etc along with monoclonal Antibodies, therapeutic proteins and other complex biologics). Our facility also includes Bio-Safety Level 2+ suite to develop and manufacture high containment product classes. These capabilities have for sure empowered us with a significant advantage," narrates Atin Tomar, Co-Founder & CEO.

Among the handful of Custom Development and Manufacturing Organizations (CDMOs) focused on biological products, Yapan Bio stands out to be the only biotech firm

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Thank You!



Yāpan bio

Yapan Bio Private Limited
221 & 222, Building 450, MN Park,
Synergy Square 1, Genome Valley, Shamirpet,
Hyderabad - 500078, Telangana, INDIA

+91-40-23480049
corporate@yapanbio.com
www.yapanbio.com