



Introduction



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

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About Yapan Bio

- Biotechnology company serving the Contract Development and Manufacturing (CDMO) market for Vaccines and Biologics/Bio-therapeutics
- Process Development, Characterization and GMP Manufacturing
- Facilities for High Containment/Infectious Agents (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)
- 33.33% owned by Piramal Pharma

Vision Statement

“To be the preferred collaborative partner to the global biotechnology and biopharma companies for successful development of Vaccines and Biologics/Bio-therapeutics through world-class Research and Development combined with efficient and compliant manufacturing services”

Services: Process Development, Characterization and GMP Manufacturing

Vaccines:

- Recombinant Vaccines (Protein antigens, Virus Like Particles, Nano-Particles etc.)
- Viral Vector Based Vaccines
- RNA/DNA Vaccines

Biologics/Bio-therapeutics:

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

Expression Systems/Platforms:

Mammalian Cell Culture; Insect Cell Culture; Microbial Fermentation

Services Offered

Process Development

- Cell Line Development
- Optimization and scale-up for high 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, TFF (UF/DF), Depth filtration, Chromatography
- Analytical method 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

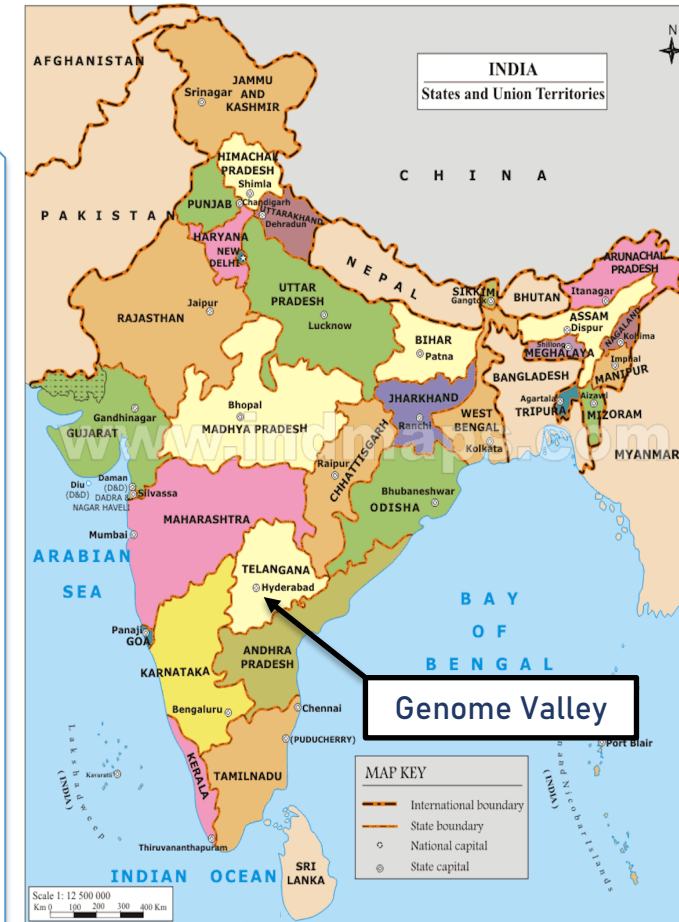
- Cell and Virus seed banking
- Rocker, Stirred Tank and Adherent Cell Bioreactors
- Up to 1000L Stirred bioreactor scale
- Utilization of single-use (disposable) technologies
- Separate suites
 - Non-infectious organisms
 - Infectious organisms (BSL-2+)
- Fill/Finish On-Site: Aseptic Formulation, Fill & Finish (Lyophilization & Liquid in Vials)
- Stability Studies

Additional Support Offered

- Third Party CRO management for outsourced activities and testing:
 - 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.)

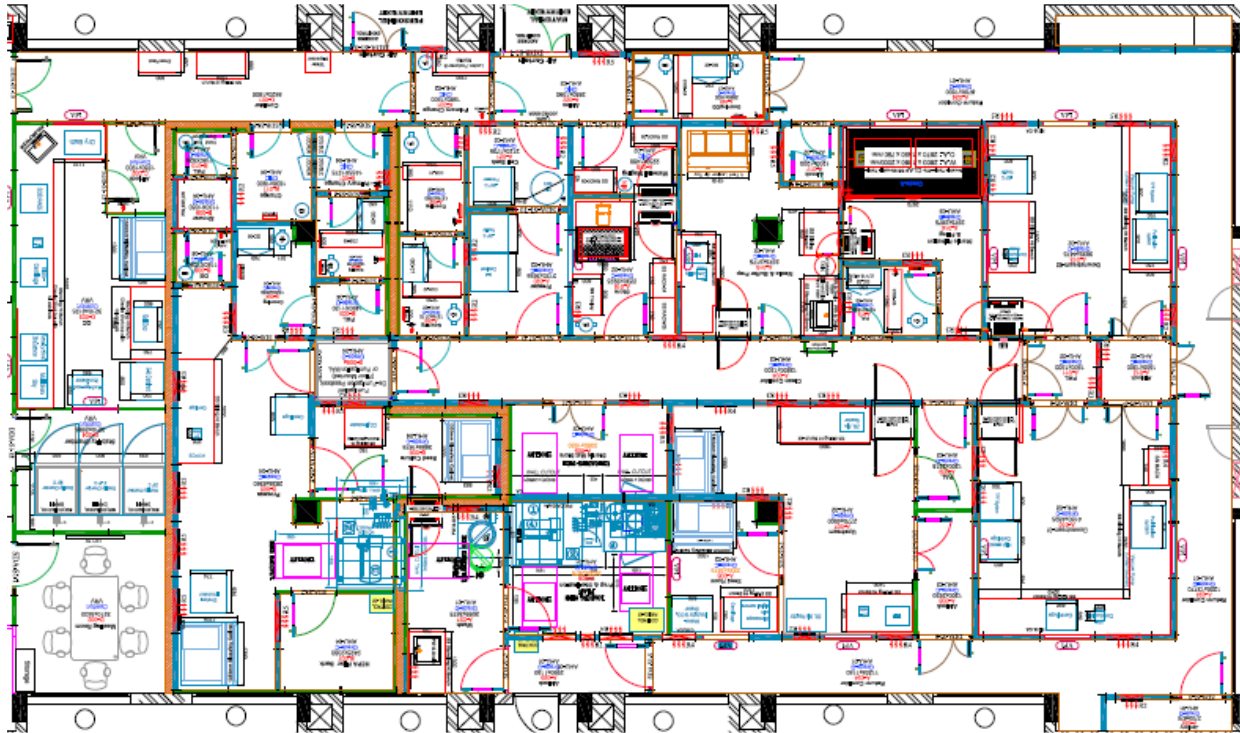
Located at Genome Valley, Hyderabad

- India'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



GMP Facility

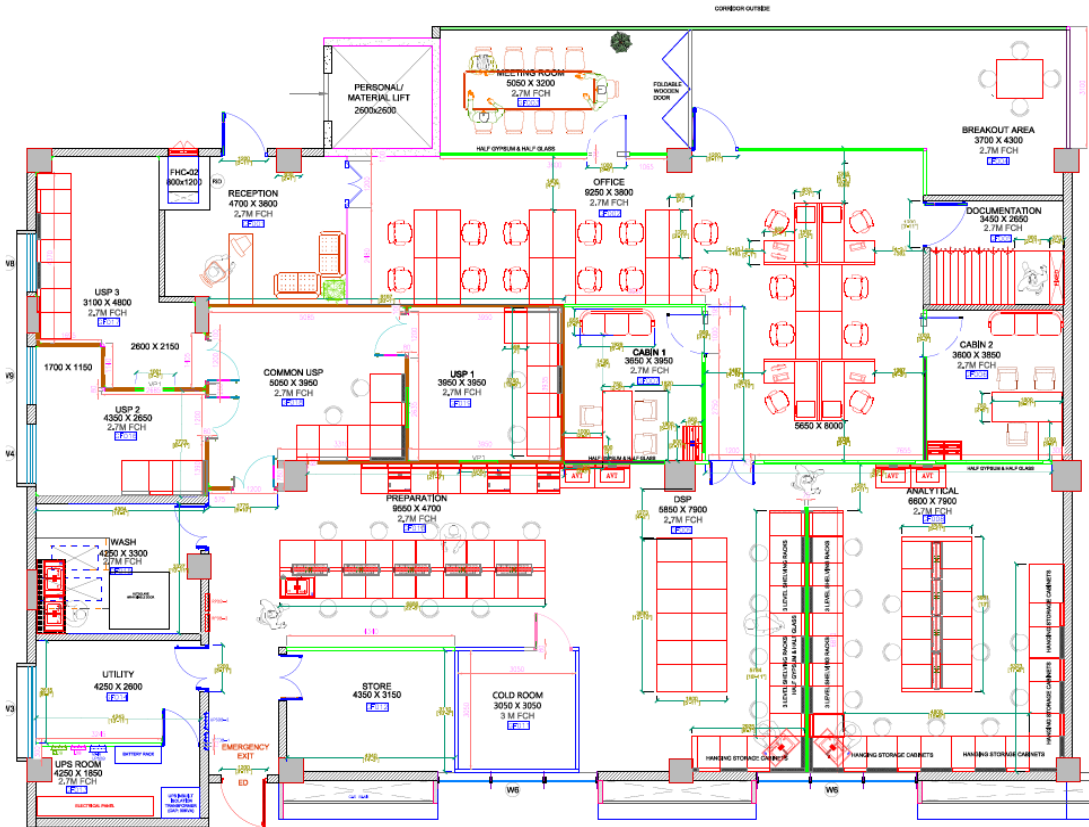
450 MN Park



- ~6360 Square Feet
- 2 Separate GMP Suites
- Up to 200L Bioreactor Scale
- 1 Suite with BSL-2+ Containment
- Class A/B, C and D areas
- Unidirectional Flow
- Quality Control Lab

Process Development Facility

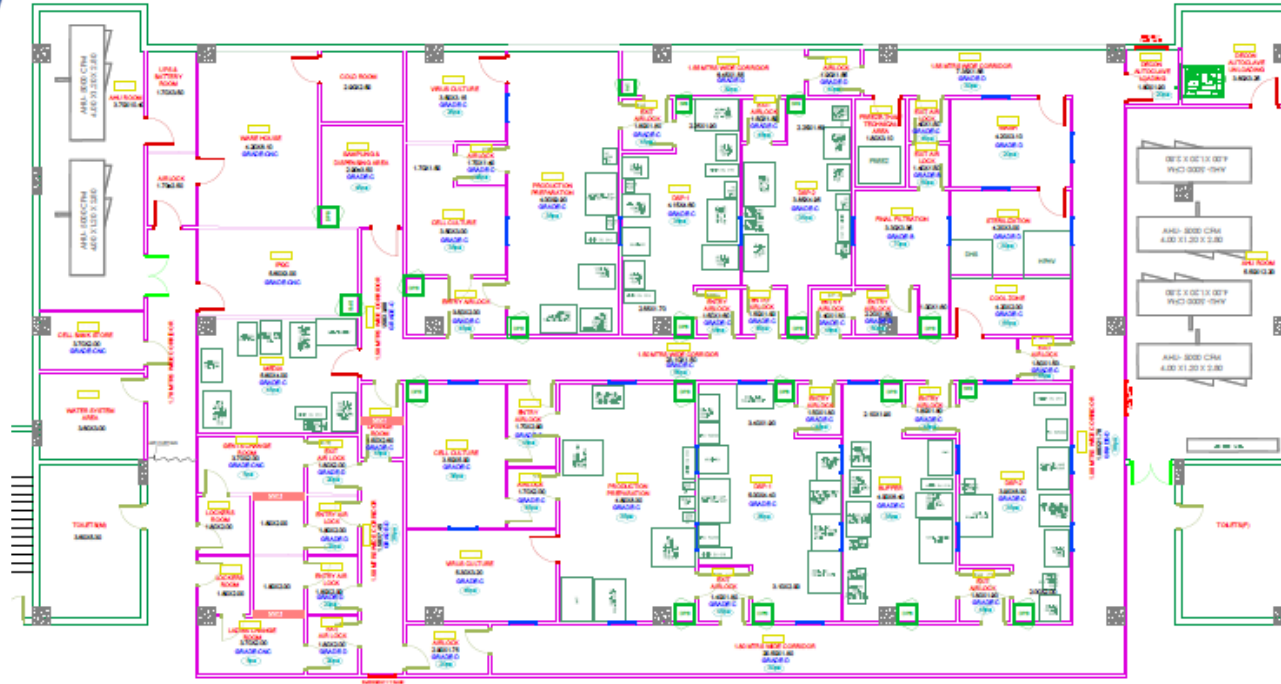
270 Touchstone



- ~6825 Square Feet
- 3 Separate Upstream Suites with independent Supply and Exhaust
- BSL-2 Containment
- Downstream Process Development Lab
- Analytical Development Lab
- Common Preparation Area
- Utility and Support Areas

GMP Facility

270 Touchstone



- ~13,500 Square Feet
- 2 Separate GMP Suites
- Up to 1000L Bioreactor Scale
- BSL-2 Containment
- Class A/B, C and D areas
- Unidirectional Flow
- Quality Control Lab

Summary: Yapan Bio Advantage

- Integrated services: from early-stage/lab-bench through process development & scale-up to process characterization and GMP manufacturing for clinical studies
- Niche capabilities: development and manufacturing for next generation and highly complex molecules/product classes (recombinant vaccine, viral and non-viral vector-based products, Gene Therapy etc); high containment facilities for development and GMP manufacturing (BSL -2+); monoclonal antibodies
- Result Oriented: Customization, flexibility and transparency is the key
- Global quality standards: Documentary/data support for regulatory filings
- Flexible partnership structure: Milestone or FTE/Retainership based collaboration
- 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 expression/technology platforms for novel product development
- Experience of developing monoclonal antibody (mAb), recombinant vaccine and gene therapy products for global biotechnology companies
- Potential for expansion for later stage manufacturing



On a Mission to Serve the Global Biotechnology Industry

YAPAN BIO

In the words of **Eula Biss**, the famous non-fiction writer, "Imagine the action of a vaccine not just in terms of how it affects a single body, but also in terms of how it affects the collective body of a community." Those who witnessed the deadly pandemic in the recent past know the importance of the above statement. It led to the loss of many lives, and the vaccine was an extremely effective intervention that prevented the world from collapsing. Our lives returned to normal thanks to it. Over the years, many companies have developed vaccines that have protected us from various diseases. We may know the names of the vaccine on the market today, but we rarely know who made them. Our focus in this edition will be on a company that has made a significant contribution in the development of novel vaccines in a short time. **Yapan Bio Private Limited** is a Contract Process Development and Manufacturing Organization (CDMO) serving the global biotechnology industry. They provide process development and GMP-compliant manufacturing services for vaccines

and biologics/bio-therapeutics for human clinical trials worldwide. Capabilities at Yapan also include development and GMP facilities for high containment product classes (up to Biosafety Level 2+).

This company was founded by **Mr. Atin Tomar, CEO, and Mr. Nirav Desai, COO, in 2019**. Having worked in the biotechnology field for over two decades, they come with a wealth of knowledge and experience that they have put to use at Yapan Bio. They have been part of the development of many successful vaccines and biologics/bio-therapeutics currently being used by humanity. Having received recognition and accolades in this field, they decided to wear the hat of the founders, which led to the birth of Yapan Bio. Since then, there has been no looking back, and the company has contributed to multiple novel product development efforts in a short span of time.

OUTLOOK BUSINESS/OCT 2022

"The Best Emerging Biotechnology Company - India" Global Health & Pharma Biotechnology Awards 2021



Best Emerging Biotechnology Company - India

One To Watch

Yapan Bio is India's emerging Biotechnology company serving the niche market of Custom Development and Manufacturing for Vaccines and Biologics/Biotherapeutics. Offering end-to-end services in Process Development, Characterisation and GMP Manufacturing. Yapan is a trusted and valued partner to biotech and biopharma companies around the world.

Based at Genome Valley in Hyderabad, India, a thriving hub of the Life Sciences Industry, Yapan Bio is well-situated to be the collaborative partner to global biotech and biopharma corporations. The Contract Process Development and Manufacturing Organisation (CDMO) serves the industry as a leading developer and manufacturer of vaccines, biologics and bio-therapeutics for human clinical trials.

As one of the very few CDMOs to have a focus in the niche and high potential field of vaccines and biologics, including gene therapy, Yapan relies heavily on world-class Research and Development married with compliant, highly efficient technologies to facilitate the firm's fully integrated capabilities.

Yapan's services are broken down into four key areas of Process Development, Process Characterisation, GMP Manufacturing and Additional Support, that includes Third Party CRO management for outsourced activities and testing, short-term product storage, and product supply and distribution. From early-stage research to robust process development and scale-up to GMP manufacturing, Yapan is able to support a broad spectrum of cell-culture, viral and microbial based systems that form the basis of research and innovation in biosciences, thanks to the team with decades of industry experience and market-leading resources.

The Yapan facility is designed and qualified to operate at Biosafety Level 2 (BSL-2) and Biosafety Level 2+ (BSL-2+), in order to safely work with infectious materials that are required for research, development and manufacturing in the fields for vaccines and gene therapy. Designed in accordance with global GMP guidelines, the site handles multi-product processing with segregation between organisms, products, technologies, as well as processing steps and components that are varying in levels of cleanliness. Across its two suites, the Yapan facility provides state-of-the-art tools and technologies required to explore the full scope of complex biologics, cell technology, and vaccine development, a feat that is currently unmatched within the global sphere of biotechnology and biopharmaceuticals.

Recognising that its niche expertise means Yapan is trusted by biotech and biopharma companies around the world for specific research and high containment requirement products, the firm adheres to strict quality control measures, and an ethos of customisable, flexible integrated services for clients. Depending on the scope or scale of a project, Yapan is able to offer a versatile partnership structure in a milestone or FTE-based collaboration with clients.

Those clients are able to benefit from the insights of a strong team with extensive experience



in developing vaccines and biologics from initial conception to commercial scale GMP manufacturing. Led by founders Atin Tomar and Nirav Desai, Yapan takes a results-oriented approach to supporting its clients, employing its characteristic agility and innovation to cultivate bespoke solutions in research and development of vaccines or biologic products. Adhering to strict standards for safety and quality, Yapan offers its clients inimitable products based on outstanding research and with the potential for expansion through later stage development and manufacturing, giving clients sustainability in their solutions that is unmatched across the industry.

This year, Yapan adds its recognition as the Best Emerging Biotechnology Company of India to its roster of previous accolades, among which is the firm's proud title of "The Company To Watch Out For" at the 4th Annual Asia Pacific Bioprocessing Excellence Awards 2020 (Singapore). As the firm continues to look ahead to further innovation in its research and expansion in its capabilities, there is no doubt we can continue to see big things from Yapan in its future of growth.

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Yapan Bio

Biotechnology Awards 2021

Best Emerging Biotechnology Company - India

“The Company To Watch Out For”

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



"10 Most Promising Biotechnology Companies 2020" Silicon India Magazine

Yapan Bio

recognized by **siliconindia** Magazine as

siliconindia 10 MOST PROMISING
BIOTECHNOLOGY
COMPANIES - 2020

*The annual listing of '10 Most Promising Biotechnology Companies – 2020'
recognizes the maneuvering evolution of the biotechnology industry and
the business acumen by the companies*



Anamika Sahu
Managing Editor

Thank You!



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