

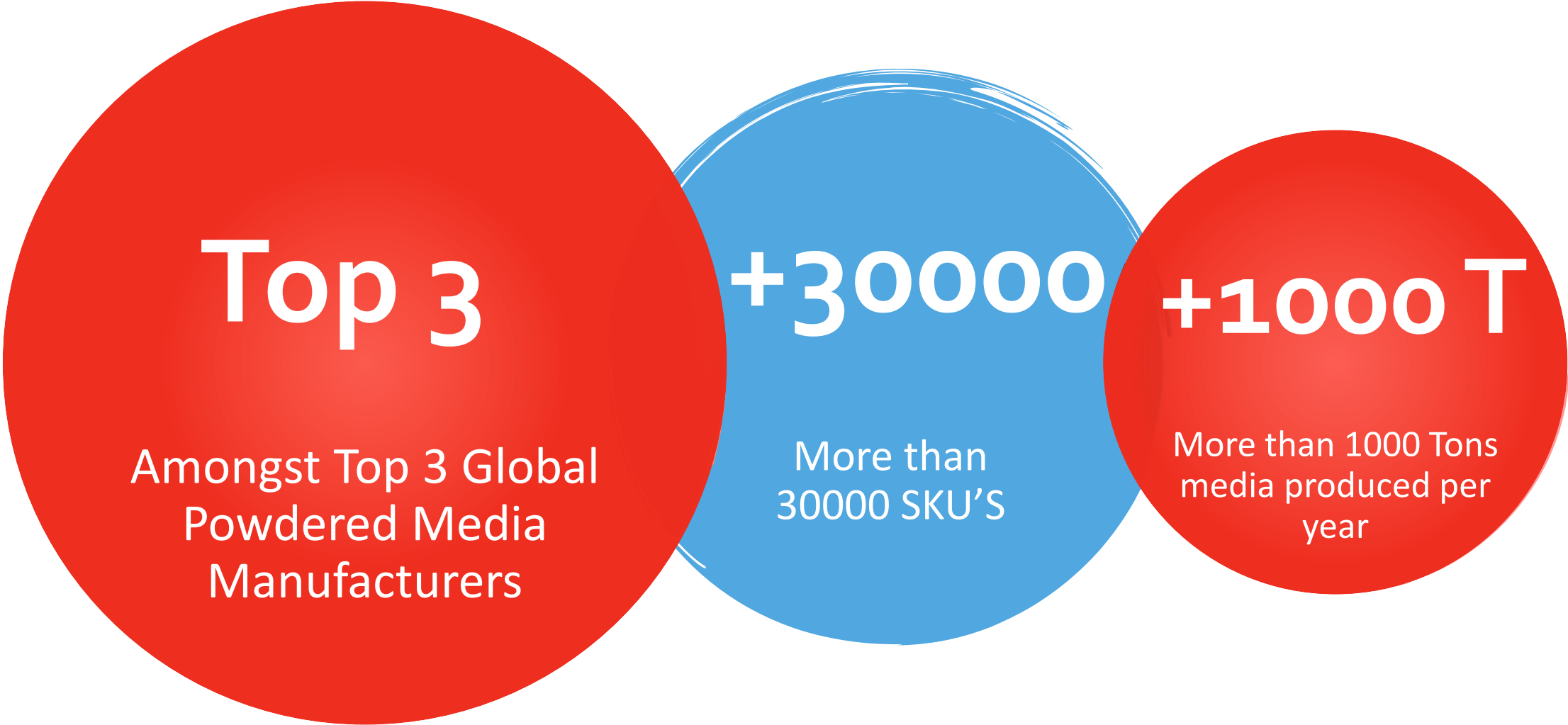


**HIMEDIA**®

For Life is Precious

# The HiMedia Brand

A Leading BioSciences Company in the Service of Humankind since **48 years**



# Global Presence



- 15 Manufacturing Locations in India
- Exporting to over 150 countries worldwide
- 335 + Global Channel Partners
- Offices & Warehouses in India, Germany and USA



# State of Art Infrastructure

## HiMedia Laboratories – New Headquarters – Thane C40





# State of Art Infrastructure



Media Manufacturing Facility



Protein Hydrolysate  
Manufacturing Plant



R&D Facility



# Upcoming cGMP Facility as per Industry Standard 5.0



- Animal free
- Antibiotic free
- QBD integrated process with the help of PAT
- Integrated by IOT & Data Analytics

# Our Business Verticals



Microbiology



Cell Biology



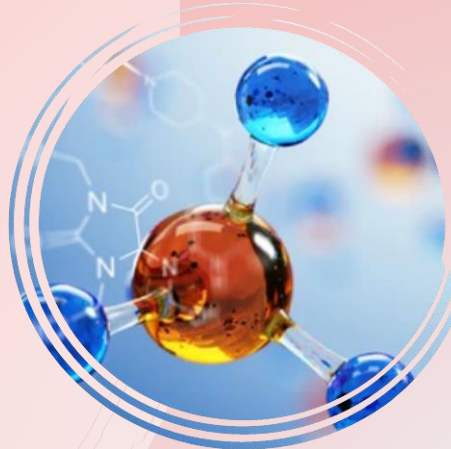
Plant Tissue Culture



Molecular Biology



Hydroponics  
Soilless Farming



Chemicals &  
Biochemicals



Consumables &  
Equipment



# OUR CAPABILITIES





01

### Advanced Technology

- Cryogenic milling
- Automated filling lines
- End to end traceability
- IOT
- In-House developed and controlled setups

02

### Manufacturing Capacity

- Powder media: 5000kg/batch
- Liquid media: 1000L/batch
- 60 tons per day in 2023
- 100 tons per day in 2024

03

### Customization Flexibility

- Customized formulations
- Customized packaging

04

### Bulk Packing Capacity

- Powder media: In drums
- Liquid media: In bags

# Our Strengths in Production

# Our Quality Checkpoints



## Raw Material Testing

*Identity, purity and quality*

- HPLC Analysis
- FTIR Analysis
- GC
- Potentiometric Analysis
- Amino acid Analyzer
- UV spectrophotometer
- Polarimeter



## In process Testing Controls

*Critical Process Parameters (CPP)*

- Particle size analysis
- Particle size distribution
- Principle Component Analysis
- Homogeneity Analysis



**CQA**

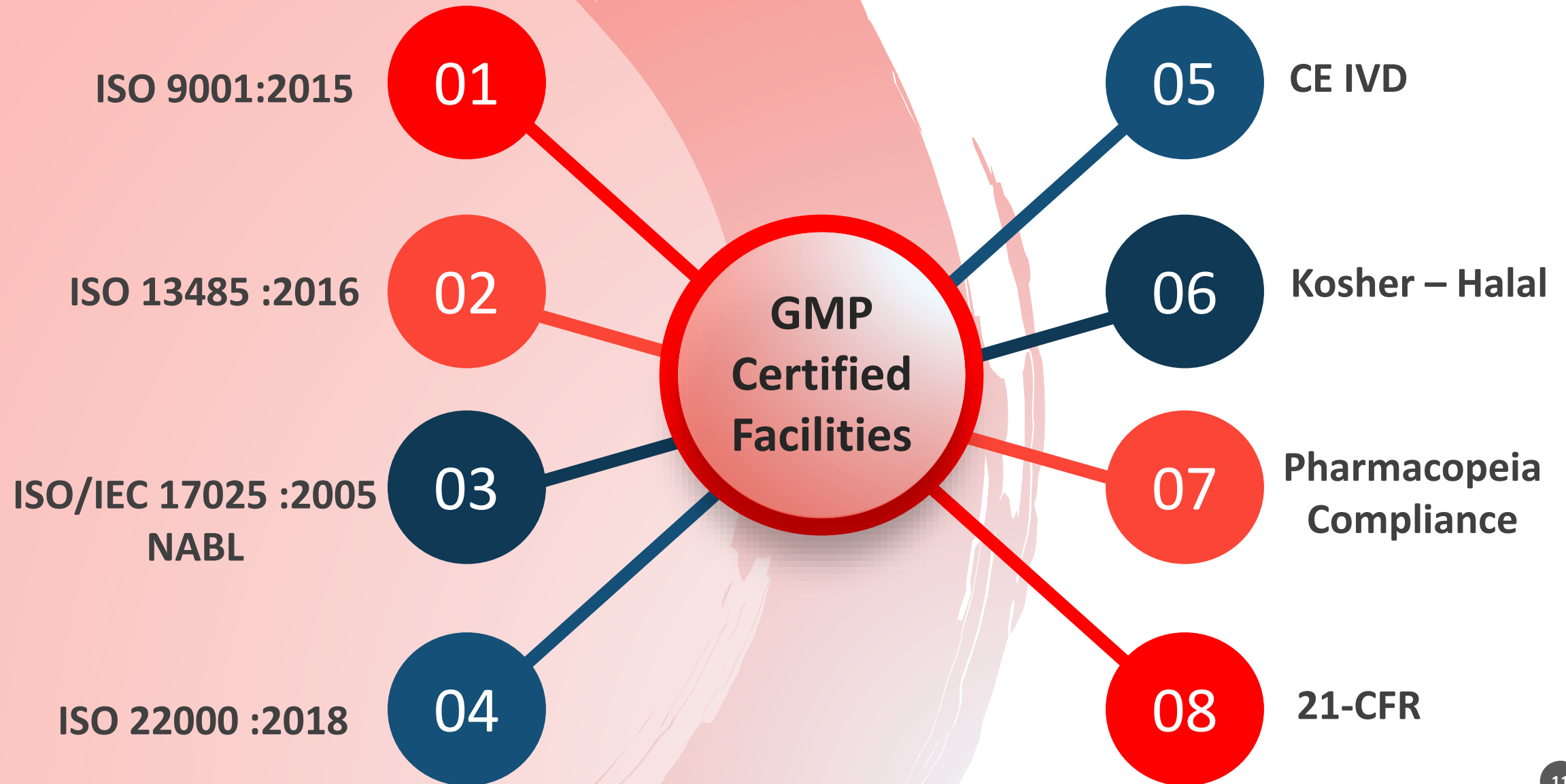
## Finished Product Testing

*Critical Quality Attributes (CQA)*

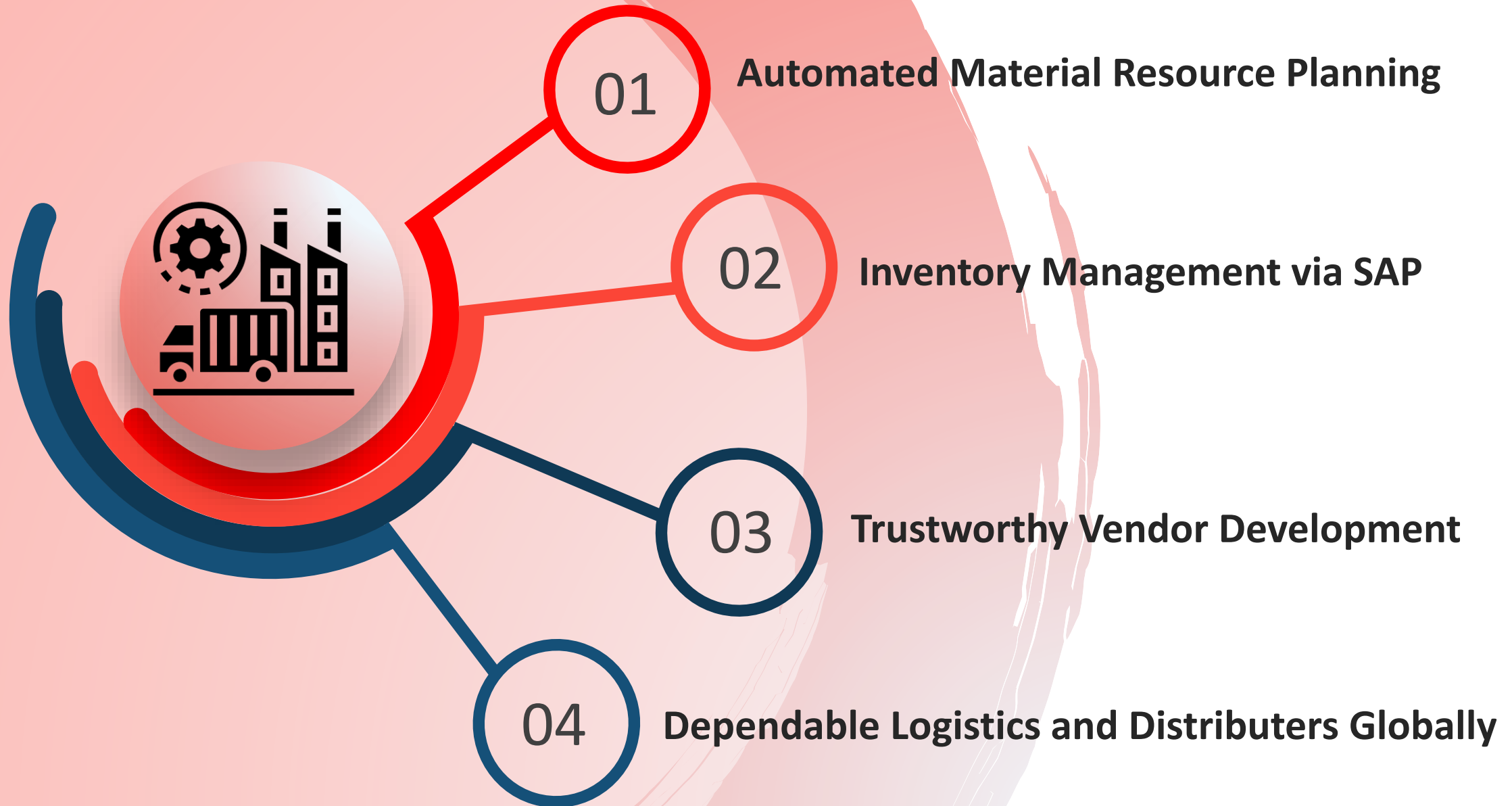
- Application specific testing
- Serial Subculture
- Endotoxin



# Our Regulatory Compliances



# Our Supply Chain Expertise





# Our Logistics Capabilities

**300+ Tons**

Cargos shipped per  
month in India

**+125000**

**Sq. Ft**

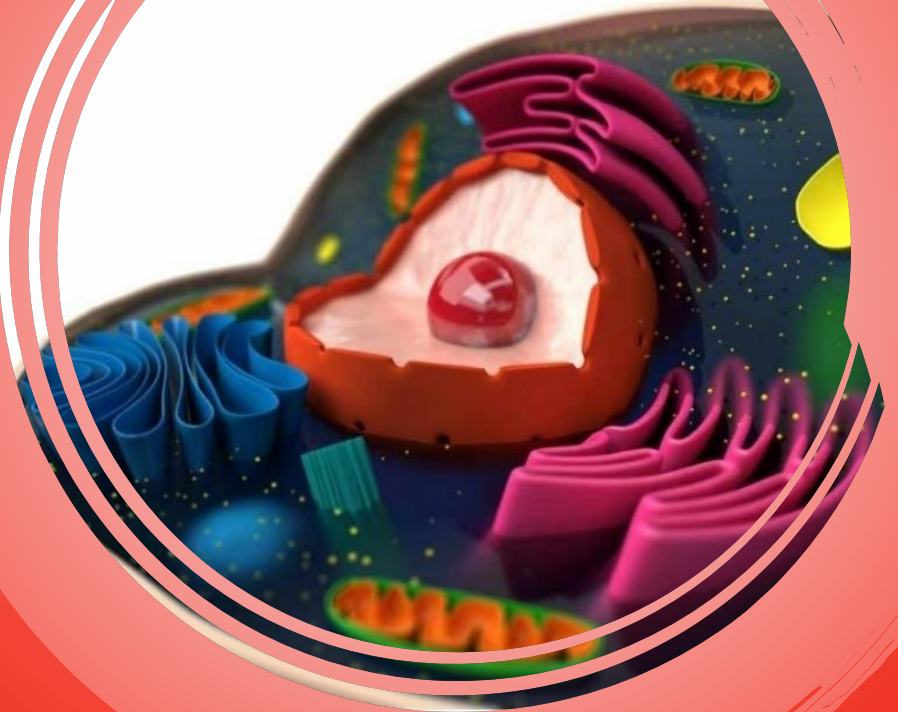
Warehouse Area

**50+Tons**

Cargos shipped per  
month for Export

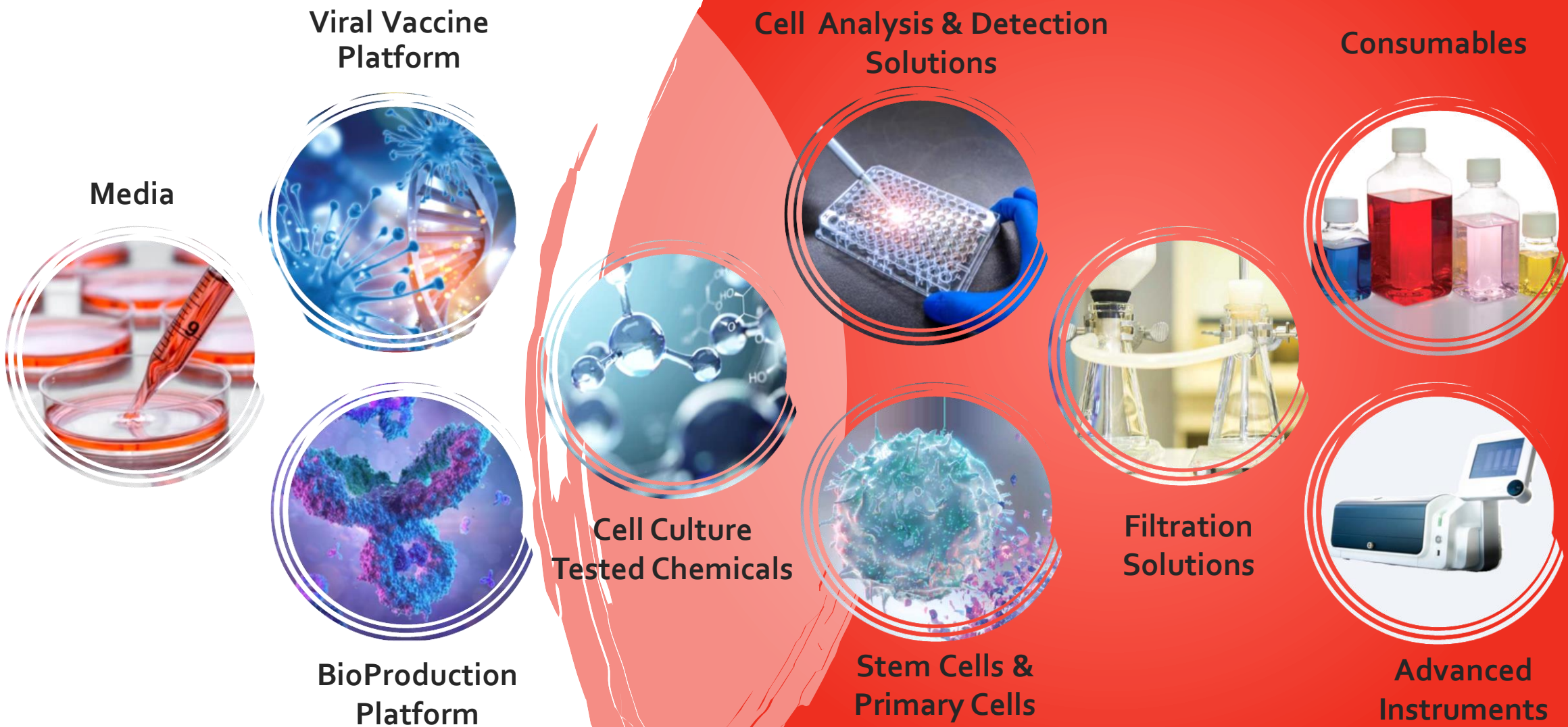


# CELL BIOLOGY DIVISION

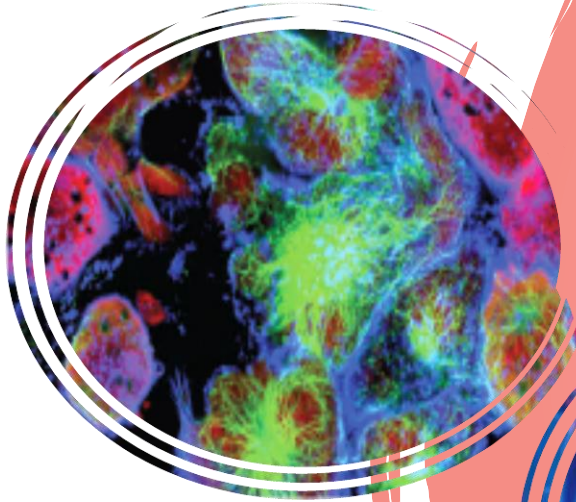




# Our Product Range



**ATCC (In India)**



**Skill Development Modules**



**Custom Service Platform**





# R&D : A Systematic Approach to Media Development & Optimization

## High Throughput Tools

Cell Line Banking

Media development

Feed development

Process development

Process Validation  
by QbD



Media & Feed  
Blending

DoE

Automated  
Platforms

# Biopharma Platform

**Comprehensive range of clone-specific serum-free, protein free media and feed supplements and Bio-Production services**



## MEDIA

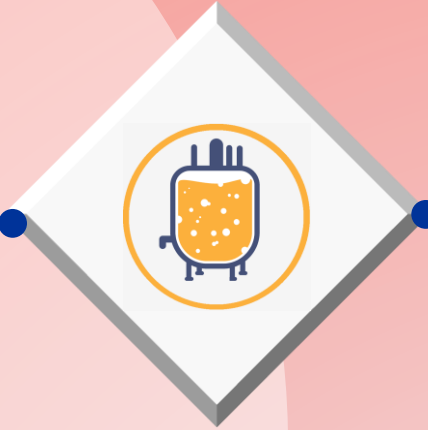
### Serum & Animal Free Medium

- CHOin1™ Serum Free CHO Medium

### Universal Feed Supplement

- CHOin1™ Feed Medium

### Serum Free Supplements



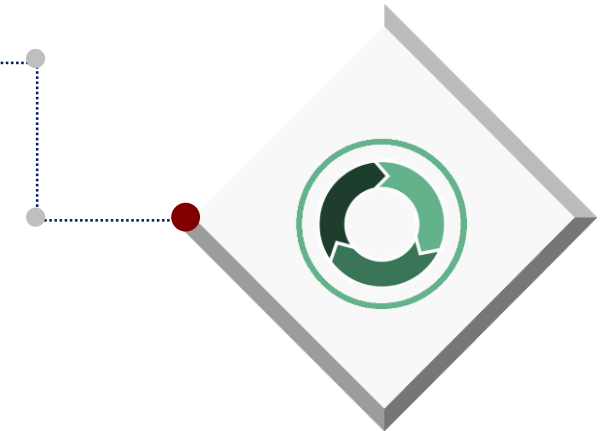
## BIO PRODUCTION SERVICES

### Clone Specific Media & Feed Development

- Assured Clone Security
- Systematic Development

### Spent Media Analysis

### Media Optimization

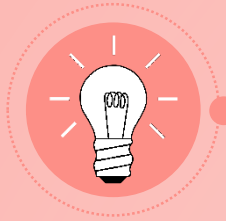


## PROCESS DEVELOPMENT

**From Clone to Protein**

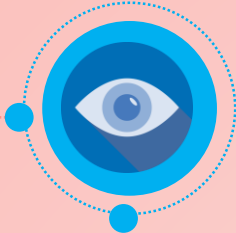
# Media Development & Optimization

Design of Experiments (DoE): A Multivariate Data Acquisition Tool



## Media Mixture DoE

Optimization of Basal Medium



## Two Level Factorial DoE

Testing the effects of multiple nutrient groups supplementing the basal medium



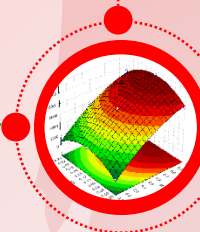
## Central Composite DoE

Determine the optimal concentrations of functional nutrient groups identified in the previous step



## Comprehensive Analysis

Shortlisting of best performing medium and feed



## 5 Level Factorial Design for Feed

Optimization of feed composition and feed strategy



## Process Optimization

Increased productivity



# Scale Up Optimization



**Scale I:**  
High throughput  
screening (10 – 15ml)

01

## Accuracy by Automization

Screening of >1000 media combinations in Bioreactor tubes



**Scale II:**  
Growth Factor  
Optimization (50ml)

02

## Top Down Approach

Screening of >500 media combinations in shake flasks to identify critical growth factors



**Scale III:**  
Lab scale bioreactors  
(0.4L- 1L)

03

## Process Optimization

Process control at Lab scale bioreactors for productivity



**Scale IV:**  
Complete Process  
Optimization (10L)

04

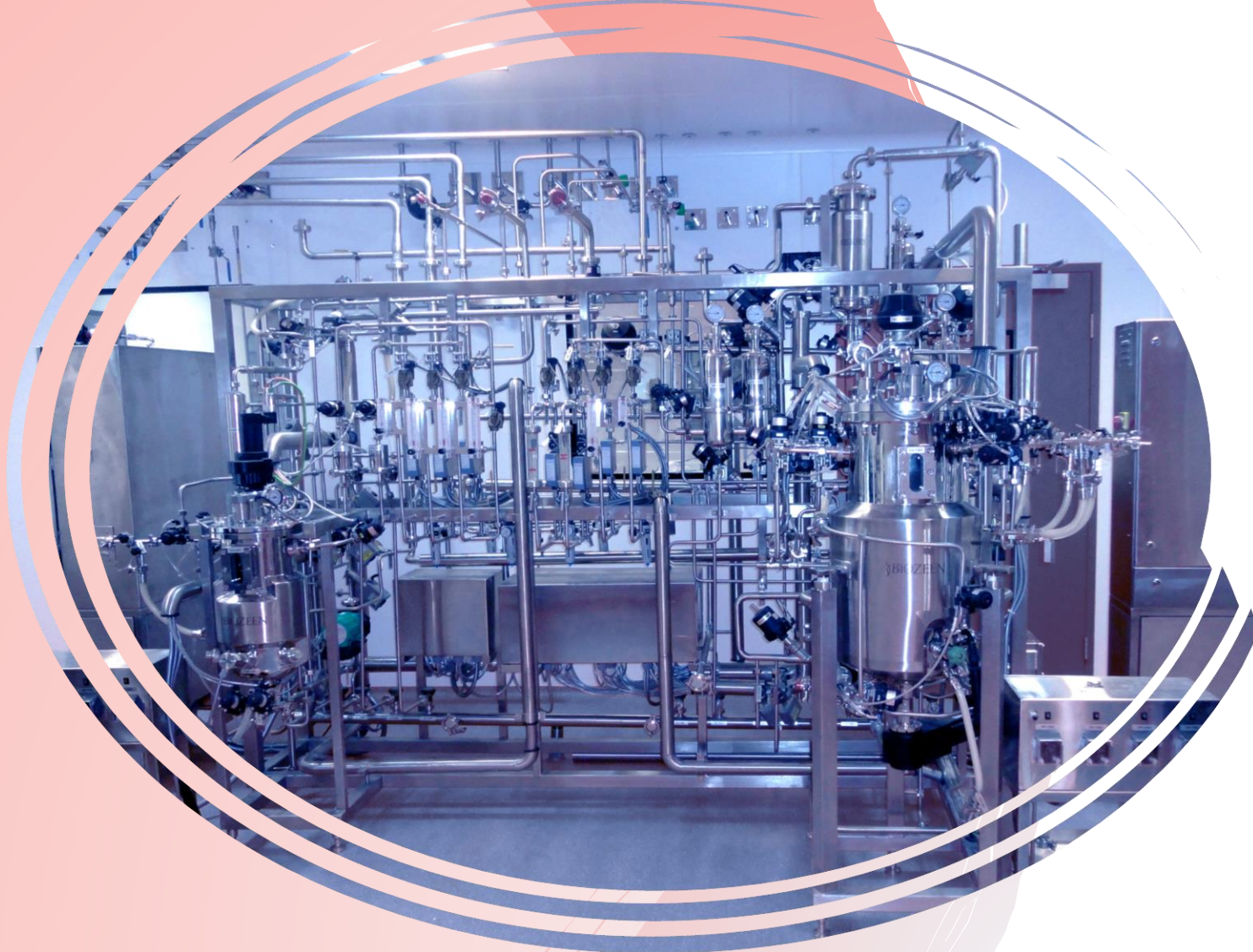
## Process Validation

Suitability analysis for quantitative and qualitative productivity of the process for commercial application

**Optimized Medium and Feed...**

**Assurance of high productivity**

**Scale V :**  
**Pilot Scale Plant in-situ sterilizable Bioreactor System (50L)**



# Viral Vaccine Platform

**Accelerate Your Viral Vaccine Development with our complete range of vaccine specific media**



## MEDIA

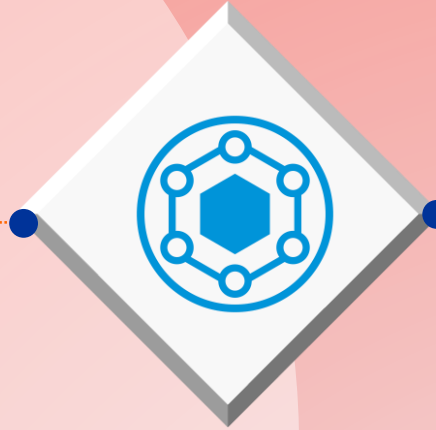
*We offer wide range of Serum-free and animal component-free medium for Human Viral Vaccine & FMD Vaccine*

### Human Viral Vaccine

- CELLin1™
- HEKin1™

### FMD Vaccine

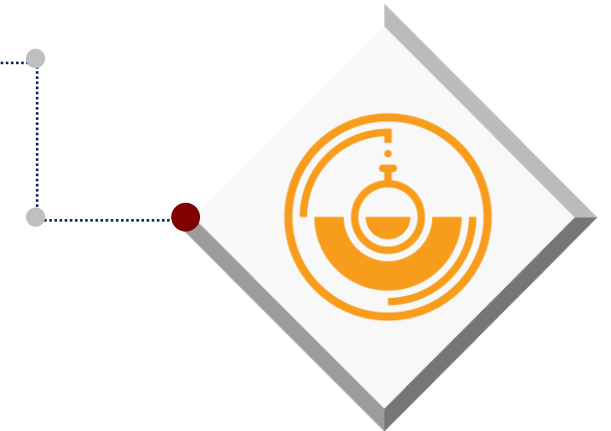
- BHKin1™
- GMEM



## CHEMICALS

*We offer Multicompendial chemicals that meets Pharmacopeia Testing Specifications.*

- Chemicals meeting USP 41-NF 34, EP 9.0, JP 17 and BP 2016 testing specifications
- Complete Technical Dossier available



## CONSUMABLES

*Upstream vaccine development and manufacturing needs with our*

- HiFactory
- Roller Bottles
- Erlenmeyer flasks



# Stem Cells Platform



## CELLS

- HiFi™ Bone Marrow Mesenchymal Stem Cells (HBM-MSCs)
- HiFi™ Human Wharton's Jelly Mesenchymal Stem Cells (HWJ-MSC)
- HiFi™ Human Adipose Derived Mesenchymal Stem Cells (HAD-MSC)
- HiFi™ Human Dental Pulp Stem Cells (HDP-SC)



## MEDIA

- Expansion Medium
- Differentiation Medium
- Freezing Media



## KITS

- Culture Kits
- Differentiation Kits
- Staining Kits



## SERA & GROWTH FACTORS

- MSC Qualified Sera
- Cytokines and Growth Factors

# Primary Cells Platform



## CELLS

*Comprehensive portfolio of normal peripheral blood mononuclear cells (PBMCs) Isolated from healthy donors*

- Normal Human PBMCs
- PBMCs, Single donor
- Purified Cell Subsets

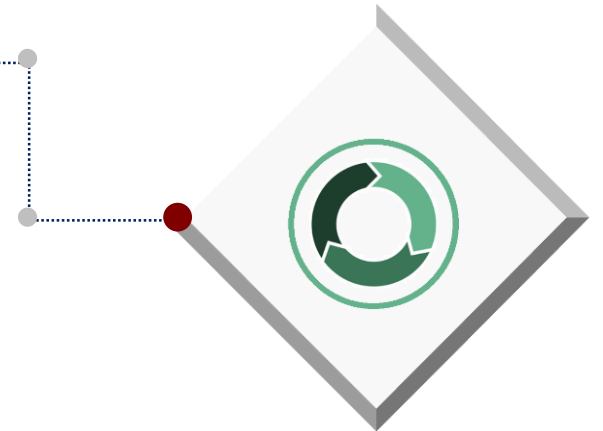
We deliver freshly isolated **PBMC's** in 24 hours



## MEDIA

### smarT™

T cell Expansion Medium,  
Research grade A Serum-free, Xeno-free  
medium for expansion of human T cells



## PRIMARY CRYOPRESERVED HEPATOCYTES

*Cryopreserved primary hepatocytes  
suspension and plateable certified  
for metabolism, induction and  
transporters*

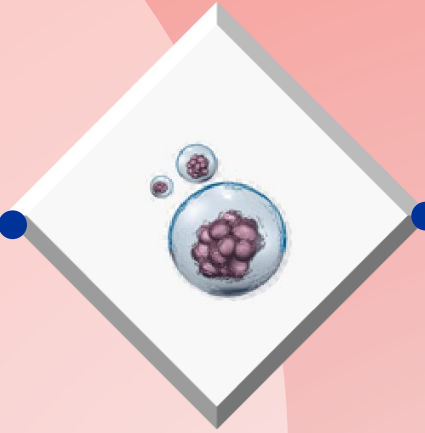
# Cultivated Meat Platform

Environmentally sustainable and ethically sourced growth media, primary and stem cells, and food grade chemicals and reagents.



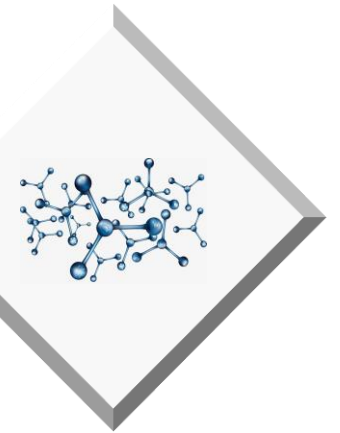
## MEDIA

- Powdered as well as liquid formulations, for mammalian cells.
- Serum-free media for best consistency, traceability, and safety.
- Customized media as per your requirements in terms of media formulations, optimization & scale-up
- We also provide Media made from food grade chemicals



## ANIMAL PRIMARY CELLS & STEM CELLS

- We offer Optimized Media & Bio Processing Service for Customer Specific Cell



## FOOD-GRADE CHEMICALS AND REAGENTS

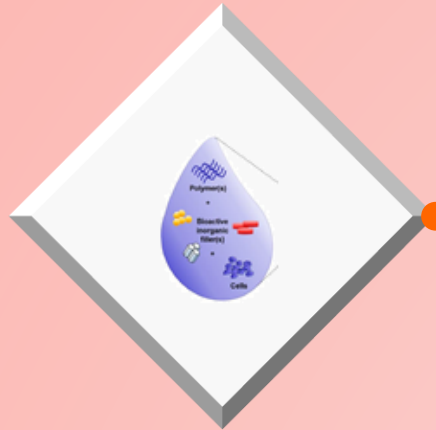
- We have a comprehensive range of chemicals and food grade chemicals including amino acids, antibiotics, growth factors, biochemicals, cell dissociation and cryopreservation reagents used in cell culture.

**We evaluate food safety of each ingredient used in medium w.r.t to food safety regulation given by USFDA**



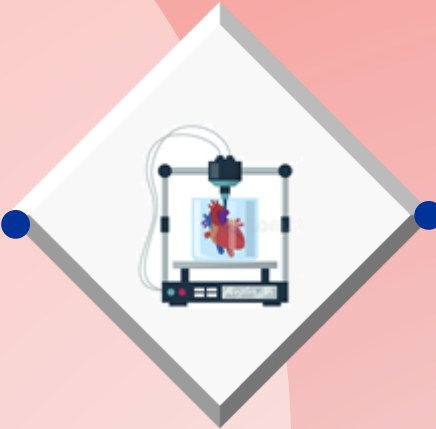
# 3D Cell Culture Services

HiMedia, as the leading supplier of 3D bioprinters and biomaterials, enables researchers to shape the future of health.



## EDIBLE BIOINKS AND 3D BIO SCAFFOLDS

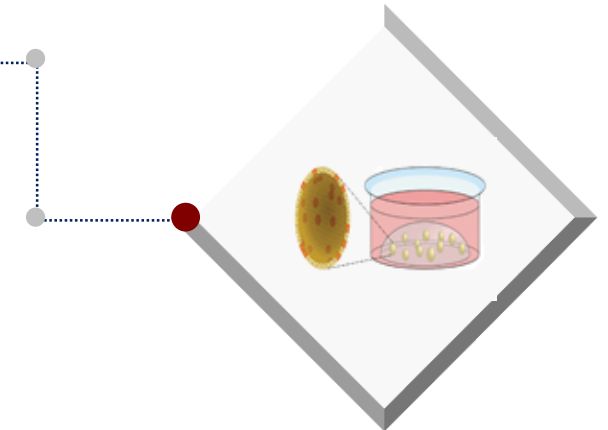
- Our experts at HiMedia are concentrated on developing the most efficient and affordable Bioinks and 3D Bio-scaffolds to facilitate innovation in bioengineering



## 3D BIO PRINTER

*Affordable 3D Bioprinting, Customised for You*

- HiMedia has collaborated with NBIL to bring you the extrusion-based bioprinters, specifically designed to address the requirements of the tissue engineering community.
- Print your scaffold designs in petri dishes and multi-well plates, or even customized lab-on-a-chip devices



## ORGANOID & SPHEROID MODELS

- Media Optimization
- 3D Model development & characterization
- Drug testing services

# Cell Culture Tested Chemicals Platform

Comprehensive range of chemicals and specialty chemicals that are tested for cell culture applications



## CELL CULTURE TESTED CHEMICALS

- Comprehensive range of chemicals and specialty chemicals that are tested for cell culture applications

## MULTICOMPENDIAL CHEMICALS

- Chemicals meeting USP 41-NF 34, EP 9.0, JP 17 and BP 2016 testing specifications
- Complete Technical Dossier available
- Customized labelling & packing

VERSION [0.0]  
APRIL 7, 2017

**PRODUCT DOSSIER**  
PRODUCT CODE: TC150  
PRODUCT NAME: D-(+)-MANNOSE

HIMEDIA LABORATORIES PVT. LTD.  
A 516, SWASTIK DESA BUSINESS PARK, VIA VADHANI ENCL.  
EST. LBS MARG, MUMBAI 400 086, INDIA

HIMEDIA LABORATORIES PVT. LTD. *CONFIDENTIAL*

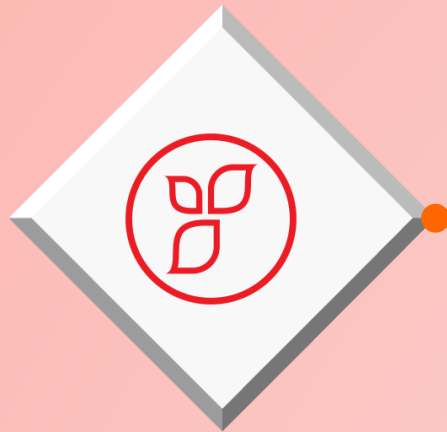
### LIST OF DOCUMENTS

Sr. No.	Description
1	Product Dossier Summary
2	Annexure I: Manufacturing Process Flow Chart
3	Annexure II: Product Packing and Labeling Specifications
4	Annexure III: Declarations
5	Annexure IV: Other Certifications
6	Annexure V: Method of Analysis (Chemical Tests)
7	Annexure VI: Method of Analysis (Cell culture test)
8	Specification Sheet
9	Certificate of Analysis (COA)
10	Material Safety Data Sheet (MSDS)
11	Product Stability Data
12	Source Change Intimation

**Complete Technical Dossier (CTD)**

# Cell Analysis & Detection Solutions

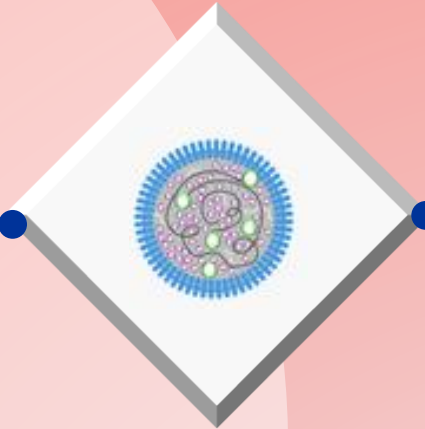
High throughput screening assays for versatile applications like drug discovery, live monitoring of cell activity, cell proliferation, toxicity testing & basic research.



## CELL ANALYSIS KITS

*Bioprocess involve wide range of cell viability/cytotoxicity kits to check the efficacy of biosimilars.*

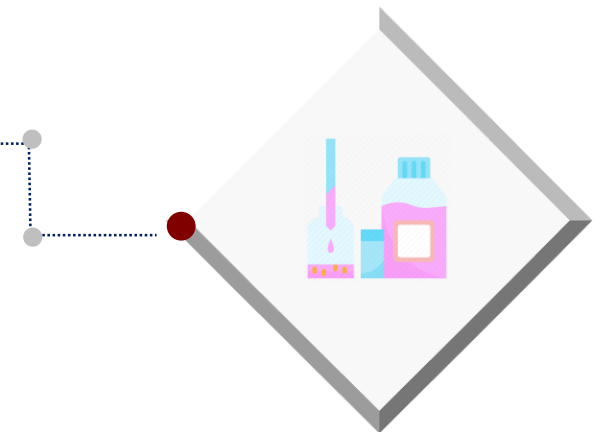
- **Cell viability kit based on**
  - Cellular ATP content
  - Metabolic activity
  - Nuclear DNA content
  - Detection of intracellular components
- **Cell cytotoxicity kits based on**
  - Enzyme release



## MYCOPLASMA DETECTION AND ELIMINATION PLATFORM

*Test your cultures before they test your patience*

- Mycoplasma Detection Kits
- Mycoplasma Elimination Kits



## STAINS AND INDICATOR DYES

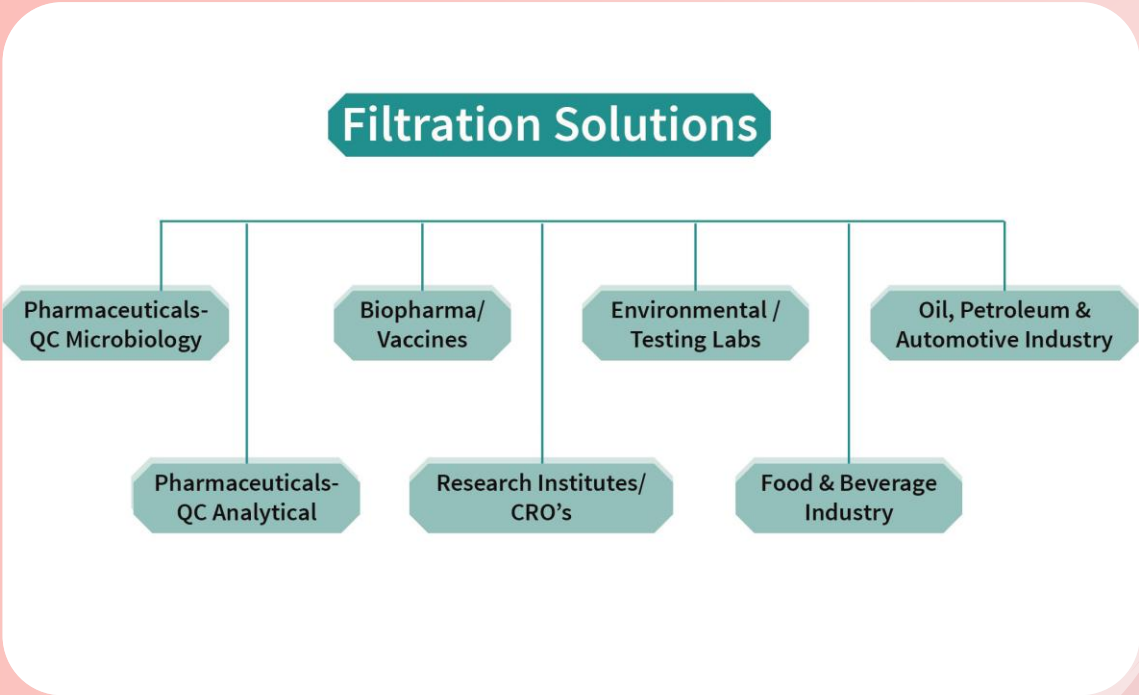
*Discover your cultures and cellular components with performance tested stains and dyes*

- Live/Dead Cell Stains
- Stem Cell Differentiation Indicator Dyes
- Blood Cell Stains
- Stains for Histology
- pH Indicators



# Filtration Solutions

HiMedia has come up with range and various solutions of membranes, syringe, and filtration assembly to cater exclusively for present industrial requirement of quality manufacturing standards, product performance and application support for laboratory scale to production scale filtration.



# Consumables

Tissue Culture Flask

HiFactory™

Tissue Culture Roller Bottles

Tissue Culture Multiwell Plates

Tissue Culture Dishes

Bioreactor Tubes

PET/PETG Bottles

IVF Culture Dish

Confocal Dish

Tray Plate

Insect Breeding Dishes


Centrifuge Tubes

Erlenmeyer Flasks

Cell Culture Scaffold

# THANK YOU

HiMedia Laboratories Pvt. Ltd. 

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[www.himedialabs.com](http://www.himedialabs.com) 

<https://www.linkedin.com/showcase/cell-biology/> 