Biologics CDMO

INTEGRATED DRUG SUBSTANCE & DRUG PRODUCT CAPABILITIES

COMPANY

An Established CDMO for 40+ Years

1980

- Founded by Subhash Bagaria

1980–2006

- Grew as a CMO for pharmaceuticals serving the Indian market
- Glaxo was our first client in 1980, largest client till 2017

2006–2015

- Grew as a global CDMO adding sites in Europe & USA for manufacturing and development
- Sales of 100+ million USD serving 100+ Customers

2012

- Built and operating India's largest Biopharma CMO plant with GMP certification
- 80, 400, 2 x 2000L + 200, 1000L cell culture manufacturing capacity

2016

- Sold global Pharma business to Recipharm
- Kemwell to focus on Biopharma CDMO business

2017–2019

- Development, Scale-up and Supply of Clinical Phase 1 to Phase 3 mAb material for US trials
- Commercial DP manufacturing for two mAb products

2020

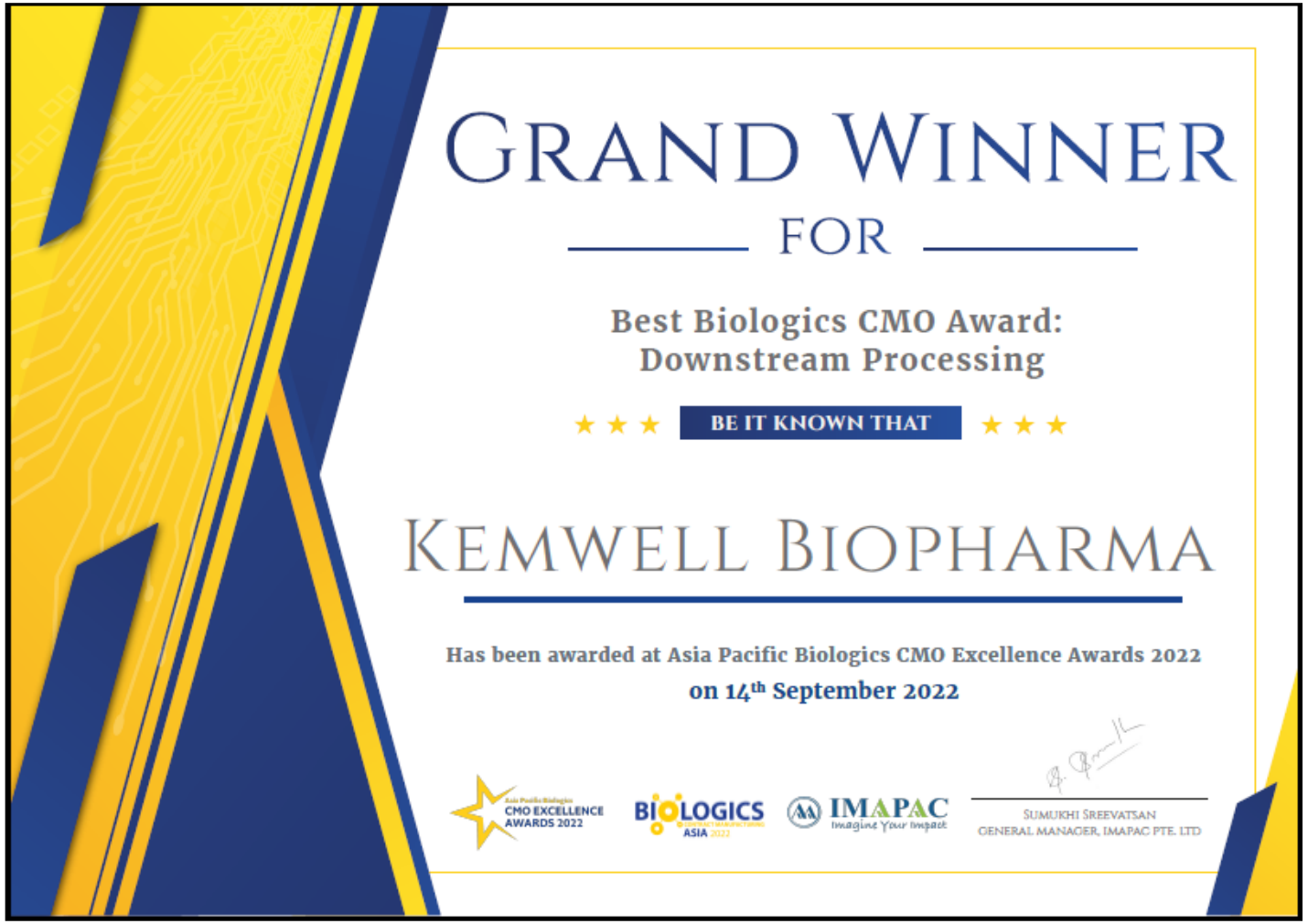
- First Indian CDMO to make commercial DS
- Two projects from US clients for development of novel complex fusion proteins
- Transferred COVID-19 antibody for commercial DP Manufacturing

2021

- Established cGMP Cell therapy manufacturing facility in collaboration with Stempeutics

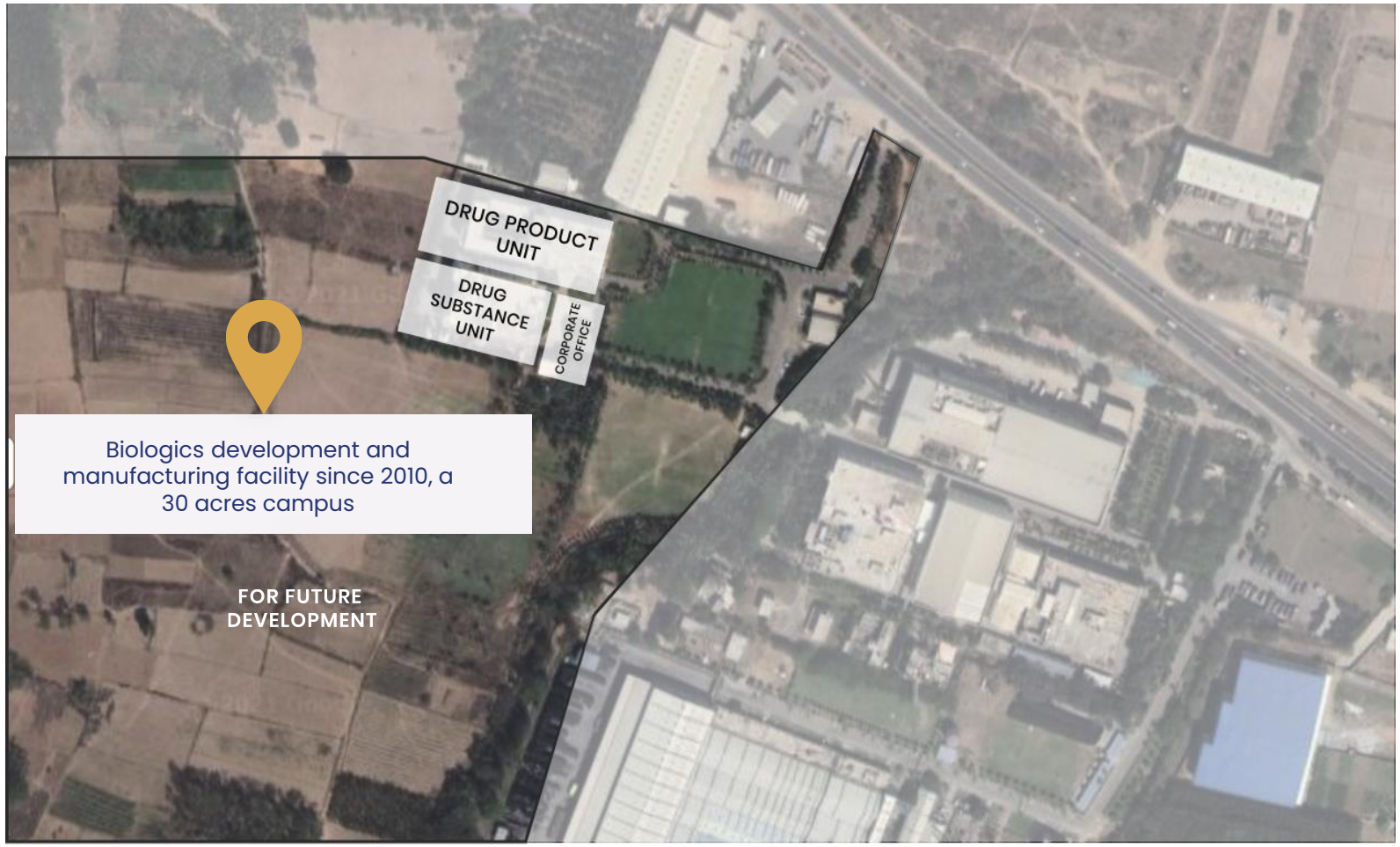
AWARDS

Bioprocessing Excellence in DSP and Best Biologics CMO



SITE MAP

Kemwell Campus, Bangalore, India



LOCATION

- Site is strategically located in Bangalore, India
- 1.5 Hrs from Bangalore Airport which is well connected to international destinations
- 1 hr from Bangalore City
- Closest hotels are 15 - 30 minutes away

DEVELOPED BIOTECH ECOSYSTEM

- Bangalore's biotech ecosystem is well developed
- Suppliers – Merck Sigma, Merck Millipore, Pall, Cytiva (GE), Sartorius, all located in Bangalore
- Talent is available in Bangalore, a biotech hub for manufacturing, QA, QC operations and freshers through reputed educational institutions

COMPANY

Vision and Values

GLOBAL LEADER

To be a global leader and first choice Biologics CDMO for global biopharmaceutical companies

TRUSTED PARTNERSHIP

Provide customized solutions to clients that accelerate their research and be their most trust worthy go-to partner

Responsibility

is first towards the patients

Integrity

we do as we say and we say as we do

Transparency

building trust with our partners through clear communication

Excellence

from scientific research to efficient operations

COMPANY

Management Team and Advisors

Anurag Bagaria, Chairman and CEO

- Over 20 Years of Experience, second generation entrepreneur
- Pharma business built to 100+ Million USD
- MBA from Kellogg Business School and BS in Chemical Engineering, Cornell University

Karan Bagaria, Managing Director

- Over 14 Years of Experience, second generation entrepreneur
- Led Strategic acquisition of Cirrus Pharmaceutical Inc, USA and divestiture of stake in Millipore India
- MBA from Babson University and BS in Business Administration from Boston University

Shabbir Anik, Advisory Board Member

- Over 35 Years of Experience
- CDMO experience at Patheon (Head of Development) and Althea (CEO)
- Senior positions at Amgen/Onyx, Sutrobio

Sanjay Lodha, Head - Operations

- Over 26 Years of Experience in Biopharma Manufacturing
- Senior positions at Glenmark, Dr. Reddy's and Zenotech
- Masters in Biochemical Engineering from IIT, Delhi

Madhava Paranandi, Head PD & MS&T

- Over 19 Years of Experience in USA and India
- Previous experience include Centocor, Biogen, Dr. Reddy's
- Masters in Chemical Engineering from Villanova University, USA

Deepak Gupta, Head – Quality

- Over 20 Years of Experience in Quality
- Previous experience includes Intas Biopharmaceuticals, Biological E & Panacea Biotech.
- Masters in Microbiology

RELIABLE & FLEXIBLE PARTNER

Contract Development and Manufacturing

Process Development

- AMBR®250, 5L,10L, 50L SUB, 80L SS

Mammalian Cell Culture

- Drug GMP Substance - up to 2000L
- Drug Product – Lyo & Liquid vials

Supporting US and EU Trials

- Experience in supplying clinical materials for phase I and phase III

State-of-the-art Facility

- Meeting FDA, EMA regulations

265+ Employees

- Across PD, QC, QA, Manufacturing

Quick Turn Arounds

- Flexible to support and increase speed to clinic

First & Only CDMO in India

- Batch / lot acceptance >98%
- OTIF > 95%

One-Stop Solution

- Integrated development and manufacturing
- Flexible and time-efficient services

DEVELOPMENT TO COMMERCIAL MANUFACTURING

Integrated Development for your Product

Cell Line Development

Outsourced to a partner & managed by Kemwell

Process Development Upstream and Downstream

Capabilities for mammalian cell culture process development – CHO, NS0, etc.

Extensive process characterization

Analytical, Formulation Development and Stability Studies

Analytical method development, qualification and validation

Liquid and Lyo formulation development

Long term, accelerated and custom stability studies

Preclinical and Clinical cGMP Manufacturing

Scale up, preclinical and clinical cGMP manufacturing of drug substance and drug product

Commercial cGMP Manufacturing of Drug Substance and Drug Product

USFDA, EMA & other global regulatory compliant facility

EXPERTISE

Process Development

- Shake flasks, AMBR®250, 5L, 10L (glass bioreactors), 50L (SUB), 80L (SS) – adaptable to support perfusion systems
- Non-GLP and GLP tox material generation
- Well characterized and geometrically similar bioreactors in pilot and GMP facility
- Integrated with analytical development and formulation development services
- Process characterization

High Throughput Upstream and Downstream process development for all **mammalian cell-culture based protein therapeutics**

- Monoclonal antibodies
- Fusion proteins
- Bi-specific antibodies
- Other mammalian cell-culture derived protein therapeutics
- Novels and Biosimilars

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DEVELOPMENT

Analytical Capabilities

Protein Related Impurities and Variants

- Charged variant by CEX & cIEF
- Size related impurities by SEC, SDS-PAGE (NR) and CE-SDS (NR)
- Degraded protein by –SDS-PAGE, CE-SDS (NR)
- Qualification of Leached Protein A
- Oxidized and reduced impurities by RP-HPLC
- IgG purity. Quantification of free heavy chain & light chain, non-glycosylated IgG, Intact IgG & other fragmented species by Capillary Electrophoresis
- Isoform variants by IEF, CZE and IEF with western blotting
- Glycan profiling by Capillary Electrophoresis and UPLC

Process Related Impurities and Identity

- CHO HCP quantification –ELISA
- Residual DNA determination
  - Q-PCR & Pico-Green method
- Protein A contaminant qualification by ELISA
- Mycoplasma by RT-PCR
- BET test
  - Kinetic chromogenic lysate assay
  - Gel clot assay
- Identity
  - Peptide mapping
  - Immunoblotting
  - Electrophoretic techniques

In *vitro* Bioassays

- Cell proliferation assays
- Anti-proliferation assays
- CDC (Complement Dependent Cytotoxicity) assays
- Cell based cAMP release assay
- Binding assays
- Reporter gene assay

Miscellaneous

- Compendial methods for parenteral i.e. Sterility, Endotoxin, Visible and sub-visible particulate matter, Degree of coloration and opalescence
- Content assays by Absorbance, Colorimetric and HPLC based methods
- Raw material analysis including moisture content, melting point, refractive index, FTIR and various identity and assay methods
- Any outsourced test managed by Kemwell, for e.g. SPR, MS, biophysical characterization, viral clearance to established partners like BioReliance, CRL, Intertek

DRUG PRODUCT

Formulation Development

Pre-formulation Studies

- Evaluation of biophysical characterization
- Assessment of thermodynamic stability
- Identification of critical factors that impact stability

Formulation Screening Studies

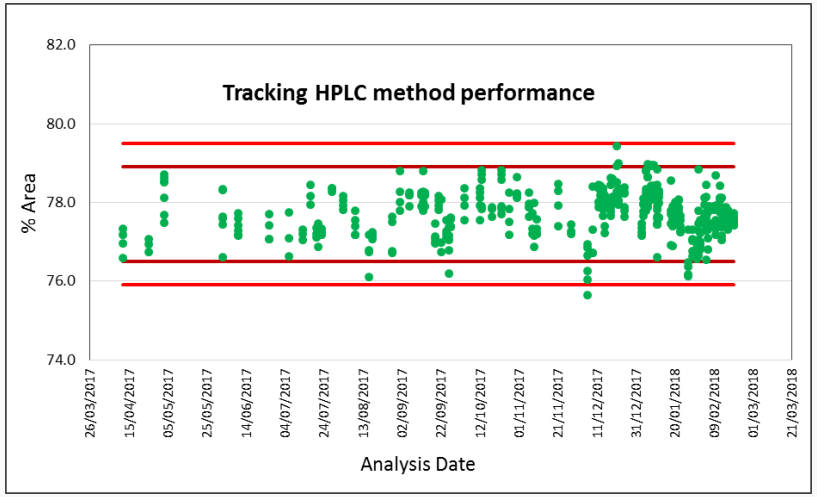
- Selection of optimal formulation
- Integrated formulation and analytical development to ensure selection of right methods for evaluating degradation routes that enable formulation screening studies

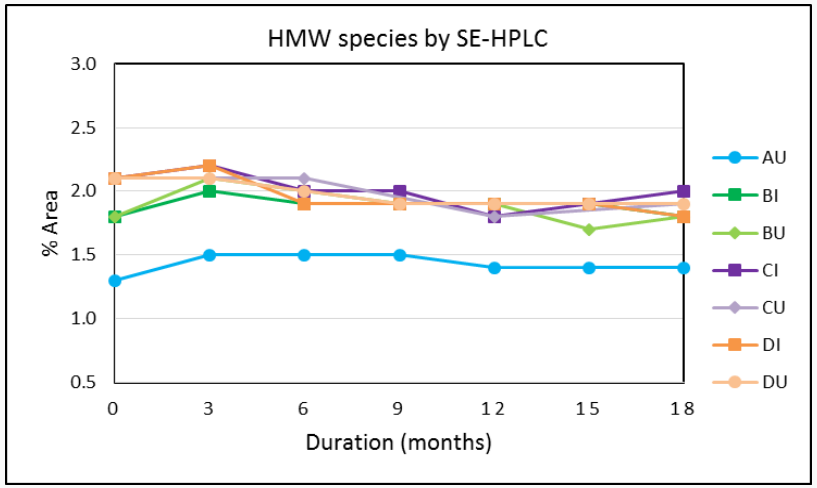
Lyophilization Cycle Development

- For proteins that have low stability in liquid form
- Optimization of each cycle ensuring efficient, robust and scalable process that can be transferred to GMP manufacturing
- Lyophilization cycle process development is performed using lab-scale lyophilizer

Standalone Analytical and Stability Studies

- Methods development, qualification and validation
- Completed analytical methods transfer and validation for multiple projects
- Tracking performance of analytical methods
- Developed and optimized lyophilization cycles
- Formulation development at ~150 mg/ml in pre-filled syringes
- Stability studies for DS and DP: 2-8°C, 25°C/60% RH, 40°C/75% RH, -80°C and -20°C or customized condition





ASSURED QUALITY

GMP Manufacturing

FDA and EMA compliant facility. Licensed to manufacture commercial DS and DP. CIS, MENA, Southeast Asia registration in progress

Drug Substance – up to 2000L scale

Drug Product – Lyophilized and Liquid Vials

Flexible to support quick turnarounds and increase speed to clinic

Experience in supplying and supporting US IND trials, including Phase III manufacturing

40+ customer audits, 3 QPs form EU, Mock PAI by ex-FDA auditor

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MANUFACTURING

GMP Drug Substance

FACILITY

BI-Sartorius + Cytiva - multi-product, hybrid technology - SS & SUB, designed to purify high titer 5g/L @ 2000L

CLINICAL MANUFACTURING

Clinical trial material supplied for trials in US and ROW up to 2000L scale

COMMERCIAL SUPPLY

Manufacturing one globally approved mAb at 2000L scale, 20+ batches per annum

BIOREACTORS

80L → 400L → 2x2000L stainless steel bioreactors

200L → 1000L single use bioreactors

HARVEST

Harvest - Continuous centrifugation and/or lenticular filtration options for 3M, Millipore and Sartorius

PURIFICATION

Downstream - Multiple chromatography and TFF steps; pre- and post-viral segregation

CAPACITY EXPANSION

Provision to add up to 12000L bioreactor capacity. Flexibility of adding single-use (up to 6x2000L or 3x4000L)

MANUFACTURING

cGMP Drug Product

COMMERCIAL SUPPLY

Supplying commercial mAb drug product for APAC market (customers include US and Indian MNCs)

STERILE DOSAGE FORMS CAPABILITIES

- Liquid and lyophilized vials
- Vial sizes from 2ml to 50ml

VIAL FILLING

Integrated vial filling line from Bausch+Ströbel

LYOPHILIZER

Lyophilizer: 80 sq.ft. shelf area with automatic CIP and SIP facility

FUTURE POSSIBILITY – Q1 2024

Pre-filled syringes - OPTIMA

Liquid Vial Capacity	
Vial Size (ml)	Max. Batch Size (vials)
2	42,000*
5	33,600*
10	30,000
20	15,000
50	6,000

*1-shift operation
Maximum batch size: 300L (Formulated bulk)
Available change parts at Kemwell – 2R, 6R, 10R, 15 ml, 20 R, 50 ml

Lyophilized Vials Capacity	
Vial Size (ml)	Max. Batch Size (vials)
2	29,000
5	15,000
10	13,000
20	8,000
50	4,000

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Pre-filled Syringe (PFS)– Salient Features

Make	OPTIMA
Design	Integrated Filling Machine with Isolator
Debagger Unit	Semiautomatic
Filling & Stoppering	Automatic
Mode of filling	Rotary Piston Pump & Peristaltic pump
Filling Accuracy	1.5% (Fill volume 1 ml)
Line Speed	~11,000 UNITS/HR. ~5500 UNITS/HR WITH 1% IPC
No. of Heads	5 head
IPC	Automatic
Decontamination cycle	60-90 mins
Software	Configured SCADA, 21 CFR Part 11 compliant
Operational by	Q1 2024

TIMELINE

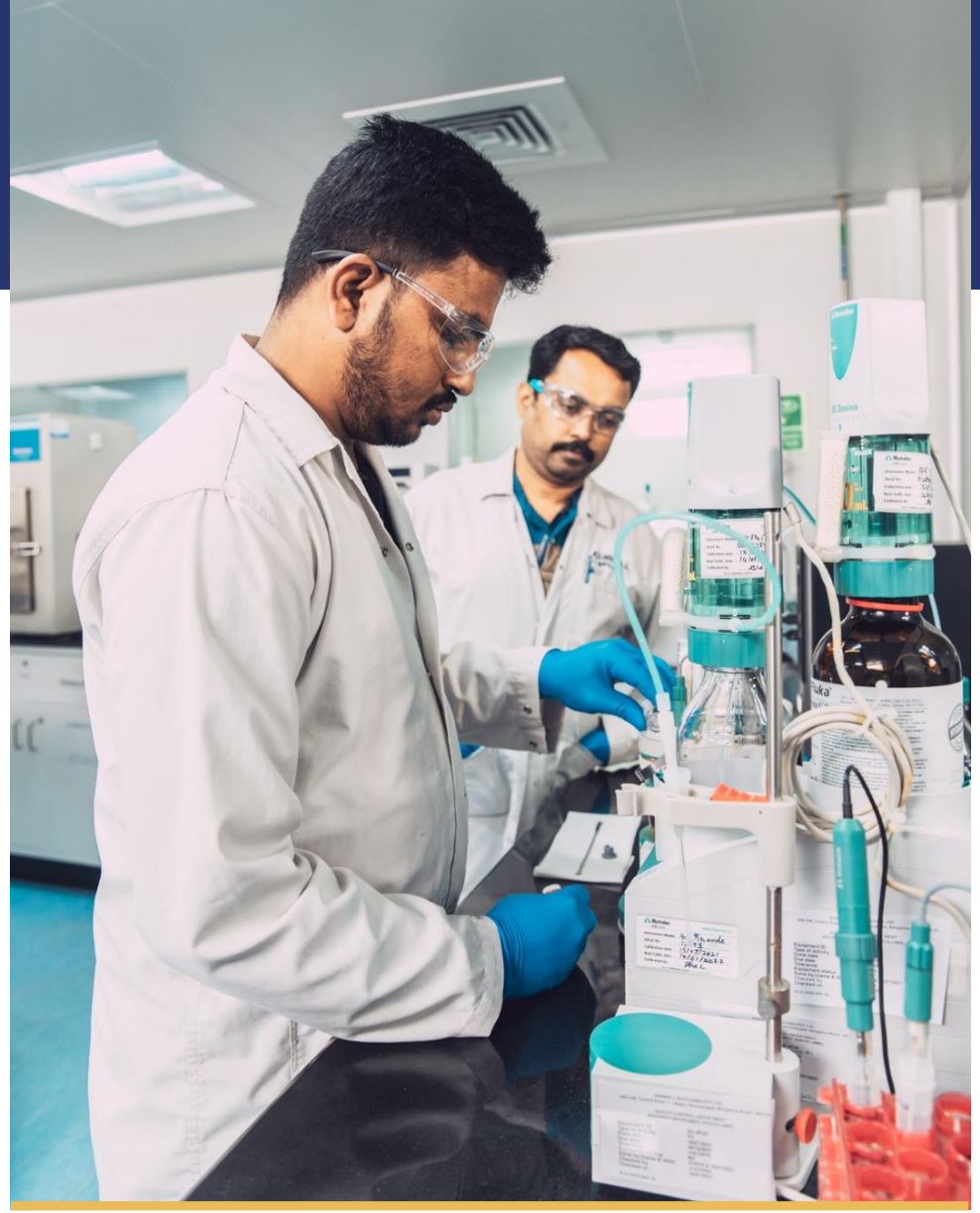
From Cell Line Development to Clinical Phase I

Activity	Duration (Months)	Months														
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Cell line development	7															
MCB Preparation	2															
Analytical method development and qualification	5															
Upstream process development	4															
Downstream process development	4															
Formulation development	4															
Process scale-up (50/80L) / Tox batch	2															
DS GMP Mfg. preparation, Engineering batch - 400/1000L	2															
Clinical DS GMP Mfg - 400/1000L	2															
DP GMP Mfg preparation and Engineering batch	1															
Clinical DP GMP Mfg	1															
Stability DS & DP (Clinical)	36															

TRUSTED PARTNER

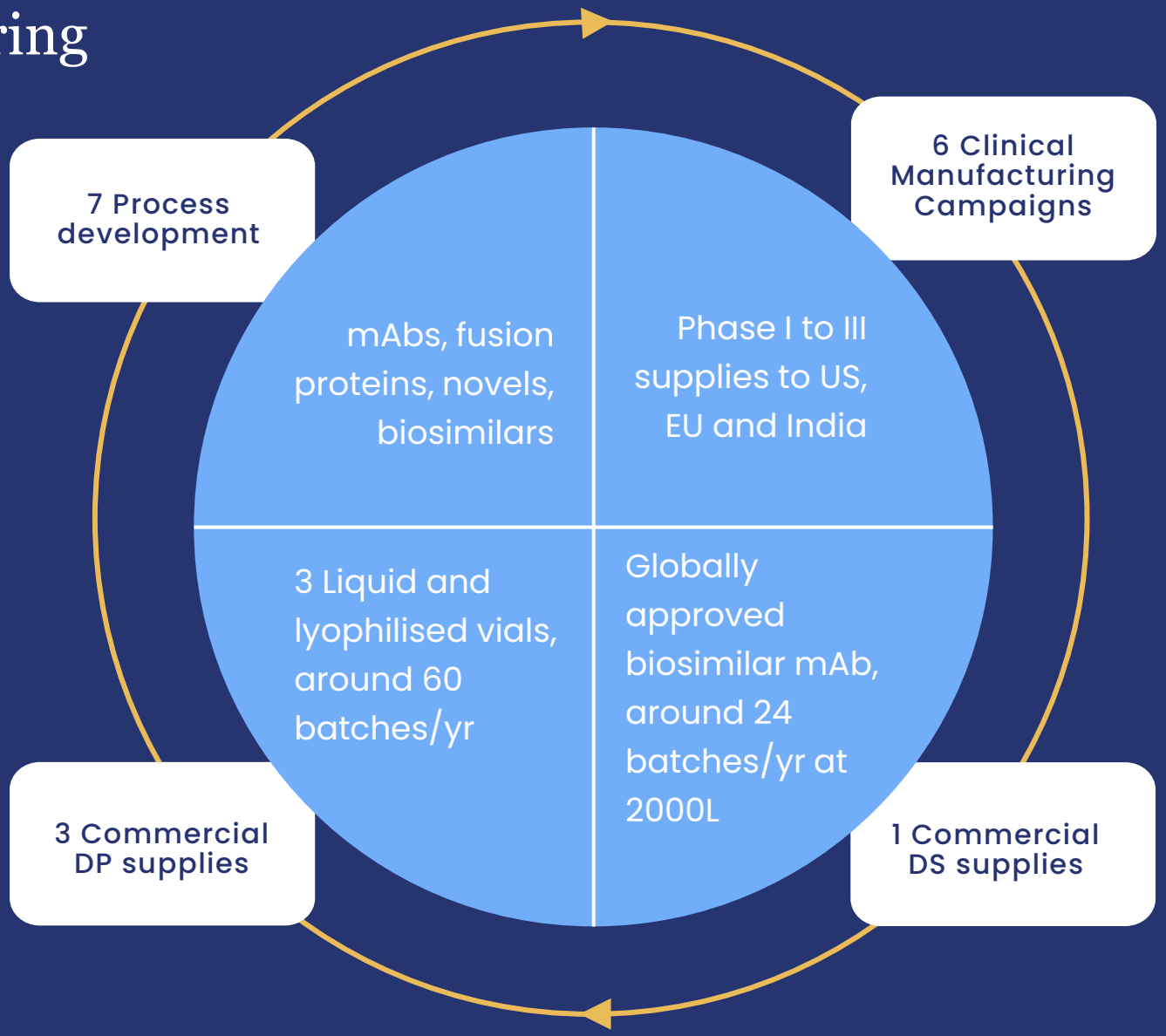
Why Kemwell

- Integrated Service Provider - Drug Substance and Drug Product
- Diverse experience - monoclonal antibodies, complex fusion proteins, recombinant proteins and bispecific antibodies
- First CDMO in India licensed to manufacture commercial DS
- 4 years accomplishments - 7 projects in process development, 6 clinical manufacturing campaigns including Phase III batches for USA trial, commercial supplies for 1 DS and 3 DPs ongoing
- Hybrid technology - SS and SUB with scale flexibility to support early clinical to commercial demands - 400L, 1000L, 2000L
- On time, In full and Right the first time
- Time and cost competitive, customized service offerings



ACCOMPLISHMENTS IN 4 YEARS

Development to Manufacturing



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ALLOGENIC CELL THERAPIES

Cell Therapy Manufacturing

GMP MANUFACTURING

- 4,000 sft GMP facility commissioned, PPQ manufacturing in Q2/Q3 of 2022 and expected commercial manufacturing from early 2023.
- Scalable GMP manufacturing to support clinical and commercial manufacturing
- Manufacturing under ‘Grade A’ Biosafety cabinets with ‘Grade B’ background

FILL & FINISH

- Cryo-bags and Cryo-vials with different types of cryopreservation materials

COMPLIANCE

- Experience in PIC/S GMP standards and Indian FDA cGMP standards in Cell Therapy area
- Facility compliant to international GMP regulatory standards

TEAM

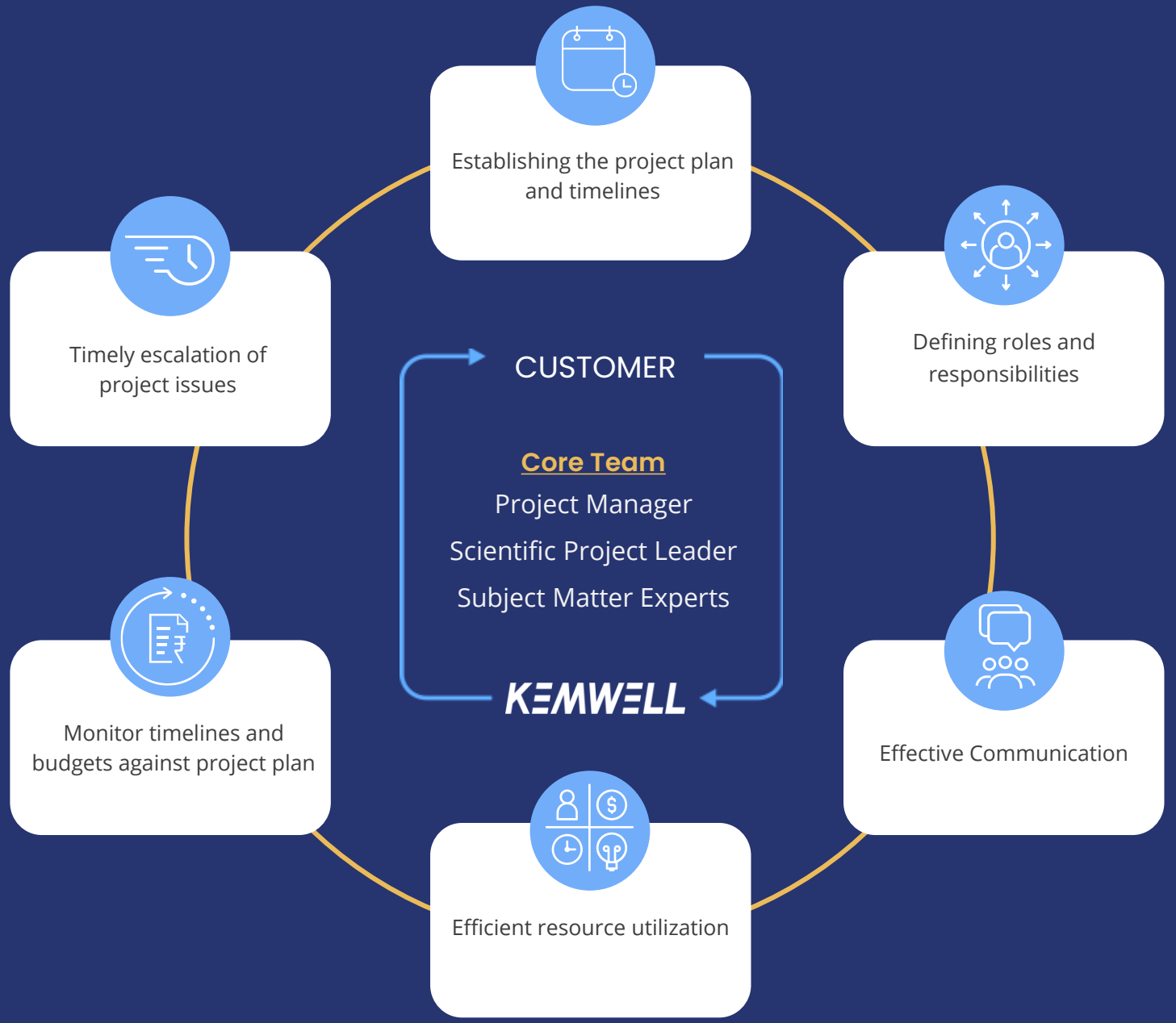
- Talented manpower with experience in large scale manufacturing

LOGISTICS

- Experience in handling overseas logistics and cryo-shipments

CUSTOMER ENGAGEMENT

Project Management



NEXT STEP

Future Expansion

Process Development

- High Resolution Mass Spectrometer – ORBITRAP. Under Installation.
- Surface Plasmon Resonance – Biacore by Q4 2022

Drug Substance

- Future expansion -up to 12000L in bioreactor capacity in existing shell place (for e.g. 6x2000L)

Drug Product Fill & Finish Capability

- Pre-Filled Syringe line by Q1 2024

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Building Strategic Customer Relationships

FLEXIBLE MODELS

- Traditional fee for service
- FTE model

LONG TERM PARTNERSHSIPS

- Dedicated facilities
- Build new capabilities in R&D and manufacturing
- Ability to build and run large scale manufacturing plants

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