

KEMWELL

KEEPING YOU COMPETITIVE

Kemwell Capabilities

INTEGRATED DRUG SUBSTANCE & DRUG PRODUCT DEVELOPMENT & MANUFACTURING CAPABILITIES





History, Vision & Values

Kemwell Biopharma

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
- **Other clients include Janssen, Merck, Pfizer, AstraZeneca etc**

2012

- **Built CDMO facility with technical collaboration with Boehringer Ingelheim**

2006-2015

- Grew as a global CDMO adding sites in Europe & USA for manufacturing and development
- Sales of 100+ million USD serving 100+ Customers
- **Faced several FDA, EMA & PMDA audits**

2016

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

2021

- **Established cGMP Cell therapy manufacturing facility in collaboration with Stempeutics**

2024

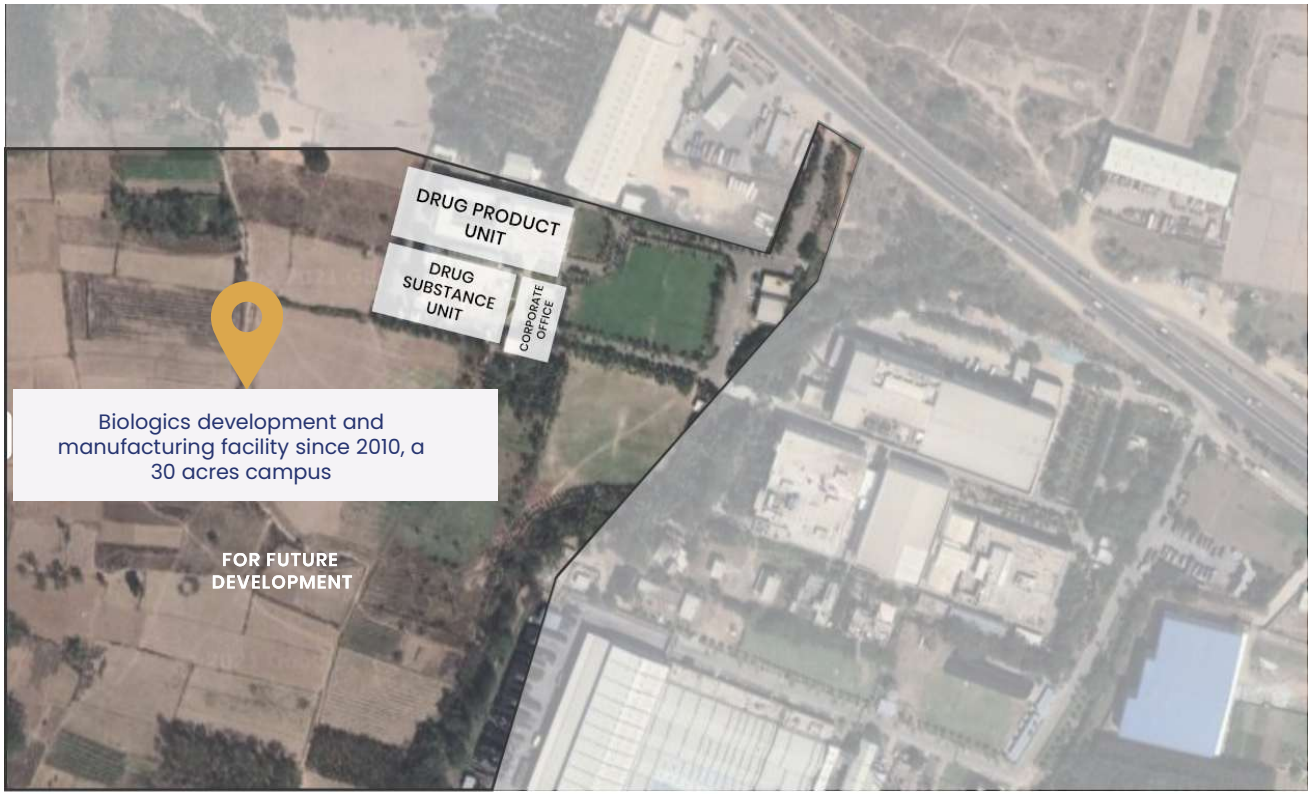
- **Addition of PFS capability**

2025

Recently audited and approved by USFDA

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

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Management Team & Key Personnel

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, Kellogg School of Management and BS in Chemical Engineering, Cornell 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

Arvind Kushwaha, Head Quality

- 23 years of experience in Biologics
- Previous experience include Amgen, Lonza, Intas, Dr. Reddy's
- Overseen regulatory inspections for FDA, EMA, MHRA
- Masters in Industrial Microbiology

Sanjay Lodha, Head - Operations

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

Madhava Ram Paranandi, Head PD, MS&T, PM

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

Team Strength -300 + Employees

- PD, MSAT (40)
- Operations (150)
- Quality (122)

Leadership team brings 100+ years of cumulative expertise in end-to-end biologics operations

Regulatory Summary

KEMWELL'S ACHIEVEMENTS

Summary of Regulatory Inspections at Kemwell

Recently inspected by US FDA (Q2, 2025). Approval received in October 2025.

Facility qualified and approved by Indian FDA and NPRA Malaysia for PIC/S.

Mock PAI was performed by ex-FDA auditors in 2017 and December 2023 in readiness for supplying commercial DS & DP for biosimilars. No critical or major observations found in the mock PAI.

NPRA audit conducted in May 2023. No critical or major observation. Got approval from regulatory agency.

Products manufactured at Kemwell are under registration in 35 countries.

No observation pertaining to data integrity.

EU Annex-1 compliance assessment was carried out by ex-MHRA auditors in Aug 2024. The identified gaps have been addressed.

Recently inspected by a QP (Q3, 2025) for clinical supplies to UK/EU.

- US FDA - 1
- Client audits - 36
- Indian FDA - 14
- QP - 3
- Mock PAI - 2
- NPRA from Malaysia (member of PIC/S) - 2

~60 audits faced since 2017

Kemwell Capabilities – PD, QC, DS and DP Manufacturing

DEVELOPMENT TO COMMERCIAL MANUFACTURING

Integrated Development for your Product

Cell Line Development

- Outsourced to a partner & managed by Kemwell
- Identifying partners who use latest technology to increase titer
- Worked with multiple partners in US and Europe so far

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
- Stability studies including forced degradation 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
- DP manufacturing including formulation-fill-finish, labelling and packing
- Shipment to client appointed site for distribution

EXPERIENCE

Handling Diverse Scope of Projects

- Process development for biosimilar mAbs, novel mAbs and complex fusion proteins
- Generational stability of clones
- Process optimization for yield improvement of novel mAb using AMBR®250
- DoE to optimize DSP unit operations
- Ability to do technology transfer at multiple scales, providing flexibility to customers
- Biosimilarity assessment – analysis of CQAs and characterization using Mass-spec and SPR
- DoE to optimize an enzymatic processing step at harvest
- Lyo process development for 2 biosimilar mAbs
- Resin Lifetime Studies
- Analytical method development, qualification and characterization services

EXPERTISE

Process Development

- Shake flasks, AMBR®250, 5L, 10L (glass bioreactors), 50L (SUB), 80L (SS) – adaptable to support perfusion systems. Downstream has AKTA PURE, AVANT, PILOT, KR2i TFF system etc
- 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
- Multi-specific antibodies
- Other mammalian cell-culture derived protein therapeutics
- Novels and Biosimilars

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DEVELOPMENT

Analytical Capabilities: In-process, Release and Characterization

Protein Related Variants & Content

- Charge variants by cIEF
- Size related impurities by SEC
- Oxidized and reduced impurities by RP-HPLC
- Hydrophobic variants by HIC-HPLC
- IgG purity - Quantification of heavy chain & light chain, non-glycosylated IgG, Intact IgG & other fragmented species by Capillary Electrophoresis (CE)
- Glycan profiling by Capillary Electrophoresis and UPLC
- Polysorbate content
- Protein content by SoloVPE

Process Related Impurities & Identity

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

In *vitro* Bioassays

- ELISA for potency
- Reporter gene assays
- Cell proliferation assays
- Anti-proliferation assays
- ADCC (Antibody Dependent Cellular Cytotoxicity) assays
- CDC (Complement Dependent Cytotoxicity) assays

Characterization

- Characterization by Mass Spectrometry, including intact mass, sub-unit mass, peptide mapping, oligosaccharide identification, disulfide linkage etc
- SPR based binding kinetics for Fc receptors

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Analytical Methods

Category	Analytical test	Attributes
Compendial	Compendial methods – pH osmolality , SVPC	Physicochemical properties and Particulate content
Purity	SE-HPLC	High molecular weight
	IEX-HPLC/cIEF	Charge variants
	UV280	Protein concentration
	NR-CE SDS and R- CE SDS	Fragments, HC, LC
Biological activity	Binding ELISA	Potency
Thermal stability	DSC	Melting point (Tm)
Particle size distribution	DLS	Hydrodynamic radii

DSC and DLS are outsourced to a contract lab in Mumbai, India, which is qualified by Kemwell Quality.

MANUFACTURING

GMP Drug Substance

FACILITY BUILT IN TECHNICAL COLLABORATION WITH BOEHRINGER INGELHEIM IN 2012

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 (40 batches / year)

25L → 200L → 1000L single use bioreactors (20 batches / year)

HARVEST

Harvest - Continuous centrifugation and/or depth filtration

PURIFICATION

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

Column sizes : 250, 300, 600, 800 and 1000 mm

CAPACITY EXPANSION

Provision to add additional manufacturing capacity in stainless steel or single-use depending on the client requirements

MANUFACTURING

GMP Drug Product

CLINICAL & COMMERCIAL SUPPLY

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

STERILE DOSAGE FORMS CAPABILITIES

- Liquid and lyophilized vials, PFS
- Vial sizes from 2ml to 50ml; PFS from 0.2 to 3.0 ml

VIAL FILLING

Integrated vial filling line from Bausch+Ströbel

LYOPHILIZER

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

PRE-FILLED SYRINGES

Optima (Germany) with Isolator

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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Track Record

KEMWELL ACHIEVEMENTS

New Technology Initiatives

N-1Perfusion	Concentrated Fed- batch (Perfusion)	TFF for High concentration formulation	Mass spectrometry	Surface Plasmon Resonance
• Proof-of-concept runs completed for a mAb product • Generated ~50 million cells/ml in 5-6 days using ATF-2 • Inoculated fed-batch at high density (12x and 20x) • Comparable titer and PQA achieved in less number of production days • Media optimization to be performed to see if titer productivity can be further increased	• Proof-of-concept run completed for a mAb product • A 100% increase in mAb titer was seen using the concentrated fed-batch approach with same duration as fed-batch	• Experience with 2 biosimilars and 1 novel antibody • High viscosity challenges were overcome by using excipients (screened using available literature) and by optimized cassette selection • The process was successfully scaled-up to our GMP facility at 2000L scale	• Added Mass Spec (Q Exactive Plus – Orbitrap from Thermo) in 2022 • Developed methods for amino acid sequencing, sub-unit mass, disulfide linkage, peptide mapping, N- glycan profile etc • Demonstrated biosimilarity for 3 projects using in-house mass spec capabilities	• Added SPR (Biacore T200 from Cytiva) in 2022 • Developed methods for SPR based binding for FcRn receptors • Demonstrated biosimilarity for 3 projects using in-house SPR capabilities

NOVELS

Track Record

Product	Type	Development	Manufacturing	Project
Novel-1	IgG4 mAb	Upstream and downstream process	For tox studies at 80L scale	The development was done for EU/US. The project was kept on hold by the customer after the tox studies due to internal prioritization.
Novel-2	Complex non-Fc Fusion protein	Upstream, downstream and formulation development	400L scale manufacturing for Phase-I supply	Kemwell developed and manufactured the DS and DP. **Supplied DP for Phase-1 trials in US**
Novel-3	Complex Bi-functional Fusion protein	Upstream & downstream process	For tox studies at 80L scale	After successful scale-up to 80L scale for tox studies, the process was transferred to customer site for further scale-up
Novel-4	IgG1 mAb	None	1000L Single-use in H1 2025	Successfully scaled-up to 1000. **TT to DP completed in <6 months. Supplied DP for Phase-I trials in US. Material for Phase-2 in US/EU to be manufactured in June 2026**
Novel-5	Tri-specific antibody	Upstream, downstream and formulation development	1000L Single-use in H1 2026	Supply of DP for Phase-I trials in US. Successfully developed a high concentration formulation for Opthalmic indications. Process optimization ongoing. **IND submission by late 2026.**

BIOSIMILARS

Track Record

Product	Type	Development	Manufacturing	Scale	Project details
Biosimilar-1	IgG1 mAb	Upstream & downstream process	For clinical trials in India	400L	The development and manufacturing was done for India trials
Biosimilar-2	IgG1 mAb	No	Site transfer, Process validation and commercial manufacturing	2000L	Kemwell is the second site for the client for supplying to India and neighboring markets. This product is approved in US & EU. Kemwell manufactured DP is currently being registered in 40+ countries. **Tech transfer of DS to PV completed in 8 months!**
Biosimilar-3	IgG1 mAb	Upstream & downstream process	For Phase-I and Phase-III trials in US	2000L	The client decided to put the project on hold prior to BLA submission.
Biosimilar-4	IgG4 mAb	Upstream & downstream process	For clinical trials in the US	2000L	Process development completed, Phase-1 manufacturing completed; **IND filed in Q1 2026. Process characterization to begin Q2, 2026**
Biosimilar-5	IgG4 mAb	Upstream & downstream process	For clinical trials in India	400L	Process development completed, Phase-1 manufacturing completed; **CT initiation in Q2 2026**
Biosimilar-6	IgG1 mAb	Upstream & downstream process	For clinical trials in the US	2000L	Process development Ongoing, **IND submission planned Q2, 2027**

NOVELS

Track Record – Solving Challenges of Complex Proteins

Type of Project	Product type	Scope of the project	Challenges & Achievements
Novel	Non-Fc Fusion protein	Process Development, Method Development & qualification, Phase-I supply for trials in US	1. RCB titer was very low (0.25 g/L). USP optimization was performed to increase the titer to 1.0 g/L. 2. High HCP content in DS (~8000 ppm). Novel membrane adsorption step was added to clear the HCPs during in-process stages, along with a high salt wash step for Chrom-III stage. 3. Baseline formulation provided by customer was not working (protein was unstable). A DoE was conducted to screen pH, buffers & excipients and final formulation was chosen ✓ **Provided DP for Phase-I trials in US**
Novel	Bifunctional fusion protein	Process Development, Pre-clinical batch manufacturing, tech-transfer back to client	1. RCB titer was 1.5 g/L. USP optimization was performed to increase the titer to 2.5 g/L. 2. Fragmentation was observed during upstream process (~12-15%). DSP process was developed to remove the fragments resulting in 5-7% using multi-modal chromatography step ✓ **Process was successfully scaled-up to 80L for pre-clinical material generation**

NOVELS

Track Record – Solving Challenges of Complex Proteins

Type of Project	Product type	Scope of the project	Challenges & Achievements
Novel	Trispecific antibody	Process Development, Method Development & qualification, Phase-I supply for trials in US	1. Removal of associated host cell proteins • >100 ppm HCP detected in the drug substance during early development • Combination of novel single-use membrane adsorber and a multi-modal chromatography with arginine wash resulted in significant reduction of associated host cell proteins. 2. Significant opalescence observed during high concentration TFF • Established correlation behavior between viscosity and protein till ~200 mg/mL to identify the ideal concentration for Drug substance. • Optimized TFF with respect to cassette configuration, TMP and Cross flow to extend the Cgel point at which opalescence is expected. 3. Challenges in development of analytical methods- SEC and CESDS • Aberrant artifact fragment in nrCE-SDS was resolved by optimizing the sample preparation in nrCE-SDS (SDS buffer pH, incubation temperature and time) • Optimized the SEC method for separation of pre-peak and characterized pre-peak as isoform variant of Tri specific antibody using SEC-MALS

BIOSIMILARS

Track Record – Solving Challenges of Biosimilar Development (mAb 1)

Type of Project	Product type	Scope of the project	Challenges & Achievements
Biosimilar	IgG4 mAb	Process Development, Method Development & qualification, Phase-1 & 3 supply for trials in US	1. RCB titer was low USP optimization was performed to **increase the titer by 60%.** Feed strategy was optimized to achieve the increased titer. 2. Matching glycan profile Supplements were added based on DoE in AMBR250 to optimize the glycan distribution to match with that of the RP 3. Formulation development to navigate patents Formulation excipients were modified and final formulation selected based on comparative short-term stability study with RP. 4. High concentration TFF challenges TFF was developed to achieve a final DS concentration of 200 mg/ml with a combination of optimized cassette selection and refined load conditions ✓ **Process was successfully scaled up to 2000L and Phase-1 material was manufactured successfully**

BIOSIMILARS

Track Record – Solving Challenges of Biosimilar Development (mAb 2)

Type of Project	Product type	Scope of the project	Challenges & Achievements
Biosimilar	IgG4 mAb	Process Development, Method Development & qualification, Phase-1 & 3 supply for trials in US	1. Titer enhancement for COGs reduction USP optimization was performed to **increase the titer by 40%**. Feed strategy was optimized to achieve the increased titer. 2. Matching glycan profile Supplements were added based on DoE in AMBR250 to optimize the glycan distribution to match with that of the RP 3. Matching charge variant profile DSP optimization was performed to match the acidic variants. This was achieved by performing DoE to optimize load pH, elution pH and gradient composition. To achieve higher recovery along with similarity, a non-platform approach with pH gradient with the same resin was developed and successfully implemented in Manufacturing. ✓ **Process was successfully scaled up to 400L and Phase-1/3 material was manufactured successfully**

BIOSIMILARS

Track Record – Solving Challenges of Biosimilar Development (mAb 3)

Type of Project	Product type	Scope of the project	Challenges & Achievements
Biosimilar	IgG1 mAb	Process Development, Method Development & qualification, Phase-1 & 3 supply for trials in US	1. Titer enhancement for COGs reduction Extensive media and feed screen was performed to scout for the best combination to enhance titer. Further optimization resulted in 75% increase in titer. 2. Matching glycan profile Supplements were added based on DoE in AMBR250 to optimize the glycan distribution to match with that of the RP. 3. Formulation development to navigate patents Formulation composition is being modified and final formulation will be selected based on comparative short-term stability study with RP.

BIOSIMILARS

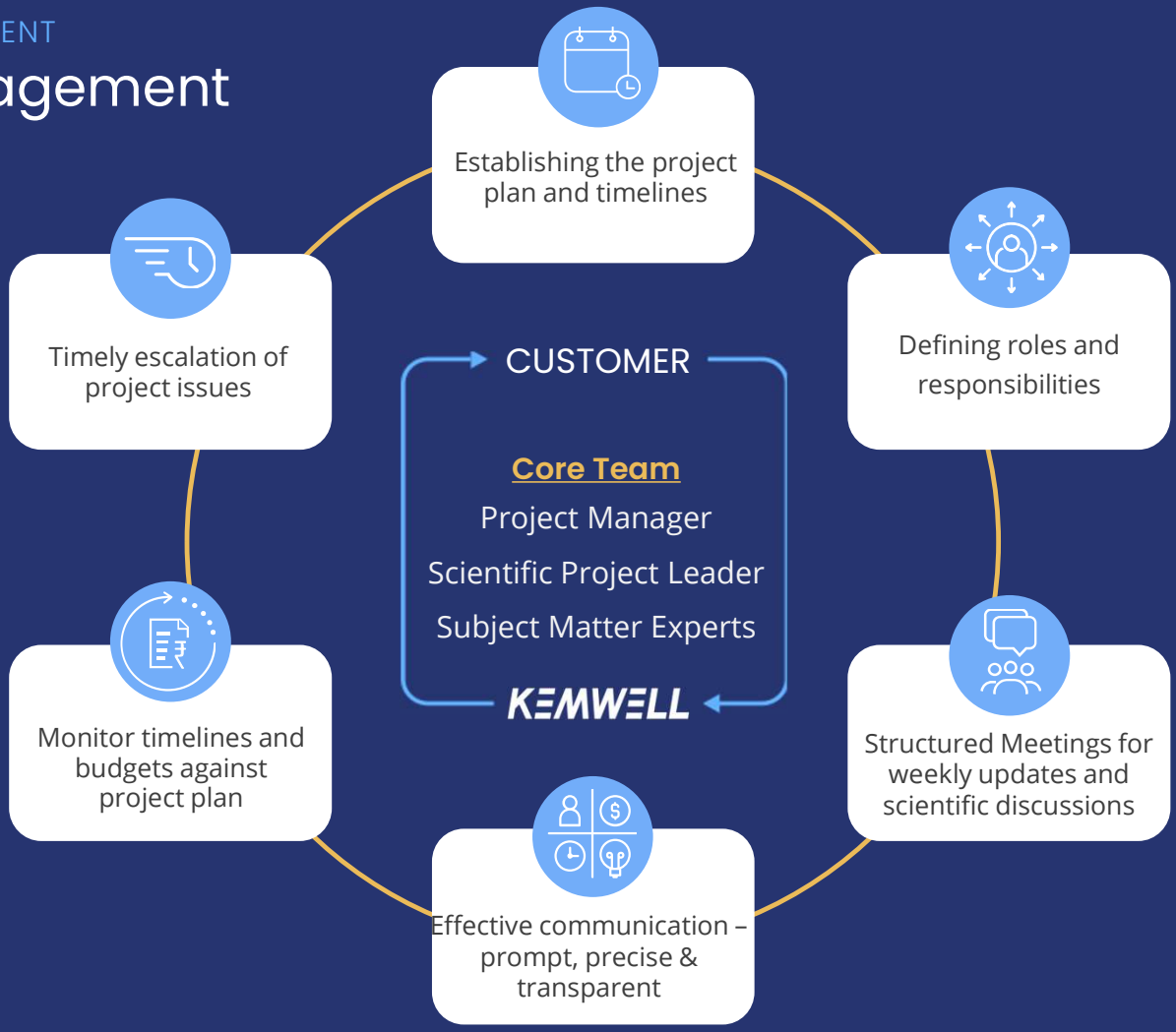
Track Record – Solving Challenges of Biosimilar Manufacturing

Type of Project	Product type	Scope of the project	Challenges & Achievements
Biosimilar	IgG1 mAb	Alternate DS & DP Manufacturing site for a globally approved biosimilar. PV followed by commercial manufacturing	1. Bioreactor geometry was different between the customer site and Kemwell. Scale-up calculations were considered based on Kemwell bioreactor geometry and pilo-scale batches were taken as proof-of-concept. 2. Customer did not want Engineering batch A thorough risk assessment of the process was done by Kemwell and customer jointly and PV was successfully completed without the Engineering batch. 3. Stringent timelines from customer for PV. PV was completed within 8 months of tech transfer ✓ **Till date 65+ DS and 100+ DP commercial batches have been manufactured**

Project Management

CUSTOMER ENGAGEMENT

Project Management



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