KEMWELL

Keeping You Competitive

Key Company Facts:

Corporate Headquarters	Bangalore, India
Year Founded	1980
Facilities	5 in India, 2 in Sweden
Employees	Over 1200 worldwide
Customers	Include 5 of the top 10 pharma companies
Countries	Supply to over 80 countries worldwide
Services	Small and large molecule product development and manufacturing
Regulatory Approvals	FDA, EMA and PDMA (Japanese Regulations)

About Us

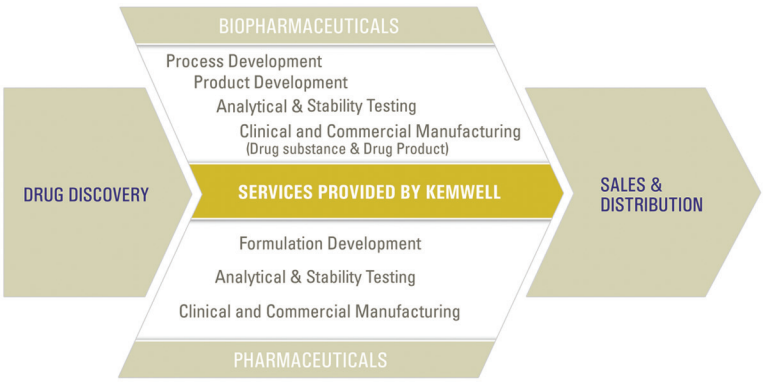
Discover Why Kemwell is Voted India's Best CMO

Kemwell is a 100% customer-oriented company with deep expertise in contract development and manufacturing services for pharmaceutical and biopharmaceutical products. When you outsource with us, we bring over 30 years of experience to your projects.

Headquartered in Bangalore, India, Kemwell has five facilities in India and two in Sweden, catering to 5 of the top 10 pharma companies of the world. Throughout our journey, we have maintained our pure-play status as a 100% contract services provider without foraying into any products of our own. This has strengthened our core value and work culture that the "Customer Comes First. Always."

This commitment to respecting IP rights and working collaboratively with our customers has won the confidence of the top pharma companies of the world, with companies trusting Kemwell to supply some of their highest-selling products for decades.

Today, Kemwell services companies such as Allergan, Bayer, GSK, J&J, Novartis and Pfizer, manufacturing many top brands and employing over 1200 people worldwide.



The Kemwell Commitment: *Keeping You Competitive*

Kemwell's vision is to be the first-choice strategic partner for pharmaceutical and biopharmaceutical companies worldwide.

Kemwell has the experience, expertise and infrastructure in place to meet your every need. Discover how our development and manufacturing solutions can keep you competitive:

Quality:
- Guarantee highest standards of quality and compliance
- Global regulatory approvals

Service:
- Reduce time between drug development and commercialisation
- Benefit from high customer service levels

Value:
- Do more with less in R&D and manufacturing
- Innovate to streamline manufacturing

Whether you are looking for biologics process development, pre-formulation studies, formulation development, stability studies, analytical support, clinical batch production, commercial-scale manufacturing or packaging, Kemwell is the ideal partner for you.

Through collaboration and innovation, Kemwell meets every challenge successfully, refusing to rest until the customer is satisfied.

Development • Manufacturing • Biologics

Drug Development

Idea to Product: Simplified

Kemwell's Pharmaceutical Development Labs are led by a management team with the necessary experience, scientific knowledge, vision and steadfast commitment to meet the customers' innovative and developmental needs. The management team guides Kemwell's scientific workforce composed of highly experienced and well-qualified professionals who spearhead resources from India and Sweden to find the best solution for you.

Kemwell's experienced scientists have developed formulations and analytical methods for conventional and specialized dosage forms. Analytical testing methods are designed to meet your exact specifications, while supporting rapid development timelines. Our Analytical Developmental labs are equipped with highly sophisticated and advanced equipment to support all developmental needs.

We can support your outsourcing needs from discovery to clinical supplies to regulatory filing, guaranteeing quality, service and value.

Development Services:

- Pre-formulation
- Formulation development IND, NDA, BLA, 505(b)(2), ANDA or OTC filings for oral solids, semi-solids, liquids and injectable dosage forms
- Analytical method development and validation
- Stability studies
- Process development/ Scale-up (using QbD princinples)
- Clinical supplies and labeling
- Tech transfers
- Dossier preparation
- QP release

Oral Care R&D: A Successful Collaboration

In 2008, Kemwell set up an R&D facility in Bangalore, India in partnership with one of the world's leading pharmaceutical companies, GlaxoSmithKline (GSK). This R&D centre has been set up to cater to GSK's global oral healthcare development projects, with the facility and staffing put in place by Kemwell in a record timing of six months.

Kemwell was selected by GSK owing to our senior management's commitment to diversification and innovation, our ability to deliver a new GMP facility and skilled manpower, and our commitment to planning, delivery and quality.

Discover how we can collaborate with you to meet your needs too.

Collaborative • Transparent • Innovative

Manufacturing Services:

- Tablets (IR, CR, XR, EC, bi-layer)
- Hard gelatin capsules
- Suppositories
- Liquid orals
- Semi-solids
- Parenterals (vials, lyophilized vials, PFS)

Packaging Services:

- Blisters: all materials
- Containers: glass bottles, plastic bottles, aluminium and plastic tubes
- Sachets/Pouches
- Drums

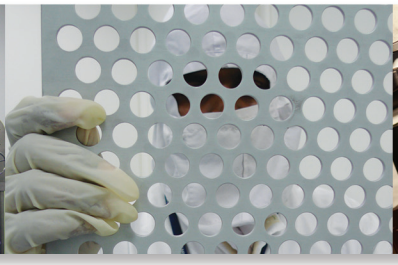
Manufacturing & Packaging

Our Experience and Expertise, at Your Service

Contract manufacturing is an excellent way to bring your product to market quickly and efficiently. Whether you are looking to modify an existing product, add a new product to your portfolio, or increase current manufacturing capacity, the Kemwell team is prepared with critical resources including people, facilities and equipment. With Kemwell, you will find expert solutions in product development, sourcing, manufacturing and distribution from facilities that are certified by FDA, EMA and PDMA (Japanese) regulatory authorities.

By providing high levels of customer service and quality, accurate documentation and delivery on time, Kemwell can guarantee you a reliable commercial supply.

Kemwell also offers a range of packaging solutions to address the challenges faced by the pharmaceutical industry. We fulfil specific requirements by providing high and low throughput packaging lines.



Quality is the Foundation of Our Success

Kemwell meets current Good Manufacturing Practices (cGMP) as per International Quality Guidelines and continues to invest in people, processes and equipment to ensure that Kemwell remains a quality leader in every aspect of our business. Our Quality System is the foundation of our operations and through SOPs, training and a range of process controls, we ensure that all products meet the highest quality standards.

We are dedicated to strict cGMP compliance and the methods, facilities and controls used for manufacturing, packaging and holding of all finished pharmaceuticals produced at Kemwell are in accordance with global cGMP regulations. Employee training programmes, equipment and process validation, and self-inspection programmes are part of our commitment to quality assurance.

The entire company is committed to an ongoing quality improvement process. Special emphasis is placed on thorough documentation and review of the entire manufacturing and control process. Documents are reviewed and updated to fulfil regulatory requirements and to maintain highest compliance standards.

Biopharmaceuticals

East and West Combine to Find You the Perfect Solution

We bring our 30-year experience and expertise in pharmaceutical services to provide biopharmaceutical product development and manufacturing services. We have built a state-of-the-art 15,000 sq. mt. biopharmaceutical facility in Bangalore, India that was designed by Boehringer Ingelheim, Germany. The facility offers services ranging from full-service process development, drug substance manufacture, formulation and fill & finish at the cGMP manufacturing facility in Bangalore.

Kemwell has an advanced set of capabilities that will take your projects from development to commercialization.

Development Services:

- Process development
- Analytical development
- Formulation development
- Pre-clinical manufacturing

GMP Manufacturing Services:

- Drug Substance
  - Clinical manufacturing
  - Commercial manufacturing
- Drug Product
  - Integrated vial filling line
  - Lyophilization
  - Pre-filled syringes
- Support Services
  - Analytical testing
  - Stability testing
  - cGMP cell banking and storage
  - Regulatory submission support

Biopharmaceutical Services:

- Process development
- Clinical manufacturing
- Commercial manufacturing
- Aseptic filling (vials, PFS, lyophilization)
- Analytical and stability services

Offering a Full Range of Services

Kemwell also offers stand-alone, platform-based analytical services. We are equipped with state-of-the art analytical techniques required for routine testing and characterization of recombinant therapeutics. Our wide array of capabilities includes:

Cell Culture based *in-vitro* Bioassays:

- Cell proliferation & Anti-proliferation assays
- Antibody Dependent Cell Mediated Cytotoxicity assays (ADCC)
- Complement Dependent Cytotoxicity assays (CDC)
- cAMP release assays
- Reporter gene assays

Application of Capillary Electrophoresis (CE):

- Glycan profiling of recombinant mAbs
- Analysis of isoform variants
- CE-SDS for identity and purity determination

Drug Substance • Drug Product • Mammalian Cells

Our Facilities

Indian Facilities

Oral Solids Facility: Kemwell's oral solids facility is a state-of-the-art facility built in Bangalore to manufacture up to five billion tablets and capsules for global supply.

Covering over 15,000 sq. mt., the facility has been designed to marry flexibility with stringent measures for contamination control.

Liquids Facility: Kemwell has been manufacturing liquids for the Indian market since 1985 and is one of India's largest liquids manufacturer. In 2012, we commenced operations at our new liquids facility in Bangalore, India. This is one of the largest liquids manufacturing plants in India, spanning 25,000 sq. mt. and was built and qualified in 24 months. With a capacity of 300 million bottles per year, we can manufacture and fill syrups, suspensions, mouthwash and pediatric products.

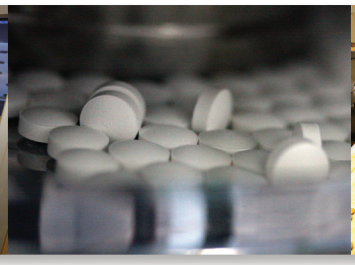
Semi-Solids Facility: Kemwell's semi-solids facility has been operational since 2001. We manufacture gels, ointments, creams and solutions for various topical and ophthalmic applications.

Biopharmaceutical Drug Substance Facility: Kemwell offers full-service contract biopharmaceutical process development and manufacturing of mAbs and recombinant proteins in mammalian cells at our newest 15,000 sq. mt. facility in Bangalore, India. Through a strategic collaboration with Boehringer Ingelheim, Kemwell is a single-source provider, supporting early product development to commercial supplies of biopharmaceutical products.

Fill & Finish Facility: Kemwell operates a state-of-the-art, sterile cGMP Formulation-Fill-Finish facility, providing comprehensive pharmaceutical development and manufacturing services for large and small molecule drug products in vials and PFS including lyophilization capabilities.

Certified by:

- EMA/MHRA
- FDA
- MCC
- PDMA
- TGA



Swedish Facilities

In 2006, Kemwell acquired a 16,000 sq. mt. facility in Uppsala, Sweden, from Pfizer, retaining all manufacturing contracts and people on site. This facility has over 50 years of experience in supplying pharmaceutical products to countries like the US, Europe and Japan. In 2010, we opened our second pharmaceutical production plant in Uppsala and doubled the production area to 31,000 sq. mt.

Our new pharmaceutical facility is characterised by a high level of automation and flexibility in order to satisfy the high and varied demands of our clients. Our employees have extended experience and are highly competent in the area of large-scale production.

We have been inspected by USFDA, EU and Japanese regulatory authorities and supply to over 80 markets worldwide. Our core process technologies include making the active pharmaceutical ingredient (API), wet and dry granulation, tabletting, capsule filling, semi-solid moulding, coating and vision inspection. We can also offer packaging in both blisters and bottles.

We also provide QP release services for Europe for products manufactured at our site or outside the EU, thereby covering the full chain of QA responsibility for API and finished products.

Marrying European and Asian strengths, we can provide you with the best solution from both worlds, for any stage of your product's lifecycle.

Small Molecules ◦ Large Molecules ◦ 100% Contract Services

How We Can Help Keep You Competitive

- Drug Development
- Clinical and Commercial Manufacturing
- Clinical and Commercial Packaging
- Biopharma Process Development
- Biopharma Drug Substance Manufacturing
- Biopharma Drug Product Manufacturing

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