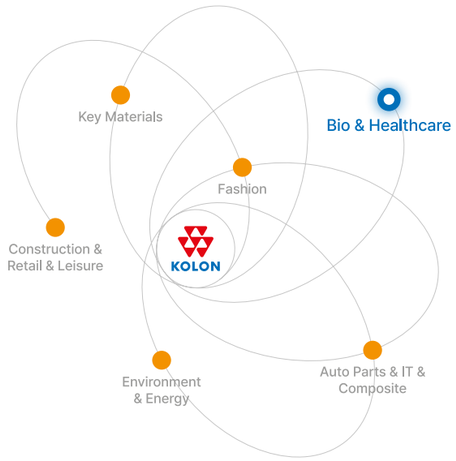
KOLON BIO TECH CDMO

KOLON BIOTECH

ABOUT KOLON GROUP

KOLON is enhancing the specialization
of each business and global competitiveness
as a holding company.



HISTORY

1954 - 1956 Foundation

Introducing nylon to a domestic market

In 1954, Kaemyeong Corporation, a nylon distributor,
was founded as a starting point of the KOLON group.

1957 - 1962 Leap

Producing nylon domestically for the first time

In 1957, Korea Nylon was founded.(Currently KOLON Corporation)

1963 - 1976 Growth

Growing as an integrated chemical fiber corporation

In 1963, Korea Nylon exports the first stretch nylon fiber.
In 1971, The first overseas branches were established in Osaka, New York.
In 1973, KOLON SPORT was founded.
In 1976, KOLON Chemical was founded.

1977 - 1989 Diversification

Expansion of national key industries and new business

In 1977, KOLON Engineering was founded.
In 1979, KOLON Trading Company was founded.
In 1983, Samyeong Pharmaceuticals was taken over.(currently KOLON Pharma)

1990 - 1999 Selection & Focus

Strengthening R&D capacities and establishing core values

In 1990, KOLON Data Communications was founded.
In 1992, KOLON Central Research Institute was founded.

2000 - 2009 Challenge & Growth

Pioneering new markets and securing a dynamic force for new growth

In 2000, Tissuegene Asia was founded.
In 2006, KOLON Life Science was launched, and a new vision "Lifestyle Innovator" was declared.

2010 - Present Evolution & Transformation

Enlarging territories for future business.

In 2015, KOLON BASF innoPOM, a joint venture with BASF, was founded.
In 2020, The dealership business of imported automobiles was expanded.
(Audi, Volvo, Autocare services, etc.)
In 2022, World's Longest Driving Distance Record, Attomax Golf Ball developed.
In 2020, Kolon Life Science spun off it's bio manufacturing business to create standalone company,
Kolon Biotech.

Why KOLON?

Strong Track Record & Global Standard Quality System

- Expansive expertise in Biologics(Cell and Gene therapies), Small Molecules (APIs, DP), and Specialty Chemicals.
- Fully compliant with global regulatory standards (MFDS, PMDA, FDA), ensuring product safety and efficacy.
- Extensive track record of passing inspections and quality audits by authorities in Japan and South Korea.
- Established and strategic partnerships with global leaders in the industry.

Customization Capabilities

- Early implementation of scalable processes tailored to project needs.
- Flexible slot operation to minimize the development period.
- Comprehensive End-to-End CDMO Services including Cell Banking, Pre-clinical and Clinical grade batches and Commercial products development.
- Analytical services adhering strictly to cGMP guidelines to ensure top-quality production.

Innovative Technologies

- Implementation of 2D Automated Manufacturing for precision and efficiency.
- Advancement in bioprocessing with 3D Bioreactor Upscaling.
- State-of-the-art techniques: X-ray and γ-ray Irradiation, and Cell Cryopreservation methodologies.

Tailored End-to-End CDMO Service

Kolon Biotech's IND Clearance Solution

Kolon Biotech proposes Turnkey projects to support your IND clearances and advancement into Clinical Phase Trials.
We provide our long experience and expertise to bring additional value to your Drug Pipeline.
An assigned and representative Project Manager will support you from the beginning to the end of the project.

Trouble Shooting during Manufacturing
Shares in-house developed Quality Tests
CMC Documentation

- Offers GMP Compliant Process Optimization
- Flexible Manufacturing Schedule
- Offer Bilingual Documentation for Global Clinical Trials

Tailored End-to-End CDMO Service

Cell Banks · Pre-Clinical

Starting Point in Production

Working within GMP regulations, Kolon biotech offers Cell banking service and Preclinical grade production to customers. The banks and Tox batches are fully characterized and fully compliant to GMP.

01

Cell Banking service
- Research Cell Bank (RCB)
- Master Cell Bank (MCB)
- Working Cell Bank (WCB)

02

Preclinical grade service

Phase I · Phase II

Early-Stage Pipelines

A reliable CDMO that prioritizes your drug development plan is essential for achieving your R&D milestones when you have limited resources during your early-stage drug development.

01

Achieving Development Milestones
- Establishing a CMC Packaging
- Securing your Drug for Clinical Phase Trials

02

R&D Budget Management

03

Process Verification & Optimization
- Obtaining your Target Batch Size
- Compliance to GMP Standards

Phase III · Marketed

Late-Stage Pipelines

Successful commercialization requires the establishment of a manufacturing site, stable operations, and the incorporation of cost reduction know-how. Kolon Biotech has successfully manufactured more than 100 consecutive commercial batches and is now offering its experience and expertise as a Long-Term Partner.

01

Further Process Development
- Applies Scale Up Technology
- Process Change Control

02

Secured Cost Effectiveness
- Improves Productivity and Manufacturing Costs
- Optimizes Manufacture Lines

03

Commercialization
- Manufacture Site Registration
- Secures Supply Volume

Standard Procedures for CMO Projects

Step 01

Consultation and RFQ

- **Services Inquiries & Questionnaire-based Meetings**
- **Batch Size, Timeline Discussions**
- **Proposal of Project Scope and Estimated Quotes**
  ※A CDA may be signed before any discussions if needed.
  ※The final quote is revised and finalized after signing the CDA with references to the agreed project details.

Step 02

Defining Work Scopes and Contracting

- **CDA**
- **Quotation and Negotiations**
- **Project Kick-off Meeting**
  1) Reviewing optimized process point
  2) Project scheduling
- **Contract Finalizing (MSA. Work Plans, QAG, and etc.)**

Step 03

Tech Transfer & Raw Materials Procurement

- **Technology Transfer**
- **Project BOM Finalization**
- **Procurement & Use Test of Raw Materials**

Step 04

Project Initiation

- **Pilot Study**
- **Aseptic Process Validation**
- **GMP Manufacture and Filling**
  Throughout the project, a project manager will be assigned to facilitate the project and will take the following steps for approval review;
  1) Initiation of work tasks and obtaining documented approval
  2) Management of deviations
  3) Provision of final reports for each work task, which will be reviewed until completion
- **Release Test**
- **Long Term Stability Tests**

Step 05

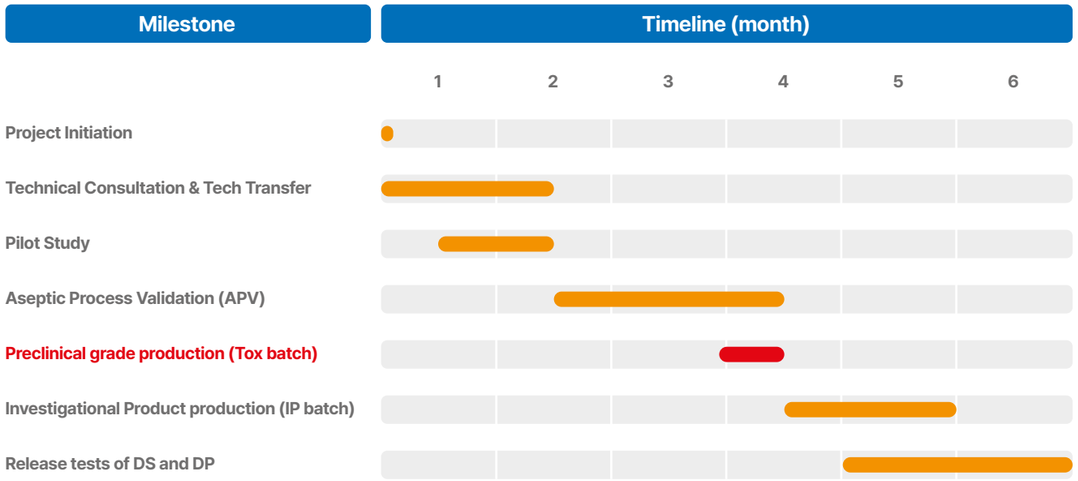
Project Completion

- **Results Verified and the Client's Inspection**
- **Settlement of Service fees and Raw Materials Consumption Expenses**

Fast CMC timeline

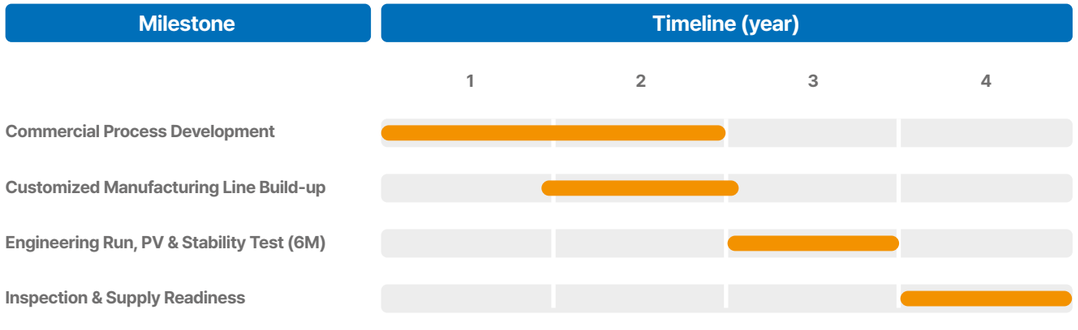
For Early-Stage Project

- 3.5 months from tech transfer to tox batch delivery
- 6 months from tech transfer to release tests of IP batch



For Late-Stage Project

- Establishment and qualification of exclusive manufacturing equipment for client's product
- BLA documentation support and regulatory inspections
- Stable supply for initial volume



Quality Center

Kolon Biotech's Quality System complies to cGMP practices and operates a specialized Quality division. Kolon Biotech warrants that all manufacture practices comply with cGMP regulations and strictly manages all GMP data.

Analytical Services

Microbiology

- Mycoplasma Test
- Sterility Test (Membrane Filtration, Direct inoculation)
- Method Suitability Test
- Endotoxin Test
- Growth Promotion Test
- Strain Performance Test
- Bioburden Test

Virus

- Adventitious Agents Test (in vitro)
- Replication Competent Retrovirus Test (in vitro)

Molecular Biology

- Appearance Test
- Protein Quantification Test (ELISA) for Potency
- Cell culture
- Colony formation assay
- Western Blot Test
- Total cell count and cell viability Test
- Cell confirmation and purity Test
- ELISA for Residual Test (For BSA, Col I , etc.)
- Real Time PCR, PCR Test

Key Analytical Instruments

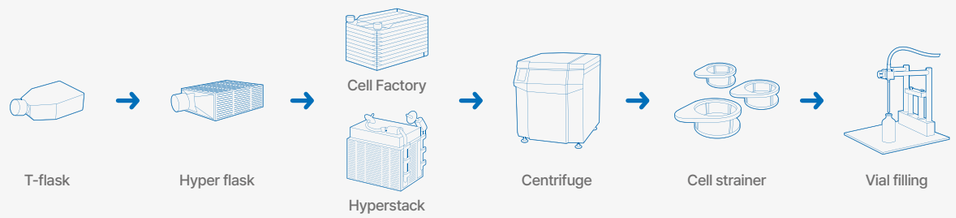
- HPLC(UV-Vis, Waters)
- UV spectrophotometer (Shimadzu)
- FACS Lyric™ (BD)
- MCS 150 (for Endotoxin Test, Charles River)
- HIAC 9703+ (for USP 788, Beckman Coulter)
- NC-250 (Cell Counter, Chemometec)
- NC-202 (Cell Counter, Chemometec)
- Osmomat auto (GONOTECH)
- Sartocheck4 (for Filter Integrity Test, Sartorius)
- C1000 Touch™ (for PCR test, BIO-RAD)
- CFX96 Touch™ (for RT-PCR test, BIO-RAD)
- EPOCH (Micro Plate Reader, BioTek)
- pH/Conductivity Meter (Thermofisher Scientific)

- **Physical and chemical tests can be conducted according to major pharmacopoeias such as KP, JP, and USP.**
- **Any other required analytical methods can be transferred and validated.**

Innovative Upscaling Technologies (2D & 3D)

- 2D Automated Closed Platform(ACP) minimizes contamination risks and human errors.
- The upscaling of 2D ACP and 3D bioreactors increases cell yield per culture area compared to the existing process.

Conventional(Hyperstack & Cell Factory) Process

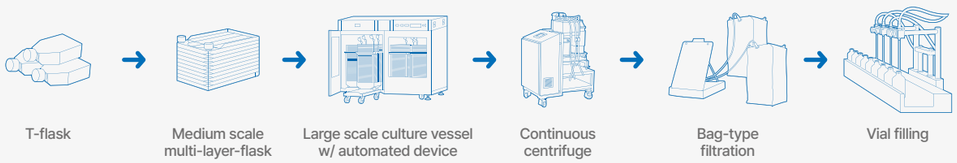


2D Automated Closed Platform

A large-scale 2D cell production platform is capable of producing adherent cells with enhanced aseptic tech.

Process layout

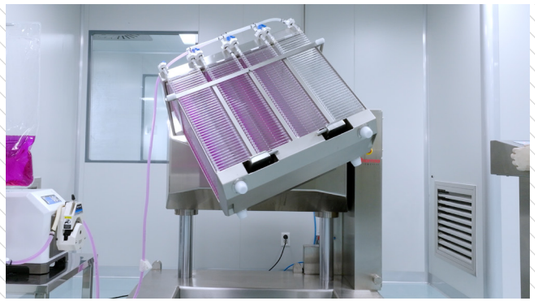
- Closed process addresses the risk of contamination
- Automated manipulation ensures high batch-to-batch consistency & reduced process time



3D Bioreactor Process

Adherent cells are grown on the surface of the microcarrier to enable 3D culture.

2D & 3D Automated Manufacturing Technology



Our Manufacturing Facilities

More than 20 years experience for Cell and Gene therapy

Bio Plant 1

Chung-ju, South Korea

2,230 m²

- GMP clinical and commercial manufacturing capabilities
- 4 clean rooms
- Cryostorage facility

Bio Plant 2

Chung-ju, South Korea

14,700 m²

- GMP commercial manufacturing capabilities
- Process development capabilities
- 12 clean rooms + future area
- Cryostorage facility

Biologics(Cell and Gene)

- Allogeneic and Autologous cell
- Adherent and Suspension cell

1. Compliance with requirements of regulatory authorities

- MFDS, GMP Approval
- FDA Drug Establishment Registration
  Identifier: 3019016602
  DUNS: 695108528
- PMDA/FDA Inspection (In Progress)

2. Manufacturing 100⁺ batches

3. Cell types

- Somatic cell, Stem cells
- T cells, NK cells, Dendritic cells
- iPSCs, Exosome

Major Equipment

Kolon Biotech's Bio-plant has optimized facilities in manufacturing advanced biopharmaceutical products and offers flexibility in its suites upon clients' requested timeline and volume.

B1 Plant

Clinical and Early Commercial product

Floor	Area Manufacturing Equipment	
2F	**Production Area** - Bio-safety cabinet (BSC) 4 sets - 850L(C/F 10Layer x 12) CO_2 incubator 16 sets - Centrifuge (12L/cycle) 3 sets - M1 Filling Machine(400vials/hr) 2 sets	
1F	**QC Area**	**Warehouse** - LN_2 Storage tank 8 sets - γ(gamma)-ray irradiator 1 set - Controlled rate freezer (CRF) 2 sets

B2 Plant

Mass Commercial product

Floor	Area Manufacturing Equipment	
3F	**Future Area**	
2F	**Production Area** - Bio-safety cabinet (BSC) 16 sets - 2,000L(C/F 40Layer x 16) CO_2 incubator 16 sets - Automated Cell Factory Manipulator (ACFM) 8 sets - Centrifuge (kSep, 16L/cycle) 2 sets - M1 Filling Machine(400vials/hour) 6 sets	**Process Development Area** - Bioreactor 3L 2 sets, 15L 2 sets, 80L 1set - L1 Filling Machine(500vials/hour) 1 set - Filling Machine(3,000vials/hour) TBD
1F	**QC Area**	**Warehouse** - LN_2 Storage tank 23 sets - Controlled rate freezer (CRF) 1 set

Manufacturing Facilities

Small Molecule(APIs)

- Generic APIs Development
- Pharmaceutical Intermediates
- CMO & new drug CMS

1. Compliance with requirements of regulatory authorities
- MFDS, GMP Approval
- PMDA, GMP Approval
- FDA, GMP Inspection(Planned)
- EU Whitelist Registration

2. Japan, No. 1 Korean API supplier
- 18 APIs & 60 companies

3. Global, No.1 Loxoprofen supplier

API Plant

Chung-ju, South Korea

16,837 m²

- GMP clinical and commercial manufacturing capabilities
- Process development
- 9 Production lines
  - Capacity : Max. 1,050T/Yr
- Main items
  - Loxoprofen Na
  - Zaltoprofen
  - Flurbiprofen
  - Pitavastatin Ca
  - Rosuvastatin Ca
  - Losartan K
  - Argatroban
  - Donepezil HCl / Base
  - Olopatadine HCl
  - Fexofenadine HCl

Small Molecule(DP)

- Oral Solid Dosage
- Oral Liquid Dosage

1. Compliance with requirements of regulatory authorities
- MFDS, GMP Approval
- PMDA, GMP Approval

2. Specialized dosage form
- ER(extended release) pellet technology
- Operating 3 Fluid bed Granulator

3. Operating PTP auto packing line

Dae-jeon, South Korea

11,565 m²

- GMP commercial manufacturing
  - capabilities
- Main dosage form
  - Tablets
  - Capsule
  - Granule
  - Dry Syrup
  - Syrup
  - Stick-pack

Specialty chemical

- Anti-dandruff Agent
- Anti-fouling Agent
- Emollient and preservative

1. Compliance with international guidelines
- Approval of EFfCI (European federation for Cosmetic Ingredient)
- Preparing for cGMP Certificate for AF Shampoo in US
- Approval of ISO 9001

2. World-leading manufacturer of anti-dandruff agents for shampoo

Gimcheon, South Korea

4,925 m²

- Commercial manufacturing capabilities
- Process development
- Capacity : Max. 7,860T/Yr
- Main items
  - Zinc Pyrithione
  - Piroctone Olamine
  - Sodium Pyrithione
  - Copper Pyrithione
  - MPPO(Modified polyphenylene oxide)

KOLON BIOTECH

We should

Work and Create Waves to Win with Innovative,
Excellent way of Research.

From Lab To Market

Cell & Gene Therapy Specialized CDMO

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