

# Why Outsourcing ATMPs Manufacturing to Kolon Biotech

Kolon Biotech is a Contract Development and Manufacturing Organization with specialty in Cell&Gene therapy and Exosome therapy. With highly skilled teams, we can support your journey from the initial manufacturing to the final commercialization.

## Customization capabilities to meet client's specific manufacturing needs

- Capable of process improvement as well as new process development including scale-up
- Manufactured various types of Cell&Gene therapy and Exosome therapy



## Clinical to commercial manufacturing capabilities

- Experienced in a wide range of batch sizes and scales
- Quality system complying with cGMP regulations



## End-to-End Support

We offer a sequence of integrated end-to-end services in order to help our clients to accelerate commercialization process of their products. Clients may select one or multiple services upon their needs

### Technology Transfer

- Customized process design to address needs of technology transfer
- Providing all the necessary validation documentations for technology transfer

### Process Development

- Strong process & technology expertise in various areas
- Established scalable and robust manufacturing processes with reproducibility

### Production

- Specialized in Cell&Gene therapy and Exosome therapy manufacturing
- Experienced in clinical and commercial product manufacturing

### Logistics

- Storage and transportation services to ensure the product quality

### Quality

- Stringent quality management system with diverse analysis service options

Complete Fluid System for Cell&Gene and Exosome Therapy

### Regulatory Support

- GMP documentation support in compliance with regulatory guidelines

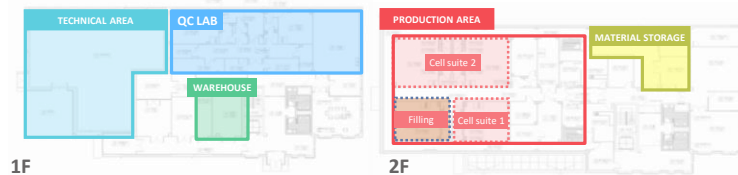
## Strong Track Record

No.	Product	Service		Phase
		PD	Mfg.	
1	Cell	✓	✓	Clinical & Commercial
2	Gene Modified Cell	✓	✓	Clinical & Commercial
3	Stem cell	✓	✓	Clinical
4	Exosome	✓	✓	Clinical

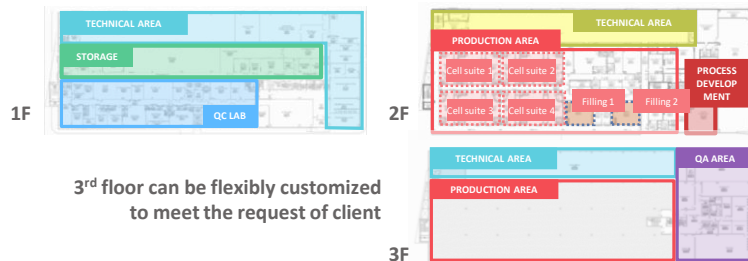
## Flexible Facilities

We have two facilities which can offer full services & equipment necessary to meet the growing demand for product development/manufacturing

### B1 Plant - 2,230m<sup>2</sup>

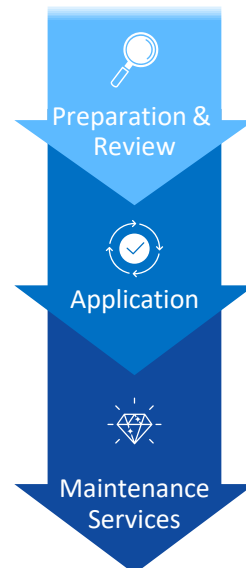


### B2 Plant - 14,700m<sup>2</sup>



## Clinical Trial Support

We can provide regulatory support for Advanced Therapy Medicinal Products (ATMPs) from IND to BLA



- Common Technical Document (CTD)
- Risk Management Plan (RMP)
- Official meetings (e.g., Type A/B/C meetings)
- IND application
- EOP meeting
- BLA application
- IND amendments and maintenance
- Document update (CTD, RMP, protocol, etc.)
- Regulatory support in accordance with client's development plan



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Number of Cell Suites

7,630m<sup>2</sup>

Clean Room Area



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