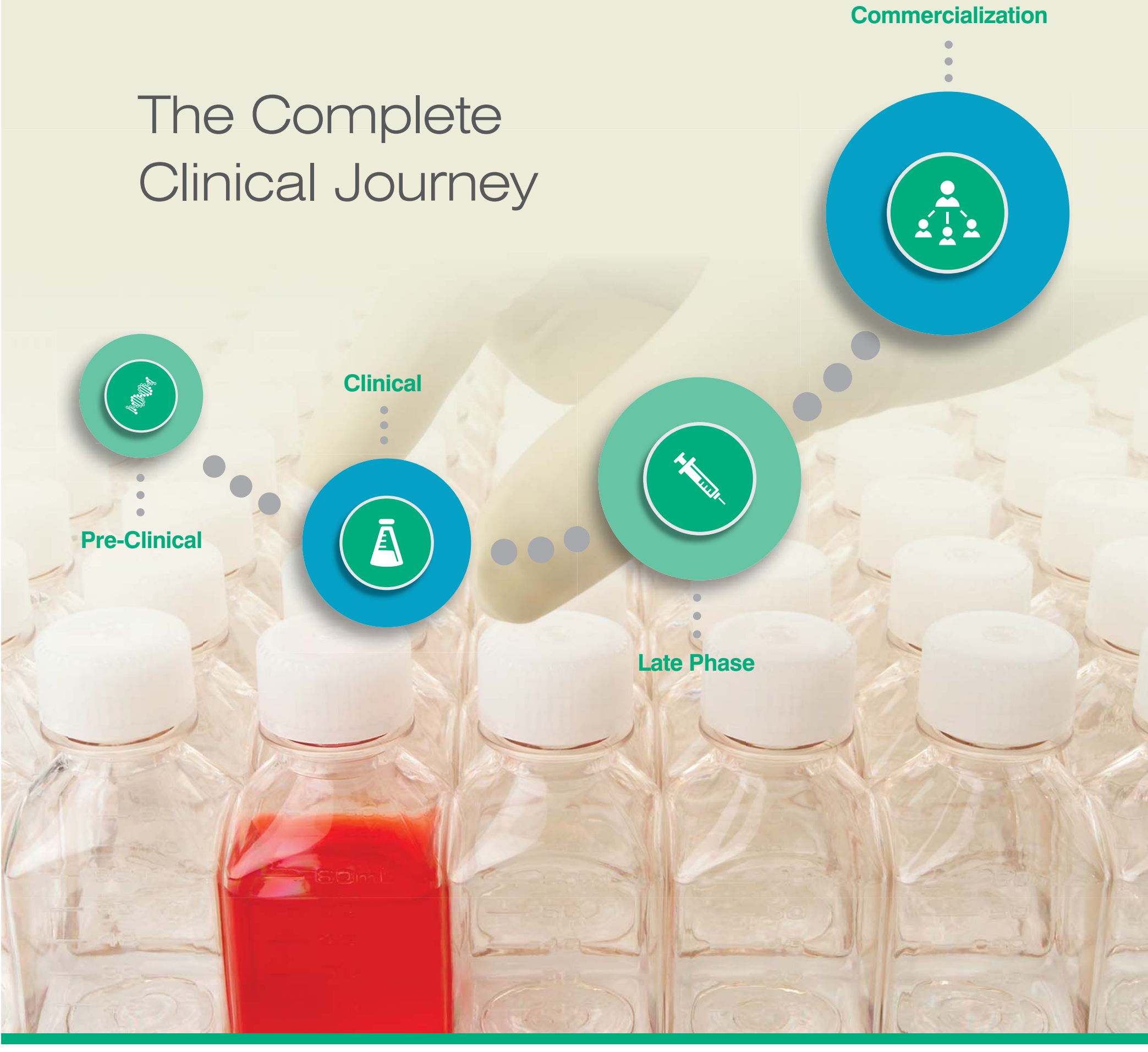
FUJIFILM
Value from Innovation

Diosynth
biotechnologies

The Complete Clinical Journey



Your Biologics & Vaccines CDMO partner of choice.

FUJIFILM Diosynth Biotechnologies is a world leading cGMP Contract Development and Manufacturing Organization supporting our partners in the biopharmaceutical industry in the development and production of their therapeutic candidates. As a global organization we operate as a network with locations in Research Triangle Park, North Carolina, USA; College Station, Texas, USA and Billingham, United Kingdom. As a partner to our customers, we bring extensive process and analytical development and cGMP manufacturing experience to meet your needs at every stage of the product lifecycle, from efficient protein expression, process design and cGMP manufacture, through to process validation, commercial production, and post approval product lifecycle management.

Committed to work in partnership with our customers along the clinical path.

Proven track record

Our track record in delivering successful programs will provide manufacturing support as your product reaches its next clinical stage quickly, economically and on time. Our experience includes:

- Development and manufacture of 300+ proteins
- Extensive clinical and commercial cGMP manufacturing experience, including six commercial products and 20+ process validation campaigns
- Expression in bacteria (including *Escherichia Coli* and *Pseudomonas*), yeasts (including *Pichia pastoris* and *Saccharomyces cerevisiae*), insect cells (*Baculovirus)*, and mammalian cell lines (including CHO, NSO, SP2/0)
- Gene Therapy with Viral Vector Development and Manufacturing Expertise including Adenovirus, Adeno-associated virus (AAV), Lentivirus, Poxvirus, and Baculovirus (sf9/sf21) among others
- Development, scale up, and validation of PEGylation unit operations, to include site specific PEGylation chemistry (linear and branched forms of PEG) as well as other conjugations (including peptides and small molecules)
- World class technical services and R&D teams on all sites for seamless technical transfer and scale-up to cGMP manufacturing
- Track record of on-time delivery through experienced and distinctive program management teams
- Routine commercial manufacture of drug substance to support regulatory approvals in multiple markets

Proven development & scale-up

Our experience ensures process development is applied appropriately, dependent upon the development needs of customer products at different clinical stages.

- Over 280 process and analytical development scientists
- Wide range of constructs and expression options including development of a customer's existing system or creating one *de novo* from our family of microbial and mammalian therapeutic protein production systems, including our proprietary technologies, pAVEway™ for microbial expression and Apollo™ for mammalian expression

Microbial fermentation	ambr250, multiple 5L and 15L fermenters Pilot scale at 50L and 115L
Cell culture	ambr15, multiple 2L, 5L, 10L, 15L, and 20L bioreactors Pilot scale at 200L

cGMP manufacturing

As a manufacturing network, we have highly flexible clinical and commercial cGMP facilities for microbial fermentation, cell culture gene therapy and viral vaccines production.

With a broad range of production scales, a track record of >1000 cGMP batches, an outstanding regulatory record and a licence for six commercial products, we can provide a tailored and cost-effective manufacturing solution for each product. We employ well-established protocol-based technology transfer to bring in customer processes, or operate the efficient processes developed and/or optimized by our own scientists.

Manufacturing capacities across our network

Microbial fermentation	50L, 100L, 200L, multiple 2,000L fermentation and multiple 5,000L Dedicated suites for the production of High Potency Biologics
Cell culture	Stainless Steel: 650L and 2,000L Single Use: 200L, 500L, multiple 1,000L, multiple 2,000L
High containment manufacturing	State-of the-art flexible manufacturing facilities with Mobile Clean Room Technology BSL-2+ ready and BSL-3 capable
Downstream processing	Flexible plant configurations Processing including disposables technology and refold volumes of up to 10,000L

Manufacturing support services

The following additional services are offered to reduce complexity and risk of multiple suppliers:

- cGMP cell banking facilities for production of Master and Working Cell Banks
- Buffer screening studies to support downstream process development
- Development of stable product formulations
- Generation and characterization of reference material
- Full range of *in-house* analytical methods for in-process and drug substance and drug product analysis
- Full range of stability testing capabilities for drug substance and drug product
- Full process characterization study design and execution
- Phase appropriate method validation
- Development and manufacture of antibody drug conjugates through alliance with Piramal Healthcare

Quality and regulatory support

We work in partnership with our customers to provide all the necessary quality and regulatory support through an independent quality unit that ensures your products will meet international regulatory requirements. Our regulatory history includes FDA (CBER & CDER), MHRA, EMA, Health Canada, ANVISA, and certification by JMHLW, among the agencies that have inspected our sites.

- Regulatory support for IND/CTA submission, DMF and CMC as required
- QC analysis and release of raw materials, environmental and water in-process/final, sample retention
- Ownership and use of qualified or validated methods
- Quality agreement followed by routine interactions with customer throughout the program
- QP release

Program management

Our partnership approach to program management enables a collaborative and trusting relationship, ensuring that we meet our customers' strategic, technical and quality goals in a timely and cost effective manner.

- Each program is supported by a dedicated, multi-disciplinary team led by an experienced and focused program manager
- Close customer interaction is promoted through regular teleconferences and face-to-face meetings
- Programs are milestone structured to ensure timely delivery

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June 2016