BioCina

YOUR MICROBIAL EXPERTS

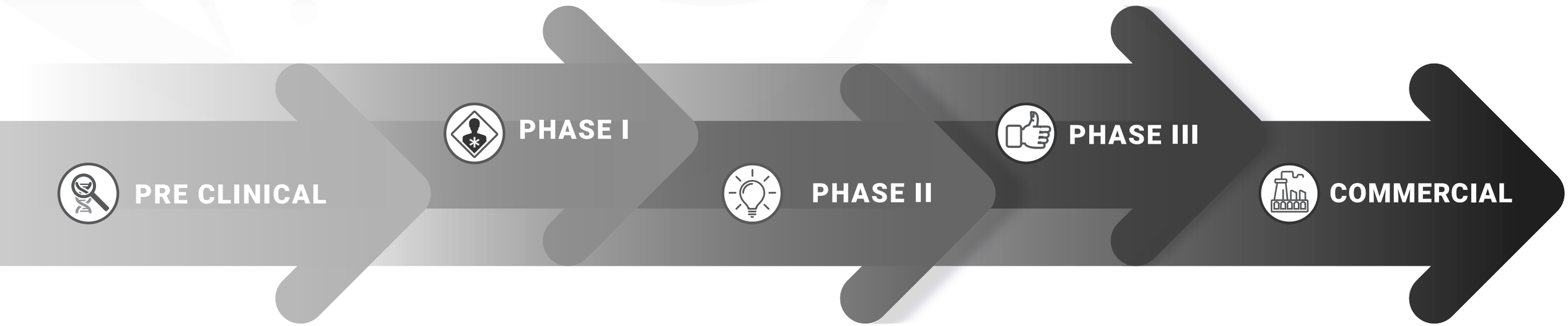
High Quality, Cost-Effective Microbial Process Development and cGMP Manufacturing Solutions for recombinant proteins and GMP Plasmid DNA.

www.biocina.com

BioCina

Excellence in the business and science of development and manufacture of biologics

Our professional and experienced project management team will guide the efficient development, delivery and supply of all your contract development and cGMP manufacturing requirements.



CELL LINE

Expression vector development/clone selection

Cell banking

Cell bank purity, viability and plasmid stability

FERMENTATION /UPSTREAM

Small scale upstream process development

Fermentation product yield and process optimisation

R&D fermentation scale: 0.4 L to 20 L

cGMP manufacturing scale: 170 L to 500 L

Conjugation chemistry

DOWNSTREAM

Downstream process development with processing capabilities through to pilot scale

Downstream process optimisation

cGMP manufacturing chromatography scale:

Isocratic: up to 2000 L/hr

Gradient: up to 600 L/hr

Tangential Flow Filtration

Bulk Drug Substance final fill

ANALYTICAL

Test method development and optimisation for in-process control, release and stability testing

Reference standard generation, qualification and characterisation

Process microbial control

VALIDATION AND TECHNOLOGY TRANSFER

Phase specific validation

Transfer ‘in’ and transfer ‘out’ of early phase and commercial processes

Process performance qualification

Equipment and facility validation

Supply chain validation

QUALITY OF SERVICE

Best in class quality systems

Experienced project management staff

Highly skilled and experienced workforce

Contract development and manufacturing experience include: recombinant proteins such as enzymes, antibody fragments, peptides, multimer peptide repeat vaccine candidates, conjugated vaccines, cytokines, growth hormones and plasmid DNA.

Your cGMP partner bridging the gap from laboratory bench to first-in-human trials and beyond.

ABOUT US

40

YEARS OF CONTINUOUS OPERATION AND FDA APPROVED (JAN 2023)

4592m2

MANUFACTURING FACILITY SIZE

1050m2

GMP WAREHOUSE

EXPERIENCE WITH OVER

50

DIFFERENT MOLECULES

UP TO

500L

GMP MANUFACTURING SCALE FERMENTATION

US$21mil

UPGRADE TO FACILITY AND cGMP WAREHOUSE IN 2016

>30

CUSTOMERS GLOBALLY

43%

CASH BACK ON ALL R&D SPEND UP TO COMMERCIAL MANUFACTURE

Full cGMP manufacturing capabilities, cutting edge equipment for consistent, high quality supply.

Australian Government R&D Tax Incentive

Managed by AusIndustry (www.business.gov.au) and the Australian Taxation Office (www.ato.gov.a u). 43.5% cashback incentive for eligible R&D expenditure including clinical trials, analytics and study drug manufacture.

Australia is an ideal location for your clinical trials:

No Investigational New Drug (IND) requirement.
Fast regulatory approval averaging 6 weeks, saving 6 to 9 months.
Facilities for preclinical and Phase 1, 2 and 3 trials .
Full range of services: clinical, data, bioanalytical, and applied clinical pharmacogenomics.

Global Regulatory Compliance:

Our Facility is licensed by the **Australian TGA** and is currently the only microbial drug substance facility of its kind in Australia to be approved by the **US-FDA**. The site has supported product approvals in Europe and other highly regulated markets.

BioCina

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