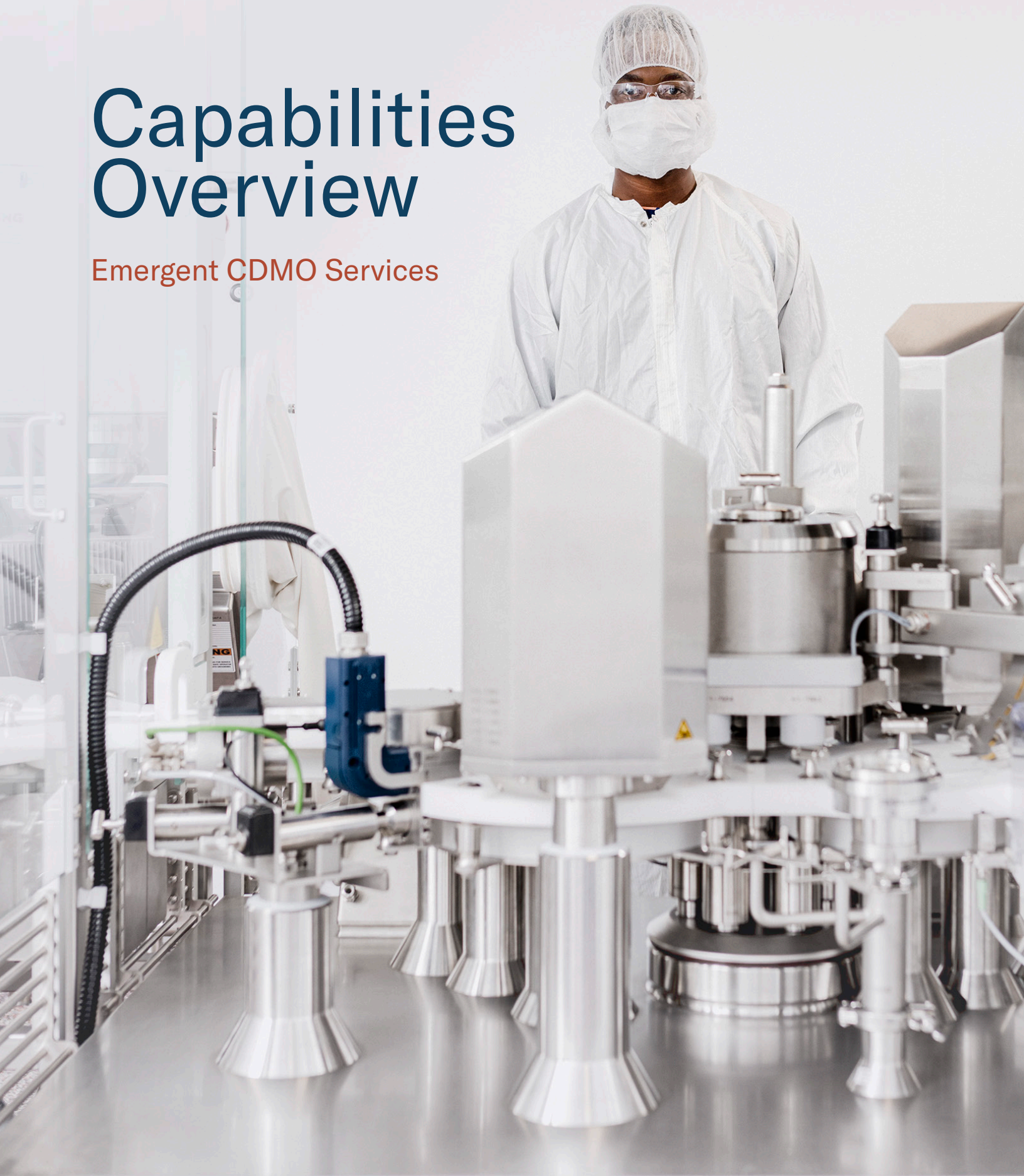
EMERGENT® CDMO

# Capabilities Overview

## Emergent CDMO Services



# Services built for repeat success

Your high-potential idea needs a high-performance partner to help expedite the process development and commercialization pathway.

Every service we offer at Emergent is designed to that end. We don't add services to check boxes — we add them to solve problems. When we assist you to bring your life-saving, life-extending product to market efficiently, everybody wins.

That's how we tackle the most pressing public health threats in one of the most tightly regulated, highly scrutinized industries in the world.

## SUSTAINABLE SOLUTIONS

Whether you lead a small group of inspired scientists or a global pharmaceutical powerhouse, you share a common objective: to overcome every obstacle in the way of your product's success.

So wherever you are in your journey, whatever challenges you face, Emergent experts can help guide your project successfully through all stages of the drug development lifecycle.

## INSPECTED BY GLOBAL REGULATORY AGENCIES

Across our network of sites, Emergent has experience with cGMP inspections by a broad range of global regulatory bodies, including:

| COUNTRY/REGION | REGULATORY BODY |
|---|---|
| USA | FDA |
| EU | EMA |
| BRAZIL | ANVISA |
| INDIA | FMDA |
| CANADA | Health Canada |
| GREAT BRITAIN | MHRA |
| SWITZERLAND | Swissmedic |
| THE RUSSIAN FEDERATION | Minzdrav (MoH) |
| SOUTH KOREA | MFDS |
| JAPAN | PMDA |
| IRELAND | HPRA |

# Development Services

The comprehensive, integrated suite of development services available through Emergent CDMO are designed to sync seamlessly both with one another and with your team's specific needs. From drug substance and analytical development to drug product development and product scale-up, we have the capabilities to help your scientific discovery advance to its next key milestone and beyond.

## DRUG SUBSTANCE DEVELOPMENT

We collaborate closely with your team — from pre-clinical through commercial stages — to apply the platform that works best for your program. Then we put the best technologies to work when it comes time to scale, including up to a 50L to 200L scale in single-use-bioreactors as well as 250mL microbioreactors.

**TECH**
- Mammalian
- Plasma Protein

**CLINICAL SCALE**
- Shaker flask
- 250mL microbioreactors
- 10L bioreactor
- 50L bioreactor
- 200L bioreactor

### UPSTREAM

- Development of scalable, aseptic upstream processes
- Adherent and serum-free suspension adapted A549 cell culture
- Media and feed screening
- Seed expansion development aligned with manufacturing site capabilities
- Optimization of bioreactor/ fermentor operating conditions

### DOWNSTREAM

- Development of harvest conditions (filtration, TFF, centrifugation)
- Protein purification development, including inclusion body isolation and refolding
- High throughput resin screening with Tecan®/Cytiva robotics platform
- Column and membrane purification development
- Optimization of chromatography conditions (pH, conductivity, residence time, binding, and/or elution conditions)
- Filter screening (bioburden reduction, nanofiltration, TFF, and sterile filtration process for BDS)

### KEY EQUIPMENT

- Ambr® 250 microbioreactors
- iCELLis® nano bioreactors
- Sartorius 10L stirred-tank bioreactors (mammalian and microbial)
- Xcellerex™ XDR 50 and XDR 200 (mammalian)
- Xcellerex™ XDR 50 (microbial)
- Alternating tangential flow (ATF) perfusion technology
- Tecan® system
- AKTA™ Pure, Avant, Pilot, Ready
- Repligen KrosFlo® systems
- kSep® centrifuge
- GEA Westfalia Disk stack centrifuge

## DRUG PRODUCT DEVELOPMENT

For drug product development from pre-clinical through commercial, Emergent provides your team with the full suite of cGMP-compliant development processes across viral and non-viral platforms. You can leverage a broad array of technologies, screening, and formulation equipment, presentation formats, and capacity that ranges from 1L to 200L.

**TECH**
- Viral
- Non-Viral

**SCALE**
- 1L to 200L for DP Manufacturing

### LIQUID

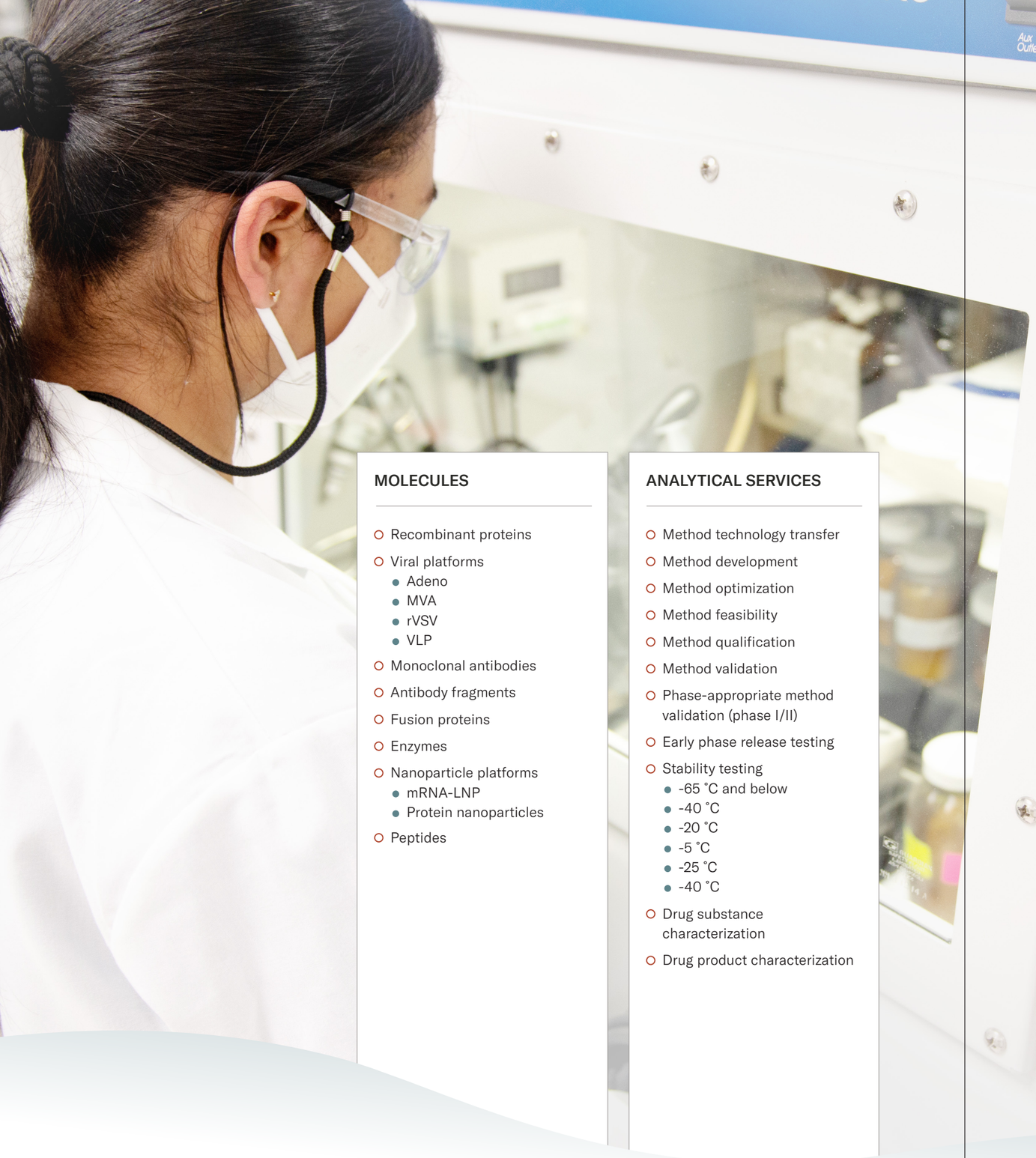
- Pre-formulation studies, including forced degradation and excipient screening
- Formulation development
- BDP formulation process Development
- Product characterization
- Protein/peptide characterization
- Particle characterization
- Fluid characterization
- Potency

### LYOPHILIZATION

- Lyophilization development:
  - Thermal characterization
  - Sequential optimization of freezing, primary drying, and secondary drying steps
  - Development lot production and non-GMP stability

### KEY EQUIPMENT

- BioQuell® isolator
- Single-use mixers (Allegro™ 50L, Mobius® 10-200L)
- Development lyophilizers:
  - VirTis 50L Ultra EL – pilot scale unit (full capacity ~2500 10mL vials/run)
  - VirTis Advantage Plus – small scale R&D preparations (~150 vials/run)
  - MicroFD – small scale unit for scale up study with heat flux monitoring and edge/center vial simulation for cycle development/ optimization/scale up (19 vials)
  - Two LyoStar III, one with sample extractor and TDLAS technology



## MOLECULES

- Recombinant proteins
- Viral platforms
  - Adeno
  - MVA
  - rVSV
  - VLP
- Monoclonal antibodies
- Antibody fragments
- Fusion proteins
- Enzymes
- Nanoparticle platforms
  - mRNA-LNP
  - Protein nanoparticles
- Peptides

## ANALYTICAL SERVICES

- Method technology transfer
- Method development
- Method optimization
- Method feasibility
- Method qualification
- Method validation
- Phase-appropriate method validation (phase I/II)
- Early phase release testing
- Stability testing
  - -65 ˚C and below
  - -40 ˚C
  - -20 ˚C
  - -5 ˚C
  - -25 ˚C
  - -40 ˚C
- Drug substance characterization
- Drug product characterization



## ANALYTICAL DEVELOPMENT

Through comprehensive analytical development processes, our team helps yours stay on-point, on-track and on-spec. So whether you're working toward critical pre-clinical milestones (where API behavior might be a key driver) or pushing through early-stage clinical research (where purity and potency may be dominant concerns), you can rely on Emergent to help you achieve key analytic goals and support your validation and documentation requirements.

## ANALYTICAL CHEMISTRY CAPABILITIES

- HPLC/UHPLC
  - SEC
  - RP
  - IEX
- LC-MS
  - Peptide mapping
  - Oligo profiling
- Amino acid analysis
- FTIR
- Western blotting
- JESS

## BIOCHEMISTRY CAPABILITIES

- Titer ELISA
- Impurity ELISA
- SDS-PAGE
- CD SDS
- Western blotting
- Total protein
  - A280
  - BCA
  - MicroBCA
  - Bradford
  - Lowry
  - SoloVPE
- Compendial testing
- Agarose gel electrophoresis
- PCR, qPCR, RT-qPCR,
- Potency
- Viral infectivity
  - TCID50
  - Plaque Assay
  - IU Assay
- UV-Vis spectrometry
- Fluorescence spectrometry
  - PicoGreen total DNA
- BLI
  - Octet

## KEY EQUIPMENT

- Waters™ and Agilent® HPLC instrumentation
- Waters UPLC instrumentation
- Gyrolab® xP
- LabChip® GX II
- Scientific Thermo® LC-MS

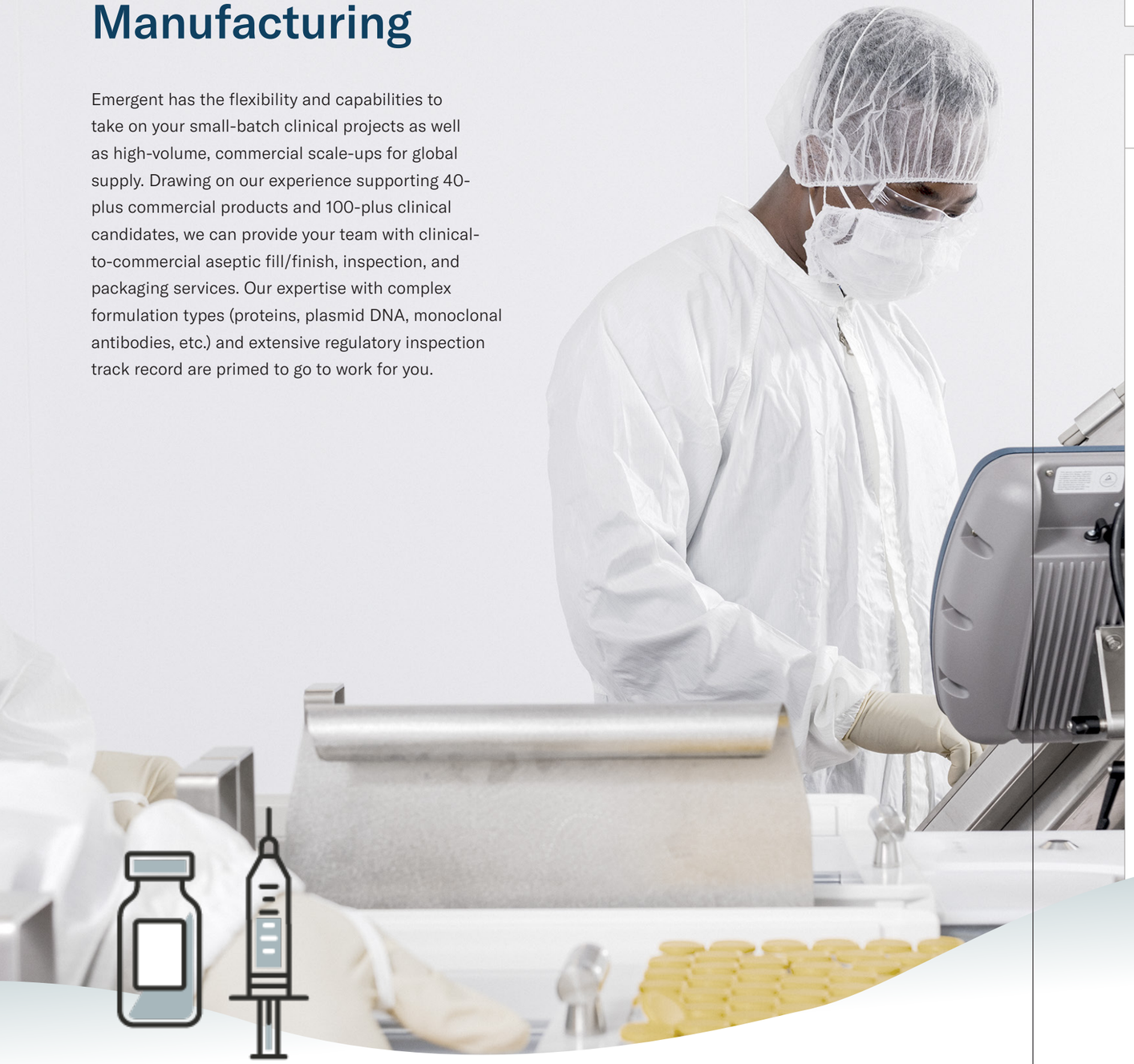
# Drug Substance Manufacturing

As your team strives to navigate an increasingly complex discovery and development environment, you can capitalize on our upstream and downstream drug substance manufacturing expertise to optimize your clinical or commercial program.

| TECHNOLOGIES | SCALE | DOWNSTREAM PROCESSING |
|---|---|---|
| **MAMMALIAN**<br>○ Monoclonal antibodies (mAbs)<br>○ Recombinant proteins<br>○ Bi- and multi-specific antibodies<br>○ Antibody fragments<br>○ Fusion proteins<br>○ Cell lines: CHO, NS0, HEK293, PER.C6, Vero | ○ Single-use bioreactors<br>● 50L<br>● 200L<br>● 500/750L<br>● 2000L<br>● 4000L | ○ Centrifugation<br>○ Chromatography<br>○ Filtration<br>○ UF/DF |
| **PLASMA PROTEIN**<br>○ Polyclonal antibodies from human and equine plasma<br>○ Polyvalent therapeutics<br>○ Monoclonal antibody therapeutics | ○ 240L stainless steel pooling tankage<br>○ 480L stainless steel pooling tankage<br>○ 1000L human hyperimmune<br>○ 1000L equine hyperimmune | ○ 1800L working volume<br>○ Up to three segregated viral zones<br>○ Chromatography<br>○ Filtration<br>○ UF/DF |

# Drug Product Manufacturing

Emergent has the flexibility and capabilities to take on your small-batch clinical projects as well as high-volume, commercial scale-ups for global supply. Drawing on our experience supporting 40-plus commercial products and 100-plus clinical candidates, we can provide your team with clinical-to-commercial aseptic fill/finish, inspection, and packaging services. Our expertise with complex formulation types (proteins, plasmid DNA, monoclonal antibodies, etc.) and extensive regulatory inspection track record are primed to go to work for you.



| TECHNOLOGIES | SCALE | KEY EQUIPMENT |
|---|---|---|
| VIRAL | ○ 1 x high speed fill line<br>• 2R (available Q1 2023)<br>• 10R (available H2 2023) | ○ Groninger® Integra |
| NON-VIRAL | ○ 2 x vial fill lines (2mL – 100mL) | ○ Chase Logeman® (single- and double-headed filler) |
| | ○ 1 x syringe fill line (0.5mL – 20mL) | ○ Inova® SV122 |
| | ○ 3 x large-scale lyophilizers | ○ IMA Lyo – 240 sq.ft.<br>○ Hull Lyo – 216 sq. ft.<br>○ Martin Christ Lyo – 74 sq. ft. |
| | ○ 1 x multi-format isolator line (vials and syringes)<br>• 2R<br>• 10R<br>• 1mL-long PFS | ○ Groninger® FlexPro 50 |
| | ○ 1 x terminal sterilizer | ○ Fedagari |
| | ○ 1 x multi-format isolator line (vial & syringe)<br>• Vial: 2R–50R<br>• Syringe: 0.5mL – 10mL | ○ Cytiva® SA25 |

If you're taking on the world's most formidable health threats, Emergent has the scientific, regulatory, quality, and manufacturing experience, and seamless technology-transfer capability to harness the urgency, ability, and scalability needed to bring your product to market.

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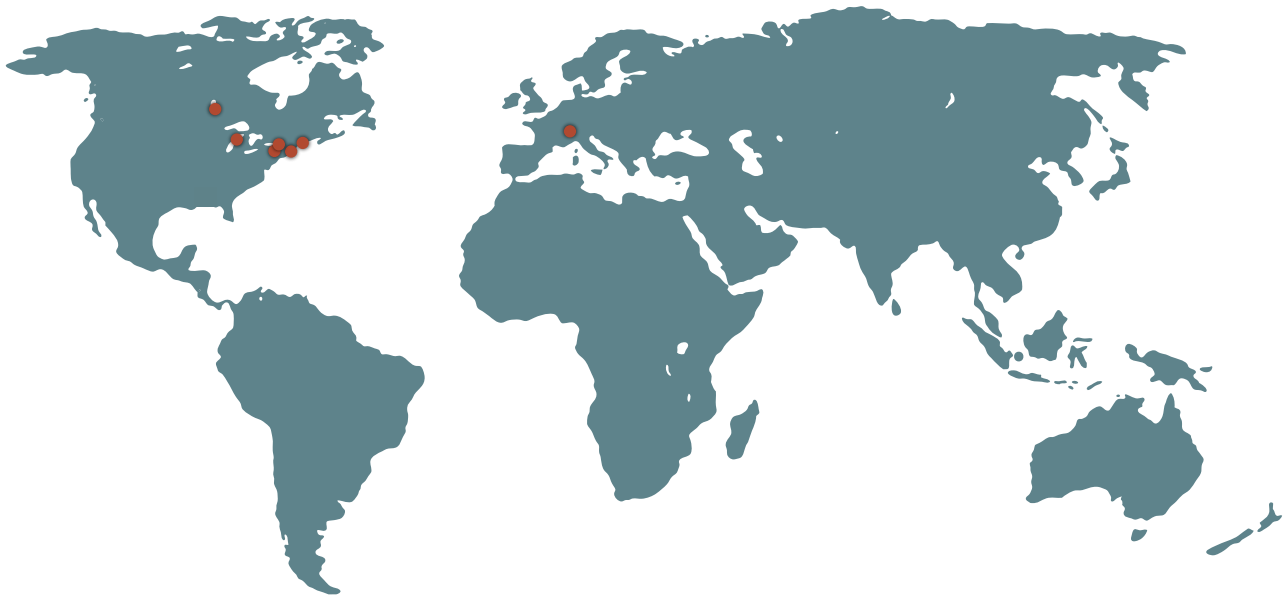
# Development and manufacturing sites



- **BALTIMORE, MD (Bayview)**
  Drug Substance
- **BALTIMORE, MD (CAMDEN)**
  Drug Product
- **BERN, SWITZERLAND**
  Drug Substance
- **CANTON, MA**
  Drug Substance
- **GAITHERSBURG, MD**
  Development Services
- **LANSING, MI**
  Drug Substance
- **ROCKVILLE, MD**
  Drug Product
- **WINNIPEG, CANADA**
  Drug Substance and Drug Product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