

CLINICAL MANUFACTURING AT EVOTEC

MANUFACTURING AREAS

▶ Truly integrated CMC capabilities fully supporting drug product development and GMP manufacturing from FIH to Phase III clinical development programs

1800+

m² (19,000+ sq ft) in total

15

Independent manufacturing suites

4

Independent inhalation manufacturing rooms

4

Independent dispensing rooms

TECHNOLOGIES

▶ No need to align different sites/providers for development, process transfer and GMP manufacturing: time optimization, risk mitigation, project management expertise

20+

Technologies for solid/liquid dosage forms and dry powder inhaler

40+

Equipment models/types

4+

Enabling technologies:

- ▶ Milling/micronization
- ▶ Top-down/bottom-up nanosizing
- ▶ Spray-drying
- ▶ Hot Melt Extrusion

- ▶ High containment handling (OEB4: 1-10 $\mu\text{g}/\text{m}^3$ and OEB5: $\leq 1\mu\text{g}/\text{m}^3$)
- ▶ Solvent processing

▶ Clinical supply capabilities covering a broad number of dosage forms (for oral and inhalation delivery), and handling compounds up to OEB5 (OEL > 0.5 $\mu\text{g}/\text{m}^3$)

70+

Clients worldwide (EU, US, Asia)

100+

Projects in 2019–2020

300+

Drug product batches per year, on average

- ▶ Clinical batches for Phase I-II-III and commercial
- ▶ Primary and secondary packaging
- ▶ Development, scale-up, transfer to clinical manufacturing: all under the same roof

▶ Small scale commercial manufacturing for niche therapeutic indications (rare diseases/orphan drugs)

CLIENTS & PROJECTS

Learn more: *If you would like to hear more about how our experts can help with your clinical manufacturing requirements, contact us at info@evotec.com*