



FACILITY OVERVIEW

Riccarton, UK

Our Biologics facility, located in Riccarton, United Kingdom, provides a wide range of testing solutions for biopharmaceutical/biological products including GMP cell line characterization, cell-based bioassays, physicochemical, and analytical testing to support process validation, lot release, and stability studies for European, US, and international markets.

Background

- Acquired in 2018
- Activities from Tranent Biologics facility will transition to Riccarton in 2020
- Staff and procedures from over 25 years of GMP testing at Tranent
- Planned expansion of services in 2020

Staff

- 60+ employees with planned growth to 100+ by 2023

Laboratories and Facilities

- 2,043 m² (22,000 ft²) of high quality lab and office space
- Located approximately 17 miles from the main Tranent site, and near Edinburgh Airport on the Heriot-Watt University campus

Service Areas/Study Types

- Bulk harvest and end-of-production testing
- Cell line characterization
- Contamination and impurity testing
 - bacteriophage
 - other adventitious agents
 - residual DNA
 - endotoxin
 - residual process materials

- Genetic stability
- *In vitro* potency and bioassays
- Drug substance and final drug product release
- Custom method development
- Physicochemical testing
- Stability testing
- Vaccine safety assays
- Gene therapy support

Compliance, Certifications, Accreditations and Professional Affiliations

Charles River's Riccarton facility operates in compliance with the following regulatory agencies or accredited organizations:

- UK Medicines and Healthcare Products Regulatory Agency (MHRA)

Quality and Process Initiatives

- Lean Six Sigma program
- On-site IT support and backup
- Online data collection and integrated instrumentation



EVERY STEP OF THE WAY