charles river

FACILITY OVERVIEW

Ballina, Ireland

Our facility located in Ballina, Ireland is designed for execution of Good Manufacturing Practice (GMP) pharmacopoeial quality control and safety assays, medical device testing, custom method development, potency bioassays, and microbiology.

Background

- Founded by BioLabs Europe in 1976
- Acquired by Charles River in 2002

Laboratories and Facilities

- 74,900 sq. ft./6,958 m^2
- Purpose-built laboratory facilities
  - 25,747 sq. ft./2,392 m^2 in dedicated laboratory space
  - Over 40 animal rooms with anti-lock entry, alarmed and monitored 24/7
  - Specialist high biosecurity test facilities
  - Licensed to work with level 2 GMOs and BSL 1 and 2 pathogens
- SPF animal breeding on site: CD1 mice, MF1 mice, and ferrets

Staff

- Approximately 130 employees

Service Areas/Study Types

- Potency (*In vivo*) - neurotoxins, hormones, antivenoms, antitoxins, allergens
- Vaccine support services
  - Immunogenicity/Immunopotency
  - Bacterial and viral challenge studies
  - Anti-infective challenge studies
  - *In vivo* stability and safety
- Abnormal toxicity/General safety
- Biological reactivity
- Water testing (EP and USP)
- Physicochemical testing
  - pH and appearance
  - Osmolality
  - Conductivity
  - Water content (volumetric, coulometric)
  - Sub-visible particles
  - Gel electrophoresis (different type of gels and staining methods e.g., Coomassie, silver)
  - Western blot
  - Protein concentration (A280, BCA, Lowry)
  - Size exclusion (SEC-HPLC)
  - HPLC/UPLC methods (RP, peptide map)
  - Ion exchange chromatography
  - Wet chemistry, e.g., aluminium content
  - Capillary electrophoresis to separate proteins by size or by pI
- Rabbit pyrogen testing (USP <151>, EP 2.6.8, 21 CFR 610)
- Monocyte activation test (MAT) EP 2.6.30
- Blood factor analysis

EVERY STEP OF THE WAY

Service Areas/Study Types (Continued)

- *Ex vivo* analysis
  - Multiple types of ELISA
  - Single radial hemolysis (SRH)
- Method development and transfer
  - Range-finding studies
  - *In vivo* and *ex vivo* assay development
  - Competitor comparative studies – new product screening and characterization
- Antisera generation supported by ELISA titration of Abs and specificity by western blot
- Microbiology
  - Sterility (isolator and clean rooms)
  - Preservative efficacy testing
  - Disinfectant testing
  - Microbial limits
  - Microbial challenge and hold time studies
  - Bioburden
  - Cytotoxicity
  - Endotoxin testing
  - Antibiotic testing
  - Environmental monitoring (at client locations)
- Biosafety testing
  - Mycoplasma testing - cultivable and non-cultivable methods
  - *In vitro* adventitious agents
    - Indicator/detector cell line method
    - Readouts: Cytopathic effects, haemabsorption, haemagglutination
- *In vivo* biosafety testing/adventitious agent testing
  - EP, FDA Guidance for Industry 2010 methods available
  - Adult mouse, suckling mouse, and embryonated egg assays
  - Guinea pig assays available for viral vaccines
  - MAP (+ LCMV challenge), HAP, and RAP assays

Compliance, Certifications, Accreditations and Professional Affiliations

Charles River Ireland operates in compliance with the following regulatory agencies or accredited organizations:

- Good Manufacturing Practice (GMP) inspected by Health Products Regulatory Authority (HPRA)
- Animal Protection & Welfare (SI 543 of 2012 and 2010/63/EU) inspected by Health Products Regulatory Authority (HPRA)
- U.S. Food & Drug Administration (FDA)
- Drugs Directorate, Bureau of Biologics, Canada
- Brazilian Ministry of Health
- Russian Ministry of Health

Quality and Process Initiatives

- Lean Six Sigma program
- Excellent regulatory compliance history

Humane Care Initiative

Charles River is a worldwide leader in the humane care of laboratory animals. We work hand-in-hand with the scientific community to understand how living conditions, handling procedures, and stress play an important role in the quality and efficiency of research.

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