



FACILITY OVERVIEW

Ballina, Ireland

Questions for our scientists?

Visit <https://www.criver.com/consult-pi-bi-how-can-we-support-your-program>

Our facility located in Ballina, Ireland is designed for the execution of Good Manufacturing Practice (GMP) pharmacopoeial quality control and safety assays. We support [medical device testing](#), [vaccine support services](#), biosafety testing, custom method development, [potency bioassays](#), and [microbiology](#).

Background

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

Laboratories and Facilities

- 70,000 ft² /6,503 m²
- Purpose-built laboratory facilities
 - 25,747 ft² /2,392 m² 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 140 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
- Biological reactivity
- Water testing (EP and USP)

- Physicochemical testing
 - pH and appearance
 - osmolality
 - conductivity
 - water content (volumetric, coulometric)
 - sub-visible particles
 - purity by gel electrophoresis (different type of gels and staining methods, e.g., Coomassie, silver)
 - identity by western blot or ELISA
 - protein concentration (A280, BCA, Lowry)
 - different Chromatographic methods using HPLC/UPLC methods (SEC, RP, peptide map)
 - ion exchange chromatography
 - wet chemistry (e.g., aluminum content)
 - separation of proteins by size or by pl using capillary electrophoresis (CE-SDS, iCE)
- [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)
 - western blot
 - ELISpot
- 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)

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.

AAALAC Accreditation

Charles River Ireland conforms with AAALAC International standards as set forth by the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123); Irish implementing legislation; and the Guide for the Care and Use of Laboratory Animals, NRC 2011 and received full AAALAC Accreditation in 2017.

