



Key Considerations for Potency Assays

R. Mark Jones, Ph. D.

Director, Scientific Portfolio Management

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FOUNDED 1947

We currently operate

130+

facilities in

20+

countries

We supported the development of

80%

of the novel
FDA-approved drugs
in the last 5 years

Our focus

on timelines and accuracy in every stage of development means you can count on reliable, reproducible results—every step of the way.

DIVISIONS



DISCOVERY SERVICES



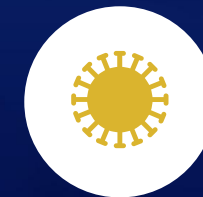
SAFETY ASSESSMENT



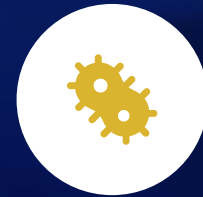
LABORATORY SCIENCES



RESEARCH MODELS & SERVICES



BIOLOGICS TESTING SOLUTIONS



QC MICROBIAL SOLUTIONS

Our global impact

7 GMP Testing facilities
in US and EU

~200 client audits
every year



The working relationship, responsiveness, and progress on our project with Charles River have been exceptional to date. We are provided with rolling updates before the meeting, which is very appreciated. We meet with a team that are motivated, enthusiastic and forward-focused at every meeting. The progress on such a time-sensitive project is beyond our expectations, and the team at Charles River Laboratories is really embracing our sense of urgency.

- Global Healthcare Company

UNITED STATES

- Malvern, PA
- Wayne, PA
- Wilmington, MA



EUROPE

- Ballina, Ireland
- Châtillon, France
- Cologne, Germany
- Erkrath, Germany



40,000

testing reports delivered to
clients every year

100,000+ tests performed per year

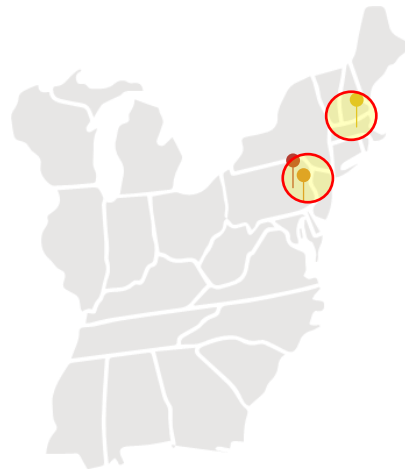
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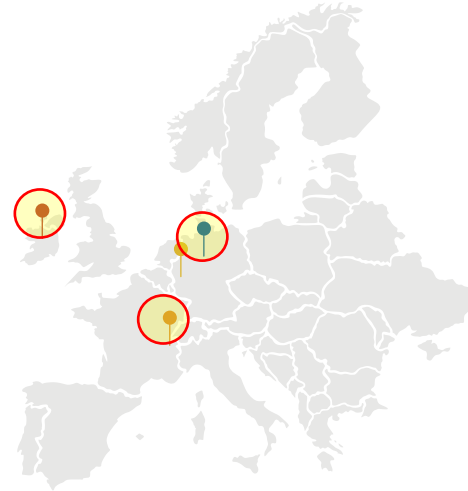
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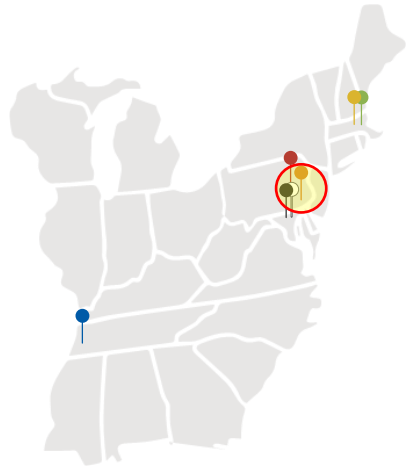


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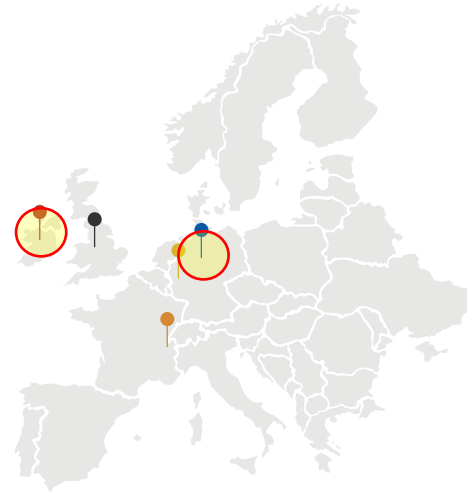
Our Locations

Global In-vitro Bioassay / Potency Assay



UNITED STATES

- Malvern, PA
- **Wayne, PA**
- Wilmington, MA
- Shrewsbury, MA
- Memphis, TN
- Baltimore, MD
- Rockville, MD



EUROPE

- **Ballina, Ireland**
- Châtillon, France
- Cologne, Germany
- **Erkrath, Germany**
- Keele, UK

Leading Experts associated with specialist and industry consortium groups to guide your studies

- Assays for **monoclonal antibodies**
- Assays for **Cell therapy** products
- Assays for **Gene Therapy** products
- Potency Assays for **Cytokines** and **Hormones**
- Cytotoxicity, cell survival and apoptosis assays
- Assays for **Toxins**
- Assays for **Vaccines**

- Thousands of GMP routine analyses each year
- > 45 active methods
- >12 validations / qualifications of new methods
- 1-3 GMP transfers
- 2-5 new ATMP projects

With so much at stake,
select a partner with the capacity
and capability to deliver.

mark.jones2@crl.com

www.criver.com

877.CRIVER.1




charles river

Backup

4/13/2026



In vitro Bioactivity Assays

Readouts and Statistical evaluation, Devices and Automation, Software

Assay Readouts

- + Fluorescence (including HTRF)
- + Absorbance
- + Luminescence
- + Analysis by flow cytometry
- + qPCR

Statistical evaluation

- + Parallel line analysis
- + Four parameter fit
- + Five parameter fit
- + EC₅₀ determination
- + Equivalence test

Devices

- + 4 Plate Readers (Tecan)
- + 1 Plate Reader (Molecular Devices) in 2025
- + 4 Flow Cytometers (BD)
- + 1 qPCR Cycler (BioRad)

Automation

- + 1 Nucleic Acid Purification Device
- + 1 Electroporation Device (plate-based)
- + 1 Cell Counter
- + automated pipetting / liquid handler ordered
- + Plate washer (in 2025)

Software

- + PLA
- + SoftMax Pro
- + JMP

In vitro Bioactivity Assays

Timelines

- + Setup / Familiarization (nonGMP)
 - + approx. 8 runs
 - + approx. 10 weeks
- + Optimization (nonGMP)
 - + dependent on number of runs, typically 1-2 per week
- + DOE
 - + approx. 8 weeks
- + Transfer (GMP)
 - + approx. 15 tests
 - + approx. 6 -8 weeks
- + Validation (GMP)
 - + approx. 30 tests
 - + approx. 12 weeks
- + Routine (GMP)
 - + approx. 4 weeks