\/ RoukenBio

GMP-ready potency assay development

Our team has decades of experience in designing, developing, and conducting potency assays.

Why choose RoukenBio to develop your potency assay?

- Expert-led guidance on phase-appropriate assay methodology
- Design of custom reporter cell lines and bioassays for any mechanism of action
- · Potency assay method development to support phase 1 clinical trials and batch release
- Provision of qualified GMP-ready potency assays
- Confirmation of reporter bioassay suitability and performance against primary cell models



Limited accuracy assessment at expected qualification range of assay

Cell-based potency assay developed for a monoclonal antibody therapeutic. Luminescence endpoint established using target cells engineered to constitutively express the target antigen and luciferase as a viability marker. Cell death by ADCC is observed via a decrease in luminescence signal. Two assay runs were conducted to provide an early indication of accuracy and precision over the intended qualification range of the assay.

Run	Target Potency (%)			
	50	100		200
1	48.2	95.1	95.2	177.5
2	55.0	100.1	98.7	205.2
Maximal Inaccuracy (%)	+10.0%	-4.9%		-11.2%
Precision (%GCV ¹)	9%	3%		10%





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RoukenBio - The CRO redefined

Backed by our brilliant minds, we have turned the traditional CRO model on its head, by fostering a collaborative and personalised approach. Our mission is simple:

Solve problems. Deliver quality data. Propel your drug discovery breakthroughs.

United by a passion to make sense of complexities and overcome challenges, we apply our specialised knowledge to big-picture thinking. We will explore every option to deliver over and above for your project.

We are thought leaders with a deep understanding of immunology, bioassays, molecular biology and a track record of groundbreaking discoveries and novel cell-based tools.

Contacts

