BioReliance®
Contract Testing Services

MERCK

Technical Seminar

Biosafety & Quality Control of Cell Therapies

Wednesday 2nd December 2026, Saxocell, TUD Dresden

Time	Subject
11:00-11:15	**Registration**
11:15-11:30	**Welcome and introduction to BioReliance® Contract Testing Services** • Services and modalities supported • Global facilities including introduction to new Darmstadt site
11:30-11:45	**Overview of evolving regulatory landscape for cell and gene therapies** • High level overview of QC related guidance issued by key global agencies/Pharmacopeia and where these apply in the manufacturing process (2020-current)
11:45-12:30	**Overview of QC testing expectations for cell lines used to produce viral vectors used in cell and gene therapies e.g. lentivirus** • Highlight regulatory updates (e.g. ICH Q5A Viral Safety) and expectations for MCB, WCB and EOPC testing • Changing technology for cell line characterisation (CLC) and ethical / sustainable approaches (3Rs)
12:30-13:15	**Lunch & networking**

13:15-14:00	**QC testing requirements for viral vector mediated cell therapies**
	• Using lentivirus example, outline of biosafety and analytical testing requirements
	  • Relevant regulatory updates will be highlighted as well as differences in expectations for LV used for *ex vivo* versus *in vivo*
	• Rapid release testing required for autologous cell therapies e.g. *ex vivo* CAR-T
	  • Options for rapid microbiological safety and viral safety methods
	  • Autologous product release testing (APRT) operational processes within BioReliance® Contract Testing Services
	  • Regulatory expectations for use of rapid, alternative approaches
	QC for non-viral mediated cell therapies
	QC testing expectations for mRNA/LNP delivery vehicles, with a focus on emerging sequencing technlogies for QC testing

14:00-14:10	**Q&A**
14:10-14:15	**Closing remarks**
14:15-14:45	**Post-event networking**

The life science business of Merck operates as MilliporeSigma in the U.S. and Canada.
© 2020 Merck KGaA, Darmstadt, Germany and/or its affiliates. All Rige hdt.s MRerscekr,v the vibrant M and BioReliance are trademarks of Merck KGaA, Darmstadt, Germany or its affiliates. All other trademarks are the property of their respective owners. Detailed information on trademarks is available via publicly accessible resources.
MK_FL3761EN 2019-21555 04/2019