

Eurofins DiscoverX Grants Bioassay Certification to VelaLabs of Austria

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Eurofins DiscoverX announces partnership with VelaLabs through their Certified CRO Program for PathHunter® Bioassays that will enable VelaLabs to perform highly reproducible potency lot release assays under GLP/GMP conditions

Fremont, CA – February 24, 2020 – Eurofins DiscoverX, the products company of Eurofins Discovery, today announced their partnership with VelaLabs of Vienna, Austria, in which Eurofins DiscoverX is granting the status of Bioassay Certified CRO to VelaLabs as a certified provider of PathHunter® assay services. VelaLabs has successfully demonstrated their capability to expeditiously implement client-sponsored GLP validation programs that use the PathHunter platform.

Eurofins DiscoverX recently launched their CRO certification program to support the needs of biotech and pharma companies to partner with CROs and CDMOs that can seamlessly and expeditiously run potency lot release programs for bioinnovator and biosimilar drugs. This certification provides biopharma developers a transparent platform to access experienced CROs, while at the same time broadening and connecting the network of key stakeholders involved in successful drug development. To obtain this CRO certification, Vela Labs has proven to successfully transfer multiple client-sponsored assay methods using the PathHunter platform, resulting in highly reproducible cell-based potency lot release assays for complex biologics.

This certification program plays a critical role, as biopharma product developers have to prove their drug products are safe and effective (potent). The development of the potency assay starts during the preclinical phase. The potency assay is optimized while the product moves through downstream development, and is typically fully validated by the time an IND is filed. Potency can be determined via a binding assay, however, regulators prefer the use of a functional assay that mimic conditions in living cells when the molecule allows for it. Functional potency assays are performed utilizing cell-based assays, such as the PathHunter assays developed and produced by Eurofins DiscoverX.

“PathHunter bioassays are being adopted by top global pharma and biotech companies as mechanism of action (MOA)-reflective functional assays for potency lot release studies. The simplicity of the platform, coupled with a broad menu, makes it attractive for our clients to drive their drug molecules for filings by using the assays. We are delighted to work with VelaLabs, a leading clinical CRO, and excited that they are the first CRO to gain this certification. This certification should provide a more seamless transfer of assays. We will continue with our mission to provide easy to implement, simple qualified MOA-reflective assays that enable transfer to CRO’s as seamlessly as possible,” stated Sailaja Kuchibhatla SVP and General Manager of Eurofins DiscoverX. “It is a pleasure for us to bring our previous expertise with the PathHunter platform into a long term collaboration with Eurofins DiscoverX,” said Markus Roucka, Managing Director of VelaLabs.

For more information on Eurofins DiscoverX's CRO Certification program, visit discoverx.com/crocertainment

About Eurofins DiscoverX

For drug discovery and development scientists, Eurofins DiscoverX is the trusted product solutions provider that can accelerate your programs with confidence with qualified reagents, cell lines, and assays ready to run today.

Eurofins DiscoverX develops and manufactures cutting edge assays, stable cell lines, membrane preps, enzymes, and reagents for drug discovery and development from our 3 R&D and manufacturing centers of excellence – San Francisco Bay Area California; St. Louis, Missouri; and Poitiers, France.

Rediscover how Eurofins DiscoverX expertise and trusted products accelerate your programs and enable you to take your drug to the next phase with confidence. With end-to-end support every step of the way for your programs from Discovery to QC lot release.

Eurofins DiscoverX is the products brand of Eurofins Discovery, the leading drug discovery products and services provider. For more information, visit <https://discoverx.com/home>

About VelaLabs

Founded in 2006, VelaLabs is a world -wide acting, GMP-certified and GCLP-compliant contract laboratory that offers in-depth analytical characterization services for pharmaceuticals including proteins, biosimilars, hormones, monoclonal antibodies and peptides. Combining a focused, customer – orientated approach, a highly motivated team and a broad expertise in analytical development and quality control, VelaLabs supports its customers starting from exploratory research activities over preclinical & clinical phases up to product commercialization and market release in Europe.

VelaLabs became a member of the Tentamus group in 2016 and is headquartered in Vienna, Austria.

For more information, visit <https://www.vela-labs.at/> or www.tentamus.com