

Solving the
complexity of
compliance



revvity

Compliance solutions with multimode plate readers,
enhanced security software, and commissioning services

Guiding you through the process

Reaching compliance according to the laws and regulations of each country can be a tedious, complicated process, and being GxP* compliant is necessary for delivering therapeutic treatments to market. Pharmaceutical and biotechnology companies, including clinical research organizations, need to have well-defined standard operating procedures (SOPs), reliable instruments, compliant software, validated assays and systems, and testing procedures to ensure everything performs at an optimal level.

Simplify compliance for your VICTOR Nivo™, EnVision™ XCite, or EnVision Nexus™ multimode plate reader with the help of our Enhanced Security software. In addition, our wide range of assays can help you achieve your research goals, and our qualification services will make sure your multimode plate reader and software are operating at the recommended technical specifications.

Ready to get started? We can help guide you through the complexity of the compliance process with our proven solutions, customer training, and technical support so you can focus on your science and research.



**Refers to "good practice" guidelines established in a regulated market such as good manufacturing practice (GMP) or good laboratory practice (GLP) when dealing with electronic records detailed by the FDA, EU, or WHO. Exact designations and terms may vary.*

†Can include GLP, GMP, 21 CFR p11, EU Annex 11, etc.



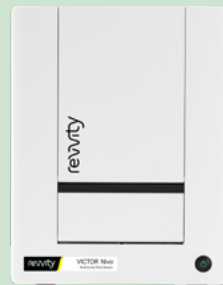
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VICTOR Nivo multimode plate reader

The VICTOR Nivo™ multimode plate reader is a fully equipped, high-performance, filter-based system with all the major detection modes you need for everyday biochemical and cell-based assays. It's a compact, lightweight unit so you can free up valuable lab space for other activities.

In addition, the VICTOR Nivo system features optional Enhanced Security software that contains easy-to-use tools to help you reach compliance for 21 CFR Part 11 and EU Annex 11.

[Learn more](#)



EnVision XCite multimode plate reader

The EnVision™ XCite multimode plate reader offers multimode detection capabilities for target-based screening. With the combination of filter based and monochromator based detection, the EnVision XCite provides the flexibility required for busy multiuser labs - increasing productivity and elevating confidence in your scientific results.

In addition, the EnVision XCite system features optional Enhanced Security software that contains easy-to-use tools that help you reach 21 CFR Part 11 and EU Annex 11 compliance.

[Learn more](#)



EnVision Nexus multimode plate reader

The EnVision Nexus™ multimode plate reader provides lightning speed and superior sensitivity across all detection technologies. It is the new standard in high-throughput screening on a brand-new innovative platform for your most demanding applications.

In addition, the EnVision Nexus system features optional Enhanced Security software that contains easy-to-use tools to help you reach compliance for 21 CFR Part 11 and EU Annex 11.

[Learn more](#)



Software you can trust

Our multimode plate readers feature an optional Enhanced Security software that contains easy-to-use tools to help you reach compliance for 21 CFR Part 11 and EU Annex 11.

Software is not compliant without the development and implementation of other elements. To better support your standard operating procedures, we included useful features for our Enhanced Security software, plus additional services and support.

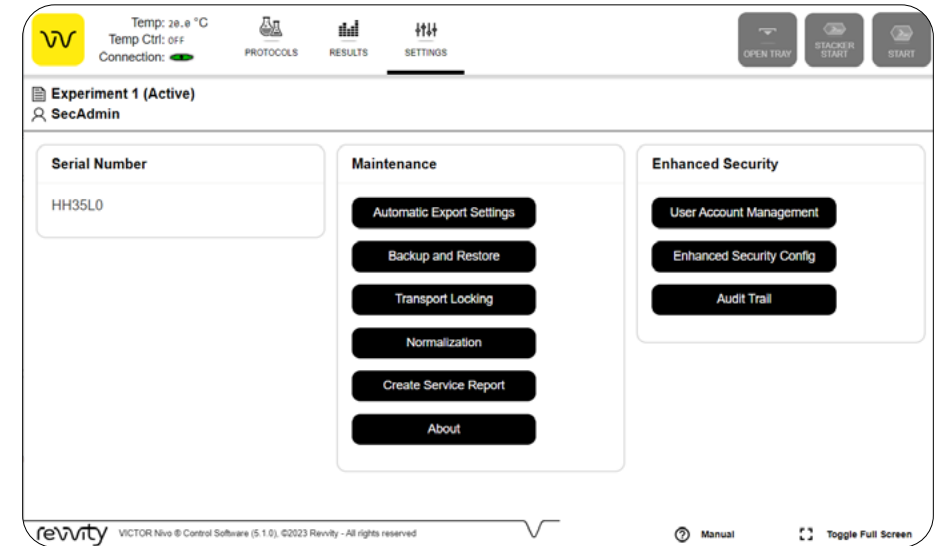
Key features include:

- User management
- Audit trail
- Electronic signatures
- Reasons for change
- Additional audit trail viewer for remote access

Our services include:

- Commissioning Services
 - Installation Qualification (IQ)
 - Software Qualification
 - Operation Qualification (OQ)
- Performance validation for assay
- Declaration on certification for R&D and manufacturing
- Consultation to align multimode plate reader to your company's SOPs

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VICTOR Nivo settings screen for Security Administrator





Quality assurance brings peace of mind

Once you receive your multimode microplate reader, one of our local, highly trained service technicians will install it for you. At that time, the Enhanced Security software license will be activated and you will have access to your control software. The system will then be ready for integration into your regulated environment and your company's network. In addition, our qualified experts will provide multimode plate reader training to your staff.

Over the lifecycle of a multimode plate reader, several qualification tests are performed. These tests ensure the instrument is performing optimally. Revvity performs these qualification tests and provides you with certificates as proof of GxP compliance.



| *Revvity will provide you with certificates as proof of compliance.

► Installation qualification (IQ)

This test is done during the instrument installation phase. The goal is to verify the multimode plate reader was delivered as ordered, functional, and properly set up. Also, we'll ensure all necessary documentation is available as well.

► Software qualification

This test is performed during the instrument installation phase. The goal is to verify the multimode plate reader software was delivered and installed as ordered, functional, and set up accurately.

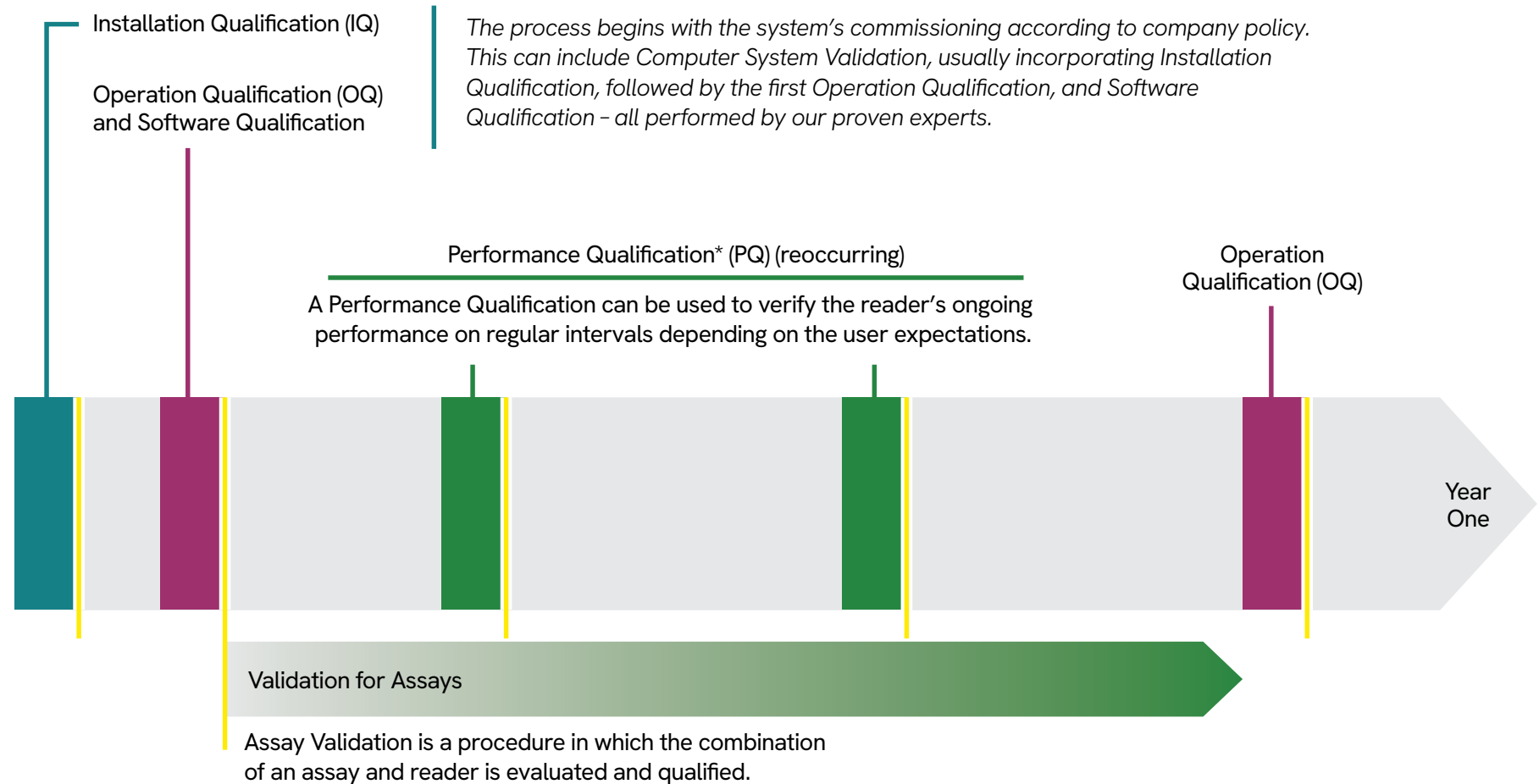
► Operation qualification (OQ)

This test verifies the multimode plate readers are performing to the standards as described in the specification sheet or user requirements. The OQ is a reoccurring process, recommended to be performed on a yearly basis.



Validations and qualifications for total compliance

Integrating a multimode plate reader into your GxP lab involves different validation and qualification steps. We can perform these services for you and certify your reader is performing at its optimal specifications.



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**Performance qualification can be performed daily/weekly/monthly based on your established SOPs. Please reach out to your local Revvity representative to see how we can support your regular performance qualification.*

Assay technology made simple

Multimode plate readers work hand in hand with assays to yield the results of an experiment in GLP environment or manufacturing test in GMP setting.

For this assessment, an assay is calibrated along with all relevant parameters such as dynamic range, LLD, and ULD. This ensures the proper foundation is established and your test results moving forward will be consistent and accurate.

From off-the-shelf kits to custom labelling to complete development, we can assist you in creating these necessary tests.

Learn more about our [drug discovery reagents](#).

Microplates

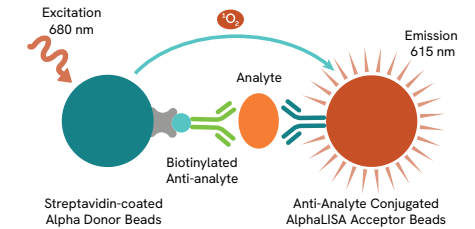
With our years of experience in high-throughput screening, our expert team has developed microplates that address the most common screening challenges. Our microplates have been engineered to deliver the highest quality data for high-throughput screening as well as imaging applications.

[Learn more](#)

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ALPHA

This bead-based, no-wash alternative to traditional technologies provides a wider dynamic range and faster time-to-results.



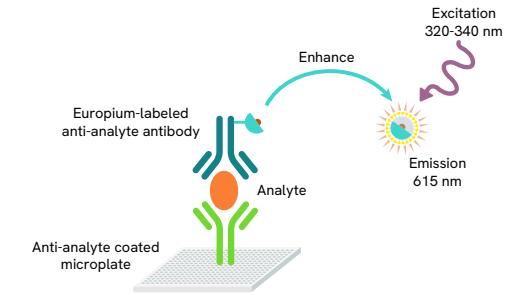
TR-FRET

HTRF® and LANCE® Ultra™ are homogeneous proximity assay technologies that combine the benefits of time resolution (TR) with fluorescence resonance energy transfer (FRET).



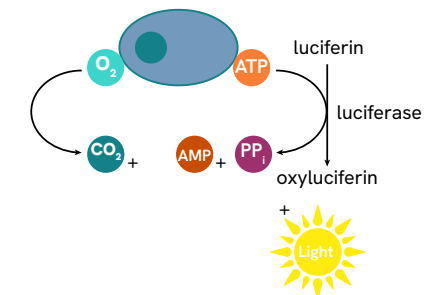
TRF

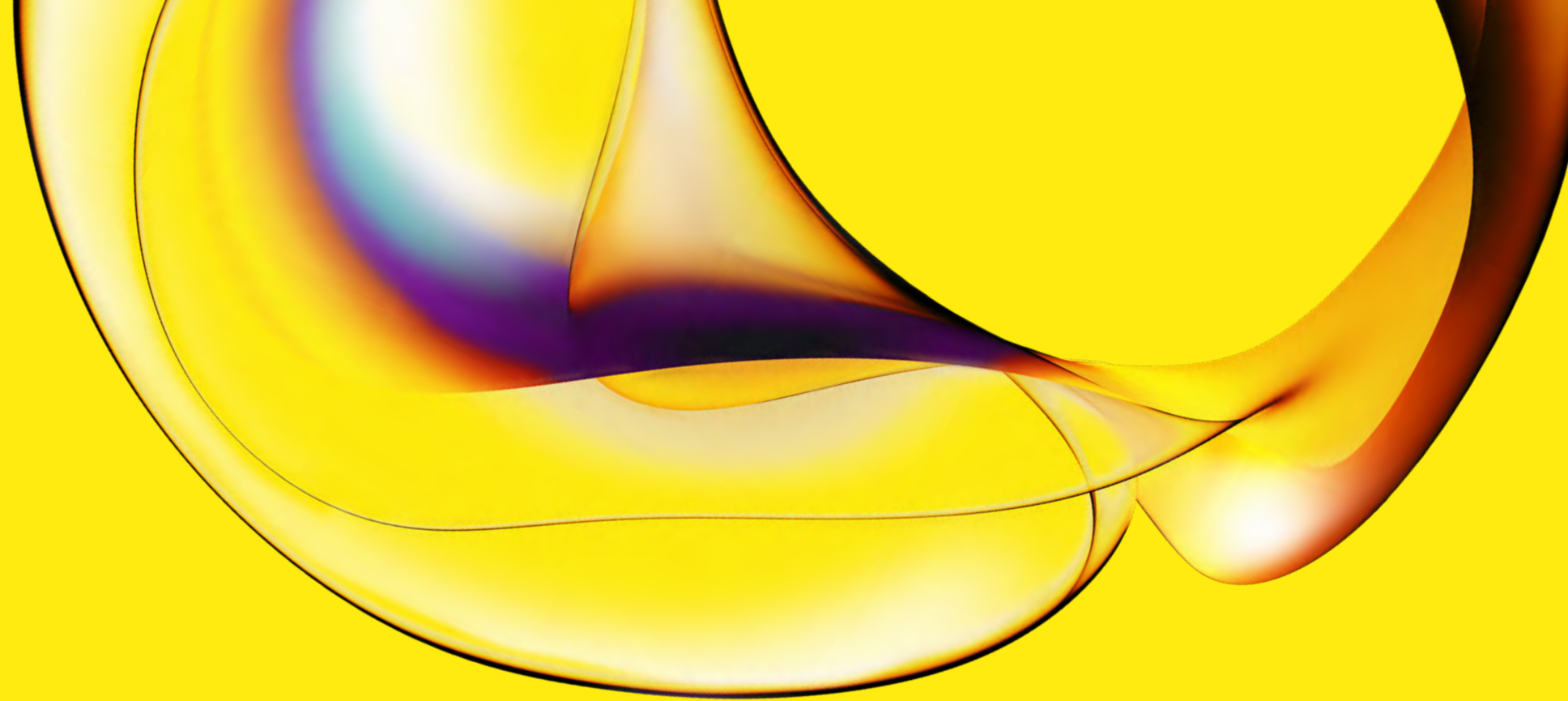
DELFLIA® TRF (Time-Resolved Fluorescence) is a proven, robust immunodetection platform with a similar assay principle to that of a traditional ELISA, but with the added benefits of utilizing a lanthanide chelate to reduce background and improve assay dynamic range.



Luminescence

Luminescence assays like reporter gene, cytotoxicity, and cell proliferation assays allow for the study of transcriptional gene expression, virus life cycles, and cell viability with simple, reproducible results over a wide dynamic range.





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