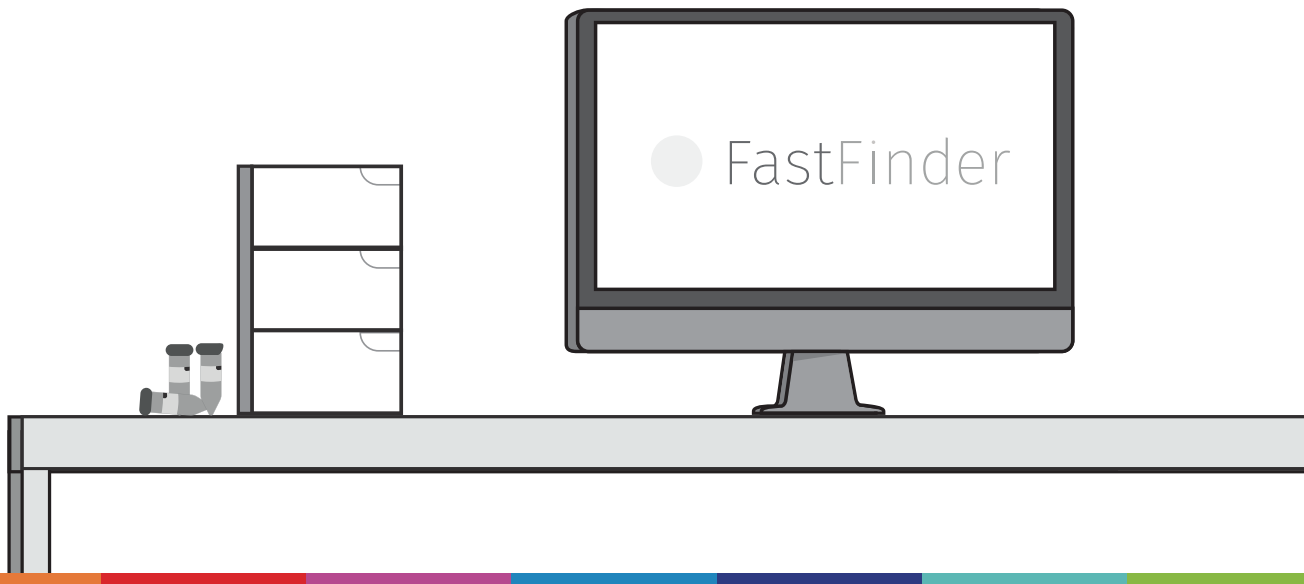
» *Quality and Regulatory compliance with **FastFinder***

Importance of regulatory compliance in Molecular Diagnostics

» Regulatory compliance is a key concern for molecular labs operating in the diagnostic space. Especially now that regulations are undergoing change in different geographies, including the US, Europe, and China. In Europe, the implementation deadlines for the new IVDR regulations are around the corner. In the US, new guidelines on LDTs are in draft. In a complex and changing regulatory environment, labs are facing changing business risks in a space that requires them to extend responsibilities in addition to their core competencies.

Alternatively, labs choose partners that provide them with the right tools to build a compliant, reliable, scalable and effective lab infrastructure. UgenTec is a reliable partner for labs that want to rest assured their software environment supports their compliance requirements.



FastFinder supports your regulatory compliance

» In this brief overview, we will discuss how the FastFinder platform supports compliance in a clinical setting, and cover:

- How UgenTec supports diagnostic labs and Molecular Diagnostics companies with global IVD registrations and approvals of its analysis software (EU - IVDR, US - FDA, AUS - TGA, CAN - Health Canada) How FastFinder is built under an ISO13485 Medical Device Quality Management System
- How the FastFinder software platform is built under a strict Medical Device Quality Management System, compliant with ISO 13485:2016 and 21 CFR Part 820
- How we implement requirements regarding security and traceability, guided by CFR 12 Part 11 with regard to document trailsdocument trails

IVD registration and approval of kits with integrated decision support software

If you're bringing a test to market, you can rely on UgenTec as a trusted partner to support you with the IVD registration or approval of your assay and the data analysis and interpretation support software linked to its result generation.

This expertise is not just limited to assisting with FDA submissions. UgenTec has the necessary experience with IVD registrations and/or approvals, including our analysis software, in the EEA, US, Australia and Canada.

During this process, UgenTec collaborates closely with assay developers. As an assay developer, you will typically incorporate the FastFinder software's "Assay Plugins" in your assay development project - or extend an existing assay with FastFinder capabilities and submit an IVD registration and or approval, such as, but not limited to, a 510(k) in the case of FDA.

UgenTec has well established expertise and experience to assist you with input to your IVD registration/approval file, **including documented risk management**, full Assay Plugin **design documentation**, the necessary **reference numbers**, and a well-documented **Design Master File**.

An ISO13485:2016 and 21 CFR Part 820 compliant Quality Management System

UgenTec builds its FastFinder software platform under an ISO 13485:2016-accredited medical device Quality Management System. This means we have a strong, documented and externally audited framework in place to ensure we conceive and create software that meets the customer's requirements, as well as regulatory requirements for medical device software. Our Product Life Cycle (PLC), i.e. how we collect customer input and requirements, how we design and specify our software, how we document, develop and test it, how we validate, verify and deploy it, and how we maintain and support it, is compliant with IEC 62304 an international standard on medical device software - software life cycle processes. UgenTec has a Post Market Surveillance program in place to ensure our platform performs at high standards, and have strict procedures to deal with software issues, assess their impact and correct and prevent them.

Audit trails, documented user actions, and robust authentication and authorisation

To ensure secure access to your own data, the FastFinder platform is built with a user-centric authentication and authorisation model, which enables features like 2-step validation (where a result by 1 operator has to be confirmed by a second scientist) and audit trails. For example, whenever a user overrides an assay result in the software through the "Resolve" function, she/he is required to enter a rationale, which is stored in the audit trail for future reference.

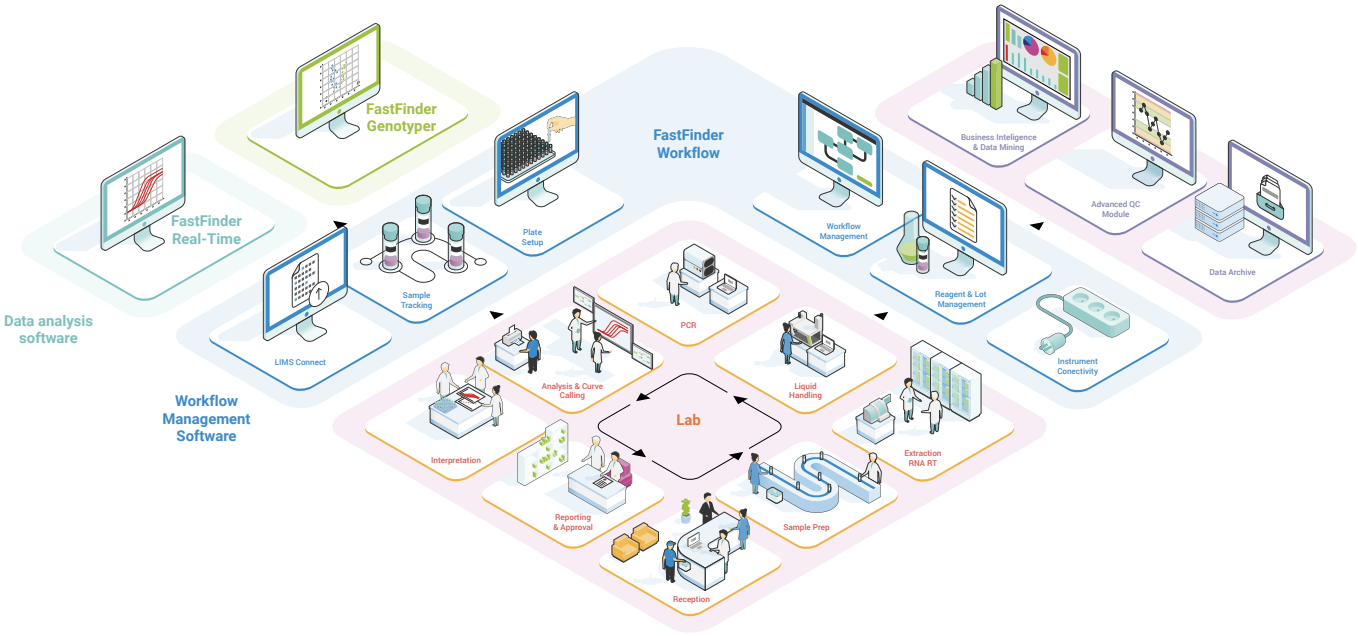
To learn more about UgenTec's security and traceability measures, consult our security white paper or our primer on hosted solutions.

All relevant actions and/or changes are documented in the FastFinder audit trails, which are US CFR 21 Part 11 and Eudralex Annex 11 compliant.

Conclusion

» With FastFinder, you get access to a powerful platform that is built from the ground up with quality and regulatory compliance in mind. Equally, you'll be able to rely on an experienced team of experts that will help you with the software portion of your IVD submissions to regulatory instances. And you'll be able to rest assured that UgenTec's FastFinder platform supports your lab or diagnostic kit provider in its compliance needs.

UgenTec



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