SOLUTIONS BRIEF

Helix ALM for Life Science

Trace and Track All Development Assets for Complete Project Visibility

Life science organizations face constant challenges from competitors, government regulations, international standards, productivity and quality issues, and more. To remain competitive, these organizations must reduce compliance overhead costs, streamline R&D processes, and accelerate time to market.

Perforce's Helix ALM (formerly TestTrack) traces and tracks all development assets, helping life science organizations achieve complete project visibility with total validation confidence.

Perforce Helps You Trace and Track:

- Artifact relationships
- Customer complaints
- Deviations
- Digital assets
- Feature requests
- Reporting
- Requirements
- Risk
- Source code
- Test plans and procedures
- Traceability matrices
- User stories
- Validation and verification
- Work items

With a seamlessly integrated solution, you will gain superior traceability and visibility throughout the entire product development lifecycle—enabling your engineering teams to collaborate and promote better decision-making.

As a result of this integrated development approach, you will be able to easily document and defend FDA, IEC, and ISO regulations and standards.

Requirements and Risk Management

Requirements mistakes and scope creep can have the costliest effect on product quality and budget.

Helix ALM manages the complete requirement lifecycle from concept to production, including planning, analysis, decomposition, workflow, traceability, review, change control, and reporting.

Helix ALM helps teams keep development projects on track by facilitating collaboration, automating traceability, integrating and mitigating risk, and satisfying compliance needs. With hundreds of requirements and development items to manage, Helix ALM not only establishes design control but also provides intuitive ways — such as a dynamic traceability matrix and project dashboards — to help you organize and analyze information quickly.

Test Planning and Management

Today's life science products are becoming increasingly more complex, with aggressive development schedules. Verifying and validating these products requires hundreds to thousands of unique test procedures, the time to execute them, and the ability to efficiently manage the results.

Helix ALM manages your entire testing and QA process, including planning, protocol creation, scheduling, execution, measurement, and reporting. With Helix ALM, you'll know what has been tested, what hasn't, and how much effort remains to deliver a quality, compliant product.

Helix ALM can also help demonstrate a repeatable, accurate testing process, provide detailed historical reporting, data and results, and ensure all information is secure and protected from unauthorized access. When quality is important and objective evidence is required, Helix ALM is essential.

Perforce Life Science Solutions

Issue and Task Management

Helix ALM puts improved quality, communication, and reporting within reach. Tracking work items, issues, and feature requests is a critical component of any development and quality control process. The earlier and quicker issues are resolved, the lower your development cost and the higher your product quality. Helix ALM allows users to read, modify, comment on, and reassign issues according to pre-set business rules and roles. Helix ALM logs every user action in an encrypted, checksum-verified database to ensure a compliant records management process.

Professional Services

Perforce's professional services team can provide configuration, implementation, reporting, validation, data migration, and training, helping you implement a traceable, compliant, and effective end-to-end solution for your product development lifecycle.

With experience in the medical devices sector, and years of working with small start ups to large life science organizations, our professional services team provides industry best practices blended with your current procedures for a more automated and tailored solution.

Our solution engineers can also configure the software to meet or exceed FDA regulations for 21 CFR Part 11, Part 210, Part 211, Part 820.30, IEC 62304, IEC 60601, ISO 14971, ISO 14385, and cGMP. They can also help with internal validation and completing GxP assessments.

We will work with you to deliver a solution that reduces human errors, creates greater visibility, improves daily efficiencies, automates documentation, saves valuable time, and streamlines the auditing process for your organization.

Select Life Science Customers

- Alere Informatics
- bioMérieux
- Bio-Rad Laboratories
- Bracket Global
- Clarity Medical Systems
- Fractyl Laboratories
- HeartFlow
- Hologic
- ICON
- NDS Surgical Imaging
- Medivation
- Medtronic
- St. Jude Medical
- vRad
- Ximedica
- ZOLL

About Perforce

Enterprises across the globe rely on Perforce to build and deliver complex digital products faster and with higher quality. Perforce is best known for its highly scalable version management and collaboration platform that securely manages change across all digital content – source code, art files, video files, images, libraries - while supporting the developer and build tools your teams need to be productive, such as Git, Visual Studio, Jenkins, Adobe, Maya and many others. Perforce also offers complete project lifecycle management tools to accelerate a project's delivery cycle by linking the requirements, test plans, source code, and helpdesk in an integrated platform. Perforce is trusted by the world's most innovative brands, including Pixar, NVIDIA, Scania, Ubisoft, and VMware. The company has offices in the US, the United Kingdom, Germany, Canada and Australia, and sales partners around the globe. For more information, please visit www.perforce.com.

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