



Certification and Validation of Polarion Processes

Nick Entin, VP R&D

Welcome - Willkommen – Vítejte – Accueil – Tervetuloa – Welkom – Bienvenida – Benvenuto – Karşılama - 歡迎 - स्वागत - Boas-vindas

Certifications, Audits and Assessments

- Certifications
 - Prove that Polarion's development process is compliant to expected standards. Customers in specific branches have confidence of possibility for certifying Polarion for their needs and use-cases
- Audits
 - Customers make strategic decisions on investing in Polarion, they need to be sure Polarion is scalable to their extend, have solid infrastructure and risks of disaster are minimized
- Assessments
 - Those help to objectively analyze level of maturity and prepare steps for improvements

Certifications

**ISO 26262/
IEC 61508/
EN 50128
Qualification by
TÜV NORD:**

"We're just thrilled about Polarion's tool qualification for ISO 26262. This saves us a lot of time and money in our own qualification process."

Maria Eugenia Zuniga, Quantum Technologies



Audits

The audit reviewed the following areas as defined in the audit agenda:

1. General Organizational Information
2. High-level Product Demonstration
3. General Information/Quality Management System
4. ISO 26262 certification
5. Software Development Life Cycle (SDLC) Processes
6. Code Escrow
7. Coding Standards Process
8. Testing Strategy
9. CFR 21 Part 11
10. Release Management Procedures
11. Configuration Management
12. Software and Application Security
13. Training and Vendor Management
14. Maintenance and Support/Help Desk

Audits



Auditor Comments

During our review of Polarion, the following was noted:

1. Polarion has a strong quality management system with very detailed Standard Operation Procedures (SOPs) that govern the company's behavior.
2. Polarion has strong knowledge of 21 CFR Part 11 to ensure they are up to date with current regulatory obligations. These aspects are integrated into their development and testing strategy for their ALM product. Polarion is pursuing additional industry recognized certifications to further demonstrate their commitment.
3. In our professional opinion, Polarion demonstrated a very high degree of rigor and preparedness for the audit. The Polarion team was very well prepared, aligning the right personnel to answer all of our questions in a concise manner and providing in-depth supporting documentation. Furthermore, Polarion was very transparent and forth coming with their current state processes and future state plans, particularly in identified areas of improvement including developer peer reviews and application security. While the organization is quite small, they have assembled a competent team that has a razor sharp focus on continuing to deliver a market leading product. We also observed a concerted effort by the Product Management and the Customer Services organization to engage with Polarion's clients through a continuous feed-back mechanism regarding product improvements, enhancements as well as a well-designed process to track and resolve user issues.

Assessments

- Self-Assessments
 - Features or practices, e.g.
 - CFR 21 part 11, digital signatures
 - Variants
 - Scalable Agile
 - Processes, e.g.
 - Customer satisfaction
 - Early-access-program
- External Assessments, e.g.
 - Scrum
 - Test-Driven-Development, Behavior-Driven-Development

Thank you.