

Precision Systems, Inc.

SUPPLIER QUALITY PROFILE

Name of Supplier: Precision Systems, Inc.

Address: 453 Easton Road

City: Horsham

State: Pennsylvania

ZIP: 19044

Name of parent co. if any: None

Number of years in business: Twenty-five (25) years in business

President: Walter P. Johnson

Phone#: (215) 672-1860 x20

Form of business organization: Pennsylvania Corporation

Principal products and services

Software engineering, design, and development servicing the pharmaceutical, semi-conductor, process control, and telephony markets. Provides full life-cycle approach to development.

Follows ISO, cGMP, and Title 21 CFR Part 11 development standards.

Development in Assembly, C, C++, .NET, JAVA, JAVA Script, VB, VBA, XHTML, HTML, OPC, COM/DCOM, DLL, and numerous other languages, scripting, databases, DCS systems, and development systems.

All project designs and development are organized using an object-oriented approach.

Development projects include: PC systems, embedded, and real-time design and development of custom systems for applications ranging from Graphical User Interfaces, to control and monitoring systems, to embedded real-time critical systems.

PSI is a software engineering firm that has devoted it self to providing customers with quality software systems that exceed customer requirements. Our diverse background in PC and embedded microprocessor development provides the customer with products that are superior to their competitors. All software engineered pharmaceutical systems follow ISO standards, cGMP requirements, and Title 21 CFR Part 11 compliance. All phases in development follow the life-cycle approach providing full documentation, development standards, testing, and test results.

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The following are published answers to Frequently Asked Questions concerning PSI and the approach taken to software development.

FAQ's

| QUESTION | |
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| 1. Does PSI have a formal, printed quality policy? | <p>PSI maintains the following SOPs. These documents cover all topics and especially quality control.</p> <ol style="list-style-type: none">1. SOP Software Engineering & Development2. SOP Software Test & Validation3. SOP Change Control4. SOP Configuration Management5. SOP C Language Development6. SOP C++ Language Development7. SOP JAVA Language Development8. SOP VB Language Development9. SOP Assembly Language Development10. SOP DLL Development |
| 2. Is the policy fully supported by top management? | <p>All employees are required to know all company SOPs and are tested on each of them.</p> |
| 3. Do you have a printed quality manual, which spells out how the quality policy will be implemented? | <p>Although quality is covered within the entire document set noted above, the "SOP Software Test & Validation" specifically covers the approach to ensuring a quality-released product.</p> |
| 4. Has top management made a decision to become registered under ISO 9001, 9002, or 9003? | <p>PSI follows all ISO standards for development. For the pharmaceutical industry, PSI follows cGMP and Title 21 CFR Part 11. These standards exceed the ISO standards for software development. Covex LLP has audited PSI for Merck & Co. Inc. and has been approved by Merck & Co., Inc. for pharmaceutical software development conforming to FDA requirements.</p> |
| 5. Is there an ongoing training system for all employees? | <p>All employees are trained in the company SOPs at PSI. In addition, employees are provided with outside training in specific areas.</p> |
| 6. Do you have a formal standard operating procedure manual which outlines how your business is run? | <p>PSI maintains the following plans and documents.</p> <ol style="list-style-type: none">1. Customer Contracts & Non-Disclosures2. Employee Contracts & Non-Disclosures3. Team Member Handbook4. Employee Handbook5. Business Continuity Plan6. Disaster Recovery Plan |

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| 7. | <p>Do have a documented quality audit system to continuously record any efforts to improve product quality?</p> <p>At conclusion of each project an evaluation is performed to determine methods of improvement. After review, approved changes are applied to the company SOPs.</p> |
| 8. | <p>Is corrective action taken on nonconforming software identified by your customers?</p> <p>All software is audited prior to release to ensure conformance to all standards and regulations. All warranties are honored and software is corrected according to the Configuration Management SOP. Evaluation action items are performed to determine if the problem should have been corrected and to determine methods to reduce the likelihood of future problems.</p> |
| 9. | <p>Are your customers advised on that action?</p> <p>Customers are always notified upon detection of nonconformance, resolutions, and action items.</p> |
| 10. | <p>How does PSI manage the software?</p> <p>PSI utilizes a source control system to identify and trace any and all changes to software. This system provides an automated logging and tracking system.</p> |
| 11. | <p>Do the results of training become part of every employee's permanent training record?</p> <p>Every employee is required to read and understand the company SOPs. All employees are tested on their knowledge of the materials. Test results are placed into their permanent record.</p> <p>Outside training is also provided in specific areas and placed into their permanent record.</p> |
| 12. | <p>Is there a designated person who handles customer and product specifications?</p> <p>All received data and materials are recorded and placed in a designated secure area by the assigned project manager. All documentation is archived and/or bound. All released systems follow release SOPs and are archived accordingly.</p> |
| 13. | <p>Is there a designated person or responsible individual who handles technical assistance requests?</p> <p>Technical assistance is managed through the assigned project manager who either provides the information or passes the request to the appropriate team member with the most knowledge in a particular area of development.</p> |
| 14. | <p>Can you supply, without additional cost, certificates of compliance?</p> <p>PSI was audited by Covex LLP for Merck & Co. Inc. Merck has offered to pass along the audit of PSI.</p> |
| 15. | <p>Are all products, or components of products, which you sell to us made within the United States?</p> <p>All designs, documentation, and software are developed by PSI staff in the United States.</p> |
| 16. | <p>Is there a policy concerning product safety and liability?</p> <p>All software is rigorously tested at multiple stages based on the company SOPs. Each line of each method of each module of each program is tested. Systems are both white and black box tested. Within the systems, cGMP standards are followed to ensure all events are recorded.</p> |

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| 17. | <p>Is there sufficient traceability on product features and on product releases?</p> <p>During product development, PSI provides trace ability of features from the test plans back through each step in the life cycle of documents to the URS / FRS.</p> <p>PSI utilizes source code control to track each and every change to any software component of a system. All releases are archived and provide a full history of changes applied.</p> |
| 18. | <p>Do you have documented programs covering incoming, in-process and final inspection of your products?</p> <p>Our SOPs require that during the life cycle of a software product, reviews be held to ensure the quality of documents, code, tests, or test results. Each reviewer is held accountable and is required to approve or disapprove the information presented.</p> |
| 19. | <p>Are there formal procedures regarding the handling of nonconforming materials at all stages of production?</p> <p>With respect to software engineering and the company SOPs, all non-conforming documents, code, tests, or test results must be corrected.</p> |
| 20. | <p>Will the procedures prevent shipment of nonconformities?</p> <p>All development must pass the following as described in the company SOPs:</p> <ol style="list-style-type: none">1. Documented Programmer Development Test results2. Development Test Plan results3. Factory Acceptance Test results4. Site Acceptance Test results |
| 21. | <p>Do you maintain a production/incoming “Hold” or “Quarantine” area, with release procedures, for nonconforming product?</p> <p>Should nonconformance occur prior to release, the condition is documented, corrected, retested, and the customer is notified.</p> <p>Should nonconformance occur after official release, the customer is immediately notified. Direction is then requested from the customer.</p> |
| 22. | <p>Is there a formal procedure to ensure that proprietary item drawings, or customer specifications have been approved in-house, or approved by your customer(s) before production?</p> <p>With respect to software engineering, all documents require signature approvals. The required signature approvals must be provided before continuance of the project. At least one signature is required from the customer before development can continue and customer’s management, prior to start of the project, approves this approach.</p> |
| 23. | <p>If yours is a proprietary product(s), are our customers notified in advance of any design or component changes?</p> <p>If using proprietary software products, either PSI’s or an outside source, the customer is always notified and is required to acknowledge the use of the software component.</p> |

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| 24. | <p>Do either quality assurance inspectors or production employees have the authority to stop production of an item in the event nonconforming product is detected during production?</p> <p>PSI fully backs the philosophy of allowing a reviewer to prevent the release of any software or component should it be non-conforming. All standards of development must be followed.</p> |
| 25. | <p>Are production personnel held accountable for standards of quality for their individual performance in the manufacturing process?</p> <p>Yes. Traceability of development, changes, documented reviews, are all provided within the scope of the company SOPs. All phases of development require signatures or identification.</p> |
| 26. | <p>How do you start a project?</p> <p>Projects generally begin with the URS or FRS describing the product to be developed. Many times PSI is employed to create those documents. A "Project Plan" is created based on the requirements of the URS or FRS.</p> |
| 27. | <p>What's in the Project Plan?</p> <p>The Project Plan defines the management approach to the project and provides a development, test, and implementation schedule. The Project Plan includes:</p> <ol style="list-style-type: none">1. Master Project Plan2. Project Plan for Change Control3. Project Plan for Configuration Management4. Project Plan for Quality Assurance5. Project Plan for Risk Analysis6. Project Plan for Problem Reporting7. Schedule for Development, Test, and Implementation |
| 28. | <p>How do you quote a project?</p> <p>Projects can be quoted as "firm fixed", "cost plus" or "time & material".</p> |