



# QUALITY MANAGEMENT SYSTEM ISO 9001:2000 CERTIFICATION

## Business Success Stories

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## High-Tech Industry

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**siteROCK.com**, a high-tech startup specializing in monitoring of large E-commerce and B2B websites such as CommerceOne, and AskJeeves. Testimonial from Dave Lilly, President: California ISO 9000 Consulting (Caliso Consulting) was essential to siteROCK being registered under ISO 9001 in record time. They quickly and accurately assessed the readiness of siteROCK to pass the final audit by making the intellectual effort to really understand our business processes. This allowed us to focus our efforts on those things that were really needed both to improve our business and to obtain the certification. The detailed plan for implementing their recommendations and pre-audit that they prepared was followed to the letter and resulted in our obtaining registration without any non-conformances, on time, and under budget. Rarely have I worked with a consultant who so clearly took our business objectives as his own. By recognizing the uniqueness of siteROCK's business and culture, Caliso Consulting produced the intended result even when that directly reduced the fees that we would have been willing to pay for the insightful, on target advice that we received. At this point, I am pleased to say that we are not only an ISO registered company, we are a better managed company as a result of Caliso Consulting consulting contribution. We are looking forward to a long and mutually rewarding relationship with them.

**Syndeo**: Testimonial from Syndeo's management: "Syndeo, a high-tech startup specializing in fault tolerant, telco-grade IP telephony applications, decided to achieve ISO 9001 certification to validate its design management system and to distance itself from its competitors. With no employees having direct ISO 9000 experience, we decided to consult with Caliso Consulting. Their help in determining how the ISO standards apply to our company and how to mold our existing procedures into a documented system enabled us to achieve compliance before the first customer shipment. Certifying our design management system allows our marketing group to differentiate our product's quality from our competitor's, a great advantage when dealing with customer's concerns about working with startups. Caliso Consulting's professionalism and ability to be flexible with our fast paced environment were exactly what Syndeo needed to achieve compliance." Actually, Syndeo achieved ISO 9000 certification with TUV of Germany after 5 months of implementation without any nonconformance! The TUV auditor was amazed especially coming from a high-Tech start-up.

**APPRO International** was experiencing unprecedented growth, with new prestigious OEM accounts for computer telephony, data pumps and industrial computers. The ISO certification became pressing to obtain or maintain the approved supplier status with large clients like CISCO Systems, and an upgrade of the management system in order to handle the increased demand was necessary. After trying 2 consulting firms and wasting precious time and money, Caliso Consulting was selected and started driving the implementation of ISO 9001. The task was challenging with the multilingual environment, and the heavy workload of the "Approians". 6 months later, in early April 98, and at approximately 40% of the originally estimated consulting costs by the other consulting firms, APPRO successfully passed their registration audit (ISO 9001) with Underwriter Laboratories (UL). 2 Days later they passed their most strategic customer supplier audit to be approved as a major supplier.



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## Medical Devices and Biomedical

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**BioSurgical**, which manufactures hi-tech medical devices, contracted Caliso Consulting in order to achieve ISO 9001/EN 46001, and CE Certification. ISO 9000 and the medical device supplement EN 46000 are mandatory in order to apply for CE certification. This requirement has been effective since 06/28/1998, as part of the European Medical Device Directive (MDD). The strategy was to achieve ISO/EN to both satisfy FDA/GMP requirements and obtain European Community certification so that the product can be sold in Europe. After 5 months of hard work lead by Steve Briana the Director of Manufacturing Engineering in implementation, and preparing the CE certification dossier, BioSurgical successfully passed their ISO 9001/EN 46001-certification audit with TUV-Essen. The CE certification will follow in the next 2 months.

**BioInterventional**, which manufactures hi-tech medical devices, contracted Caliso Consulting in order to achieve ISO 9001/EN 46001, and CE Certification. ISO 9000 and the medical device supplement EN 46000 are mandatory in order to apply for CE certification. This requirement has been effective since 06/28/1998, as part of the European Medical Device Directive (MDD). In order to start selling the product in Europe as soon as possible, the strategy was to parallel process the CE certification with the FDA approval. After 3 months of quality system upgrade, implementation, and preparing the CE certification dossier, BioInterventional successfully passed their ISO 9001/EN 46001-certification audit with TUV-Essen. The CE certification was achieved a few months later. Their products are now being sold in Europe!

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## Printing Industry

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**Xyan Corp** is a holding of 80 Printing companies throughout the nation. The most important clients in the software and hardware industry, representing 70% of their business demanded ISO certification in order to maintain Olympian as an approved vendor. The implementation work started with Caliso Consulting in October. The implementation added valuable improvement, and efficiency to the operation. In early March 98, Olympian successfully passed their registration audit (ISO 9002) with Underwriter Laboratories (UL).



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## Aerospace Industry

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**TiNi Aerospace**, which manufactures highly innovative shape memory devices used by NASA, JPL and Lockheed Martin for satellites and unmanned space missions such as the Hubbell telescope, contracted Caliso Consulting in order to achieve ISO 9001. The strategy was to achieve certification in order to bring a higher level of efficiency and control to their operation, as well as have the world class ISO 9001 label with a renowned registrar in order to increase their marketing penetration. Michael Bokaie, the dynamic President, and Adam Perkins, the QA Manager, put in their full effort and commitment in order to fully internalize the ISO implementation and make it happen. Caliso Consulting provided full assistance, training and support. On September 1<sup>st</sup>, TiNi successfully passed their certification audit, on time and saved 35% on the budgeted ISO implementation cost.

**Onyx Optics Inc.**, which manufactures unique laser optical components (crystals), was required by government and by large aerospace clients to be ISO 9002 certified. Although, the primary objective was to achieve the certification in a timely and cost-effective manner, Onyx's president, Helmuth Meissner, wanted to use the ISO implementation process to build a better organization. Onyx was experiencing very fast growth, and he knew that his company had to rise to the challenge of becoming a world class laser component manufacturer. He contracted with Caliso Consulting in order to achieve both of his goals. The improvements brought by the careful ISO implementation exceeded Helmuth's expectations. It helped his fast growing company expend effortlessly, and provided higher customer satisfaction to his clients while controlling cost. Certification was also achieved very smoothly with Underwriters Laboratories (UL) on target.

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## Government

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**Offshore International** is a unique service organization, which provides a shelter program for companies that wish to manufacture in Mexico under the NAFTA agreement. They provide facilities, labor, import/export, administration, and facilities maintenance for the client. The client does not exist legally in Mexico. All he has to do is provide the management staff, equipment and proprietary processes, and manufacture his product. He thus benefits from the cheap labor without facing some of the difficulties associated with existing legally or operating in Mexico. Offshore's client base, under the shelter program, consists of over 17 US firms, employing over 11000 employees in the hi-tech, low-tech, biomedical, and automotive industries. ISO 9002 certification was a strategic priority in the stride to climb from # 7 to #1 Maquilladora organization in Mexico and the US. The uniqueness of the services provided made the ISO implementation extremely challenging and beneficial. After 11 months of hard work, both facilities in Mexico, Saltillo and Guaymas, as well as the Tucson, facility were certified to ISO 9002 by TUV with Caliso Consulting as the consulting firm. The operation also became a lot more efficient at meeting the growing demand of its customers, and has enjoyed the increased customer satisfaction brought by better control over its unique processes and services.

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## Distribution Industry

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**Aeris**, a company distributing high-end scuba diving instruments and equipment, started the implementation of ISO 9002 with the help of Caliso Consulting. Although



Aeris was a new company, ISO 9002 certification was strategically critical as a marketing differential advantage, and necessary in order to start on the right foot with an ISO compliant management system. The motivation of all the Aeris team and the positive leadership made the implementation effortless. ISO 9002 certification was achieved in mid-January with SGS International.

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### **Food Processing and wine industry.**

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**Scott Laboratories**, a wine testing and cork processing company, contracted, with Caliso Consulting in order to achieve ISO 9002 certification. Even though Scott Laboratories was already a world class organization, they wanted to reach the next level in efficiency and total quality by adopting a management system compliant with ISO 9000. After the initial gap assessment, the targeted time for reaching the objective was 5 month, and the Scott Lab team led by Phil Penna, the dedicated Cork Operations manager, started working with Saad and his team to implement ISO 9000 requirements in the organization. In November the certification was achieved with flying colors with TUV-Essen as a Registrar.

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### **Service Industry.**

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**EPC Identification Systems and Q-CEE Products**, manufacturers and suppliers of identification systems (labels, stamps etc.), jump started the ISO 9002 implementation process in March 1999. The Caliso Consulting team provided the training, and consulting to a very enthusiastic EPC team. After 2 previous attempts to implement ISO 9000 by EPC in the past 6 years, this time was the right time. On June 30<sup>th</sup>, certification was achieved with flying colors with TUV. Here is what the General Manager, had to say: " Caliso Consulting's professionalism helped our organization visualize and better appreciate the many operational benefits beyond certification that would be realized if we could shift our thinking about how we get things done at EPC. Our group immediately felt comfortable with their approach and as a result we were able to make the important changes that were necessary."

**Trayer Engineering**, a leading designer and manufacturer of electrical switching gears for utility companies, committed in winter 1998 to achieve ISO 9001 by Spring 1999. The objective was to use ISO implementation to improving the management system in order to become the worldwide leader in the switching gear industry. John Trayer, the dynamic president, contracted Caliso Consulting to work with Greg Holmes, the QA Manager, and reach both of those objectives. The team effort and top management's commitment paid off very quickly, and certification was achieved in May 99. The improvements and increase in efficiency for Trayer have been tremendous.

**Glasforms Inc.** was under pressure from their strategic customers the Utility Companies, and customers from the Pacific Rim to be ISO certified. They contracted 2 different consultants over a 6 months period of time. The result was a lot of money spent, discouragement, skepticism and a very inadequate and noncompliant Quality System. As a final attempt they contracted Caliso Consulting. The rates were extremely competitive, the availability, responsiveness and hands-on approach worked wonders. Glasforms was ready within 3 months, on budget, and obtained



their certification at the first audit (ISO 9002). Caliso Consulting then helped get their second facility in Alabama was certified in September 1998

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### **Software and Hardware Industry.**

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**Zoom Tech Inc.**, the servicing center for ACER and AOPEN computer hardware, set a goal to achieve world class quality and obtain ISO 9002 certification in 4 months. They contracted Caliso Consulting in December 98, which started driving the implementation effort with the very dedicated Zoom Tech team. Maurice Chin the committed President, adopted the ISO 9000 standard as his new way of conducting business, and it paid off almost immediately: the operation became a model service center with virtually no customer complaints or product nonconformity. The certification audit with TUV was passed without a single finding, on time and under budget! Even the TUV auditors were amazed....

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### **Telecommunications and IT.**

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**NexTrend Technologies Inc**, the manufacturer of Tangent, NextStar, and NextPC computers interviewed several consulting firms in November 98. Caliso Consulting was the only one that offered real hands-on assistance to obtain certification in less than 6 months, and the consulting program was customized to work with the company's culture and personalities. The implementation started in coordination with Jeff Chen and Chuck Keller the management representative and with full support from the President. In mid-March, 4 months after the start of the implementation, the preliminary audit with TUV went so well that the auditor thought that it should have been a certification audit! Needless to say that the certification audit in mid-April was a formality for NexTrend. They saved 30% on the consulting cost and were certified well ahead of schedule.

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### **Medical software.**

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**Stentor**, which develops very innovative medical imaging software contracted with Caliso Consulting in order to achieve ISO 9001 and EN 46001 certification. Stentor is a startup company on the cutting edge of imaging and high speed Internet information distribution. They wanted to do it right and embrace ISO 9000 and EN 46001 from the get go, and operate in a highly efficient and structured manner from the moment of inception. The certification was timed with the market introduction of their innovative products. The Stentor team started embracing the ISO and EN requirements effortlessly starting July 99, and with efficient and effective guidance and training from Caliso Consulting, they achieved the certification 3 months later, on time for the market release of their product and 30% under budget.

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### **Plastics and Composites Manufacturing.**

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**Darcoid Rubber Company**, a major manufacturer of rubber gaskets and seals for filtration equipment, contracted with Caliso Consulting to achieve ISO 9002 certification within 5 months, at 40% less cost than budgeted cost, and attain a higher level of efficiency and organization. After 4 months of hard and constructive



work with the motivated DRC team, certification was achieved on target with Underwriters Laboratories (UL), without even going through a preliminary audit. The UL auditor was very impressed, and here is what Art Lawrence, the President of DRC had to say: "The ISO 9002 certification and the true economic benefits possible through adherence to the new management system and procedures, would not have been realized without the most competent assistance of Caliso Consulting. They provided the communication skills, organized the project effort, and trained our people from top to bottom so they could adjust to the way business is going to happen after Y2K....."

**Silicon Valley Printed Circuits (SVPC)** a world class manufacturer of printed circuit boards, set a goal to achieve ISO 9002 certification in 6 months and at reasonable cost. They contracted Caliso Consulting in October 98, which started driving the implementation and training efforts with full support from top management. The consulting and assistance of Caliso Consulting was tailored to meet the exact needs of the company without over-burdening their system. The ISO 9000 implementation brought the SVPC team to a higher level of efficiency and cohesion, and culminated with the certification, in early April to ISO 9002 by TUV-Essen. The team effort and effective implementation also resulted in savings of 40% on the budgeted consulting implementation cost.

**APCT**, which manufactures printed circuit boards, interviewed several ISO 9000 consultants in order to achieve registration by December 1998. The motivation for certification was strategic because of the competitiveness of the circuit board market, but also quality driven. Chuck Elsbree, the committed President wanted a better performing system as well as ISO certification. Caliso Consulting was selected and a Gap Assessment was conducted. The conclusion was that certification could be achieved by September 1998 or sooner, and substantial savings in the estimated consulting costs could be achieved if all the Caliso Consulting recommendations were taken in a timely manner. The commitment and responsiveness of the APCT team was so great that the implementation of ISO 9002 went very fast. The certification date was pulled, and APCT passed their registration audit with Underwriter Laboratories (UL) in late August, 4 months ahead of schedule, and at 60% of the originally estimated cost. There is nothing like Management's Commitment to make it happen!

**MP OPTICOM**, which manufactures Fiberoptics couplers and isolators, contacted Caliso Consulting after going through 2 consulting firms in 3 years, and never completing ISO 9001 implementation. The Caliso Consulting team reviewed the Quality System documentation generated. It had been over-documented to point of paralysis! MP and Caliso Consulting worked on simplifying the quality system, and implementing ISO 9001 requirements, which were missed by the two previous consulting entities. The training was parallel processed, and 3 and half months later, on September 30th, MP Fiberoptics passed their ISO 9001 certification audit with TUV. Top Management was ecstatic from the great improvement their latest implementation process brought to their operation, and was rewarded with ISO 9001 registration, and on budget!

**DANALCO**, which manufactures unique and patented waterproof gloves and socks, landed a big order with NATO. But NATO required ISO 9002 certification, or compliance. To be compliant required passing an audit with military auditors coming from Europe. Obtaining the ISO certification with a reknown Registrar was chosen over being audited by NATO... Danalco called Caliso Consulting for help. In a little over 2 1/2 months, the 17-employee company passed the registration audit with



TUV. The big contract went through, and the quality system has also brought structure and improvements to the DANALCO operation.

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## Equipment Industry

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**American Underwater Products** (Oceanic, PPS, ROMI, Design 2002), a holding of diving and life support equipment: Fins, Snorkels, Masks, Suits, Regulators, Analog and Digital Gauges, Computers, Dive vehicles and all kinds of accessories. All the equipment is conceived, built, tested and "Dived" in-house. The worldwide sales network and testing and validation team of OCEANIC set to achieve certification by the end of 1997. A consultant was hired in June of 1997. In late August, progress was minimal, a lot of money was spent, the management team frustrated. Caliso Consulting was contacted and in 2 1/2 months a tremendous amount of work was accomplished, all employees regained confidence, and dropped any skepticism resulting from the previous consultant. The day before Thanksgiving, November 25, 1997, the certification audit ended with a recommendation for certification by the Registrar SGS.