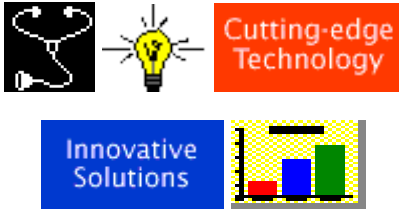


Our Company



IF you want permanent solutions to your regulatory compliance & Lean 6 Sigma challenges, call us TODAY!

Executive Summary

Clients: We work with medical device, pharma., biotech and life science professionals to help them achieve their Regulatory Compliance, Lean Six Sigma and new product commercialization project objectives within demanding deadlines and budgetary constraints.

Why to Work with Us: Clients choose to work with us because they believe we would give them the best chance to successfully complete their project.

The 28+ years of Costas Chantzis' impressive and verifiable accomplishments when he solved technical and business challenges that others had considered unsolvable, his micro and macro experience over the full life cycle of a product and outstanding professional references – sometimes from people the clients know personally – plus our integrity, ethics and overall conduct during the various consultant selection meetings, all of that is unmatched by our competition.

We always seek to exceed our clients' expectations and usually we succeed. Typically, our clients receive tangible benefits that are in addition to the originally agreed to project objectives/deliverables and as a result they recoup their out-of-pocket consulting expenses in record time. Finally, our clients get from us "on the job training how to fish" while others "give them fish."

We have helped medical device, pharmaceutical and biotechnology companies achieve breakthrough quality, regulatory compliance, manufacturing productivity and profitability improvements through our proprietary templates/methods for development and commercialization of new product winners (design controls, failure mode and effects analysis, design history file, validation of product design and manufacturing process), data mining, metrics design, statistical analysis, intellectual property and business analysis/valuation, strategy development, me-too products' repositioning/market differentiation and product/process quality improvements.

Examples of Industrial Accomplishments

[LEAN, Six Sigma, Baldrige Operations, Continuous Process Improvements and Business Performance Improvements:](#)

- Assisted major diagnostic kits manufacturer complete re-validation of numerous marketed products that did not meet minimal FDA requirements, \$3.1 billion in annual sales. Activities included design controls, risk assessment, remediation, product and process characterization, protocols for and review of test method and process validation; equipment installation and operational qualification.
- Demonstrated feasibility for a productivity improvement project to an insulated coated glass manufacturer in just eight weeks. Project involved the development and feasibility testing of a software process optimization program for the cutting, packing, loading and processing of insulated glass and other materials with minimal waste. Potential client savings at \$86 million annually through 8%, 36% and 18% improvements of its cutting, annealing/tempering and coating manufacturing operations, respectively. Exceeded by 260% client's original project target. Resulted in the cancellation of a \$50 million new manufacturing equipment purchase.
- Turned-around the profitability of an electro-mechanical equipment manufacturer, having a 40 people business unit with \$3.2 million annual sales but zero net profit. Performed critical evaluation of the strengths and weaknesses of current mfg., engineering and Q.C. operations and/or depts. Developed and helped to implement recommendations for improving overall productivity, internal and external communications, and resolving operational and other business bottlenecks. Provided alternatives for resolving product design and/or manufacturing defects.
- Helped a start-up manufacturer of patented fiber-optic technology catheter products streamline its operations and untap a new market, a \$7.5 million opportunity. Identified and resolved a number of safety and environmental hazards related to chemicals ventilation and mfg. site's soil contamination. Resolved a number of quality product defects related to calibration and stability of electronic hardware; surface treatment and subsequent adhesive bonding of plastic, glass and metallic product component surfaces. Refocused activities of engineering staff and helped them apply proprietary know-how to other technologies for expanding their product line.
- Assisted sutures manufacturer improve by 52% and 15% respectively its quality and cost. The cleaning, siliconization and drying cycles were reduced to two from twenty four hours. Resulted in \$1 million annual savings.
- Helped medical device manufacturer eliminate a chronic liquid filling product defect and increase its production rate by 20 fold. Resulted in \$300 thousand annual savings.
- Developed Cost of Quality, Performance and Productivity models for the identification, correction and prevention of related business inefficiencies in any company that utilize 44 quantitative criteria, metrics.
- Assisted plastic bottle closures manufacturer resolve chronic quality defect. Made tooling and equipment modification recommendations which resulted in the renewing of long term purchasing contract with previously unhappy, key customer, valued at \$3.5 million.
- Assisted high speed color copier equipment manufacturer

We relish the challenge ... and are prepared to meet it.

Our Services

LEAN, Six Sigma, Baldrige Operations, Continuous Process Improvements and Business Performance Improvements: Time to market, new product development system improvement; Reengineering; Business unit profit improvement; LEAN, Six Sigma, Baldrige manufacturing process yield, quality, cost and performance improvement; Cost-of-Quality and Profitability Due diligence, Improvement; Vendor certification, selection of alternate materials and equipment; On site project reviews; Training seminars and work shops.

Regulatory Compliance: Validation, regulatory compliance, technology transfer, process/system improvement and remediation, regulatory compliance audits, remediation plans development and implementation, templates for and development, execution, data analysis, and final report development of ES/COMM./IQ/OQ/PQ/PV/PKV protocols for facilities/utilities, equipment, and computer systems (GxP and 21 CFR Part 11 regulations); Development and revision of standard operational procedures (SOPs), Validation Master Plans and establishment of quality systems; Leading edge knowledge in biomaterials, material surface treatment, tribology, colloids, cutting tools, membranes, powders, gels, fluid pumping and processing, aseptic filling, lyophilization, sterilization and packaging; Proprietary models/templates for due diligence of regulatory compliance comprising systems of quality, facility and equipment, materials, production, packaging and labeling, laboratory controls; Thorough know-how in process analytical technology (PAT), quality by design (QbD), quality function deployment (QFD), Chemistry, Manufacturing and Controls (CMC), design controls, system/component impact assessment, critical process parameters, critical quality attributes, deviation investigation, root cause analysis, FMEA's, CAPAs, quality risk management, PMA, 510K and IDE, modeling, statistics; on site project reviews; training seminars and work shops.

Product Development: Idea generation; User needs establishment; Invention; Patenting; Technical and business feasibility; Modeling and prototyping; Design specification; Claims; Process pilot line; Manufacturing scale-up; Experimental design; Project management; Accelerated aging, failure analysis and stress testing; Clinical trials; FDA submissions; Product launch; On site project reviews; Training seminars and work shops.

Business Development: Technical and business feasibility; Business planning; Due diligence; Technology transfer; Intellectual property assessment and management; Business opportunities assessment; Licensing/royalty rates; On site project reviews;

- resolve stubborn contamination problem. Established chemical nature of contaminant and recommended solution alternatives. Annual cost savings at \$370 thousand.
- Helped diagnostics instrument manufacturer improve by 125% rehydration of multi-component powder reagent. Directed both the client's and vendors' manufacturing process optimization by adjusting granule particle size distribution, bulk density, mixing, concentration and drying of reagent mixture.
- Assisted liquid medication manufacturer resolve chronic product defect. Recommended surface treatment technologies for modifying wettability and spreading of utilized liquids and help company improve by 28% product quality. Resulted in \$2.5 million annual savings.
- Developed outsourcing manufacturing strategy for cardiovascular products manufacturer. Presented advantages and disadvantages of each recommended option and helped in the establishment of new manufacturing plan.
- Improved by 32% sharpness of needle for blood gas syringe at manufacturing plant of a sister division. Resulted in timely launch of "Precision Glide" worldwide advertising campaign and turned around politically explosive situation.
- Improved by 35% dissolution of lyophilized heparin powder for blood gas syringe. Optimized granule particle size, binders, concentration and freeze drying parameters. Resulted in timely launch of new product, a \$10 million market opportunity.
- Improved by 50% quality of blood collection tubes with computer model predicting performance and revised Chemistry, Manufacturing and Controls (CMC.) Established and controlled silica powder's particle size distribution and agglomeration, the most important process parameters. Resulted in \$2 million annual savings.
- Identified and satisfied unmet needs of customer by inventing and completing quantitative competitive evaluation of suction catheters and suction canister membranes. Solved air flow restriction and sealing problems, which reversed \$500 thousand product back orders. New advertising campaign resulted in \$5 million sales gain.
- Reduced tubing and adapter costs of molded suction catheter by \$175 thousand annually. Solved seventeen year old extrusion and molding problems.

Regulatory Compliance:

- Completed regulatory compliance due diligence of an intimate health, class II medical device product line comprising 21 product families, \$250 million market segment. Within 10 days, identified gaps of Design History Files (DHF's), systemic issues against ISO13485/21CFR820, prioritized each gap with risk description, occurrence probability, detectability and provided practical solutions with estimated resources (manpower and out-of-pocket costs) and timing for closing gap to senior management. Documentation review comprised labelling and advertising communications, Chemistry, Manufacturing and Controls (CMC), toxicity, clinical and safety data; controlled consumer evaluation trials, complaint history, CAPA's, MDR's, SOP's and change control documentation. Developed new product development process templates consistent with Process Analytical Technology (PAT), Quality Function Deployment (QFD) and Quality by Design (QbD.) Developed templates for user requirements, product claims / quality attributes, failure mode and effects analysis (FMEA) and traceability of user requirements/product claims with product quality attributes inclusive of Cotter's marketing mix of the 4 P's

Training seminars and work shops.

Industry/Market Segments Served

- [Medical Devices, Diagnostic Instruments, Consumer Care and Pharmaceuticals](#)
- [Biomaterials, Biocompatibility and Toxicology](#)
- [Specialty Chemicals](#)
- [Glass Tubing, Rod, Container and Sheetting Products](#)
- [Metallic Tubing, Rod, Wire, Container and Sheetting Products](#)
- [Coatings, Lubricants, Hydrogels and Adhesives](#)
- [Membranes and Filters](#)
- [Powders, Tablets, Fillers, Binders, Granules and Agglomerates](#)

Technology Expertise

- [Computer Programming, Modeling, Simulation, Optimization, Software Engineering Technologies](#)
- [Cutting Edge Blade, Needle, Suture and Trocar Technologies](#)
- [Material Characterization, Treatment, Conditioning and Packaging Technologies](#)
- [Material Degradation, Accelerated Aging, Stress Testing Technologies](#)
- [Metallic Welding, Drawing, Annealing, Tempering, Cleaning, Passivation, Eletro-polishing, Grinding, Lubrication Technologies](#)
- [Liquid Mixing, Dispensing, Atomization, Spraying, Lyophilization, Drying Technologies](#)
- [Powder Mixing, Blending, Handling, Processing, Dispensing, Rehydration, Lyophilization and Drying Technologies](#)
- [Cream, Gel, Paste Mixing, Blending, Handling, Processing, Dispensing and Packaging Technologies](#)
- [Membrane and Filtration Technologies](#)
- [Glass Cutting, Forming, Annealing, Tempering, Cleaning, Coating, Packing and Processing Technologies](#)

Product Knowledge

- (product, place, price and promotion.)
- Completed Quality Systems remediation of injection molding plant for medical devices in response to a 483, inclusive of SOPs for calibration, maintenance, materials' traceability/reconciliation, setup/in-process/terminal inspections, computer systems' disaster recovery, CAPA's, respective training for involved quality systems and commissioning, engineering studies for establishment of critical process parameters, IQOQ, PQ and PV of various injection molding, printing and packaging equipment for a night guard protector – new product launch. Resulted in improved product quality and significant quality inspection cost savings due to reduction of labor-intensive QC inspections to once per shift from once per hour.
- Led the packaging validation group of large NJ pharmaceutical company comprising three equipment validation engineers for the validation of packaging processes for over 200 current and new liquid, ointment, cream, aerosol and tablet pharmaceutical products. Ensured all consent decree, cGMP Workplan commitments and regulatory compliance initiatives were completed ahead of time and in full compliance with company standards. Completed commitments on time for compliance audit responses and preventative actions on protocol variances. Supervised group towards the completion of over 150 equipment qualifications and packaging validations in support of the Validation Certification Program (VCP), New and Base Business Product Presentations. Drove Continuous Quality Improvement as a mindset. Reduced equipment qualification protocol variance occurrence rate to 13%. Achieved 75% first pass regulatory compliance approval rate for protocol variance reports.
- Led consulting teams and completed GAP analysis, remediation plans implementation, IQ/OQ/PQ protocol generation, execution, data analysis, and final report preparation projects for facilities/utilities, equipment, and computer systems (GxP and 21 CFR Part 11 regulations.)
- Audited existing validation reports and developed Periodic Quality Evaluation documents for lyophilization, autoclaving, washing, depyrogenating, aseptic liquid filling and packaging, air handling/conditioning (including environmental monitoring), laminar hood, tank, clean-in-place (CIP), sterilize-in-place (SIP) and sterile water treatment processes of a Fortune 50 pharmaceutical company.
- Developed and executed IQ, OQ, PQ and PV protocols/reports for the validation of analytical laboratory instruments, liquid, cream and tablet packaging equipment for contract packaging and drug manufacturing companies.
- Completed documentation and product quality audits about the state of control of about 100 manufacturing equipment and processes for over 3,000 products at 1,000 employee healthcare manufacturing facility. Assembled documented evidence that supported the continued use of manufacturing equipment and processes until validation activities were completed. Documentation audit comprised the assessment and remediation of over 2,000 SOPs. Product quality audit comprised the assessment of quality control, nonconformance, process yield and product incident report (complaint) data for the last 12 months. Established template for and completed 40 calibration SOPs. Established template for correctly determining the criticality of over 3,000 medical products and reclassified their performance characteristics. Established template for and completed the development of 35 analytical, material and product test methods.
- Brought medical device manufacturer into FDA compliance, reduced by 35% all required documents for manufacture,

- Portable blood gas analyzer, safety and contaminated needle destruction units, antimicrobial, thromboresistant coating and treatment technologies for various types of catheter and wound management products.
- New generation diabetes monitoring device, fiber optic, blood and body fluid sensors/membranes, heart valves, pacemakers, blood collection and storage containers, kidney dialysis, oxygenator and heart/lung bypass devices, syringes, needles, blades and micro-surgical cutting instruments, and sutures.
- PTCA-perfusion-fiber optic-central vascular-electrophysiology and suction catheters, guidewires, micro-catheters and coils, stents, heart valves, pace makers, antithrombogenic, biocompatible, antimicrobial and infection-resistant technologies, dental and other surgical implants, bone graft plaster formulation, laparoscopic and incontinence devices, teeth grinding night guard.
- Collagen hemostatic and drug transdermal delivery systems, sterile injectables, hospital waste disposal products, wound management, surgical drains and reservoirs, infection control devices, contact lenses, tortuous and capillary-pore microfiltration membrane and industrial filtration systems, gloves, towels and surgical drapes.
- Hepatitis, retrovirus, cardiovascular disease, cancer, thyroid disorders, fertility, drug monitoring, congenital and respiratory related test products.
- Intimate health personal lubricants / stimulants, moisture enhancing agents, body massage agents. Allergy and Respiratory (Asmanex Twisthaler - mometasone furoate inhalation powder, Clarinex - desloratadine, Foradil Aerolizer - foradil aerolizer, Nasonex - mometasone furoate monohydrate, Proventil - albuterol and albuterol sulfate, Afrin, Claritin - tabs/syrup/, Drixoral.)
- Anti-Infectives (Noxafil - posaconazole.)
- Cancer Therapies (Intron A Injection - interferon alfa-2b recombinant.)
- Hepatitis (Intron A Injection - Interferon alfa-2b, recombinant, Peg-Intron powder for injection, Rebetol.)
- Skin Disorders and Sun Care (Diprolene lotion & cream - betamethasone dipropionate, Elocon lotion, ointment & cream - mometasone furoate, Lotrisone cream/lotion - clotrimazole/betamethasone dipropionate, A+D ointment with zinc oxide.)
- Liquid insulin.

Our Unique Strengths

- We have a genius to solve complex technical and business problems that others considered unsolvable. We simply do what others can't.
- You receive your desired deliverables within defined budget and time constraints.
- You get billed only upon receipt of desired management and control of the related products and, significantly improved the quality of collected data.
- Assisted major diagnostic kits manufacturer with \$3.1 billion in annual sales to complete re-validation of numerous marketed products that did not meet minimal FDA requirements. Activities included design controls, risk assessment, remediation, product and process characterization, Chemistry, Manufacturing and Controls (CMC), protocols for and review of test method and process validation; equipment installation and operational qualification. Manufacturing processes involved various solutions, mixing, lyophilization cycle, filtration, pumping and aseptic filling, process hold time and sonic welding operations for hepatitis, retrovirus, cardiovascular disease, cancer, thyroid disorders, fertility, drug monitoring, congenital and respiratory related test products.
- Researched, developed and improved the performance of blood collection test tubes, needles, syringes, blades, lancets, catheters, drains, hemostats, wound healing and closure agents, sterile solutions, drapes, gloves, towels, bacterial filters and associated manufacturing processes; Transferred technology, validated, troubleshoot and improved the performance of manufacturing processes in plants throughout the US, Mexico, Puerto Rico and England.
- Improved by 32% sharpness of needle for blood gas syringe at manufacturing plant of a sister division. Validated process resulted in timely launch of "Precision Glide" worldwide advertising campaign and turned around politically explosive situation.
- Improved by 35% dissolution of lyophilized heparin powder for blood gas syringe. Optimized granule particle size, binders, concentration and freeze-drying parameters. Validated process resulted in timely launch of new product, a \$10 million market opportunity.
- Improved by 50% quality of blood collection tubes with computer model predicting performance. Established and controlled silica powder's particle size distribution and agglomeration, the most important process parameter. Validated process resulted in \$2 million annual savings.
- Solved airflow restriction and sealing problems, which reversed \$500 thousand product back orders. New advertising campaign resulted in \$5 million sales gain.
- Reduced tubing and adapter costs of molded suction catheter by \$175 thousand annually. Validated processes eliminated seventeen-year-old extrusion and molding problems.
- Developed new package and product performance profile for haemostatic implant agent. Projected annual savings, \$1.5 million with FDA efficacy test costs reduced by \$225 thousand.
- Qualified and validated PVC suction catheter kits for radiation sterilization. Evaluation schedule compressed from twelve months to six. Resulted in \$125 thousand annual savings.
- Qualified and validated new bottom web for sterile solution tray with high volume form/fill/seal packaging equipment. Help redesign and build packaging dies in three months.
- Developed and implemented Documentum based Global Quality Standards Electronic Document Management System and website in 6 months. Lead the development teams for 12 Facility and Equipment Global Standards and 35 Quality System Global Standards. Exceeded all historical expectations for development and approval of these standards. Implemented Web-based global training program using WEBEX and INTERCALL that saved \$500M in travel costs.
- Development and implemented a global Quality Document Management System. Including development and rollout 130 global, Quality Standards to pharma and device plants

deliverables.

- Your company realizes a 10 to 15:1 return on its investment.
- You receive dedicated and first class service from seasoned consultants who are available 24 hours a day.
- You recover our competitive fees within weeks from the initiation of work on your project.
- Your employees get trained in our know-how so they can be self-sufficient and more productive in the future.

Partial List of Industrial Collaborations

- Abbott Laboratories
- Alcoa
- American Home Products
- Baxter
- B. Braun
- Becton Dickinson
- B. F. Goodrich
- BPG International
- Cardinal
- Eli Lilly
- Johnson & Johnson
Consumer Products Division
Ethicon Division
- Kimberly Clark
- Medtronic
- Minolta
- P. F. Labs
- Schering Plough
- W. L. Gore
- A number of start-up ventures.

Client Comments

"We placed Costas at one of our large pharmaceutical clients. The team he worked for was extremely pleased with his performance. His work quality was excellent. He completed the projects on time and went above and beyond what they originally brought him into work on. I would highly recommend hiring him for any contract needs that fit his expertise." *April 1, 2009*

Top qualities: Great Results, Personable, Expert
[Diane Plante](#)

Hired Costas as a Business Consultant in 2008
Account Executive, Cost Management Incentives, Inc
1-800-509-4248

"Costas is a true expert that goes above and beyond to achieve the project objectives for his customers. He immerses himself in the project and has a can do attitude. I am very pleased with what he has helped our company achieve." *April 1, 2009*

Top qualities: Great Results, Expert, High Integrity
[Frank Lesniak](#)

Hired Costas as a Manufacturing Medical Device Consultant in 2007
CEO, BPG International
1-610-565-2661

worldwide. Developed/led training workshops for site responsible individuals. Lead standards development team. Developed Standards Rollout Website and online assessment and implementation tracking tool. Developed matrix to ensure New Quality Standards fully comply with CFR 210 and 211, 220, EC and ICH guidelines and regulations. Implementation completed on time.

- Developed and implemented an internal audit program for World Wide Medical Affairs (WWMA) Clinical Development Program. Lead corrective action for the Audit of the Drug Safety department that reduced late Serious Adverse Event Reporting from 70% to zero late in 3 months. Developed and implemented CMOM mission vision and values workshop to create esprit de corps for newly created department. Implemented WWMA Global glossary on Lotus Notes. Created CMOM Lotus Notes Workspace for intradepartmental communication. Directed development and implementation 30 Global Standard Operating Procedures for WWMA.
- Led implementation of Global Document Management System using Documentum. Develop new strategy for internal audit system that changed focus from static compliance to Improving ROI. Developed new Quality System Workshop and Global Quality Council Strategy.
- Developed a strategy to transform the Quality Information System and obtained capital-funding approval of \$5MM for this project. Selected and led a multi-plant team that developed and implemented an enterprise wide Laboratory Information Management System (LIMS). This is largest systems project in ETHICON's Quality Assurance history. Cost reduction of \$1.2MM, Quality System consistency, increased compliance, transcription error reduction. Validated, nationwide, integrated quality database, which provided key tool for strategy to foster organizational transformation from assessment to prevention mode of operation.
- Chaired Needle Standards Committee, a team chartered to reengineer Needle Quality System. Developed and implemented revision to corporate defect classification policy that significantly reduced liability to 483 observations and recalls. Needle Quality System revisions and training program saved \$1MM in rejects in 1995. Awarded Vice President's Award for Teamwork in 1995 for this successful effort.
- Provided QAE support to team that validated and implemented the change of Ethylene Oxide Sterilization from 12/88 EO/Freon to Oxyfume in six months. This team won the Vice President's Award in 1995.
- Supervised team that developed operator certification program that reduced QA headcount by 40% while maintaining quality metrics and compliance.
- Provided in-process inspection, finished goods inspection/disposition, GMP Audits, quality engineering to the Somerville needle making, Suture Assembly and Sterilization processes (Co60 and ETO).
- Initiated a Quality Improvement Process using employee empowerment that reduced by 70% and 60% the finished goods failure rate and process deviation, respectively. Facility recognized as best in Quality Improvement Process in 1991.
- Initiated Good Manufacturing Practices (GMP) Committee to develop and implement GMP education program for the 1200 associate plant work force. Reduced Corporate Regulatory audit observations by 80%. Ethylene Oxide Sterilization audit of July 1991 was the first ever to receive zero observations.
- Pioneered ETHICON's Quality Career Development Program in 1989. This program refocused associates to other jobs; resulting in a H/C reduction from 90 in 1989 to 40 in 1993,

"Costas and I worked at Eli Lilly at the same time providing commissioning, qualification, computer systems validation and overall regulatory compliance work for the Parenteral manufacturing facility. Although much of what we did specifically for this client is not to be shared in a public forum, we were involved with periodic reviews that targeted risk-based areas that needed improvements. This was concurrent to some FDA visits, Warning Letters, and 483s. Needless to say, there was a lot of pressure. Costas was a true engineering professional, competent, team-player, gracious, fun-loving, and we developed a very good working relationship. I would not hesitate to work with Costas again; it was an enjoyable and positive experience! Mark L. Westerman, MBA" *April 2, 2009*

[Mark Westerman, MBA](#), *Validation and Qualification Manager, CREW Co (at Eli Lilly)* I was with another company when working with Costas at VTS Consultants, Inc
1-317-796-0237

"Costas' knowledge and self-motivation are two of his greatest assets. His experience enables him to put processes and improvements into place very quickly and he has the important, but often overlooked, quality of ethos. People genuinely like working with Costas. His sense of humor and his knowledge-base make Costas a great team leader and an excellent candidate to inform and influence clients." *April 1, 2009*

[John Anderson](#), *Business Development Manager, CH2M HILL*

Worked directly with Costas at TechnoBusiness Solutions
1-732-560-5700

"I've known Costas since I was a student up to now. He's been a consistent performer with high integrity, firm convictions, and beliefs that led him to many success and discoveries in work and life. Costas isn't afraid to be a leader; he's a born leader. Not afraid to be first; to try something new. Through many adversities, Costas has overcome and thrive to them all." *April 1, 2009*

[Ceferino Gonzalez](#), *Student, Polytechnic University I* was with another company when working with Costas at TechnoBusiness Solutions

Seminars & Workshops

- Seminar Speaker and Conference Panel Member - Injection Molding, Medical Devices, Pharmaceuticals and FDA: Four key steps to develop a FDA compliant, competitive and profitable Quality System for your Injection Molding business, June 18, 2008, Engel Medical Days 2008, York, PA
- Seminar Speaker: Injection Molding Business - Your roadmap to breakthrough quality, productivity and profitability in less than one year without "breaking the bank," March 19, 2008, SPE Susquehanna Chapter, Eters, PA
- Chairman of 3.5 hours Regulatory Compliance and Business Excellence Workshop: Regulatory Compliance and Business Excellence Lessons

without a layoff.

- Established a validation committee and teams in 1989. Completed validation of all critical processes within 2 years in response to new FDA requirement. Only facility that achieve our targeted goals.
- Led plant QA team in program that achieved ISO 9000 certification in 1994.
- Directed the Quality Assurance Program for Becton Dickinson's transnational, sterile-pre-filled syringe business. Technologies included: Ethylene Oxide and Cobalt 60 sterilization, glass forming, stainless steel and rubber processing. Responsible for domestic and international regulatory affairs. Trained, audited and assured CGMP in three production facilities located in the US, France and Mexico. Worldwide sales \$60MM. Developed Quality Systems, process validation protocols and related training programs for transfer of syringe manufacturing from US to Mexico. Developed and implemented process/facility validation program for new Ethylene Oxide facility in 1987. Revised and streamlined complaint analysis and documentation system.
- Hired to revitalize the quality program of a division that had over \$100MM yearly sales, four plants (US & UK) and produced over two billion units per year of high volume glass, plastic and rubber disposable blood collection devices as a strategy to counter a Japanese entry into B-D's market that had taken 40% of market share from B-D in 5 years. Provided QAE support to a quality improvement program that help regain all lost market share and increase it 10% over pre-threat level in four years.
- Directed the design of new facility for startup *in vitro* diagnostic reagents, H/W & sterile plastics (IVD) facility. Vendor program saved \$300K in costs.

Product Development:

- Developed a simple but powerful due diligence intellectual property model for continuous screening and quantitative evaluation of new product ideas that incorporates 154 market, technology, manufacturing, distribution, legal and other related criteria.
- Invented methodology for quantification of adhesion force of a teflon coating film onto a stainless steel, cardiovascular catheter product. Assisted company gain product release to Japan, \$100 million business opportunity. Refocused the technical efforts of biomedical start-up venture for a new, fiberoptic sensor product line. Business potential at \$350 million.
- Helped medical manufacturer modify its new product design so it could get around specific patent claims. Consulted company for completion of stability, accelerated aging/stress evaluations and 510K submission to FDA.
- Helped heart valve manufacturer resolve new product design and cost overrun problems. Recommended surface treatment technologies for improved biocompatibility of fabric, other product components and suggested product manufacturing strategy.
- Helped transdermal drug manufacturer identify technologies and develop manufacturing process for new product. Accelerated project schedule by seven months. Projected \$12 million sales for first year. Assisted client estimate the manufacturing cost of new drug delivery product and recommended commercialization strategies.
- Led efforts of two venture groups developing biosensor technology for portable blood gas analyzer. Resulted in small company acquisition with \$20 million market

Learned (Seminar Speaker); Case Studies on How-To Troubleshoot Quickly and Correctly Your Material and/or Process Problems With Analytical Laboratory Expertise/Know-How; Data-Driven Methods for Regulatory Compliance and Business Excellence; Case Study - Improving Manufacturing Performance & Cycle Time at DuPont Pharmaceuticals, Interphex 2007 - April 26, 2007, New York, NY.

- Seminar Speaker: Developed and presented 3 hour workshop with subject "Lean Six Sigma for Pharma Manufacturing: Benefits of Compliance" with only 4 hours prior notice and was congratulated by the seminar attendees and International Quality & Productivity Center (IQPC) Conference Director, July 24 - 26, 2006, Philadelphia, PA
- Chaired the "GMP Requirements. Outsourcing and Manufacturing of Active Pharmaceutical Ingredients" conference, New Orleans, LA, March 2001. Presented seminar titled "Technology Transfer Strategies: From Research & Development to Manufacturing and Product Commercialization."
- Chaired the "R&D Alliances for Pharmaceutical / Biotechnology: Build Collaborations and Consortiums to Achieve Maximum Commercialization" conference, Boston, MA, October 2000. Conducted a 3 1/2 hours Workshop, titled "Valuation, Contracting and Licensing Agreements, Strategies for Newly Developed Technologies," Boston, MA, October 2000.
- Presented seminar on "Technology Transfer - Developing an Effective Documentation Management System" as part of the conference titled: "Manufacturing Active Pharmaceutical Ingredients (APIs) - Effective sourcing and supply chain management of APIs. Cleaning validation for API manufacturing facilities. Critical strategies for API regulatory requirements, validation, outsourcing and technology transfer," Atlanta, GA, December 1999.
- Chaired the "Biotechnology and Pharmaceutical Patents, Licensing, Trademarks and Intellectual Property" conference in San Francisco, CA, July 1999. Presented seminar on "Valuation of Intellectual Property, Licensing and Negotiation Strategies." Presented a seminar titled "Intellectual Property Valuation and Technology Transfer."
- Presented seminar on "Business Transformation results and practical, common sense approach to problem resolution. " through Re-engineering and Continuous Improvement ... powerful models and practical strategies for an ever rapidly changing global business environment," Princeton, NJ, May, 1999.

Publications

C. Chantzis:

- Aspirating device US patent invention # 4,691,702 assigned to Becton Dickinson, 1987.

opportunity.

- Designed and proved feasibility of blood plasma separation tube. Product was developed and marketed with \$5 million first year sales.
- Invented and developed suction catheter for airway management of critically ill patient. Received design patent. Coordinated market testing of new product.
- Developed new package and product performance profile for hemostatic implant agent. Projected annual savings, \$1.5 million with FDA efficacy test costs reduced by \$225 thousand.
- Purchased, operated, and interpreted Analytical Research Lab data including a Nicolet FTIR Microscope with Micro ATR objective and Mettler Hotstage, Perkin-Elmer GC/MS, and a SIS Thermal Desorber (ThDsb) for GC/MS sample introduction. Developed numerous analytical methods using such lab instruments to quantitate and characterize the application of drugs and other active surfaces to drug-eluting stents, catheters, and other implantable medical devices for preventing restenosis, pain, infection, excessive friction. Completed various cardiology catheter extrusion and material science/spectroscopic characterization studies for catheters and respiratory devices.
- Installed, operated, interpreted, and maintained Analytical Research Lab including: a Shimadzu GC/MS with a Direct Insertion Probe, a SIS ThDsb, a Hewlett-Packard GC with an FTIR Detector, and a Nicolet FTIR Microscope with Micro ATR and Mettler Hotstage. Sherwood's expert in polymer, elastomer, and biomaterial processing, technology, chemistry, physics, characterization, analysis, and additives. Developed numerous methods of ThDsb/GC/MS and ThDsb/GC/IR analyses to identify and quantitate coatings, drugs, contaminants, "blooming" and additives in and on medical devices, and contaminants, vent clogs, plate out, and causes of corrosion on injection molds and other processing equipment. Troubleshoot various processes to eliminate "blooming", vent clogs, plate out, corrosion contaminants. Developed numerous methods using Nicolet software and Micro ATR FTIR for "instant analyses on contact" of many devices for quantifying radiation dose, plasticizer content, formulation, durometer.
- Part of team that ended voluntary recall of extremely successful bioresorbable implant, AngioSeal arterial puncture closure device. Designed polarized microscopy videotaping analytical method that identified the molding defect causing spurious low break force failures. Correction of this defect ended recall and maintained critical production launch. Eliminated bubble formation during AngioSeal molding, preventing a recall and maintaining critical production launch. Prevented shutdown of \$100 MM/yr. syringe factory by rapid solution of resin problem and development of FTIR method and software for statistical incoming inspection of pellets by factory labs.
- Part of team that implemented new material for Genius Tympanic thermometer that could withstand cleaning chemicals without tracking, improving quality/saving millions of dollars in replacement costs. Worked on numerous implantable bioresorbable and biostable coated/drug coated devices.
- Consulted start-up company on all technical issues involved in startup of new plastic medical devices product including design, mold acquisition, production cost analyses, raw material selection and prototyping.
- Managed Analytical Research Lab including a Hewlett-Packard 5890 Series II GC with a Thermo Nicolet Infrared Detector and software, and a Thermo Nicolet FTIR Microscope with ATR objective and Mettler Hotstage. B-D's

- Technology licensing chapter on "valuating new technologies, the licensing process and negotiation tactics", Pharmaceutical/ Biotech R&D Alliances for fee-publication, Center for Business Intelligence (CBI), October 23-24, 2000.
- Audio-acoustic proficiency testing device US patent invention # 6,417,435 assigned to C. Chantzis, et. al., 2002.

J. Donohue:

- "Predicting Shelf Life from Accelerated Aging Data: The Variable Q10 and D&A Techniques"; in MD&DI magazine; June, 1998; J. Donohue, et. al.
- Medical Design and Manufacturing Conference Proceedings; Anaheim, CA; February, 1997; "How to Predict Shelf Life from Accelerated Data", J. Donohue.
- METCON '96; Worldwide Metallocene Conference; Houston, TX; June, 1996; "Syndiotactic Polypropylene: Stability to Gamma Radiation", J. Donohue.
- ANTEC '96; The Annual Technical Conference of the SPE; Indianapolis, IN; May, 1996; "The Donohue and Apostolou Process: Predicting Post-Rad Shelf Life from Accelerated Aging Data"; J. Donohue, et. al.
- SPO '95; Business Forum on Specialty Polyolefins; Houston, TX; September, 1995; "Syndiotactic Polypropylene: Radiation-Induced Oxidative Degradation", J. Donohue.
- "Metallocene Catalysts: Driving the Polyolefin Revolution"; in Medical Plastics and Biomaterials magazine; Fall, 1994, J. Donohue.
- ANTEC '94; San Francisco, CA; May, 1994; "Thermal Decomposition of Bis-Toluidene Sorbitol into Benzoates during the Molding of Polypropylene", J. Donohue.
- SPO '93; Houston, TX; September, 1993; "The Fire Within: Post-Irradiative Degradation of Polypropylene"; J. Donohue, et. al.
- ANTEC '91; Montreal, Quebec; May, 1991; "Radiation Initiated Oxidation of HALS Stabilized Polypropylene", J. Donohue.
- ANTEC '90; Dallas, TX; May, 1990; "Radiation Effects on Polymers and Hindered Amine Light Stabilizers", J. Donohue.
- "Free-Radical Degradation and Protection in Irradiated Plastic"; in MD&DI magazine; April, 1990, J. Donohue.
- "Shelf-Life Prediction for Radiation-Sterilized Plastic Devices"; in MD&DI magazine; January, 1990; J. Donohue, et. al.
- United States Patent No. 4,710,524; Granted December 1, 1987; "High Energy Radiation Stabilization of Semi-Crystalline Polymers"; Inventor, John Donohue; Assigned to Becton Dickinson.

- expert in polymers, additives, formulation, deformation, and competitive analysis. Team participant in first release of E Beam and Gamma sterilized syringes in the USA. Wrote all the Engineering Change Orders and implemented all these new high melt flow polymers. This increased productivity 14%, saving millions of dollars per year, and dramatically decreased the number of injection molds required for production. Patented radiation stable polyolefin formulation.
- Completed a number of projects at DuPont's Potomac River Works Development Laboratory in Martinsburg, WV that involved polysaccharide hydration, crosslinking, thermal stability, and shelf life.

Business Development:

- Completed due diligence of start-up medical device company for venture capital firm. Identified strengths and weaknesses of both intellectual and human resource properties. Compiled report with findings and made specific recommendations for resolving a number of technical and marketing issues.
- Completed business plan for antimicrobial technology and intravenous catheter product invention. Recommended technology transfer, alliance and overall commercialization strategies.
- Completed market research and identified the size, type and growth trends of worldwide application opportunities for a hydrogel specialty chemical material. Established the top ten market opportunities and estimated the annual resources that each of the top twenty participating organizations had been allocating for the past ten years.
- Assisted client in developing overall business plan for a recently acquired business. Resulted in revision of existing mission, objectives and strategies. Led to the application of existing technologies in another market segment, \$7.5 million business opportunity.

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Qualifications Summary of Costas B. Chantzis

Costas is the founder and president of TechnoBusiness Solution\$™. He has an excellent track record in the Medical Device and Pharmaceutical Industries since 1980. Costas currently collaborates with two outstanding consultants, namely John Donohue and Barry Graziano.

His areas of expertise include LEAN, Six Sigma, Baldrige, Continuous Process Improvements, regulatory compliance, Intellectual Property (IP) valuation, management and technology transfer, product and process development, quality and productivity improvements, business development, marketing and strategic evaluation. Costas is blessed with an innate ability to provide practical and cost effective solutions to stubborn technical and business problems that others had considered unsolvable.

Costas is worldwide known for his many industrial conference chairmanships and speaking engagements.

He has held technical staff and management positions in Research & Development, New Business Development, Validation/Regulatory Compliance and Operational Excellence working for Vacutainer Systems and AcuteCare Divisions, both of Becton Dickinson & Company, Schering Plough and VTS. He holds two patent inventions and has issued dozens of technical, business reports on competitive trends and proprietary technologies.

In addition, Costas has been a Technical Expert of Intota (TelTech Technical Knowledge Service) since 1991. He has consulted dozens of clients for the identification and resolution of problems in: reliability and stability testing, product and process development, manufacturing troubleshooting and quality improvement, material failure analysis and Good Manufacturing Practice areas, among others.

Mr. Chantzis received both his M.E. (Chemical) and B.E. (Chemical) degrees from City College of the City University of New York in 1980 and 1978, respectively, and his M.B.A. from Fairleigh Dickinson University of Rutherford, NJ in 1985.

The bottom line is: Costas knows how and is able to utilize both his innate skills and those in the universe in order to accomplish the desirable objectives. He has a lot of common sense and knows how to think his way through obstacles. Clients seek him out for his ability to get tough projects done as well as for his integrity and trust!

Qualifications Summary of John Donohue

John Donohue is Director of Laboratory Test Services for TechnoBusiness Solutions. He is well known in the medical device industry since 1978. He has developed several successful methods for predicting the shelf life of products such as the failure or breakage of polymeric delivery systems, the chemical and physical effects of sterilization and radiation, and the dramatic entry of Metallocene Polymers into industry.

John has had numerous publications in MDDI magazine, Medical Plastics and Biomaterials magazine, and has been a regular speaker at the ANTEC, Worldwide Metallocene Conference, and the Specialty Polyolefins Conference.

Mr. Donohue received his Bachelor's in Chemical Engineering from City College of the City University of New York in 1978.

One of John's unique abilities is the combined and synergistic use of analytical instrumentation, chemistry, and knowledge of industrial practice to solve material and processing problems that disrupt product development and/or production. His favorite machine is a FTIR Microscope and can literally do wonders with it by using it as a powerful secret weapon to uncover root causes to complex industrial material, manufacturing and product problems.

John has worked for DuPont doing Unit Ops at the Savannah River Nuclear Plant and as an explosives expert at the Potomac River Works. In addition, John worked for B-D, AHP, Mallinckrodt, and Cook. He has specialized know-how and experience in controlled release implant systems including controlled release stents.

Qualifications Summary of Barry Graziano

Barry is Director of Quality Management and Regulatory Compliance for TechnoBusiness Solutions. He has 35 years experience in Drug/Device quality assurance and regulatory affairs: New product validation and design/transfer including design reviews. Experience leading global quality system software implementation/validation projects. Extensive FDA/ISO/QSR training, auditing (developed internal and external audit programs) and procedure development. Twenty years experience with customer complaint investigation and resolutions that yielded increased market share. Expert in applying Quality Improvement Principles (CAPA) to a large variety of processes, primarily chemical based, also includes biological, woven / non-woven textiles, stainless steel devices, tablet, capsule, LVP, SVP, rubber, glass and plastics. Responsible for QA and validation of class 100 environments, Ethylene oxide, Cobalt 60 sterilization processes. Provided strategic leadership for re-engineering and quality improvement that yielded significant competitive advantage. Proven cost cutter, systematic problem preventer, and inspirational people developer/educator.

Mr. Graziano received his BA Physiology from Rutgers University in 1969 and his MA Physiology from Fairleigh Dickinson University, School of Dentistry in 1973.

Barry has worked for Pharmacia/Pfizer, Bracco Diagnostic Inc., ETHICON, Inc., A Johnson & Johnson Company, Becton Dickinson and Union Carbide Medical Products is Division in various senior and middle level management positions.

Barry's professional affiliations include Past Chair/Member Executive Committee of the American Society for Quality, Metropolitan section, Chair Metropolitan section ASQ's Annual Deming Conference and Chair of Deming Medal Award Committee 1996.

Mr. Graziano has presented ASQ Quality Conference led session on PAT in Pfizer 2005, Lead American Society for Quality, *Seminar on Computer System Validation* in 2003, 2002, 2001, 2000 and 1999, Developed and hosted American Society for Quality, *Seminar on Computer System Validation*, Jan. 22, 1998, Presented session on, *Model Life Cycle for Software Validation*, Chaired and organized ASQ's Metropolitan Section 53rd Annual Deming Conference, *Practical Applications of Deming's Philosophy*, December 8-10, 1997, Chaired and organized ASQ's Metropolitan Section 52nd Annual Deming Conference, *Deming's System of Profound Knowledge*, December 9-11, 1996, Chaired and organized Seminar on Leadership and Quality Improvement, February 7, 1995, Fordham University, NYC. Presented session on *Leadership and Human Emotion*.