

Information for Users

This List of Consultants has been compiled by members of the ASQ Philadelphia who wish to offer their services as a consultant. This listing does not signify endorsement by ASQ or ASQ Philadelphia.

Company	Services
<p>John F. Bielski Consulting ASQ: CSSBB, CQE, CQA, CBA, CMQ/OE, CQIA 484-680-6369 LeanQuality@yahoo.com cGMP13485@yahoo.com</p>	<p>Providing guidance, training or conducting Internal and Supplier audits. Will train your internal auditors and/or work with them as they learn. I have forty years of keeping Quality Systems practical, down-to-earth and LEAN. Experienced with ISO-9001, ISO-13485, ISO/TS 16949, 21 CFR 210/211 (for OTC drugs), 21 CFR 820, and Mil-Spec. Will conduct gap analysis for upgrading to ISO 9001:2015, ISO 13485:2016 and conversion from ISO/TS 16949:2009 to IATF 16949:2016. The deadline for converting 9001 & 16949 is September 2018, and is not that far away. Assistance with Risk Assessment. Can also lead or help with LEAN implementation.</p>
<p>DHD Consulting David Dychala CSSBB www.linkedin.com/in/ddychala 610-585-5659 ddychala@aurvex.com</p>	<p>Providing material engineering and product/process development services. Continuous improvement through Root Cause and Failure Mode Effect Analyses, Statistical Process Control, Control Charting, and Design of Experiments. Preparation and execution of IQ, OP, PQ protocols for process validation.</p> <p>Process auditing, mapping and assessment of training methods to improve operational efficiency and reduce variability. Development of raw material specifications and test methods, identification and development of suppliers, program/project management to enhance production output.</p>
<p>Gold Star Water Consultants, Inc. Mikel E. Goldblatt President and Principal Consultant 215-498-5188 info@goldstarh2o.com http://www.goldstarh2o.com/</p>	<p>Water and wastewater systems problem-solving, training, and site-specific practical improvements.</p>

Freelance Consultants List

Company	Services
Keystone Regulatory Services, LLC William G. McLain 717-656-9656 bill.mclain@keystoneregulatory.com www.keystoneregulatory.com	Full-service regulatory affairs and quality management system consulting for the medical device industry. Quality system (21 CFR 820; ISO 13485:2003) and risk management (ISO 14971:2000) system analysis, auditing, implementation and training, pre-market regulatory strategy and support, agency dispute resolution plus many others.
Ray Lotfi Consulting 610-308- 8495 raylotfi@gmail.com	Validation specialist for medical devices, product & process improvement, cost cutting, & global outsourcing. Evaluating and Training cGMP, ISO 13485 compliance. Expert in Risk Management FMEA.
Master Quality Consulting Michael J. McMaster, ASQ CQA, CQE, CQMgr 609-304-6314 masterquality@comcast.net	Providing the pharmaceutical, biotechnology and medical device industries proven auditing, cGMP training, quality system and regulatory compliance consulting services.
Nash Associates Robert J. Nash, Ph.D. 610-363-6147 drjnash@comcast.net	Providing consulting with ISO 9000, FDA cGMP, FMEA, SPC, design of experiments, applied statistics and statistical reports, survey construction and analysis, sustainable excellence. More than 100 corporate clients since 1986.
Optima Performance, Inc. Arthur W. Crowley 610-212-2336 artcrowley1879@gmail.com	Management Services, business performance assessment, planning, and implementing, QM System methods and processes to assure optimized performance. Business process mapping and real time measures for monitoring and improvement. Prepare clients for ISO 9000 registration and provide associated tools and software. A certified Plexus training company.

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Q&C Systems Services, Inc. Bob Wittendorf, President 484-478-2470 rwwitten@verizon.net	Providing consulting for FDA quality systems regulation, established and improved. FDA compliance for medical devices and pharmaceuticals.
John J. Salera and Associates Fax: 215-968-0310	Preparation of quality system manuals and procedures to comply with ISO9000, QS9000 and Department of Defence requirements. Design of SPC systems, including SPC management plans. Assistance in configuration management programs, failure analysis, etc.
Storti Quality Consulting, Inc. Ralph J. Storti Exemplar Global Internal and Lead Auditor 215-657-0837 ralph.storti@storticonsulting.net	Provides quality program development, audit and consulting services to utility, construction, manufacturing and industrial companies. Twenty years of quality Assurance and quality control experience. Providing training, perform surveys/assessments of existing programs and processes. Conduct audits and write policies and procedures.
Total Quality Management Joseph Siegel 610-664-8816 eljo@snip.net	Helping clients comply with ISO9000, using Six Sigma tools to create an environment stressing reduction of variability of key manufacturing elements through FMECA, Pareto analysis, quality function deployment, sampling plans, control charting, and designed experiments. Provide SPC training of these concepts.
Validation Associates, Inc. Nancy Tucker 215-354-1720 nancy.tucker@validassoc.com www.validassoc.com	Providing the pharmaceutical, biotechnology, and medical device industries with computer system validation project consulting and training services.

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<p>Watson Biotech Co., Ltd 瓦特森生物科技咨询 (上海)有限公司 LP Carl Huang USA: (+1) 215-666-6006 China: (+86) 21-5410-9876 info@watsonbiotech.net http://www.watsonbiotech.net</p>	<p>Full-service quality management system and regulatory affairs consulting to/from Greater China Region. Services include: Chinese supplier screening, audit and qualification GMP training, regulatory filing, and process improvement Interpreting and translation Market survey & development, partnership alignment Customized quality/regulatory services for special needs</p>
<p>X-Stream LEAN, LLC Alex Malek 484-941-3877 info@xstreamlean.com http://www.xstreamlean.com</p>	<p>Worldwide consulting to companies Lean Six Sigma, executive coaching and mentoring, organizational development and Supply Chain Management.</p>
<p>Xybion Corporation 215-638-9700 sales@xybion.com www.xybion.com</p>	<p>Provides enterprise-wide compliance solutions to regulated industries in the pharmaceutical, medical device, diagnostic and biotechnology sectors. Delivers a comprehensive suite of validation, technology, regulatory and business solutions.</p>