COMPLIANCE ARCHITECTS®
CONSULTING • TECHNOLOGY • OUTSOURCING

John C. (Jack) Garvey, Esq.

PROFILE

Diverse, highly-experienced attorney/engineer/consultant with extensive specialized knowledge and experience in all aspects of FDA quality, regulatory, compliance, operations and law. Expertise in regulated manufacturing activities for multiple FDA-regulated product classes, including pharmaceuticals, medical devices, biologics, foods, and dietary supplements. Demonstrated capability and expertise in quality system design, development and implementation activities. Prolific writer and developer of innovative solutions for quality management, risk management and compliance systems. Developer of Writing for Compliance®, FDA-regulated industry's first and only dedicated writing workshop dedicated to the problem of developing and writing documents for FDA inspections.

EXPERIENCE

Founder, Chief Executive Officer **Apr 2009 to Present**
Compliance Architects LLC, Robbinsville, NJ

Direct and lead all business and operating activities of Compliance Architects LLC, a leading consulting and advisory services firm dedicated to the delivery of innovative, effective quality and compliance solutions for FDA-regulated industry. Direct and provide subject matter leadership for all legal and regulatory matters. Responsible for business strategy development and execution and market opportunity pursuit. Support all company clients as lead subject matter expert for FDA quality, compliance and regulatory matters. Direct and deliver contracted consulting engagements and maintain final executive accountability for satisfactory client outcomes. Leadership actions since founding have resulted in sustained growth and sustained business profitability.

Representative Consulting Clients:

- Johnson & Johnson (multiple operating sectors and companies)
- Merck
- Piedmont Pharmaceuticals
- C.R. Bard, Inc.
- Atrium Innovations, Inc.
- Bayer Healthcare
- Ropack Pharma Solutions
- Terumo
- McNeil
- Bristol-Myers Squibb

Vice President, Quality **Nov 2008 to Apr 2009**
Halo Pharmaceutical, Whippany, NJ

Responsible Senior Executive for all quality operations at privately-held, specialty pharmaceutical manufacturer.

- Directed quality control, quality assurance, compliance and laboratory operations in support of finished dosage form manufacturing for major, branded pharmaceutical companies.
- Participated in business development strategy development and client meetings.
- As necessary, acted as counsel for the corporation for agreement review, policy development and risk identification and mitigation.

Vice President / Practice Lead, Compliance & Quality Management **Oct 2006 to Nov 2008**
The Weinberg Group Inc., Princeton, NJ

Directed the compliance & quality management practice at this 60-person, privately-held, global scientific and business consulting firm. Developed revenue targets and business development plans. Designed complex service-delivery programs for FDA-regulated clients. Participated in leadership of business.

- Developed substantive criteria and execution plan, and directed consulting efforts for complex, multi-client, FDA-enforcement action at laboratory services provider, resulting in over $6 million in unplanned revenue.
- Created and drove implementation of business development process focusing on existing and prior clients.
- Directed cross-industry initiative to develop Guidance for Quality Systems in Support of Bioanalysis.

Chief Compliance Officer **Jul 2005 to Oct 2006**
Accenture, Outsource Services Project with Bristol-Myers Squibb, Princeton, NJ

Hired to direct and coordinate international compliance office activities for innovative, cross-functional (finance, human resources and applications management), outsourcing services delivery project. Ensured global delivery centers, processes and personnel were in compliance with client's legal, regulatory, policy and procedural standards. Coordinated and facilitated training, document control, audit, issue management, and continuous improvement activities across five international sites. Directed SOX awareness communication, testing preparation and execution activities to ensure alignment of resources with client's SOX requirements.

- Led improvement activities increasing right-first-time SOX testing outcomes by greater than 60%.
- Appointed cross-functional lead for Operational Excellence initiative, utilizing six-sigma methodologies to significantly improve business and compliance outcomes.

Director, Corporate Quality & Compliance Services **Feb 2002 to Jun 2005**
Johnson & Johnson, New Brunswick, NJ

Directed internal quality and compliance consulting activities for Johnson & Johnson's pharmaceutical, medical device and consumer products' companies. Provided high-level strategic guidance on compliance issues and initiatives. Assisted Group Companies with tactical activities in support of GMP, GLP, QSR and GCP compliance and operational improvements. Directed corporate governance activities, including stewardship of Management Action Plans, inspection preparation, and recall follow-up activities.

- Led inspection preparation and compliance improvements, including project approach, HACCP plan development, and compliance gap identifications at a high-risk diagnostics company.
- Steering Committee Member - Pharmaceutical Supply Chain SAP / Documentum implementation project.
- Successfully prepared major consumer-sector facility for first FDA inspection, with only minor FDA-483 resulting. Introduced HACCP Quality Plan concept and drafted inspection preparation project plan, ensuring facility readiness for inspection.
- Facilitated and influenced a two-year operational improvement program at a major Johnson & Johnson consumer-sector franchise, significantly improving supply-chain performance, quality outcomes and compliance profile.
- At the request of Corporate Legal, acted in role of Counsel for the corporation in support of J&J's SAFE (Secure Access for Everyone) initiative, delivering legal counsel on key technology initiative and framework for future electronic transactions.

Partner, Vice President Business Development & General Counsel **Apr 2000 to Feb 2002**
ThinSpring, Watchung, NJ & Corona, CA

Founding Partner and key business leader of this early-stage technology and professional services company. Grew business from $500K to $1.8 million in 18 months. Secured "tipping-point" software sale for organization. Developed comprehensive business plan and associated operating plans; drafted commercial sales and licensing agreements; presented to venture capital firms; secured technology partnerships; developed patent content and performed prior-

arts review. Developed collateral marketing materials; developed brands and marketing approaches; and developed sales presentation content.

Directed and performed consulting activities for FDA-regulated clients. Led and delivered compliance and regulatory strategy and guidance to client companies.

- Directed development of 21 CFR Part 11 compliant Quality System for a $150 million medical device manufacturer's Information Services function in less than one month, substantially reducing compliance risk at minimal cost to the organization.
- Led and delivered business and operational consulting resulting in over $300K annually in hard cost savings to a $150 million medical device manufacturer in bankruptcy. Operational plans and advice given allowed company to continue operations and implement long-term corrective actions.
- Directed compliance consulting activities and drafted key policies and procedures for a $70 million medical device manufacturer, resulting in a successful FDA certification audit within 3 months.

Director, Quality Assurance & Regulatory Affairs **Mar 1997 to Apr 2000**
BASF Corporation, Mount Olive, NJ

Directed all quality assurance and regulatory affairs activities for BASF's Nutrition, Cosmetic and Pharmaceutical Chemical's operations. As senior QA/RA executive, participated on the Management Committee of this $650 million business. Directed the development and implementation of GMP and GLP quality systems and procedures encompassing eight regulated product classes, four business units, and ten manufacturing sites. Managed a total operational staff of 70 quality and regulatory professionals and an overall cost-center budget of $7 million. Established worldwide quality and regulatory policy and strategy.

- Nominated to and participated on Congressional Suspicious Orders Task Force. Improved BASF's reputation with Federal and State law enforcement agencies; reduced BASF's regulatory risk; and negotiated the elimination of import quotas on over $200 million in DEA regulated product.
- Provided complete regulatory leadership and market entry strategy for a new dietary ingredient which generated 1st year retail sales revenues in excess of $200 million.
- Directed an extensive re-organization of a 40-person API Quality Assurance laboratory resulting in substantial increases in service level and compliance, and resulting in a 13% reduction in headcount requirements, and greater than 20% reduction in total controllable fixed costs.
- Directed quality improvement initiative at API / excipient production facility that improved right-first-time quality performance from approximately 90% to greater than 98% in less than 6 months.
- Successfully directed management of and responses to multiple FDA inspections and 483s for drug dosage forms, APIs and excipients with no resulting Warning Letters issued.
- Established new, consolidated quality organization; established departmental strategies; and hired three quality and regulatory professionals for key functions, resulting in significantly reduced compliance risk to the division.

Regulatory Attorney / Associate Compliance Coordinator **Aug 1994 to Mar 1997**
C. R. Bard, Inc., Murray Hill, New Jersey

Coordinated response activities and tracked compliance commitments to ensure adherence to Plea Agreement with FDA. Developed and managed corporate compliance program initiatives, performed business ethics training, and implemented company-wide "whistleblower" program. Advised corporate Regulatory Compliance department on food and drug law matters.

- Successfully directed and managed all planning activities of a global, cross-functional, cross-divisional supply-chain re-engineering initiative, resulting in proposed operating capital savings in excess of $50 million.

- Investigated "whistleblower" complaint that divisional employees made unapproved design modifications to commercial product. Submitted report to CEO describing significant legal and regulatory risks.

Attorney **1991 - 1994**
Thorn & Gershon, Albany, New York
Devorsetz, Stinziano, Gilberti & Smith, Syracuse, New York

Senior Validation Engineer **1987 - 1991**
Ciba-Geigy Corporation, Suffern, New York

Production Supervisor, Packaging & Technical Services **1984 - 1986**
Ayerst Laboratories, Rouses Point, New York

EDUCATION / PROFESSIONAL LICENSES

- ***Juris Doctor*** - Pace University School of Law, White Plains, New York
- Admitted to practice law in the State and Federal Courts of New York and New Jersey
- ***Bachelor of Science, Chemical Engineering*** - Clarkson University, Potsdam, New York
- Regulatory Affairs Certified, Regulatory Affairs Professional Society, 1996