



John C. (Jack) Garvey, Esq. – Professional Biography

John C. (Jack) Garvey, Esq., founder of Compliance Architects[®], is a diverse, collaborative, highly-experienced regulatory and compliance executive with an **exemplary record** of accomplishment in FDA-regulated industry. In recent years, Jack has held **Vice President**-level positions focused on compliance and quality strategy development and **deployment** for leading **life-science** companies. In addition to experience gained through roles of increasing responsibility and accomplishment at Accenture, Johnson & Johnson, BASF, and C. R. Bard, Jack's dual background in **law and engineering** provides unparalleled ability to resolve today's complex regulatory, quality and compliance issues. Jack's unique background provides an **ideal blend of legal and scientific advocacy** that can yield robust and effective quality and compliance systems and improved compliance outcomes for **Rx and OTC** drugs, **devices and diagnostics**, cosmetics and consumer products, and **dietary supplement** and nutritional products. A sampling of specific quality and compliance expertise includes:

- Hands-on leadership, assessment, and execution of **response activities** for FDA 483s, Warning Letters, Seizures, Injunctions, Import Detentions or other adverse regulatory action;
- Assessment/audit and **remediation of under-performing quality systems**, including introduction of Operational Excellence principles, **metrics** and governance programs and **staff capability** assessments;
- Assessment of enterprise compliance risk and development of remediation and mitigation plans;
- Assessment/audit of **contract product and service providers**, and development of quality and compliance assurance plans, service level agreements, and relationship management systems;
- **Due diligence** review and assessment of external relationships, product **licensing** and acquisition and organizational **mergers and acquisition**; and
- Corporate compliance program development and deployment to **DOJ 7-Element** criteria.

Jack has developed **innovative** compliance methodologies for regulated industry focused on risk differentiation, improved compliance outcomes, and operational **cost control**, and is a **frequent speaker** at industry conferences. Jack received his Bachelor of Science in **chemical engineering** from Clarkson University and his **Juris Doctor** from Pace University School of Law, and is admitted to practice law in the states of New York and New Jersey.

Selected Compliance Assignment Successes:

- ✓ Developed completely new quality system for Medical Device manufacturer in danger of consent decree resulting in no further enforcement action;
- ✓ Built 21 CFR Part 11 Quality System for Medical Device Manufacturer;
- ✓ Led / directed multi-client audit of contract bioanalysis provider for over \$500 mm in pharmaceutical products at risk of market removal, resulting in continued market access for clients;
- ✓ Developed HACCP Product Quality Plan for at-risk class II medical device manufacturer in anticipation of first FDA inspection, resulting in no observations for manufacturing quality system deficiencies;
- ✓ Led / directed pre-FDA inspection compliance audit of contract bioanalysis laboratory resulting in first-pass FDA approval for laboratory operations;
- ✓ Led / directed multiple due diligence quality & compliance assessments of acquisition target products and companies; and
- ✓ Led / directed multiple sensitive internal compliance investigations for leading FDA-regulated companies.

Past Conference & Speaking Events:

- ❖ ComplianceOnline: *HACCP for Medical Device Compliance* (current offering)
- ❖ September, 2008: *HACCP for Pharmaceutical Compliance*, IPAC HACCP Conference, Toronto, Canada
- ❖ June 2008: *To Recall Or Not To Recall, That Is The Question & How Do You Manage A Recall Anyway*, MDM East, New York, NY
- ❖ May 2008, Moderator, Panel Contributor, *Life Sciences Panel Discussion*, LARTA Venture Forum, Santa Clara, CA
- ❖ January 2008: *To Recall Or Not To Recall, That Is The Question & How Do You Manage A Recall Anyway*, MDM West, Anaheim, CA
- ❖ August 2007: *Compliance Considerations in Pharmaceutical Product Development*, FDA Regulatory & Compliance Symposium, Harvard University
- ❖ June 2007: *Control Point Compliance Plans: A Valuable Tool for Inspection Management*, MDM East, New York, NY
- ❖ June 2007: *FDA 483s, Warning Letters & Related Legal Issues*, Orange County Regulatory Affairs 10th Annual Educational Conference, Anaheim, CA
- ❖ January 2007: *The "De Novo" 510(k) Process and the Reclassification of Class III Devices*, Orthopedic Surgical Manufacturers Association (OSMA), St. Petersburg, Florida
- ❖ September 2000, *Using Information Technology to Facilitate Post-Market Surveillance Activities*, RAPS Annual Meeting, Washington, DC
- ❖ 1999 - Moderator/Chairperson: *Structure / Function Claims... Health-Related Claims in Food Labeling: Boundaries and Issues of Dietary Ingredient Development Under DSHEA*, FDLI Annual Meeting, Washington, DC

Recommendations:

The following recommendation excerpts reflect Jack's success in FDA-regulated industry, and approach to the resolution of tough issues and assignments:

Nick Fleischer, The Weinberg Group:

Jack was the responsible executive for the project and managed the very complicated project to a successful completion, which also yielded a significant amount of unplanned revenue. Jack provided excellent internal leadership and was very effective working with the clients to ensure projects were delivered to tight timing requirements, and within budget. I also worked with Jack on a cross-industry standard development initiative, and can state that Jack took leadership to move this activity forward.

Robb Slobbe, Philips Corporation:

I can attest to Jack's professionalism, leadership and subject matter expertise.... As with all due diligence assignments, sensitivity to the organization being evaluated is paramount; however, it is important that a thorough evaluation of the operation is conducted. Jack balanced these difficult requirements extremely well. As a result of Jack's assistance ... [company] received a thorough, timely and helpful analysis of the target company's quality and compliance operation, resulting in a more complete analysis of the business case for the acquisition.

Additional recommendations available upon request.

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