

**BIOGRAPHY OF
JOSEPH A. FRANCHETTI**



Joseph A. Franchetti is the President of JAF Consulting, Inc., where he has been leading a team of compliance consultants in the Life Science and Pharmaceutical industries for over 20 years. Individually, Mr. Franchetti has addressed the Life Science, Pharmaceutical, and Medical Device Industries needs in the area of FDA Regulatory Compliance of Computerized Systems. In addition, Mr. Franchetti has over thirty years of progressive experience in information technology and data management in the life science and pharmaceutical industries. As a former Manager of Automated Computer Systems, he was responsible for the regulatory compliance, operation, and maintenance of all data systems for the research and development division of a major generic pharmaceutical company. He is also experienced in the areas of Laboratory Robotics and Automated Systems, where he led multiple project teams in developing automated systems for the testing of pharmaceutical products. In the early 90's, he was given the "Pioneer in Laboratory Robotics" Award; a peer-recognized award for the development of new applications and designing innovative and unique solutions to technical problems.

He has extensive experience with all aspects of computer systems validation and compliance and was involved with the GAMP Special Interest Group on Laboratory Systems, and is currently the Training Chairperson for the Society of Quality Assurance's Computer Validation Initiative Committee.

Joe is experienced in Project Management; Quality Systems Implementation, Pharmacovigilance and Drug Safety, Instructional Design, Vendor / Supplier and Compliance Audits; Computer System Validation; US & International Regulations and Standards (cGLPs, cGMP, & cGCPs, ISO Standards, Sarbanes-Oxley (SOX), 21 CFR Part 11, European Union, Japanese Ministry of Health Labor and Welfare); Information Technology; Quality Assurance; Quality Management Systems, Electronic Data Management; Laboratory Robotics; Laboratory Operations and Analysis; Drug Discovery; Informatics; Data Warehousing Documentation Development and Content Management.

JAF Consulting, Inc. provides Validation Program Planning & Development, Validation Project Management & Execution, E-Rec /E-Sig Planning and Remediation, Training Program Development & Execution, SOP Development and Compliance Auditing and Assessment services to its clients. With his diverse experience, Mr. Franchetti will share his knowledge of managing large-scale projects, and can effectively communicate on both technical and regulatory issues.