Contact

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www.linkedin.com/in/ginaredden (LinkedIn)
www.CodaCorpUSA.com (Company)
blog.CodaCorpUSA.com (Blog)
www.linkedin.com/groups (Other)

Top Skills

Title 21 Quality and Compliance
Qualification and Validation
Aseptic Processing

Certifications

Medical Device Single Audit Program (MDSAP) for Manufacturers
ISO 9001:2015 Lead Auditor (CEU 6.0)
ISO 13485: 2016 Lead Auditor (CEU 6.0)
ASQ Certified Quality Auditor
Lean Master Black Belt

Honors-Awards

Pi Mu Epsilon
RIT Presidential Scholarship
Kodak Technical Scholar
Melvin Jones Fellowship Award
Paul Harris Fellowship Award

Publications

Automation Validation Projects: Critical Considerations for Successful Execution
Risk Management: A Primer for Lean Quality Assurance
GMP Reform and FDA's Fast Track
Optimizing Your Budget While Using Engineering Consultants
Perspective With Purpose: Quality With Clarity

Gina Guido-Redden

Co-Owner/Founder, COO and Managing Partner of Coda Corp USA; GGuidoRedden@CodaCorpUSA.com
Olcott, New York, United States

Summary

Founder and COO of Coda Corp USA, a contract service corporation.

She holds Lead Quality Auditor and Master Black Belt certifications.

Ms. Guido-Redden has been involved with FDA and Title 21 Regulatory Affairs and Leadership for over 25 years, providing quality services in the areas of Remedial Navigation, Crisis Management, Global Change Leadership, Quality System Assessment and Development, Domestic and International Compliance, Clinical Trial Management and Executive Mentoring.

Her areas of expertise include executive level leadership in the areas of Regulatory Affairs and Compliance, Global Change and Crisis Management, Risk Mitigation, and Lean Six Sigma Project Management.

Ms. Guido-Redden is also a Charter Member and partner of The Life Science Link, a professional consortium dedicated to the growth and development of the life science industry in the western New York area and she serves as a Management coach and mentor at the Women's Business Center of Canisius College in Buffalo, NY.

Coda Corp USA primarily services Global Organizations that develop and bring to market pharmaceutical, bio-pharmaceutical therapies and medical technologies. Ms. Guido-Redden is a featured public speaker and leading industry trainer and also issues a highly circulated industry column (Perspective with Purpose: Quality with Clarity) and is regularly published in industry journals and publications, most recently, CERM Risk Insights, The Journal of Validation Technology, FDA Compliance Digest and New Generation Pharmaceuticals.

Ms. Guido-Redden can be reached by phone at 716.638.4180, or by email at GGuidoRedden@CodaCorpUSA.com.

"Quality is never an accident; it is the result of high intention, sincere effort, intelligent direction and skillful execution. It represents the wisest of many alternatives."

Experience

Coda Corp USA

24 years 6 months

Owner; COO and Managing Partner

2000 - Present (23 years)

Coda Corp USA primarily services Quality and Operations Systems, assessing, developing and implementing quality systems, validating manufacturing processes but also provides general compliance consulting.

Ms. Guido-Redden founded and continues to lead Coda's Quality Services and Regulatory Compliance divisions. In this capacity, she provides expertise toward compliance with cGMPs, GCLPs, GLPs and GCPs: Title 21 CFR, parts 600, 601, 610, 820, 210, 211, and 11, ISO and DEA regulations.

Ms. Guido-Redden oversees all client projects for quality, efficiency, and technical accuracy; providing Senior Leadership to all active projects and supplementing Sr. Leadership of client organizations.

Specialties include leading client manufacturers through complex remedial activities or dynamic change and providing global interpretation of regulatory expectations.

Client/Partner List Includes;

August 1998 - Present (24 years 6 months)

Pharmaceutical, Biopharmaceutical, Biotechnology, Medical Devices, CROs and CMOs

ACM Global Laboratories

Allergan

AMETEK/Reichert

APP Pharmaceuticals

Applied Biosciences, SQL LIMS Preferred Service Partner

Athenex

Aventis
Banner Pharmaceuticals
Bausch & Lomb
Baxter Healthcare
Beckman Coulter, User Wish List Committee Chair and Preferred Service Partner
Biokit
Bristol Myers Squibb
Buffalo Niagara Enterprise
Caliber, Imaging and Diagnostics
Canisius College; The Women's Business Center
Carestream Health
CellTech Manufacturing
Clerio Vision
Cognivue
Conax Technologies
Coopervsion
Endo Pharmaceuticals
Ethox International
Fox Pharmaceuticals Contract Manufacturing
Fresenius Kabi
GAMP, Part 11 White Paper Committee Member
Greatbatch
Hauptman-Woodward Institute
Heany
Hoffman-LaRoche
Hospira Pharmaceuticals
Hyde Engineering
Immunex
ImmunoTherpeautics, IRX
Innovation Center - Buffalo Niagara Medical Campus
Iuvo Bioscience
J & R Consulting
J&J, Centocor
J&J, Ortho – Clinical Diagnostics
Kinex Pharmaceuticals
LabVantage
Leiters
Lucid Technologies
Master Control, Enterprise Partner and GxP LifeLine Columnist/Blogger

Merck and Co., MMD
Merck and Co., MRL
Micro Systems Engineering
Monsanto
Moog Medical Devices
NextArrow
Ninaza, Clinical Application Developers for CROs
Novartis
Ortho Clinical Diagnostics, a J&J Company
Pall Life Sciences
Parke-Davis
Pastuer Merieux Connaught
Patheon, Contract Manufacturing
Pfizer
PharmaNova Pharmaceuticals
QualPak, Contract Packaging
Quintiles Consulting
Reichert Technologies/Ametek
Rhone Poluenc
ROC IT Solutions
Sanofi Pastuer
Sigma Pumps International
Sparta Systems, Preferred Service Partner
Stiefel Laboratories
Straight Forward Consulting
TEDxBuffalo
The Life Science Link
Thermo Fisher
Trinity Biotech
Tunnell Consulting
United Therapeutics
Unither Manufacturing
University of Rochester
United States Food and Drug Administration
ViewRay
Warner-Lambert
Watson Pharmaceuticals
Wyeth-Ayerst
Zoll Medical

Canisius College; The Women's Business Center
Business Coach and Professional Mentor
October 2011 - Present (11 years 4 months)
Buffalo, NY

A professional program that accepts established business owners and partners them with professional coaches who are successful business owners and professionals and leaders in their respective areas. The program is designed to offer guidance, mentorship and coaching to small business owners in order to help them grow their business or practice locally, regionally and nationally.

Coaches are selected based on their leadership abilities, business management success rate and field(s) of operation. Coaches are extensively trained and provide structured guidance to enable the advancement of the defined goals of program participants.

Center for Medical Technology and Innovation
Advisory Consultant University of Rochester
March 2021 - Present (1 year 11 months)

The Life Science Link
Charter Member/Partner
2010 - Present (13 years)

Dedicated to promoting the growth of the Life Science Industries within the Buffalo/Niagara region, the LSL leverages existing relationships with established organizations to seed the continued growth of this sector within our local economy.

The Life Science Link is an experienced and expert business development team dedicated to creating and developing new business opportunities, and to improving the operating performance of established companies in the Life Sciences industry.

The LSL connects researchers, industry executives, business development professionals, investors, and service providers in a way that promotes growing markets, guides new products and technologies through the commercialization process; ensuring the successful creation, development, and growth of emerging Life Science companies.

Comprised of a team of regional industry leaders and functional experts; the LSL partners offer skills needed to face any type of challenge that emerging organizations may face; including protection of intellectual property, business creation and profit optimization, process design, regulatory navigation and resource development. The Life Science Link provides a broad spectrum of solutions to meet a wide variety of requirements.

Merck & Co., Inc.
Remedial Management Executive Leaderhip: Consultant
2008 - 2010 (2 years)
West Point, Lansdale, PA

JCL Systems
VP of Validation Services
1998 - 2000 (2 years)

Validation Department management, Project management, design, execution and reporting of Quality Software and Hardware Qualifications. Technical writing – Validation Plans, User and Functional Specifications, protocols (IQ/OQ/PQ), reports and internal procedures. Adherence to CGMPs, Title 21 CFR, parts 820, 210, 211, and 11, ISO and DEA regulations.

UCB
Process Validation Manager
1992 - 1998 (6 years)

Facility and Process Validation; project/team management, project planning and problem solving, purchasing, scheduling. Design, execution, reporting of Control , Cleaning, Operational (equipment) and Process (manufacturing/packaging; liquid and solid), Utility/Facility (PW, OFCA, HVAC) Qualifications. Technical writing. GMP and DEA regulations, clean room experience.

Global Automation; system configuration and implementation, hardware and software validation, technical writing - protocols, reports, OPs, SOPs (system operation, system management and training), training and user manuals, monthly newsletter. Developed and administered LIMS user training program, and ‘LIMS to Lab Outreach’ program providing users technical support and continuing computer education.

R&D; method development, participation in patented research projects, independent synthesis of experimental organic compounds, analysis of

samples, adherence to GMP regulations, and communication of status to production groups.

Eastman Kodak
Research
1990 - 1992 (2 years)

Engineering and Research Division: NMR
Small molecule elucidation, molecular characterization, and magnetic field alignment and report generation.

Education

Rochester Institute of Technology
MChE, Chemical Engineering · (1989 - 1994)