

Daniel Kovacs, DTR, CQA

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PROFESSIONAL SUMMARY

Dynamic and accomplished Sr. Compliance Specialist with over 20 years of leadership experience in regulatory compliance, audits, project management, and quality systems within life sciences and manufacturing industries. Renowned for driving process improvements, managing complex investigations, and fostering cross-functional collaboration. A visionary leader committed to exceeding regulatory expectations and delivering operational excellence.

CORE COMPETENCIES

- Regulatory Compliance & Risk Management
- Internal & External Audits
- Quality Management Systems (QMS)
- Process Improvement & Gap Analysis
- Policy Development & Integration
- Leadership & Mentorship
- Cross-Functional Collaboration
- Data Analytics & Report Writing
- Microsoft Office Suite, EPIC, SAP, MasterControl, ZenQMS

PROFESSIONAL EXPERIENCE

DANIEL KOVACS CONSULTING, Carlisle, MA

Owner & Principal Consultant | January 2025 – Present

- Provide Quality Management System (QMS) support to food and life science manufacturers, specializing in compliance, audits, and supplier management.
- Conducted internal, external, and supplier audits to assess regulatory compliance, operational efficiency, and ISO/FDA/USDA readiness.
- Develop, revise, and implement controlled documents, including SOPs, policies, and training materials, ensuring alignment with regulatory requirements.
- Partner with clients to strengthen supplier quality programs, including qualification, monitoring, and risk assessment.
- Deliver tailored compliance training and guidance to cross-functional teams to improve audit readiness and regulatory awareness.
- Support companies in inspection readiness and ISO 9001 certification preparation by identifying gaps and driving corrective action plans.

ALCAMI, Pepperell, MA

Sr. Compliance Specialist | July 2023 – Present

- Championed internal and external audit readiness across five campuses, serving as the primary liaison for client and regulatory inspections.
- Designed and implemented a regulatory inspection readiness program, including training materials, best practices, and role-specific guidance.
- Led compliance integration following acquisitions, including Pacific Pharmaceutical Services (PSS) and Masy Bioservices.
- Directed the establishment of compliance teams at new facilities, ensuring seamless operations and adherence to regulatory standards.
- Increased client audit volume by 20% while maintaining a KPI closure target for audit observations.
- Streamlined environmental monitoring processes through automation, boosting efficiency and accuracy.
- Developed corporate presentations and consultation frameworks to strengthen client relationships and organizational capabilities.
- Mentored and trained cross-functional teams, cultivating a high-performance culture and ensuring sustained compliance excellence.

Quality Specialist I | Nov. 2021 – July 2023

- Advanced the external audit program, achieving a 12.7% increase in audit volume and enhancing client satisfaction.
- Accelerated investigation closure rates from 83% to 95% by implementing streamlined processes and fostering collaboration.
- Maintained QMS compliance to ISO 9001 and ISO 17025 standards, driving process improvement initiatives.
- Conducted comprehensive quality reviews, including environmental monitoring, CAPAs, and regulatory documentation.
- Delivered strategic risk assessments to bolster operational resilience and regulatory compliance.

PRATT AND WHITNEY, Londonderry, NH & North Berwick, ME

Quality Review Coordinator | Feb. 2016 – Nov. 2021

- Reduced work-in-progress inventory by 40%, translating to a \$2.1M cost reduction through an innovative supplier ERP system.
- Boosted shipment turnaround times to 24 hours by implementing streamlined processes and SOPs.
- Increased engine deliveries by 20%, resulting in \$250M in annual cost savings through data-driven decision-making.
- Enhanced compliance by reducing human error rates to 0.016% via robust quality control initiatives.

PRATT AND WHITNEY, (Advanced Coating Technologies), Middletown, NY
Parts Inspector | Sept. 2007 – Feb. 2016

- Promoted to Quality Review Coordinator for consistently delivering exceptional performance.
- Developed employee training programs, fostering an engaged and high-performing workforce.
- Introduced lean manufacturing methods, reducing waste and improving overall operational efficiency.
- Conducted risk assessments, improved workplace safety to meet OSHA standards, and advised on health and safety compliance.

WENTWORTH DOUGLASS HOSPITAL, Dover, NH
Dietetic Technician, Registered (DTR) | Sept. 2018 – May 2020

- Conducted malnutrition risk assessments, collaborating with interdisciplinary teams to improve patient outcomes.
- Successfully supported EHR migration to Epic with minimal disruptions to patient care and operations.
- Developed protocols to expedite nutrition risk assessments, enhancing workflow efficiency and staff satisfaction.

Steris Isomedix, Chester, NY
Cell Operator | Sept. 2004 – May 2007

- Follow ISO and cGMP procedures by monitoring established programs; supervising production and scheduling activities; maintaining frequent contact with cross-functional teams and minimize downtime.

EDUCATION

B.S. in Business Administration (Patient Safety & Quality)
Southern New Hampshire University, Manchester, NH | GPA: 3.9/4.0 | Aug. 2021

A.S. in Dietetic Technology
Southern Maine Community College, Portland, ME | GPA: 4.0/4.0 | Dec. 2018

CERTIFICATIONS

- Certified Quality Auditor (CQA), American Society for Quality (ASQ)
- Dietetic Technician, Registered (DTR), Academy of Nutrition and Dietetics
- Lean Yellow Belt, Mount Wachusett Community College