

NINA MALYUTINA, PH.D.

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SUMMARY

A strong quality management professional with a track record of effectively managing quality related projects and delivering superior results in audits, process improvements, and contract administration.

SKILLS HIGHLIGHTS

- Certified Lead Auditor (CQA)/QMS
- Quality Management and Compliance
- ISO9000 series
- CMMI-Dev & Svc
- FDA Regulations
- Certified FISMA Compliance Practitioner (CFCP)
- Contract Administration
- Internal & Supplier Auditor
- ASQ International Team Excellence Award Judge
- Candidate SCAMPI Lead Appraiser (CSLA)
- Certified CMMI Professional (CCP)

WORK EXPERIENCE

DB Consulting Group, Inc.

2008 - Present

VP of Quality Management and Compliance

- Directs Quality Improvement Office based on corporate and departmental strategic and tactical plans
- Leads corporate quality management activities including certification, compliance, and maintenance of a Quality Management Plan and Quality Management System (QMS)
- Manages corporate effort to achieve and maintain ISO 9001:2015 and CMMI designations
- Represents management team with registrars, auditors and consultants
- Ensures corporate compliance with applicable local, state and Federal laws and regulations
- Identifies resource knowledge gaps and administers training on quality, auditing, and safety topics
- Manages quality program budget spending and associated deadlines
- Recommends process and policy improvements for improving operational effectiveness
- Manages business development activities through marketing, branding, proposal development, technical advisory and organic contract growth
- Supports implementation of corporate goals and objectives helping the company to continuously improve performance, growth and market position
- Ensures employee compliance with safety, ethics, time reporting, federal acquisition and other applicable policies (FISMA, FAR, OSHA, etc.)

System Automation Corporation

1998 - 2008

Quality Manager / Contract Administrator

- Directed activities required for compliance with mandatory standards, including corporate quality certifications and contractual requirements
- Served as a Lead Certified ISO 9001 Auditor for the corporate quality audit program and as an authorized SEI Appraiser Team Member for project self-assessments
- Developed and audited ISO and CMM/CMMI quality management protocols and managed auditing staff
- Provided awareness and guidance to management staff in resolving quality assurance deficits
- Ensured adequate training is given to internal auditors and other employees supporting relevant activities described within the Quality Management System
- Reported on Quality Management System and contract performance to management
- Established quality policies, procedures and metrics to meet contractual requirements

Precision Therapy International

1996 - 1998

Quality Assurance / Regulatory Affairs Officer

- Implemented FDA QSR, European regulations, including the MDD and ISO 9001
- Managed activities to achieve official product certification and triaged customer support issues
- Wrote, modified, reviewed, and implemented company/R&D mandatory procedures and guidelines
- Coordinated activities required for project planning, review, and tracking of deliverables
- Performed internal and subcontractor quality audits
- Assisted with the generation of FDA product market clearance submissions
- Scheduled and conducted R&D training sessions, internal audits, QA- and regulatory-related activities

LANGUAGE COMPETENCIES AND SOFTWARE

- Languages: Bilingual (Russian)
- Software: MS SharePoint, MS Office 2013, MS Project, Sure Track, MS Outlook, Quick Books, Easy Track Complaint Processing Software, ISO Expert, Visio

CERTIFICATIONS & SPECIALIZED TRAINING

- Certified CMMI Professional (Certification Number: 12863582). Validity through December 6, 2019.
- SCAMPI Lead Appraiser Training (CMMI Institute Certificate from 1-19-2017.)
- SCAMPI Lead Appraiser Exam (CMMI-DEV), August 2017.
- Advancing Organizational Capability, Applying CMMI (CMMI Institute Certificate from 12-9-2016.)
- ISO9001:2015 Lead Auditor (TPECS) 1-28-2016: BSI/Exemplar Global. Certificate #8429634-12662.
- Auditor/Lead Auditor, International Register of Certified Auditors, Certificate No. 97056-45095 BSI, Course # A2160 registered by the Governing Board of the IQA.
- Auditor to ISO 9000, International Register of Certified Auditors, Certificate No. 96793-42143 BSI, Course # R132 registered by the Governing Board of the IQA.
- ISO 9001:2000 Auditor Transition Course (RAB Certificate No. 01-0-0405-5, April 2001.)
- Implementing ISO 9001:2000 Course conducted by CEEM, Inc., July 2001, Certificate # 01-0-0701-1.
- CMMI-SVC training conducted by the CMMI Institute-Authorized entity on 4-18-2014.
- SEI-CMMI Version 1.2 Upgrade Training (August 2008) and Process Areas Training (July 2008.)
- Introduction to CMMI Version 1.1 (Staged and Continuous), SEI, January 2002.
- SEI-CMMI v.1.1/CMM Training Courses (including the CMM-Based Appraisal for Internal Process Improvement, Introduction to the CMMI/SE/SW/IPPD, etc.) Certificates collected during 2001-2002.
- Formal Training Courses by SAIC Certified Instructors (SQA, the System and Software Estimation Techniques, etc. Certificates collected during 2001-2002.
- Food and Drug Administration Seminars.
- Certified Quality Manager Program (CFE 566) – ASQ, October 1998.
- ITIL Version 3 (Overview) – Training course conducted by Pink Elephant (Canada) on July 28, 2008.
- CFCP (Certified FISMA Compliance Practitioner) – Certificate # 113458, April 2011.
- FISMA 101 – FISMA Compliance Introduction and CFCP Exam/FISMA CENTER, November 2010.
- FISMA 251 – Ethical Hacking & Security Tools/ FISMA CENTER, March, 2012.

EDUCATION

Voronezh State Technical University

Voronezh, Russia

- Ph.D. in Business Economics
- Masters of Business Administration (Concentration: Business Economics & Engineering)