# Dr. Mark R. Willis, LP.D.

57 Locust Street, Attleboro, MA 02703
Cell: +1 (508) 272-9647
WillisQSConsulting@gmail.com

## Summary of Qualifications

An experienced global program and project manager with specialization/concentration in both the medical device manufacturing and pharmaceuticals industries. Through association with ISO, I have obtained knowledge and experience working with all types of industries from aerospace to education. Management and leadership experience in developing governance processes across the company including IT, Legal, Finance, Supply Chain, and Manufacturing.

## Education

**NORTHEASTERN UNIVERSITY, Boston, Massachusetts**
Doctorate in Law and Public Policy
Dissertation: *Counterfeit Pharmaceuticals: Are the U.S. consumers aware of the risk?*
September 1, 2018

**NORTHEASTERN UNIVERSITY, Boston, Massachusetts**
Master of Science in Regulatory Affairs for Drugs, Biologics, and Medical Devices
Sigma Epsilon Rho Honors Society
May 2009

**NOTRE DAME de NAMUR UNIVERSITY, Belmont, California**
Bachelors of Science Degree in Finance/Economics
June 1999

## Certifications & Visas

ASQ certified Quality Auditor (2015)
Project Management Professional (2011)
Information Mapping Certification (2009)
ISTQB Certified Tester Foundation Level (2008)
ASQ certified Software Quality Engineer (2007)
Pacific Institute Certification (2007)
Chinese Visa – 10 years, multiple entry (2015)

## Speaking Engagements

**Presenter**: Drug Information Association conference 2014 – San Diego, CA
- Regulatory Requirements for Qualifying a Software Vendor
- Qualifying a Software Vendor in a Regulated Industry

**Presenter**: Project Management Education Forum 2015 – Boston, MA
- Project Management Education in a Multicultural Environment
- Discussion Boards, and Blogs, and Wikis: The Evolution of the Classroom

**Lecturer**: Harvard University School of Business (2014)
- The Business of Regulatory Affairs

**Speaker:** NAAAP's 2016 National Leadership Conference – Boston, MA
**Speaker:** IQPC's 2017 Pharmaceutical Serialisation & Traceability Conference – Vienna, Austria
**Speaker:** VA Healthcare Summit 2020 – Washington D.C.
**Speaker:** 14th International Conference on Pharmaceutics and drug safety (2020) – Frankfurt, Germany
**Speaker:** 21st Middle East PharmaTech & Expo (2020) – Istanbul, Turkey
**Speaker:** MedTech Summit US (2023) - Virtual
**Keynote Speaker**: IQPC's 2018 Pharmaceutical Serialisation & Traceability Conference – Zurich, Switzerland
**Keynote Speaker**: IQPC's 2018 Pharmaceutical Traceability Conference – Philadelphia, PA, US
**Keynote Speaker**: IQPC's 2019 Pharmaceutical Brand Protection & Traceability Conference – Zurich, Switzerland

## Board of Directors Membership

**Goldmark Federal Credit Union** 2024

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## Consulting Experience

Independent Consultant – Willis QS Consulting, LLC 2018-Current

**MEDTRONIC** **2024**

- Led the development of the Hugo robotic-assisted surgery (RAS) system FDA regulatory filing.
- Managed cross-functional teams including engineering, quality, regulatory and other departments at both the US and German facilities through multiple program implementation.
- Served as the primary point of communication between internal teams and external stakeholders, facilitated clear and timely updates on program progress.
- Tasked with implementing robust risk management practices and developing contingency plans.
- Managed robust global project budgets, forecasting, and resource allocation.

**ROCHE** **2023-2024**

- Supported the analysis of global regulatory requirements to determine a corporate-wide impact and risk assessment.
- Developed a corporate-wide regulatory impact and response for global, regional, and local laws, regulations, standards, and guidance documents
- Lead program blitz covering 30+ Subject Matter Experts in five different time zones to reduce regulatory assessment backlog.

**JOHNSON & JOHNSON** **2023**

- Provided project management support for the QMS integration between the parent corporation and the Abiomed acquisition.
- Developed basic project support for multiple QMS workstreams which included creating project charters, project timelines, managing cross functional team member updates, executive stakeholder reporting, and ultimately exceeding project timelines.
- Provided regulatory subject matter expertise for ISO 13485 and global/local regulations, directives, laws, and standards.
- Integrated document standards as well as CAPA and Non-Conformance systems between J&J and the Abiomed acquisition.

**TAKEDA** **2022-2023**

- Supported a Raw Material Task Force responsible for the identification & prioritization of at-risk or impacted materials.
- Developed alternative material sourcing options & collaboration with current & new suppliers on alternative supply solutions.
- Identified short-, medium- & long-term site & global raw material supply mitigation strategies based on latest industry business intelligence.
- Tasked with purchase order & relationship management for a subset of globally strategic suppliers to buy down supply risk.
- Utilized existing ERP master data to proactively manage material lead time increases & generate 24-month forecasts.
- Consulted with Cell Therapy Operations for the creation of material flows, inbound / outbound logistics, raw material supply planning, new material establishment, production scheduling processes, Drug Product packaging / labeling solutions & ERP system strategy for start-up modality.

**STRYKER** **2022-2023**

- Performed project management duties for Stryker to ensure compliance with the both the UKCA and EU MDR regulations.
- Managed the conversion of the EU-MDR and IVDR regulatory requirements across multiple divisions and global sites.
- Managed the implementation of the new UKCA regulatory requirements including Direct Parts Marking (DPM) for all non-sterilized Class I and Class IIa devices.
- Supported and mentored SMEs assigned to Nonconformance to ensure a high level of compliance and swift resolution to the identified issues.
- Identified an implementation strategy for the transition to Planview for all Joint Replacement project management functions.

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## Consulting Experience (Continued)

**US FOOD AND DRUG ADMINISTRATION (US FDA)** **2021-2022**

- Pharmaceutical Supply Chain subject matter expert focused on the data analytics aspect as opposed to operations and quality.
- Focused on areas such as predictive modeling, data sourcing, data engineering, reducing lead times, helping analyze all aspects of data to help get materials to commercial manufacturers faster.
- Performed the role of strategic advisor to the FDA to determine how to optimize pharmaceutical supply chain in the United States, specifically following the COVID19 pandemic.
- Utilized various data models and a team of analysts to optimize sourcing processes for raw materials and enhanced the regulatory processes that govern the drug supply chain of the DAX financial index.

**CONFIDENTIAL (GLOBAL MEDTECH FIRM)** **2021**

- Provided regulatory guidance regarding global Corporate Social Responsibility laws, REACH/RoHS, WEEE, etc.
- Identified appropriate regulatory application to ensure compliance.
- Developed and presented to Senior Leadership the expectations of a company once they become a member of the DAX financial index.

**MERCK (ANIMAL HEATH DIVISION)** **2021-2022**

- Developed a global program management process for Merck's Animal Health division within 2 months.
- Evaluated a large portfolio of innovation projects, gathered details from SMEs and presented recommendations and findings to senior leadership.
- Managed Merck's API Innovation portfolio of projects which delivered $64.5M in value to the organization.

**BD, INC.** **2018-2019**

- Performed project management duties for BD, Inc to ensure compliance with the new Post Market Surveillance amendment put into place by Health Canada.
- Supported and mentored a multi-functional team in the compliance with the new EU MDR regulation.
- Managed the project by interacting with multiple functions as well as by planning, organizing, and directing the team to completion.
- Ensured that accurate data was provided in a timely manner.
- Identified, quantified, and prioritized the various initiatives and interdependencies to ensure the work was allocated efficiently.
- Monitored progress by tracking of overall project status and critical path.
- Delivered the initial phase of the project one month ahead of schedule.

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## Professional Experience

BD, INC., Warwick, RI **2019-2021**

**Program Manager** 2019–2021

- Coordinated strategic synergy savings throughout the Surgery division
- Assured project financials (NPV, Payback, etc.) were achieved throughout divisional portfolio
- Directed multi-site program impacting manufacturing, R&D, Supply Chain, Regulatory, and Quality
- Provided guidance for compliance with the US FDA Drug Supply Chain Security Act, the EU Falsified Medicines Directive, and regulatory matters pertaining to Brexit.

FRESENIUS MEDICAL CARE, Waltham, MA **2014-2018**

**Global Director, Corporate Social Responsibility** 2018

- Developed, launched/implemented and manage corporate responsibility and sustainability approach and framework, including periodic materiality assessment processes
- Strategized a communication approach regarding trends and developments for corporate responsibility and sustainability among internal and external stakeholders
- Engaged with these key stakeholders on responsibility and sustainability topics
- Ensured compliance to global regulations such as REACH, RoHS, WEEE, European Battery, etc.
- Analyzed product BOMs with various hazard materials lists and communicated with regulatory agencies as needed
- Submitted letters of conformity to ECHA and the EU
- Developed risk strategies for any supplier non-conformance or non-declaration
- Served as the organization subject matter expert for formal reporting and broader communications needs and opportunities
- Developed and maintained collaborative relationships with internal partners / functions that contribute to responsibility and sustainability to drive toward coalitions, consensus and action
- Coordinated and managed resources in 35 global manufacturing facilities, 20 distribution centers, and 2,500 clinics regarding activities focused on responsibility and sustainability project and data collection
- Maintained working relationships with third-party corporate social responsibility auditors for development and assurance regarding the non-financial report to meet the European Union regulatory requirements

**Global Director, GMQ IT Governance** 2017–2018

- Established an enterprise, regional, local, and "shop floor" level IT governance and reporting structure
- Analyzed current direct and indirect spend on IT to determine duplication and overspend
- Reduced US spend on IT by $7.5M annually within first 60 days
- Maintained presence and establish relationship with site management and IT
- Coordinated efforts with Senior Management from various corporate divisions

**Director, GMQ Global Program Management Office** 2016–2017

- Established global portfolio management standards, policies, and guidance
- Partnered with global and local vendors to ensure standard practices were implemented within all applicable locations
- Directly managed 5 Program Managers with indirect, dotted-lined management of 225 site and department level Project Managers

**Global Program Manager** 2014–2016

- Developed a global Program Management Office structure to support manufacturing, supply chain and quality/regulatory affairs.
- Managed global programs including Pharmaceutical item level serialization, compliance reporting and product reporting
- Supported and managed teams working on new product development with a strategic rollout on a global scale at multiple manufacturing sites
- Developed and implemented a global project management curriculum and performed training for 100+ SMEs regionally
- Managed and mentored 146 regional site-level project managers under the global programs
- Lead quality audits for both suppliers and software vendors evaluations

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## Professional Experience (Continued)

SHIRE PHARMACEUTICALS, Lexington, MA **2014**

**Manager, System Administration** **(6-month contract)** 2014

- Project Manager role for new product development and release in the UK
- Performed Document Coordinator role and managed the Backroom during the EMA Inspection at the Basingstoke UK satellite site
- Reorganized the department to align to corporate goals and business needs
- Managed the Quality Management Systems (QMS) including change controls, end user training, business metrics and reporting
- Developed of Business Case and Solution Requirements for the upgrade of the Audit platform

CUBIST PHARMACEUTICALS, Lexington, MA **2013–2014**

**Principle Information Technology Business Analyst** 2013–2014

- Established and maintain IT compliance procedures and change control processes
- Supported the internal investigation of the Quality Systems and IT organizations
- Implemented the eCTD file format structure to support the new product and product renewals with global health authority agencies
- Supported the external investigation of Clinical Research Organizations (CROs) and Quality Systems Vendors

FRESENIUS MEDICAL CARE, Waltham, MA **2005–2013**

**Global Quality Systems Infrastructure & Standards Manager** 2012–2013

- Researched domestic and international standards and analyze applicability as relates they to the production and marketing of FMC's products in all geographic areas and markets
- Identified emerging trends in domestic and international standards which impact FMC
- Engaged with relevant international standards organizations and assure FMC representation on key domestic and international standards committees
- Supported the investigation, development, and implementation of IT Infrastructure and solutions for addressing regulatory compliance concerns generated by the evolving stands and regulations.
- Translated IT functional requirements regarding the integration of international standards within the worldwide network of FMC
- Supported development of appropriate certification schemes and processes (i.e. ISO).
- Evaluated the impact of new or revised domestic or international standards on FMC and provide routine intelligence to the executive management team on changes in regulatory environments
- Established and maintain centralized electronic repository / library for all standards which govern business activities of FMC
- Developed and implement strategy for educating FMC on International Standards.

**Senior Business Process Manager** 2010–2012

- Partnered with cross-organizational managers to identify scope, expectations, dependencies and ensure successful project delivery. Offers input to, and ensures quality of functional and system requirements.
- Managed day to day communications with the project team and business. Effectively and proactively manage business partner expectations.
- Developed and managed project budgets and resources
- Conducted end-project evaluation and ensure lessons learned are integrated into the project.
- Supported Project Release into production.
- Supported CAPA management for IS teams
- Represented IS in internal & external regulatory audits including FDA, ISO, Sox and TUV

**Project Manager Quality Systems Validation** 2005–2010

- Implemented software application for the creation, processing and filing of Regulatory Submissions
- Provided first line IT support to the Regulatory Affairs department for their eCTD publishing tool during submissions
- Budgeted & forecasted project work effort into the future based on assumptions and limited data
- Presented to senior management on progress of the projects

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## Professional Experience (Continued)

3COM CORPORATION, Marlborough, MA **2000–2005**

**Senior Business Systems Analyst**

- Coordinated the Global standardization of Commissions
- Developed a Microsoft Access based Commissions System
- Maintained and coordinated the dynamic Sales Organization Hierarchy structure
- Managed Project Teams of up to 15 members
- Coordinated the effort to clean and standardize the sales and reporting information contained within the SAP R/3 system
- Automated the Global Executive Sales Summary Reports

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## Teaching Experience

### STONEHILL COLLEGE, Easton, MA **2023**

**Professor of Practice** 2023– Present

Responsible for developing and executing lesson plans for varying levels of courses at Stonehill College. Currently participating within the Healthcare Management curriculum teaching the following courses:

- Healthcare Foundations (HCA-105)
- Population Health Management (HCA-216)
- Healthcare Policy and Politics (HCA-220)
- Economics of Healthcare (HCA/ECO-321)
- Healthcare Supply Chain Management (HCA-326)
- Healthcare Products and Services Delivery (HCA-330)

**Faculty Senate Representative – Meehan School of Business** 2024– 2027

Faculty Senate representative supporting and collaborating throughout the Meehan School of Business. This includes working with all the faculty members from Accounting, Finance, Economics, International Business, Healthcare Management, Business Management, Information Systems, Marketing, and Sports Management to ensure each department is appropriately represented at the institution. The Faculty Senate shall have legislative powers concerning academic policies and procedures including curriculum, faculty governance, and promotion and tenure criteria.

### BUNKER HILL COMMUNITY COLLEGE, Cambridge, MA **2020**

**Part-Time Lecturer** 2020

Responsible for developing and executing lesson plans for varying levels of courses at Bunker Hill Community College (BHCC). Currently participating within the Financial Management curriculum teaching the following courses:

- Introduction to Corporate Finance (FIN-106)

### MASSACHUSETTS COLLEGE OF PHARMACY & HEALTH SCIENCES, Boston, MA **2018**

**Part-Time Lecturer** 2018-2022

Responsible for developing and executing lesson plans for Bachelors level courses at MCPHS. Currently participating within the Health Management curriculum teaching the following courses:

- Microeconomics
- Intro to Corporate Economics
- Delivering Healthcare in America

### NORTHEASTERN UNIVERSITY, Boston, MA **2014**

**Part-Time Lecturer – College of Professional Studies (CPS)** 2014– 2019

Responsible for developing and executing lesson plans for graduate level courses at Northeastern University. Currently participating within both the Project Management and Regulatory Affairs curriculums teaching the following courses:

- Project Management Practices (PJM6000)
- Project Scheduling and Cost Planning (PJM6025)
- Project Scope Management (PJM6005)
- Project Quality Management (PJM6135)
- Managing Troubled Projects (PJM6140)
- Regulatory Affairs: Strategic Planning and Management (RGA6210)

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## Volunteer Engagements

**Good Will Ambassador:** Fight the Fakes Organization
**Regulatory Policy Subject Matter Expert:** United Nations (2017-Present)
**Content Reviewer:** UN Africa Renewal

## Professional Affiliations

- New England Society for Healthcare Materials Management (NESHMM) – 2022-Present
- Drug Information Association (DIA) – 2013 - Present
- International Society for Pharmaceutical Engineering (ISPE) - 2011 - Present
- ISO Z1 Audit Member – 2010-2013
- ISO TC176 Member – 2009-2013
- ISO Z1 Quality Member – 2009-2013
- ASQ Quality Management Division Member - 2009 - Present
- ASQ Reliability Division Member - 2009 - Present
- ASQ Software Division Member - 2009 - Present
- ASQ Senior Member - 2009 – Present
- ASQ Boston Chapter Member - 2008 – Present

## Publications

**Published:**

**Author:** Counterfeit Pharmaceuticals: Are the U.S. Citizens Aware of the Potential Risks? (ISBN 978-620-0-27616-2)

**Author:** Regulatory Affairs 2020: Counterfeit Drugs and Medical Devices in Developing Countries (Medical Safety and Global Health; Volume 9, Issue 1)

**Submitted:**

**Author:** Unrealized External Factors Impacting the Medical Device Supply Chain

**In Draft:**

**Author:** Medical Manslaughter: Decomposing the Tragic Events Involving the New England Compounding Center and the Governments' Response

**In Research:**

**Author:** The Necessary Evil: Economics Behind Global Counterfeit Pharmaceuticals

**Author:** Infecting the Supply Chain: Examining a Counterfeit Drugs Path to the Healthcare Market

**Author:** Manufacturing Evil: Conversations with Drug Counterfeiters