

DEEPTI PREMRAJ

Senior Quality Engineering Leader | Software, Medical Devices, Healthcare SaaS

GREATER BOSTON AREA

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PROFESSIONAL SUMMARY

Quality engineering leader with 20 years' experience driving global software validation, automation, and compliance in regulated healthcare, biotech, and enterprise SaaS. Proven track record reducing risk, improving efficiency, and ensuring FDA and international compliance.

SKILLS

- Technical Skills
Software Quality Engineering · Test Automation · FDA Compliance · Agile & Waterfall SDLC · LIMS Platforms
- Soft Skills
Team Leadership · Cross-Functional Collaboration · Regulatory Documentation · Risk Management · Strategic Planning

KEY ACHIEVEMENTS

- Reduced manual testing time 80% with global automation framework implementation
- Directed cross-functional teams of 30+ engineers across five global regions
- Delivered FDA-compliant submissions enabling timely product approvals and market launches
- Improved release efficiency 35% by standardizing automation and Agile test practices
- Achieved zero audit findings during multiple FDA and international compliance inspections
- Hired, mentored, and advanced high-performing quality engineering teams worldwide

WORK EXPERIENCE

FOUNDATION MEDICINE, BOSTON, MA

10/2023 – PRESENT

Foundation Medicine is a leading molecular information company that specializes in genomic profiling of cancer. The company's mission is to transform cancer care by providing comprehensive genomic profiling solutions to guide personalized treatment decisions for patients.

Associate Director, Software Quality Engineering (Medical Devices & Lab Systems)

- Led global quality engineering team supporting laboratory systems and SaMD validation
- Directed end-to-end testing for LIMS migration, ensuring FDA compliance standards
- Reduced regression testing cycles 80% through scalable automation frameworks
- Managed audit readiness, achieving zero findings in government and client inspections
- Oversaw validation documentation for FDA submissions supporting product launches
- Implemented GDPR and HIPAA compliance processes across global distributed teams

ATHENAHEALTH, BOSTON, MA

01/2022 – 10/2023

Athenahealth provides a leading SaaS platform that simplifies the management of patient data, provider revenue lifecycle, and patient access to their data.

Senior Manager, Software Quality Engineering (Healthcare SaaS)

- Directed 16-person quality engineering team across Boston and India locations
- Implemented risk-based test strategies improving release predictability and reliability

- Defined release schedules and communicated changes across multiple business units
- Established performance metrics and scorecards enhancing quality accountability
- Drove hiring, onboarding, and mentoring of global QA engineering talent
- Enhanced automation coverage and improved Agile testing practices for SaaS delivery

PTC, BOSTON, MA

04/2021 – 01/2022

PTC is a leading global technology company specializing in providing software solutions and services that help organizations transform their digital capabilities focusing on areas such as product development, industrial automation, augmented reality, and Internet of Things (IoT).

Senior Manager, Software Quality Engineering (Enterprise Applications & Automation)

- Led 18-member QA team implementing automation and risk-based testing strategies
- Automated release testing process reducing errors and saving development time
- Managed QA hiring, team performance, and global resource allocation planning
- Delivered roadmap of quality initiatives improving developer efficiency and product quality

FOUNDATION MEDICINE, BOSTON, MA

09/2018 – 04/2021

Foundation Medicine is a leading molecular information company that specializes in genomic profiling of cancer. The company's mission is to transform cancer care by providing comprehensive genomic profiling solutions to guide personalized treatment decisions for patients.

Manager, Software Quality Engineering (Medical Devices & LIMS)

- Directed testing strategy for LIMS 2.0, company's largest regulated release
- Built high-performing global team integrating automation and continuous integration
- Standardized testing processes across nine Agile teams, ensuring FDA compliance
- Supported global SaMD rollouts across EU and Japan under MDR/PMDA regulations

PATIENTKEEPER(COMMURE), BOSTON, MA

07/2013 – 09/2018

PatientKeeper (Commure) is a healthcare technology company that specializes in providing electronic health record (EHR) optimization solutions for hospitals and healthcare organizations. Their software solutions aim to streamline clinical workflows, improve physician productivity, and enhance the overall patient experience.

Manager, Software Quality Assurance (Healthcare IT/EHR Systems)

- Managed global QA teams delivering EHR and financial healthcare applications
- Integrated QA into Agile development, aligning testing with product roadmaps
- Implemented automation frameworks using Selenium to improve release efficiency
- Mentored QA engineers, improving retention and professional development outcomes

IDEXX LABORATORIES, US

2012 – 2013

Lead Software QA Engineer (Medical Devices)

- Led quality assurance initiatives for diagnostic medical device software compliance

FIDELITY INVESTMENTS, US

2011 – 2012

Lead Software Quality Engineer (Financial Services)

- Led Directed QA initiatives ensuring compliance for trading and financial applications

WELLS FARGO, US <i>Senior QA Analyst (Banking Applications)</i> Conducted functional and regression testing for core banking software platforms	2011 – 2012
COGNIZANT TECHNOLOGY SOLUTIONS, US <i>Lead QA Analyst (Enterprise Applications)</i> Managed offshore QA team supporting enterprise client application releases	2010 – 2011
IBM, INDIA <i>Software QA Lead (Enterprise Applications)</i> Coordinated QA delivery for enterprise software clients across US and India	2005 – 2010
HCL TECHNOLOGIES, INDIA <i>Software QA Engineer (Enterprise Applications)</i> Executed manual and automated testing ensuring enterprise application stability	2004 – 2005

EDUCATION

VELLORE INSTITUTE OF TECHNOLOGY, INDIA, **Master of Technology**, VLSI DESIGN [Graduated 2006]

KSR COLLEGE OF TECHNOLOGY, INDIA, **Bachelor of Engineering**, ELECTRONICS & COMMUNICATION ENGINEERING [Graduated 2004]