

Mohammad Khair

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Medical device product development expert with diverse multidisciplinary skill set in medical device engineering and product development R&D, project management, and advanced technology research. Strong execution oriented technical leadership and project management skills.

Experience in various clinical application including medication infusion delivery, critical care, cardiovascular hemodynamics & electrocardiography, electrophysiology & neurology, medical imaging, diabetes glucose management, anesthesia monitoring, blood processing systems, and endoscope disinfection, renal dialysis, and maternal and infant care.

- **Engineering Management:** Director of Engineering & Project Management: Lead multidisciplinary teams of up to 60 R&D staff including electrical, software, firmware, mechanical, systems, verification, and manufacturing engineers, Also lead cross-functional support teams of Quality, Regulatory, and Clinical staff.
- **Program Management:** Responsible for more than complex medical device and capital equipment programs development from concept through development, verification, validation and launch, coordinating project teams activities and priorities, project planning, and budget analysis for up to \$25M/year. Complex and detailed schedule development for up to 2K tasks with full dependency and milestone development. Strong business and program management acumen.
- **Strategy Planning:** Responsible for technology strategy and synergy for integration, multi-generational product development planning. Business development opportunities assessment and due diligence.
- **Innovation:** Responsible for novel technology concept development, technical and clinical risk mitigation, intellectual property protection, and specification into formal product development. Sharp focus on user needs and clinical outcomes, as well as technical innovation and disciplined execution of engineering programs.
- **Software, Data, & Algorithms:** expertise in software architecture & development & data strategy and management, and algorithms development including artificial intelligence applications.
- **Regulatory Experience:** Global product launches in US, EU, Brazil, China, Singapore, and Malaysia with complete regulatory filing development and support.

Work Experience

International Computing Institute for Quran & Islamic Sciences

CEO, Chief Executive Officer

QuranComputing.org

(A Nonprofit Corporation formed the State of Delaware, USA)

May 2022 to Present – Milwaukee, WI

An executive leader establishing the foundation, vision, and mission, and providing the resources required for operations to create a state-of-the-art scientific institute that drives a mission to facilitate a modern understanding of Quran's teachings. Building technological solutions to enable modern theological insights and constructs that serves humanity and addresses its social issues. Attracting world-renowned Computing and Islamic Sciences scholars to our mission and membership of the Institute, as well as mentoring and growing the talent and skill of younger members with the motivation to create a new reference standard technological resources for the Quran including: extensive databases, software libraries for linguistic analysis, statistical analysis, and analytical algorithms including artificial intelligence for deep learning and machine learning. The institute will provide an Open Source and free-access platform that is cloud-enabled and serves diverse applications on web-browsers, mobiles, and PCs to encourage technological developments towards its mission.

Principal Engineer – Algorithms & Analytics

General Electric Healthcare (www.gehealthcare.com) MATERNAL & INFANT CARE (MIC)

July 2017 to Present – Wauwatosa, WI

Technical Leadership: Providing advanced technology leadership for clinical multi-parameters diagnostics monitoring and controls, driving advanced signal processing, computer vision, and deep-learning algorithms and predictive analytics, and therapy delivery decision support.

- Lead innovation for new product introduction in diverse clinical applications including cardiology for maternal ECG, fetal ECG, and neonatal ECG with algorithms for heart rate measurement thru motion, as well as lead development of wearable sensing technology for cardiac heart rate monitoring.
- Responsible for artificial intelligence algorithms (AI): machine learning and deep learning neural networks algorithms and applications. Provide technical leadership for next generation algorithms related to adaptive predictive models, adaptive control, smart alarms, and big data analytics of large databases, and analytics dashboards development. Development with Matlab Labview. and Firmware.
- Development of neonatal non-contact monitoring platform using Camera based computer-vision and AI Deep Learning delivering physiologic diagnostics for Heart Rate and Respiration Rate as well as physical and developmental measures.
- Architecture of clinical data and camera video streaming services to Edge servers and AWS Cloud services to perform AI inference and provide mobile access and connectivity to the data as well as data Lake storage. Leveraging Matlab Production Server for AI inference engine and parallel computing with GPUs.
- Development of algorithms for maternal & fetal ECG separation and detection for Novii product, as well as algorithms for Uterine activity detection and analysis of delivery progression.
- Development of respiration monitoring, and oxygenation monitoring during resuscitation.
- Evaluation of noninvasive fetal abdominal oximetry using reflectance oximetry, and evaluating fetal risk of Hypoxia.
- Monitoring and prediction of fetal hypoxia with a patient risk index using cardiotocographs (CTG) data.
- Evaluation of sepsis monitoring and prediction technology.
- Evaluation of Control of thermal regulation and weaning of neonates from warmers.
- Sleep and activity monitoring, and high precision continuous weight scale measurements & baby location sensing.
- Development of next generation platforms and diagnostics technology for infant incubators, thermal warmers, Neonatal ICU (NICU), and Labor and Delivery systems.
- Filed 7 patent applications, and multiple disclosures.

Director, Engineering Project Manager

Fresenius Medical Care, Inc. (www.freseniusmedicalcare.us) RENAL DIALYSIS

Sep. 2015 to Apr 2017 – Lake Forest, CA

R&D Project Management: Providing project leadership for innovative new product development (NPD) of medical devices for kidney dialysis for the home market.

- Project Leadership and Management of hemodialysis device with engineering teams including electrical, mechanical, software & firmware, and systems engineering groups as well as a manufacturing group. Cross-functional coordination of activities for design deliverables with R&D, marketing, regulatory, clinical, and quality assurance.
- Providing engineering leadership and prioritization for system level design and development activities, as well as development of design controls documentation and risk management.
- Providing project management and detailed schedule development for engineering design development, verification, and manufacturing.
- Responsibilities include setting team priorities, assessing risks, and maintaining actions and issues logs.
- Focusing team on risk & mitigation, innovation, user needs, and clinical value. Lead design changes with cross functional coordination while minimizing impact on schedule and cost.
- Executive communication with functional management and executive management on project accomplishments, actions, schedules, risks, priorities, technical issues, and project execution metrics.
- Site CAPA review board member and process administration.

- Budget review and administration.
- Staff competency assessment and staffing gap needs evaluation.

Software Engineering Leadership: Directed software development team of up to 3 software and 7 firmware engineers & manager.

- Review of software plans, software and firmware requirements, software risk analysis.
- Cross functional triage and deferral process for defects given clinical risk.
- Schedule definition of work structure and tasks for team members, prioritization of build release features and system level design changes.
- Review / release of key regulatory documentation including requirements, architecture, algorithms, UI workflow documentation.
- Provided leadership for resolution of key design issues related to safety and efficacy with deep technical reviews of all critical sensory and actuation subsystems design, performance, and algorithms.
- Coordinate human factor studies for software UI workflows.
- Support of resources for development of test platforms and tools for simulation and automation of software verification, validation, and integration testing, and tools validation.
- eConnectivity software development for home health cloud data access and therapy logging.
- Development used Linux for UI, embedded software for microcontrollers, Verilog for FPGAs.

Medical Device Design Excellence:

- Lead engineering excellence for medical devices development with full compliance to design controls procedures and FDA regulations.
- Coordinating IDE study and human factors study activities.
- Responsible for the DHF creation for the medical device. Management of technical reviews and design reviews, and release of key deliverables.
- ISO standards applied 60601, 62304, 13485, and 14971.

Manufacturing Management:

- BOM release process and planning.
- DHR development and review coordination and process improvement.
- Managed manufacturing operation for process validation, pFMEA risk management, assembly procedures, materials procurement, acceptance testing, test automation and procedures.
- Lead manufacturing transfer and configuration management activities leading to IDE build with production equivalent units.

Strategy Direction:

- Lead team for development of program long term strategies, objectives, and definition of key architectural improvements for platform software, hardware, and disposables for portability and cost.
- Drive innovation IP protection for next gen platform development, filed 7 disclosures and 2 patents.
- Business process development for product development tools such as Cognition Cockpit rollout for requirements management and traceability to design outputs and verification.

Project Director / Manager of R&D Programs & Technology

Johnson & Johnson - Irvine, CA

Advanced Sterilization Products (www.inj.com) ENDOSCOPE DISINFECTION

Sept. 2012 to Sep. 2015

Technical Leadership & Project Management: Direct and lead new product development programs for High Level Disinfection systems for automated reprocessing of Endoscopes.

- Programs included Optimus & Endoclens, programs including up to 15 internal staff, and 10 consultants. Managed directly up to (5) direct reports of mechanical, systems, and electrical engineers.
- Projects involve development of capital medical devices of electromechanical hardware, software design and development, consumable disinfection chemistry and dosing control, and endoscope connectivity.
- Directed and managed overall Optimus program. Responsible for program planning, risk identification and mitigation, capital and expense budget management, schedule development, and management of external resources for mechanical & hardware development in the US and off-shore contract manufacturing.
- Directed a cross-functional team of mechanical, electrical, software, quality, service, regulatory, and manufacturing engineering through NPD process under design controls for medical device DHF development.

- Provided technical leadership in development of user needs, usability analysis, product requirements, hardware requirements, software requirements, traceability, risk analysis and mitigation, architecture & design activities, and verification and validation activities.
- Supported labeling, regulatory, and service activities.
- Managed manufacturing transfer and manufacturing process development and qualification.
- Supported development of business strategy, financial planning, and global commercial strategy.
- Growth of Endoclen's product production volume by 4x within 2 years
 - Gained regulatory registration approval in Brazil and China for Endoclen's.
 - increasing manufacturing capacity and stabilized supply chain,
 - Lead product improvements to address safety issues and product complaints.
 - Reduced cost by 25%, improved product reliability, and design simplification with user safety enhancements, and RoHS compliance.
 - Programs activities included requirements definition & traceability, architecture & design with considerations for service, manufacturability, and reliability, clinical studies, and verification & validation.
- Trained on PMP project management process and tools by PMI.

Software management: Management leadership of software staff (2) and off-shore software development team (~7) in India for Optimus NPD projects and existing Evotech product.

- Release of key software documentation, including requirements, architecture, and verification test protocols. Update of software risk documentation.
- Release of design changes addressing defect resolutions for existing platforms.
- Delivery of documentation, code, and tools for software verification. Development for Linux and embedded microcontrollers.
- Software schedule creation, budget review, contract negotiation.

PMO program management: Used Insight tool for resources allocation and modeling for portfolio planning across projects in the organization and products pipelines.

- Modeling projects valuation, prioritization of projects.
- Budget and staffing requirements analysis, and resources allocation reporting and dashboarding.
- Administered PMO reviews for management board for projects status for all funded programs across the organization.

Technology management: Developed technical solutions targeting unmet user needs and offering enhanced usability and user interface that designs-out variability in usability models.

Director of Engineering / Sr. Algorithm Engineer

Masimo Corporation - (www.masimo.com) ANESTHESIA BRAIN MONITORING

January 2011 to Sept. 2012 - Irvine, CA

Director for SEDLine depth of anesthesia sedation and brain function monitoring technology.

- **Product Development & Software Engineering:** Direct and lead the development of next generation SEDLine product platform including embedded software, algorithms, and hardware engineering for depth of anesthesia sedation monitoring technology in the OR and ICU.
 - Integration with diagnostic pulse oximetry and pulmonary function assessment during anesthesia.
 - Directed product development activities including definition of software requirements, algorithms development and validation, design and architecture, technical reviews, implementation, verification and validation planning,
 - Directed test tools automation, verification protocols development, execution, and report release.
 - Directed development for software defects resolution for existing product and development and launch of next generation product.
 - Definition of product interface specifications and integration with other products platforms.
 - Development of embedded software on ADSP-21479.
- **Technology Research:** Lead research and development programs for advanced signal processing algorithms development on EEG electrophysiologic signals. Algorithms development included artifacts detection and management, development of measures of Sedation. Research of measures of Analgesia.
- **Regulatory Expansion:** Responsible for review, preparation, and fulfillment of requirements for regulatory approvals and engaged reviews by regulatory agencies.
 - Gained CE Mark approval for Europe.
 - Gained approval for FDA regulatory submission packages.

- ISO standards including 60601, 62304 and 13485 and 14971.
- **Group management:** Directed a group of (4) software, algorithms, and hardware engineers. Prioritization and assignment of engineering tasks, team communications, and status presentations to the executive management.

Sr. Member of Technical Staff

Hospira, Inc (Pfizer)- (www.hospira.com) MEDICATION DELIVERY / CRITICAL CARE

February 2004 to December 2010 Lake Forest, IL

Advanced Technology Center

- **Innovation Technology & Product Development:** Played a key leading role on several projects developments from concept through feasibility demonstration & definition for product development:
 - Development of automated glucose blood assay and sampling diagnostic testing device.
 - Adaptive closed-loop control for drug delivery with physiologic and metabolic diagnostics, including tight glycemic control using large volume infusion pumps for critical care applications.
 - Physiologic model based glycemic control simulations testing in Silico.
 - Adaptive model-free neural network based glycemic control and simulation testing in Silico.
 - Medication delivery infusion pumps, medication fluidic flow sensing
 - Medication infusion clinical decision support platform development
 - Minimally invasive cardiac output monitoring
 - Depth-of-anesthesia sedation advanced signal processing (SEDLine)
- Performed product opportunity development with user needs assessment, market valuation, and technology feasibility including requirements definition using Strategyn's outcome driven innovation. Presentation of programs and technologies to executive management and KOLs.
- Demonstration of technical and clinical feasibility through prototypes software and hardware development, workflow and UI analysis, simulation & modeling,
- Definition of systems and platforms requirements and architecture, advanced algorithms development and clinical validation.
- Lead the integration of medication infusion platforms with health information systems HL7 interfaces for medication orders, labs, and allergies.
- Lead the definition and development of decision support software to support customized therapy protocols. medication incompatibilities, and allergic reactions detection in client-server architecture. Integration of platform with medication delivery workflow.
- Development on Windows using ASP.NET and .NET framework, HTML RESTful, XML, and MySQL for database query and logging access, and web services update framework.
- Developed clinical hazard & risk analysis documents.
- **Program Management** of new products introductions design and development including a program in cardiac diagnostic monitoring and another program for medication delivery clinical decision support information. Cross-functional team leadership (R&D, marketing, regulatory, quality, and clinical).
- **Technology Assessment & Strategy:** member of the corporate technology assessment committee for corporate acquisition due diligence. Provide strategic guidance on technology synergies and roadmaps, and identify business development opportunities.
- **Winner** of Hospira's Excellence in Device Development Award 2004, Innovation Olympics 2010 Silver & Bronze.

Sr. Principal Systems Engineer

Baxter International, Fenwal (www.baxter.com, www.fenwalinc.com, <https://www.fresenius-kabi.com/us/>)

BLOOD PROCESSING

October 2001 to January 2004 - Round Lake, IL

- **System Design & Development:** R&D development and engineering for Red Blood Cell Pathogen Inactivation system for the donor blood supply market.
 - Development of system concept, subsystems definition & safety architecture, systems requirements, system architecture and design,
 - Lead software requirements, architecture for data management, definition of interfaces between subsystems. Software development on Linux and embedded software for microcontrollers.
 - Lead development of subsystems software, hardware, algorithms, sensory and control modules.
 - Component specification of key sensory and actuation subsystems.
 - Integration of software / electrical / mechanical for sensory and actuation subsystems at system level.
 - Verification & validation testing.

- Modeling and simulation of system performance, optimization, and stackup of tolerances analysis
- Reliability assessment of component subsystems.
- **Risk Analysis & Mitigation:** Development of FDA regulatory documentations requirements of hazard analysis, assessment, and control, risk controls, and hazard mitigation algorithms, and FMEA.
- Training ISO9000, QSR, GMP, FDA regulations and standards.

President & Founder

Cardiac Metrics – Irvine, CA (www.cardiacmetrics.com) CARDIAC ELECTROPHYSIOLOGY

January 2001 to October 2001

- **Entrepreneurial Leadership:** founded startup with a focus on mobile healthcare diagnostics sensing and cardiac rhythm management.
 - Development of Leadless Wireless ECG mobile patch providing ability to monitor 12 channels of diagnostic ECG with no lead wires.
 - Development of noninvasive Cardiac Blood Flow Balance for perfusion monitoring.
 - Development of innovations for Pulse Oximetry & Optical Glucose sensing methods.
 - Development of embedded software on Bluetooth , and TI MSP430.
 - Development of realtime streaming data analytics for arrhythmia and fibrillation, and alarms management.
 - Investment fund raising and strategic planning.

Adjunct Professor

Devry University & Harper College (www.devry.edu) May 1996 to January 2001

Taught over 450 students: Information Systems, Advanced C++ Structures, Client/Server Architectures, Labview, Embedded Control.

Senior Staff Software Engineer / Lead Software Engineer

Motorola Inc - Schaumburg, IL (www.motorolasolutions.com) BIOSENSORS / CELLULAR

May 1996 to January 2001

Advanced Technology Center - Motorola Labs

Technical & Innovation Leadership: Driving development from concept to product for innovative wireless biosensors in medical applications for point of care monitoring.

- Development of embedded platform with wireless communication protocols over Bluetooth stack.
- Lead system and software requirements, architectures, and design.
- Innovation and IP protection: Generated seven patents.

Land Mobile Products Sector, iDEN Nextel Technologies Group, BSC Call Processing

Technical Leadership: Cellular Telecommunication Infrastructure.

- Lead software engineer in development of call processing for interconnect protocols for the Base Site Controller (BSC) part of the iDEN (Nextel) system.
- Lead team of (8) software engineers for embedded software development of new products and features. Mentoring team members, performance reviews, and promotions.
- Lead requirements analysis, design, development, and testing of real time systems with multiple BSC software product releases.
- Lead platform computing and communication network performance analysis & optimization in an embedded, multitasking, and multiprocessor real-time systems. Analysis and modeling of system capacity & create performance planning tools.
- UML development: Managed and led multiple projects related to call processing subsystems and state machines definitions using SDL. Development of real time systems using SDL and automated code generation.

Sr. Software Engineer

Siemens Medical Systems, Inc - Hoffman Estates, IL (usa.healthcare.siemens.com)

Angiography X-Ray Group, Nuclear Medicine Group - MEDICAL IMAGING

August 1993 to May 1996

Technical Leadership: Nuclear Medicine Processing WorkStation: Performed as a software engineer leading the development of a post-processing workstation for nuclear medicine (product eSoft) and for

Angio/Fluoro X-ray.

- Tasks included development of software requirements analysis, software object oriented design, architecture of subsystems.

Imaging Processing Algorithms: Advanced algorithms development for medical image processing:

- Automated ROI, isocontours, interpolation & filtering.
- Optimized Filtered backprojection and Fanbeam transverse reconstruction for faster performance.
- 3D image volume reorientation and rendering methods.
- Multimodality 3D image registration and image fusion.

Systems Architecture: Design of system database information model and communications architecture.

- System integration planning and test plan generation.
- Object oriented design of system and database schema.
- Developed image reading for multiple formats: ACR-NEMA, INTERFILE, and DICOM.
- Development on Windows platforms and Unix.

Biomedical Engineer (www.rush.edu) RESPIRATORY

Rush Presbyterian St. Lukes Medical Center - Chicago, IL February 1992 to February 1993

Biomedical Research Engineer, Research in pediatric disorders of respiratory control, data acquisition, and statistical analysis.

Biomedical Engineer III, (www.northwestern.edu) NEUROLOGY

Northwestern Memorial Hospital - Chicago, IL February 1991 to February 1992

- Develop neurological research equipment in EEG, EMG, Evoked Potentials, Vestibular, Oculomotor, Caloric, Epilepsy. Research, data acquisition & analysis for neurological testing.
- Development of biomedical information system databases for equipment tracking and maintenance scheduling
- Responsible for coordinating safety testing, repair and maintenance of biomedical equipment.

Education

Executive Master of Business Administration

UNIVERSITY OF ILLINOIS URBANA-CHAMPAIGN, Chicago, IL 2007 (www.uiuc.edu)

Specialization Areas: Technology Strategy, Business Strategy, International Business, Strategic Marketing, Business Development, Investment Finance & Valuation. Corporate Finance.

Advanced study towards Doctor of Philosophy in Electrical Engineering and Computer Science

ILLINOIS INSTITUTE OF TECHNOLOGY, College of Engineering, Chicago, IL 1991 to 1998

Specialization Areas: Digital Signal Processing, Image Processing, Control Systems, System Identification, Estimation Theory, and Communications. (completed all but thesis) (web.iit.edu)

Master of Science in Biomedical Engineering

MARQUETTE UNIVERSITY, College of Engineering, Milwaukee, WI 1991 (www.marquette.edu)

Bachelor of Science in Biomedical Engineering

MARQUETTE UNIVERSITY, College of Engineering, Milwaukee, WI 1989 (www.marquette.edu)

Patent Publications

- 7,171,166 Programmable wireless electrode system for medical monitoring
- 6,897,788 Wireless system protocol for telemetry monitoring
- 6,533,729 Optical noninvasive blood pressure sensor and method
- 6,475,153 Method for obtaining blood pressure data from optical sensor
- 9,272,089 Differential pressure based flow sensor assembly for medication delivery monitoring and method.
- 8,838,218 Leadless wireless ECG measurement system and method for measuring of bio-potential electrical activity of the heart.
- 9,240,002 Systems and methods for a graphical interface including a graphical representation of medical data
- 9,451,920 System and method for monitoring arterial and venous blood oxygen, blood glucose, and blood constituent concentration.
- 20100280486 System and method for delivering and monitoring medication

20130158504	System for monitoring and delivering medication to a patient and method of using the same to minimize the risks associated with automated therapy.
20130261993	Air detection system and method for detecting air in a pump of an infusion system
20150018632	Cardiac blood flow balance monitoring between the right and left heart chambers.
20150025328	System and method for monitoring cardiac output, flow balance, and performance parameters.
US10272187	System and Methods for dialyzer flow rate estimation using measured dialyzer pressures.
20180289882	Optical detection of air bubbles in either saline or blood or a mixture of both.
20200008686	Monitoring cardiac blood flow balance relationship between the right and left heart chambers and cardiac regulation
20200359923	Methods and systems for obtaining an electrocardiogram signal of a patient via a non-adhering, direct contact electrode apparatus
20190192712	Storage apparatus and method for identifying a position of an object
20200000355	Electric biopotential signal mapping calibration, estimation, source separation, source localization, stimulation, and neutralization.
20220061689	Systems and methods for wirelessly obtaining a physiological signal from a patient
20200281496	Sensor assembly for patient monitoring systems
20210345899	Multi-sensor patch
20210361171	Systems and methods for dynamic selection of sensors for obtaining physiological data from a patient
9451920	System and method for monitoring arterial and venous blood oxygen, blood glucose, and blood constituent concentration
20210106843	Infant care device including light shielding enclosure

Technical Expertise:

- **Programming Languages:** C++, C, C#, Java, Matlab, Labview.
- **Scientific tools:** Matlab, Labview, IDL, Mathematica, Minitab, JUMP.
- **Framework:** Windows stack ASP.NET, SQL, XML, HTML RESTful, Visual Studio, .NET framework
- **Operating Systems:** Windows, Linux, Unix, iOS.
- **Embedded Development:** VisualDSP, FPGA Verilog, Communications on SPI/I2C, Serial, Bluetooth CC2541. TI MSP430F, TI TMS320F, AD SHARC ADSP-21479, ADS1298, ADS1299, ARM Processors.
- **Project Management:** PMI Project Management, Agile Development Methods, SCRUM software development.
- **ISO standards** 60601, 62304, 13485, and 14971.
- **Regulatory approvals** for FDA 510K, EU CE Marking, China's CFDA, and Brazil's ANVISA.