



GLADYS V. RANGE *ME, CKM, GSBM*

CEO Founder of GVR Systems Automation, Inc

R&D ENGINEERING LEADERS

Project & Program Management Experts

STRATEGY | SYSTEMS | TECHNOLOGY

R&D • Medical Research • Bio-Genetic • Life Science • Environmental

Patent award winning, Electro-Mechanical, and Systems Solutions Engineer US Patent Engineering Design Award “Particle measuring system with sonically measured flow rate”

R&D Alliance Management Expert - Approaching business from transaction to value, to participants by managing collaboration between functions, project teams, management, local and global infrastructures and outsourced partners in a joint like venture. Alliance venture study includes all roles, resources, and their goals, building cross-functional consensus at all levels and translates into a Business or Operating Plan and project milestones.

Main Areas of Expertise: Corporate Strategy and Leadership sectors: Medical, Genetic, Chemical, Bio-Pharmaceutical, R&D, Clinical Trials Studies, scientific infrastructure, and systems integration.

Expert Project and Program Management Leader addresses Business Requirements definition, compliant implementations, R&D, Clinical Research Management, Engineering laboratory environments, Methods, Processes, Content and Records, business requirement specifications Acquisition, analysis, functional/user requirements.

Knowledge Management Focus: Program/Project Leadership in R&D global environments. Formulate business case report, Knowledge Management (KM) business requirements, and recommendations for infrastructure, e-solutions integration.

Gladys promotes collaboration in research, communities of practice, supporting tool development and training to key organization membership, internal and external business KM practitioners, their information and technical resources.

- Engineering Management Leader & Consultant, implementing strategy and business R&D management of Engineering Solutions, Content & IMS (Information Systems Management) Integration in support of Medical and Biogenetical R&D, Pharmaceutical, Life Sciences and Environmental Collaborative Electronic Research, High Throughput Screening and Digital High Content Analysis Scientific Instruments & Data Analysis Systems.
- Implements and manages state of the art technology to the work environment maximizing operational efficiency increasing profitability, following applicable regulation, policy, FDA, QC/QA, ICH guidance, DOD, specifications and documentation
- Clinical Research Management Contractor, Led US Army MRMC MeRITS, LIMS (Laboratory Information Management System) Pilot in Bangkok Thailand, covering multiple vaccines, emerging diseases clinical trials, configured to inter-connect, satellite USA Army Command sites
- Former HGSI Bio-Analytical Sciences Proteomics Clinical Data and Sample Manager (Human & Non-Human specimens for Clinical Trial Studies supporting Phase I through Phase II), Bio-Assay Development and Quality Systems
- Former HGSI Bio-Informatics Sequencing LIMS, HTS (High Throughput Screening) Assay Development, Automation Engineer
- Former TIGR (The Institute for Genomic Research) Sequencing Laboratories Automation Engineer – Sequencing Laboratory Automation and DNA fragmentation and Oligo Nucleotide Processing Scientific Research Instrument characterization and optimization
- Former IGEN, Inc (BioVeris/Roche Pharmaceutical), Design Engineer designed Chemiluminescent sample flow cells, managed R&D and prototype of multiple sample carousels for Origin I – Chemistries and luminescence reader, incorporating sample vortexing, sample heating and magnetic particle concentration techniques
- Pacific Scientific-Hiac/Royco Div. Designed and Managed pilot production and test of several R&D optical based Instruments and devices for use in semi-conductor, hydraulic-industrial, and life sciences liquid/air particle samplers and particle counting ISO, FDA, UL, CSA, and ASA, Japan & EU Environmentally compliant instrument product development
- Former Baxter International Design Engineer Managed R&D, prototype and UL/CSA/FDA regulatory test of medical equipment and Spectra-Photometer Analysis Scientific Instrumentation
 - *IV Infusion Pump*
 - *CS3000 Blood Separator*
 - *Nephelometer*
 - *AMINCO Bowman Spectra-Photometer Analyzer*

Education

STANFORD UNIVERSITY GSB – Executive Graduate School of Business, Palo Alto California 2009

CKM International Knowledge Management Institute, Basel Switzerland 2007

Maryland University - UMUC, Engineering, College Park 1982

Engineering Montgomery College, Rockville Maryland 1981

Courses taken include Physics I, II, and III • Chemistry I and Chemistry II • Statistics • Statics • Dynamics • Calculus I, II, III, • Mathematics through Differential Equations • Computer Architecture • Digital Logic and Computer Design • Oracle I & II.

Speaking Engagements:

- **March 2010 – Medical Devices Summit** – Workshop and panel Discussion Participation
- **October 2009 – John Hopkins University Bio-Tech Project Management** Sponsor, Presentation and Panel Discussion
- **May 2009 – 12th Software Design for Medical Devices** - Philadelphia
- **October 2007 - BrynMawr** Pennsylvanian Semantic Knowledge Infrastructures Services for R&D
- **June 2005 Sept 2005, Nov 2006** - US ARMY COMMAND LIMS (Laboratory Information Management System) Conducted presentations, at **WRAIR, Washington DC, AFRIMS Thailand**, covering Regulatory Training, Software System Evaluation. System Configuration, System Validation.
- **April 2005 - CDMS** (Clinical Data Management System) Conducted **WRAIR** and **FT. Detrick Command CDMS** meetings, document evaluation, and USAMRID CDMS System Audit.
- **October 2001 - ISLAR 2001 19th Annual Symposium on Laboratory Automation and Robotics** Speaker – Assay Automation.

Professional Development

CPN – Center for Probing the Nanoscale Science & Engineering NSF at Stanford University, Workshop, 2010

Validation and Defense Acquisition Program, Washington DC

Microsoft US Army - System Security Training

ISPE– Training

IT Systems Validation Training –IT Systems Validation Training

US Army Defense Acquisition Program Training

GAMP4 Validation Model Training

Laboratory Automation – Micro Processor Control

Problem Solving Through Team Work –SGI

Plastics Design – Plastics Design Forum

Industrial Hydraulics Technology– National Technology Transfer Inc.

AutoCAD, AutoCAD Level II CADTECH Institute

Professional Association Membership

SGSB – Stanford Graduate School of Business Alumni Life Membership

CPN – Center for Probing the Nanoscale Science & Engineering NSF at Stanford University

ACS – American Chemical Society

IKMI - International Knowledge Management Institute

ASM – American Society for Microbiology

ISPE – The Society for Life Sciences Professionals

DIA – Drug Information Association

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