# Dr. Vera M. Madzarevic summary achievements

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***Strengths: leadership, knowledge, quality focus, strong oversight, responsibility, innovation, compliance, business & results oriented***

**Summary of executive skills**

* Leadership in new business development (drug, medical device and medical software development quality management, pharmaceuticals, diagnostic systems)
* Global organization and oversight of clinical research and regulatory strategies
* Effective oversight to ensure regulatory compliance to GCP/ICH, GLP, ISO 13485:2016/MDSAP, ISO 14971 2019 etc.
* Improving profitability with disruptive strategies to achieve best outcomes
* Proactive management in implementation of new regulatory strategies for clients to meet new market requirements
* Performance optimization though quality systems development and deployment
* Organizational leadership in M&A (pharmaceutical and medical device development and operations)
* Strong multidisciplinary clinical, regulatory and quality strategies to enhance business operations
* International clinical trials management and oversight
* Global submission oversight and project management (drugs and medical devices)
* Established Joint ventures & alliances for quality, safety surveillance and quality assurance
* Consensus building & teaming with client and partners for business development and retention
* Decision-making in critical challenges regarding business operations (clinical and QA)

summary of Main Professional Achievements

effective LEADERSHIP during covid19

**Established and overseen a successful and complete medical device and biotech company overhaul** to meet the challenges during these unprecedent times to deliver effective R&D and marketed product, as well as regulatory and quality conformance

Enhancement of company/client compliance and profitability

**Overseen and implemented clinical research programs and quality management processes and procedures** for an academic based clinical research organization, including effective training and evaluation of key personnel (Canadian Heart Research Centre). Consulted on effective implementation and active evaluation of multimillion phase II to IV clinical trials programme. Provided for scientific and regulatory expertise and guidance during third party and regulatory inspections.

leadership for M&A

**Established and overseen complete clinical research and quality programme** for software/medical device manufacturer (Solutions by Sequence) in preparation for successful acquisition by large medical device company (Bayer Diagnostics).

global Clinical research, Regulatory and QA leadership

**Overseen and implemented complete quality system design and regulatory compliance** (FDA/EMA/MDD) for spin off biotech and medical device company (Visible Genetics Inc.), including:

* Definition of organizational and management structure including resource planning and implementation Establishment of Standard Operational Procedures in compliance program with GCP/GLP/GMP and ISO 13485, gap management, including training program
* Provision of framework for regulatory compliance
* Organization and management of complete audit program to successfully obtain CLIA and CAP certification

**Overseen and implemented, including complete review, of clinical research program** including the implementation of quality management systems and training for a pharmaceutical company (Techsphere group) as well as :

* QA and management structure for a phase I facility in Mexico City and Pachuca, Mexico, in preparation to enter the US market.

**Played a key role in the establishment of quality management system for clinical development and marketing** as well as company structure and operations for compliance with ISO 13485:2003 and transition to ISO 13485:2016 /MDSAP for a medical device/software company with web based clinical services (CardioComm Solutions Inc.)

global Transition Leadership

**Re-structured and implemented complete quality system design and regulatory compliance** (FDA/EMA/MDD) for spin off biotech and medical device company to allow convert a **R&D operation into a commercial operation** (Visible Genetics Inc.),

**Lead the transition from experimental and preclinical phase of development of a new therapeutic product for a small pharmaceutical company to clinical development** (Institute Dr. Crescenti, Buenos Aires, Argentina) including the oversight and establishment of the clinical research development plan, quality assurance and regulatory compliance.

leadership mamagement and execution

**Successful leadership, marketing, management and operation** of a clinical research company dedicated to provide expert clinical research and quality assurance services to the pharmaceutical and medical device industry worldwide. Seamless transitioning from onsite services to virtual, web based services and applications to position the company within global players. (GRPC/Clinical Research Institute of America).

**Leadership, design, management and delivery** of the first post graduate clinical research educational program in Canada.(AAPS Inc), and in the US (Criamerica Inc.)

management and execution

**Effective management** of the final stage of the Trileptal™ global development clinical research program in the US, delivering on time and on target NDA for which company (Novartis, NJ, US.) awarded the “Business Excellence Award Certificate”.

**Establishment and oversight** of complete development, review and evaluation of regulatory submissions for clinical trials applications for a medical device company (SciCan Inc.) as well as entire design, management and implementation of entire clinical development program.

**Planning and proposal writing** of key project for Continuing Medical Education programme for Dubai Health by the American Academy for Continual Medical Education.

**Management and oversight** of multimillion clinical research programme for epilepsy and depression indications for pharmaceutical company in Canada (Ciba Geigy Canada).

consultancy, expertise and knowledge management

**Author** of professional book for GCP audit and inspection process printed by one of the top editorials in the US. (Clinical Trials Audit Preparation: A Guide for Good Clinical Practice (GCP) Inspections, Wiley, 2010), and **author** of more than 35 professional articles published in different platforms (journals, on line, LinkedIn, etc).

Successful provision of **clinical, scientific and regulatory expertise** for legal actions as Expert witness.

**Expert consultant** for the European Commission (EC) on medical, scientific and regulatory matters

**Mentoring and training** of MDs and clinical research professionals from the largest pharmaceutical companies, including federal regulatory inspectors in US, Canada and EU, in clinical research and GCP including regulatory compliance inspection.

Conducted successful **independent biomedical research** as a Research Fellow at the University of Toronto, Canada.

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| Dr. Vera Mihajlovic- Madzarevic | | | |
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| Relevant experience | | | |
| SCIENTIFIC AND CLINICAL RESEARCH | | | |
| **Global Director, Clinical Research Services and Medical Affairs (2000-now)** | | | |
| Global Research Pharma Canada (Contract Clinical Research Organization-CRO) | | | |
| As Director of GRPC and I am involved in all phases of clinical development (Phases I-IV), training and product development for our clients worldwide. We serve the pharmaceutical biotech and medical device industry. I am directly responsible for the strategic planning, implementing monitoring and management of all clinical and all scientific activities. | | | |
| As the Director of Clinical Research I am responsible for developing strategies, plans and management of clinical studies. As a Project Leader I facilitate project team activities and provide backup to other Project Leaders and Clinical Research Staff on project teams. My duties involve the management, design and implementation of clinical development studies (Phases I through IV) as well as regulatory liaison ensuring that studies are carried out in accordance with the clinical development plan, regulatory requirements, GCPs/ICH and SOPs.  Study development, cost estimation and resources allocation & recruitment.  Protocol development and implementation; writing and reviewing technical documents, clinical study reports, and clinical sections of IND/NDA/BLA/ANDA, as well as manuscripts, training material, investigators’ brochures, and all other clinical and regulatory documents.  I also handle all Safety Data to be reported to regulatory health authorities and write safety summaries for my clients. Setup Pharmacovigilance program. | | Other activities that I personally am responsible is Auditing Clinical Trials (GCP auditing), GxP pre-FDA/HPFBI auditing and CLIA certification/CAP certification auditing and implementation in Canada/EU and the US.  I am directly involved in training for auditors of Clinical Trials.  ISO 13485 conformance review, audit and inspection as well as employee training for clients (GCP audit), training in GCP, monitoring procedures and training clinical investigators.  Marketing and client liaison, promotion of services and products, planning for future potential products and services. Market research and product development.  Liaison with Health Canada/FDA/ EMA  Some of the Training courses that we offer and I personally teach on site:   * + Introduction to Clinical Research   + Good Clinical Practices, a global approach   + GCP audit procedures, How to prepare for a regulatory audit   + Monitoring Clinical Trials   + Clinical SOP writing   + GLP for Clinical Research | |
| **Senior scientist-(1998-2000)** | | | |
| Novartis Pharmaceuticals, New Jersey, U.S. Research and Development Department | | | |
| As Senior Clinical Research Scientist in the CNS department, I was responsible for all activities related to the clinical section of a NDA as well as management of a group of professionals. Some of the main tasks were as follows: | | | |
| Preparation of the NDA (New Drug Application) documentation for submission to the FDA (Food and Drug Administration) and the EU  Development strategies,  Protocol, case report forms, investigation brochures writing  Summary report writing (ISS),  Safety reports and safety analysis,  Efficacy analysis (ISE),  Safety Data analysis and conciliation of databases,  Final Clinical Trial Report writing. Responsible for writing and  follow up of Named Patient Program.(special access program)  Responsible of Emergency Drug Release Program for a  epilepsy drug. | | Submissions to regulatory authorities  Recruitment & Direct Supervision of monitors  Conciliation of all documentation  Interaction with the FDA to respond to queries related to the specific submission.  Preparation of Clinical Expert reports to the EU for Global drug approval  Interaction with biostatistics and regulatory departments in the resolution, format and delivery of the NDA  Other activities included preparation of the electronic submission of the NDA, as well as design and development of internal database for the Clinical Trials Reports, and Summary reports as well as the entire part of the clinical NDA  Management and supervision of associates | |
| Pharmaceutical Consultant, (1996- 1998) | | | |
| Consulted on a regular basis pharmaceutical clients on issues regarding clinical trials and drug development. | | | |
| **Clinical Project Manager (1993 to 1995)** | | | |
| Ciba-Geigy Canada Ltd, Mississauga, Ontario, Canada | | | |
| Responsible for the overall management of Clinical Trials in adherence to GCP SOPs. Phases II and III | | | |
| Project organization and management,  Planning and scheduling, Resources estimation, Planning and allocation  Project control,  Study cost estimation.  Protocol design and writing.  Selection of investigators and centers, Initiations, co-ordination and close supervision of Monitoring | | Training of Monitors, Investigators and coordinators, in GCP’s and trial management  Data management and resolution,  Trial close-ups.  Data analysis and report writing.  Handling of Serious Adverse Experiences SAE’s.  Interacted with Basel head office and Canada and participated in international project teams.  CNS area diseases: Stroke, Head Trauma, Epilepsy, and Depression.  Design and writing SOP’s (Standard Operational Procedures) | |
| **Head of the Clinical Research Program – AAPS Inc. (2003- 2013)** | | | |
| Responsible for the initiation, design and implementation of the Diploma Clinical Research Program at AAPS Canada (see program in aaps.ca) | | Responsible, author and instructor for Professional Development Programs: Clinical Research Audit, Monitoring, Clinical Trials, SOP in Clinical Research, GLP in Clinical Development, Good Clinical Practices a global approach, Introduction to Clinical Research. | |
| **Other Relevant Scientific Experience** | | | |
| EU (European Union) Expert consultant (2015-now) | | Expert Witness/Expert Scientific Consultant (2003-now) | |
| **Post-Doctoral Research Fellow-SCIENTIFIC LABORATORY RESEARCH (1989-1992)** | | | |
| Banting and Best Department of Medical Research, University of Toronto, CANADA | | | |
| My work was focused on the bio-analytical study of biological compounds to determine function and activity under specific circumstances. Basically, study of hormonal regulation of Adenylyl Cyclase by cDNA cloning, cell culture and DNA recombination, PCR amplification DNA sequencing and analysis. Design and development of new biochemical/molecular techniques. | | | |
| **Research Associate – Proteomics (April 1985– July 1989)** | | | |
| Faculty of Pharmacy and Biochemistry, University of Buenos Aires. | | | |
| My work was focused in the analysis, determination and quantization of biomolecules by the state of the art technology. Protein Biochemistry (proteomics), Analytical method design, Chromatography (protein and organic compound purification, characterization and quantization by HPLC ) Amino acid analysis, Chemical Modification & quality control (HPLC, Spectral Analysis). Spectrophotometry (molecular spectral analysis, derivative analysis). Scale-up. Specific studies on Human Growth Hormone included secondary and tertiary structure analysis. Also responsible for running entire laboratory operations (teaching and research) under GLP’s, and performed all grant applications. | | | |
| **Academic Teaching Experience** | | | |
| Teaching Assistant, Faculty of Pharmacy & Biochemistry, University of Buenos Aires: Biological Chemistry II Biochemistry II, Physiology and Immunology. (1985-1989)  Associate Professor: Metabolic Regulation, Faculty of Medicine, University of Buenos Aires (1988) | | | |
| EDUCATION | | | |
| Degree | Date | University | Award |
| Doctor - Pharmacy and Biochemistry (Ph.D.) Summa Cum Laude | 1989 | University of Buenos Aires, Faculty of Pharmacy & Biochemistry | Summa Cum Laude |
| Master in Sciences (M. Sc.) | 1984 | University CAECE, Buenos Aires, Argentina | Summa Cum Laude |
| Bachelor of Sciences (B.Sc.) | 1982 | University CAECE, Buenos Aires, Argentina | Summa Cum Laude |
|  |  |  | **Post-Graduate Studies** |
| The following post-graduate studies were done in the period 1985-1988 at the University of Buenos Aires: Metabolic Regulation, Genetic Engineering, Non-Linear Equations analysis and regression, Molecular Immunology. | | | |
| **Books & Publications** | | | |
| Clinical Trials Audit Preparation: A Guide for Good Clinical Practice (GCP) Inspections, by Vera Mihajlovic- Madzarevic, ISBN: 9780470248850, John Wiley (2010), Pages: 288  Are Prescription Drugs Really Safe?: A summarized expert review on drug safety written for everyone to understand, ISBN**-**978-1530021635, 2016  The Business of Clinical Trials: Book 1 - A compilation of views, ISBN**:** 9781796279566, 2019 | | | |
| Other scientific publications available upon request | | | |
| Other | | | |
| Executive director – Edupharma Canada (2017-present) | | | |
| President and head of professional development- Clinical Research Institute of America (2008-2018) | | | |
| Languages | | | |
|  | English | Spanish | Serbo-croatian |