

Mary Anne Cecutti

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QUALIFICATIONS: Extensive experience in regulated environments, focusing most recently in consultation and project management. This experience includes: planning, co-ordination and implementation of projects and programs; facilitation of workshops, brainstorming sessions and workgroups; staff supervision; training and development; writing of standard operating procedures and validation protocols; laboratory audit and inspection; computer information systems; teaching in a clinical setting; research and development: performance of routine and special laboratory procedures.

**SELECTED
ACHIEVEMENTS:**

PROJECT MANAGEMENT

DESIGNED and IMPLEMENTED process improvements for the Central Public Health Laboratory MOHLTC, Data & Specimen Handling section based on quality management principles and Provincial laboratory accreditation standards

IMPLEMENTED multiple phases of an FDA / Health Canada regulatory compliance project in the transfusion service

MANAGED introduction of Nucleic Acid Testing for a national laboratory which included construction, equipping and staffing of a new facility

COMMUNICATIONS

FACILITATED workshops, brainstorming and problem solving sessions

WRITTEN detailed submissions to regulatory agencies relating to licensing amendments, process and method validations as well as clinical trials

WRITTEN standard operating procedures and validation protocols

WRITTEN extensive legal briefs relating to laboratory licensing revocation proceedings

APPEARED in court as an expert witness

PRESENTED inspection findings to all levels of laboratory personnel

LECTURED for professional and education organisations

OPERATIONAL REVIEW & PROCESS IMPROVEMENT

ASSESSED current operations & RECOMMENDED facility and process improvements and subsequently IMPLEMENTED RECOMMENDATIONS in the Transfusion Laboratory of a large teaching hospital

DESIGNED and IMPLEMENTED research projects

DESIGNED and IMPLEMENTED a system for continuing education programs

COORDINATED cost study of laboratory tests

PUBLIC RELATIONS

ESTABLISHED excellent rapport with hospital and private laboratory owners as well as laboratory personnel as a representative of the Ministry of Health and CMLTO

RESPONDED to public and professional inquiries relating to the regulation of laboratories and their personnel

PROGRAM DEVELOPMENT

DESIGNED and IMPLEMENTED a Quality Assurance Program for the College of Medical Laboratory Technologists of Ontario (CMLTO)

- EXPERIENCE:**
- QSE CONSULTING 2001 - present
- provided services in the areas of operational review, workflow analysis, process analysis, strategic planning, quality management, project management and co-ordination (see Recent Major Projects)
 - Co-founded and co-produce *executive EDGE* – Innovations in Laboratory Management for Lab Leaders - annual conference
- PROJECT MANAGER (Contract Consultant) 1999 - 2001
Canadian Blood Services, Head Office
- managed special projects for the national testing laboratories
- REGULATORY COMPLIANCE PROJECT
(Contract Consultant) 1995 - 1998
Canadian Blood Services, Head Office (1998 - 1999)
Canadian Red Cross, National Office (1995 - 1998)
- managed implementation of multiple phases of project
 - validated national standard operating procedures
 - authored national standard operating procedures
 - provided information and support to national implementation planning team
- RESOURCE TECHNOLOGIST (Contract Consultant) 1991 - 1995
Canadian Red Cross, Toronto Centre
- reviewed and implemented regulatory compliance plans
 - designed, implemented and presented in-service programs
 - designed, implemented and presented research projects
 - implemented special technical and administrative projects
- LABSCEC CONSULTANTS 1989 - 1991
- provided consulting services in all facets of medical laboratory operations to various clients including hospitals, the Canadian Red Cross and Ontario Society of Medical Technologists
- LABORATORY INSPECTOR 1985 - 1989
Laboratory Services Branch Ontario Ministry of Health
- inspected medical laboratory facilities throughout the Province under the parameters defined by the Laboratory and Specimen Collection Centre Licensing Act
 - prepared evaluations of licensing applications and hospital functional programs relating to laboratories for Ministerial review
 - prepared extensive briefs regarding legal action initiated under the ACT
- SENIOR TECHNOLOGIST / CLINICAL INSTRUCTOR 1978 - 1985
Immunoematology
The Hospital for Sick Children, Toronto
- responsible for instruction and training of new staff, medical technology students and medical residents, special serological investigations and supervision of routine laboratory
- TECHNOLOGIST - Pathology and Immunoematology 1975 - 1978
The Mississauga Hospital, Mississauga

PROFESSIONAL ASSOCIATIONS:	CLMA Trillium Chapter – Board Member (Secretary)	2004-2010
	Member By-laws Committee	2007-1008
	Membership & Chapter Development Committee Member	2008-2010
	Clinical and Laboratory Standards Institute (CLSI)	
	Member Managing Medical Device Hazards and Recalls	2003-2005
	Member Area Committee on Healthcare Services	2002-2006
	College of Medical Laboratory Technologists of Ontario (CMLTO)	
	President	1997
	Vice President	1998
	Chair, Quality Management Program, Working Group	1997
	Chair, Quality Assurance Committee	1995 - 1996, 1998
	Non-council Committee Member	1999, 2000, 2001, 2002
	Laboratory Medicine Competency Project – CPSA/CMLTO	
	Member, Steering Committee	1995 - 1998
	Laboratory Services Restructuring Project - Ontario Ministry of Health	
Quality Management Working Group	1996	
Chair, Standards Subcommittee		
Member, Accreditation Subcommittee		
Clinical Laboratory Management Association (CLMA)	Member	
Canadian Society for Medical Laboratory Science (CSMLS)	Member	
Ontario Society of Medical Technologists (OSMT)	Member	
EDUCATION:	Schulich School of Business - York University	2000
	Masters Certificate in Project Management	
	Toronto, Ontario	
	Certification current Good Manufacturing Practices (cGMP)	1995 -2001
	Canadian Blood Services	
	Ontario Hospital Association	1987 - 1988
	Management Series	
	Toronto, Ontario	
	Laboratory Management	1984
	Ortho Diagnostics	
Toronto, Ontario		
Advanced Certification Immunoematology	1983 - 1984	
Canadian Society of Laboratory Technologists		
Hamilton, Ontario		
Immunology	1980 - 1981	
Post Diploma Program		
Toronto Institute of Medical Technology		
Toronto, Ontario		
General Certification	1973 - 1975	
Medical Laboratory Technology		
Toronto Institute of Medical Technology		
Toronto, Ontario		

PUBLICATIONS:	National Initiatives Impacting Canadian Laboratories – Parts 1,2 & 3 CLMA Review March/April, July/August, November/December 2007	
	Discussion Paper: Factors Influencing the Development of a Quality Assurance Program, College of Medical Laboratory Technologist of Ontario, June 1995.	
	Hematopoietic progenitor cells are resistant to dimethyl sulfoxide toxicity, D.R. Branch, S. Calderwood, M.A. Cecutti, R. Herst and H. Solh, Transfusion Vol. 34, No. 10-1994.	
PROFESSIONAL DEVELOPMENT ACTIVITIES	Executive War College, Miami, FL/ New Orleans LA	2006-2009
	CLMA ThinkLab, Various Locations	1997-2009
	Quality Confab, Atlanta GA	2008
	LEAN Boot Camp, Atlanta GA	2008
	Executive Edge Conference, Toronto, ON	2005-2009
	Leadership Conference & Workshop – CLSI, Vienna, VA	2006
	Leadership Conference & Workshop – CLSI, Baltimore, MD	2005
	Six Sigma & Lean Manufacturing Applications, Atlanta GA	2004
	Insight Conference, Update on Laboratory Reform, Toronto, ON	
	Leadership Conference & Workshop – CLSI, Washington, DC	
	The Roadmap to Quality (CLMA Parts 1&2), Toronto, ON	2001
	Nucleic Acid Testing Training Program - Roche Diagnostics, CA	1999
	Project Management - Lawrence Crolla, PhD	August 1998
	Planning & Executing a Successful LIS Installation - Dennis I Winsten, John M. McMahan	August 1998
	End User Clinical Software Validation - John M. McMahan	August 1998
	Platelet Symposium - CSTM Conference	May 1998
	Leadership Conference - NCCLS:	May 1998
	Building Leadership Skills, Building Consensus Influencing Change	
	Committee on TC212 Regulations	
	Blood Issues: Impact for Hospitals - OHA	March 1998
	Regionalization & Reorganization of Hospital Transfusion Services - LPTP	November 1997
	Evolving Issues in Laboratory Management - KPMG	October 1997
	Media Training - Peter Reesor & Associates	June 1997