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LABORATORIES MADE BETTER!

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WORK EXPERIENCE:

- | | |
|-----------------|---|
| 2007 to present | Principal, <i>Laboratories Made Better!</i>
Providing consulting services for laboratory quality management |
| 1996 to 2006 | Consultant, quality systems in the health care environment |
| 1999 to 2006 | Instructor, Information Mapping, Inc. |
| 1996 to 2000 | Transfusion Service Technologist, part time
Elmhurst Memorial Hospital, Elmhurst, Illinois |
| 1988 to 1996 | Director, Laboratory Quality Assurance, and
Manager, Transfusion Service
Elmhurst Memorial Hospital, Elmhurst, Illinois |
| 1979 to 1988 | Technical Director, Blood Bank
Elmhurst Memorial Hospital, Elmhurst, Illinois |
| 1978 to 1979 | Special Projects Coordinator
Aurora Area Blood Bank, Aurora, Illinois |
| 1977 to 1978 | Specialist in Blood Banking Program
Milwaukee Blood Center, Milwaukee, Wisconsin |
| 1975 to 1977 | Blood Bank Supervisor
Northwest General Hospital, Milwaukee, Wisconsin |
| 1974 to 1975 | Medical Technologist Generalist
Northwest General Hospital, Milwaukee, Wisconsin |

EDUCATION:

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|------|--|
| 1983 | Master of Arts degree in Management, Health Care Administration
Central Michigan University, Mount Pleasant, Michigan |
| 1974 | Bachelor of Science degree in Medical Technology
University of Wisconsin—Milwaukee |

CERTIFICATIONS

American Society for Quality

Certified Manager of Quality and Organizational Excellence	CMQ/OE 03063, 1998
Certified Quality Auditor	CQA 15655, 1996

American Society for Clinical Pathology

Diplomate in Laboratory Management	DLM 00107, 1990
Specialist in Blood Bank	SBB 01534, 1978
Medical Technologist	MT 093979, 1974

PROFESSIONAL MEMBERSHIPS [*Membership or appointment continues to present]

American Society for Quality — Member (1996*)

- Member — Health Care Division
- Member — Quality Audit Division
- Member — Quality Management Division

International Organization for Standardization

- Member — ISO/TC 212 Work Group 1, Quality and Competence in the Clinical Laboratory*
- Co-Leader — Project Team for revision of ISO 15189 Section 8: *Medical Laboratories—Particular requirements for quality and competence**
- Co-Leader — Project Team for revision of ISO 15189: *Medical Laboratories—Particular requirements for quality and competence* (2006-2012)

Clinical and Laboratory Standards Institute

- Member — Board of Directors Nominating Committee (2019)
- Member — U.S. Technical Advisory Group for ISO/TC 212 WG1 (2017*)
- Member — Consensus Council (2016-2018)
- Vice-Chair — Document Development Committee on QMS01 *Quality Management System Model* (2016-2019)
- Vice Chair — Document Development Committee on QMS12 *Quality Indicators* (2016-2019)
- Chair — Working Group on QMS25 *Handbook for Developing a Laboratory Quality Manual* (2016-2017)
- Member — CLSI Awards Committee (2013-2017)
- Chair — Document Development Committee on QMS21 *Purchasing and Inventory* (2014-2016)
- Vice Chair — Document Development Committee on Revision to QMS03 *Training and Competence Assessment* (2014-2016)
- Advisor — Document Development Committee on QMS24 *Using Proficiency Testing to Improve the Clinical Laboratory* (2012-2016)
- Observer — U.S. Technical Advisory Group for ISO/TC 212 WG1 (1997-2016)
- Advisor — Subcommittee on Quality Management System (2014-2015)
- Chair — Process Improvement Task Force (2014-2015)
- Member — Market Research Steering Committee (2014-2015)
- Chair — Working Group on QMS18 *Process Management* (2013-2015)
- Co-Author — QMS20-R *Understanding the Cost of Quality in the Laboratory: A Report* (2014)
- Advisor — Consensus Committee on Quality Systems and Laboratory Practice (2012-2014)
- Chair — Subcommittee on Quality Management System (2009-2013)
- Developer — Laboratory Quality Management System Certificate Program (2012-2013)
- Chair — Work Group on GP02-A6 *Development and Management of Laboratory Documents* (2011-2013)
- Member — Work Group on *Key to Quality* (2011-2013)
- Member — Consensus Committee on Quality Systems and Laboratory Practice (2002-2011)
- Chair — Work group on GP26-A4 *Quality Management System: A Model for Laboratory Services* (2009-2011)

PROFESSIONAL MEMBERSHIPS, contd.

Clinical and Laboratory Standards Institute, continued

- Observer — Subcommittee on GP35 *Quality Indicators* (2008-2009)
- Chair — Work group on GP21-A3 *Training and Competence Assessment* (2007-2008)
- Chair — Subcommittee on GP32 *Nonconforming Event Management* (2006-2007)
- Member — Work Group on GP27-A2 *Using Proficiency Testing to Improve the Clinical Laboratory* (2005-2006)
- Chair — Workgroup on GP2-A5 *Laboratory Documents: Development and Control* (2005-2006)
- Advisor — Area Committee on Health Services (2001-2006)
- Chair — Work Group on HS1-A2 *A Quality Management System Model for Health Care* and GP26-A3 *Application of a Quality Management System Model to Laboratory Services* (2004)
- Member — Work Group on GP22-A2 *Continuous Quality Improvement* (2003-2004)
- Chair — Work Group on GP21-A2 *Training and Competence Assessment* (2003-2004)
- Advisor — Area Committee on General Laboratory Practice (2001-2003)
- Member — Subcommittee on HS10 *Application of Quality System Model to Inpatient Medication Usage* (2002-2003)
- Chair — Work Group on GP26-A2 *Application of a Quality Management System Model to Laboratory Services* (2002-2003)
- Chair — Work group on GP2-A4 *Clinical Laboratory Technical Procedure Manuals* (2001- 2002)
- Member — Subcommittee on HS1-A *Quality System Model for Health Care* (2000-2002)
- Member — Subcommittee on GP26 *A Quality System Model for Healthcare* (1997 - 1999)
- Member — Subcommittee on GP21 *Training Verification* (1993–1994)

OTHER ACTIVITIES

Author of ASCP *LABMEDICINE* journal's *Quality Qorner* (2005-2010)

Member, Editorial Advisory Board for Medical Laboratory Observer Magazine (1989-1999)

Clinical Faculty, The University of Illinois/LifeSource Specialist in Blood Bank program (1987 – 1995)

Chair, Blood Utilization Review Subcommittee of LifeSource Medical Advisory Committee (1989 – 1993)

Clinical Faculty, The University of Illinois Department of Medical Laboratory Sciences, Medical Technology Program (1989 – 1992)

Faculty, The Blood Center of Northern Illinois/Michael Reese Medical Center Specialist in Blood Bank Program (1984—1986)

AWARDS

Clinical and Laboratory Standards Institute (CLSI) Russell Eilers Memorial President's Award (2013)

American Association of Clinical Chemistry Outstanding Contributions to Patient Safety (2007)

Clinical and Laboratory Standards Institute Excellence in Standards Development Award (2006)

American Association of Blood Banks Joel Solomon Memorial Award for Quality (2004)

American Society for Clinical Pathology – Associate Member Section Lifetime Achievement Award (2003)

Karen Tiegerman Memorial Lectureship, Massachusetts Association of Blood Banks (2000)

Distinguished Speaker Series, South Texas Blood and Tissue Center (1999)

Administrative Lecturer Award in memory of W. Quinn Jordan, South Central Association of Blood Banks (1997)

American Society for Clinical Pathology Associate Member Section - Distinguished Service Award (1996)

Chang Ling Lee Memorial Award, Illinois Association of Blood Banks (1994)

AWARDS, continued

Continuing Education Scholarship, Alpha Mu Tau Medical Technology Fraternity (1981)

DADE Scholarship for Immunohematology (1977)

Achievement Award, Alpha Delta Theta Medical Technology Sorority (1974)

PUBLICATIONS, Books, Chapters

Quality systems in transfusion medicine. In: Harmening DM. Modern blood banking and transfusion practices, 7th edition. Philadelphia, PA: F.A. Davis Co. 2019.

Quality systems in the laboratory. In: Harmening DM. Laboratory Management: Principles and Processes, 4th edition. St. Petersburg, FL: D.H. Publishing and Consulting, Inc. 2019.

Berte LM, Daley AT. QMS20-R Understanding the Cost of Quality in the Laboratory: A Report. Wayne, PA: Clinical and Laboratory Standards Institute, 2014.

Quality management. In: Saxena S, ed. The Transfusion Committee: Putting Patient Safety First, 2nd ed. Bethesda, MD: American Association of Blood Banks, 2013.

Understanding the cost of quality. In: Harmening DM. Laboratory Management: Principles and Processes, 3rd edition. St. Petersburg, FL: D.H. Publishing and Consulting, Inc. 2012.

Quality systems in the laboratory. In: Harmening DM. Laboratory Management: Principles and Processes, 3rd edition. St. Petersburg, FL: D.H. Publishing and Consulting, Inc. 2012.

Quality systems in transfusion medicine. In: Harmening DM. Modern blood banking and transfusion practices, 6th edition. Philadelphia, PA: F.A. Davis Co. 2012.

Transfusion service manual of standard operating procedures, training guides and competence assessment tools, 2nd ed. Bethesda, MD: American Association of Blood Banks, 2007.

The quality manual preparation workbook for perioperative autologous blood collection and administration. Bethesda MD: American Association of Blood Banks, 2007.

Quality management and quality tools. In: Saxena S, ed. The blood utilization review committee. Bethesda MD: American Association of Blood Banks, 2006.

The quality manual preparation workbook for blood banking, 2nd ed. Bethesda MD: American Association of Blood Banks, 2005.

The quality manual preparation workbook for cellular therapy product services. Bethesda MD: American Association of Blood Banks, 2005.

The quality manual preparation workbook for blood banking. Bethesda MD: American Association of Blood Banks. 2003.

Quality systems in transfusion medicine. In: Harmening DM. Modern blood banking and transfusion practices, 5th edition, 2005. Philadelphia, PA: F.A. Davis Co.

Berte LM, Nevalainen DE.

The role of quality in blood safety. In: Linden JV, Bianco C, eds. Blood Safety and Surveillance. New York, NY: Marcel Dekker Inc. 2001.

Berte LM, Nevalainen DE.

Quality Systems for the Laboratory. Chicago, IL: ASCP Press. 2000.

PUBLICATIONS, *Books, Chapters, continued*

Quality Management. In: Kurec AS, Schofield S, Watters MC, eds. The CLMA Guide to Managing a Clinical Laboratory. Wayne, PA: Clinical Laboratory Management Association, 2000.

Quality systems in transfusion medicine. In: Harmening DM. Modern blood banking and transfusion practices, 4th edition. Philadelphia, PA: F.A. Davis Co. 1999.

Nevalainen DE, **Berte LM**, Callery MF.

Quality systems in the blood bank environment, 2nd ed. Bethesda, MD: American Association of Blood Banks, 1998.

Quality management in the laboratory. In: Snyder JR, Wilkinson DS, eds. Management in laboratory medicine, 3rd ed. Philadelphia, PA: JB Lippincott Co, 1998.

Overview of a model quality program (Appendix 4). In: Accreditation Requirements Manual, 6th ed. Supplement. Bethesda, MD: American Association of Blood Banks, 1997.

Berte LM, ed.

A model quality system for the transfusion service. Bethesda, MD: American Association of Blood Banks, 1997.

Berte LM, ed.

Transfusion service manual of standard operating procedures, training guides and competence assessment tools. Bethesda, MD: American Association of Blood Banks, 1996.

Nevalainen DE, **Berte LM**, Callery MF. Quality systems in the blood bank and laboratory environment: Worksheets and transparency masters. Bethesda, MD American Association of Blood Banks, 1996.

Robbins J ed, **Berte LM**, et al.

The quality program supplement. Bethesda, MD: American Association of Blood Banks, 1996.

Overview of a model quality program (Appendix 4). In: Accreditation requirements manual, 6th ed. Bethesda, MD: American Association of Blood Banks, 1995.

Robbins J ed, **Berte LM**, et al.

The quality program. Bethesda, MD: American Association of Blood Banks, 1994.

Nevalainen D, **Berte LM**.

Training, verification and assessment: Keys to quality management. Malvern, PA: Clinical Laboratory Management Association Press, 1993.

Hoffstadter L, DeChristopher P, Perkins J, **Berte L**.

Case studies in transfusion medicine. Chicago, Illinois: American Society of Clinical Pathologists Press, 1992.

Basic antibody identification. In: Shulman IA, ed. Problem solving in immunohematology, 4th ed. Chicago, Illinois: American Society of Clinical Pathologists Press, 1992.

Developing performance standards for hospital personnel. Chicago, Illinois: American Society of Clinical Pathologists Press, 1989.

Quality assurance in the donor room. In: Green T, ed. Donor Room Policies and Procedures. Arlington, Virginia: American Association of Blood Banks, 1985.

PUBLICATIONS *Articles*

Quality management for laboratory and ancillary services. *Advance for Administrators of the Laboratory*, posted online on March 2, 2011.

<http://laboratory-manager.advanceweb.com/features/articles/quality-management-for-lab-and-ancillary-services.aspx>

The importance of new hire training: Event 2008-C. *POL Insight*, 2008: Issue 53:4-7

Laboratory quality management: A roadmap. *Clinics in Laboratory Medicine*, 2007: 27(4): 771-791.

In need of good sleuths. *ADVANCE for Medical Laboratory Professionals*, 2007: 19(6):19-21.

Patient safety—Getting there from here. *CLMR*, 2004: 18(6):311-315.

Managing laboratory quality – A systematic approach. *Laboratory Medicine*, 2004: 35(10): 621-624.

Matlow A, **Berte LM**.

Sources of error in laboratory medicine. *Laboratory Medicine*, 2004;35(6):331-334.

Nevalainen DE, **Berte LM**, et.al.

Evaluating laboratory performance on quality indicators with the Six Sigma scale. *Archives of Pathology and Laboratory Medicine*. 2000;124: 516-519.

New quality guidelines for laboratories. *Medical Laboratory Observer*. 2000;32(3):46-50.

NCCLS GP26-A: A quality system model for health care services. *AARC Times* 1999; 23(11):44-51.

Integrating quality management into clinical systems. *CLMR* 1999; 11(4): 197-202.

Berte LM, Nevalainen DE.

The laboratory's role in patient outcomes assessment. *Laboratory Medicine* 1998; 29(2):114-119.

Berte LM, Nevalainen DE.

Quality pays — In every business! *Transfusion Science* 1997; 18(4): 589-596.

Tools for improving quality in the transfusion service. *Pathology Patterns: American Journal of Clinical Pathology*. 1997; 107 (Suppl 1): S36 – S42.

Nevalainen DE, **Berte LM**.

Pounding the drum for quality — a new beat. *CAP Today*. March 1997.

Berte LM, Nevalainen DE, Peters HJ.

A quality system for the medical laboratory. *Journal of Laboratory Medicine*, 1997; 21:44-50

A standard operating procedure-based laboratory training program. *American Society of Clinical Pathologists Tech Sample®* 1996; MGM-6.

Berte LM, Nevalainen DE.

Self assessment in a quality system. *Laboratory Medicine* 1996; 2:655-658.

Berte LM, Nevalainen DE.

Writing standard operating procedures. *Laboratory Medicine* 1996;2:514-516.

Berte LM, Nevalainen DE.

Documentation pyramid for a quality system. *Laboratory Medicine* 1996;2:375-377.

Berte LM, Nevalainen DE.

Quality management for the laboratory. *Laboratory Medicine* 1996;2:232-235.

PUBLICATIONS *Articles, continued*

Nevalainen DE, **Berte LM**.

Quality systems in the blood bank incorporate QC, QA and manage change.
Advance for Medical Laboratory Professionals 1996;8:(9)6-8.

Berte LM, DeChristopher P.

Risk management in transfusion medicine. Medical Laboratory Observer 1996;3:29-34.

A quality management system for transfusion medicine...and beyond. Medical Laboratory Observer 1995;10:61-64.

Berte L, Nevalainen D.

Training verification: A new guideline from the NCCLS. Medical Laboratory Observer 1995;1:38-42.

Managing quality in the transfusion service. Laboratory Medicine 1994;25(2)118-123.

Berte L, DeChristopher P.

A phased approach to transfusion reaction investigation. Medical Laboratory Observer. November 1992.

The need for performance standards in the clinical laboratory. American Clinical Laboratory. August 1992.

Managing risk in transfusion medicine. MMI Companies, Inc. Advisory. December 1991.

The making of a certification examination. Medical Laboratory Observer 1991;10:38-41.

Quality assurance in transfusion medicine. Clinical Laboratory Science. Vol 3, No 5, 1990.

Growing into laboratory quality assurance. Medical Laboratory Observer. February 1990.

Organizing laboratory quality assurance. American Society of Clinical Pathologists *Tech Sample*®. 1989:MGM-6.

Finance for non-financial managers. Medical Laboratory Observer. September 1989

Making home transfusions work. Medical Laboratory Observer. December 1987.

Performance standards for the transfusion service. Medical Laboratory Observer. November 1987.

Cost-containment in the blood bank. American Society of Clinical Pathologists *Tech Sample*®. 1987:MGM-2.

Strategic management in blood banking. Medical Laboratory Observer. October 1986.

Cutting costs in the blood bank, Part I: A 10 point plan for streamlined operations. Medical Laboratory Observer. October 1985.

Type and screen: Seven steps to success. Medical Laboratory Observer. January 1983.

ONLINE LEARNING / AUDIOTAPES / VIDEOTAPES

Developer — American Society for Clinical Pathology *The CLS' Role in You Laboratory's Quality Management System*. An online learning course. ASCP, 2019.

Developer — Clinical and Laboratory Standards Institute *Implementing the Cost of Quality in the Laboratory*: A 5-part online learning program. CLSI, 2014.

Developer — Clinical and Laboratory Standards Institute *Laboratory Quality Management System Certificate Program*: A 14-part online learning program. CLSI, 2013.

Quality Management: A 16-part e-learning program. COLA, 2005, updated 2011.

ONLINE LEARNING / AUDIOTAPES / VIDEOTAPES, continued

Organizing Your Laboratory for Efficiency and Effectiveness. In-Service Reviews for Clinical Laboratory Science. American Society for Clinical Laboratory Science, 2005.

Quality, patient safety, and you. Oakstone Medical Publishing, March 2005.

Good Manufacturing Practice in the Transfusion Service: An e-learning program. American Association of Blood Banks, 2004.

Champions for Change: Creating a Quality System Model: Videotape. NCCLS, 2000.

Quality: Looking up to the future. Education Reviews, Inc. September, 1998.

Strategies for survival: How laboratorians must reengineer to cope with new laboratory needs: Videotape. American Association of Clinical Chemists and J&J Clinical Diagnostics, October 1996.

Risk management in transfusion medicine. Transfusion Medicine Audio Updates. July 1993.

Quality assurance in hospital transfusion medicine. Transfusion Medicine Audio Updates. June 1992.

Developing performance standards for blood center and transfusion service personnel. Transfusion Medicine Audio Updates. February 1991.

Managing for cost and quality in the transfusion service. Education Reviews Inc. October, 1990.

AUDIOCONFERENCES (Over 150 programs since 1982)

Most recent:

“Reality Check on the Recurring Cost of Bad Quality in Your Lab...”	The Dark Report, February 2017
“Applying Cost of Quality Concepts in the Laboratory”	Bio-Rad, December 2015
“Understanding the Cost of Quality”	Bio-Rad, September 2015
“How to Meet Requirements for Managing Any Laboratory Process”	CLSI, May 2015
“Understanding the Cost of Quality in the Laboratory: A Report”	Sysmex, January 2015; CLSI June 2014

WORKSHOPS, PRESENTATIONS

Over 200 programs since 1977. Listing of recent furnished on request.