

Curriculum Vitae – James D. Maatman

B. H. Barkalow & Associates, LLC
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Educational Background:

Hope College, Holland, Michigan 1967 – 1971, Bachelor of Arts Degree
Major: English, Minors: Math, Science, Education

Western Michigan University, Kalamazoo, Michigan, 1971 -1973
Postgraduate coursework: Library Science, Audiovisual Production

Grand Valley State University, Allendale, Michigan, 1977 – 1979; 1992 – 2000
Postgraduate coursework: Business Administration

Grand Rapids Community College, Grand Rapids, Michigan 2001 – 2002
Coursework: Computer Programming

Professional Experience

2012 – Present: *B. H. Barkalow & Associates, LLC*, Newaygo, MI.

B. H. Barkalow & Associates, LLC is a medical device technology and forensic sciences consulting firm.

Regulatory Expert Consultant

- FDA Quality Systems Regulations medical device compliance.
- Quality Systems (QSR, DIN EN ISO 13485) review.
- Corrective and Preventive Action (CAPA) evaluation.
- Medical device quality control assessment.
- Medical device labeling appraisal.
- Regulatory Classifications, Applications and Submissions to include 510(k), PMA, IDE, CE-marking.

1988 – 2004, 2007 – Present: [Michigan Instruments, Inc.](http://www.michiganinstruments.com), Grand Rapids, MI.

Michigan Instruments is a manufacturer of emergency cardiopulmonary resuscitation systems, respiratory care testing and training systems, and ventilator testing equipment.

President 2015 – Present;

Regulatory Consultant 2007 – 2015;

President & CEO 1995 – 2004;

Vice President 1991 – 1995;

Director of Operations 1988 – 1991

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- Managed all operations of a successful medical device manufacturing company selling products internationally.
- Responsible for compliance with FDA Quality System Regulations and ISO 13455: Quality System for Medical Devices.
- Introduced production planning procedures and organizational tools that consistently enhanced manufacturing quality, efficiency, and productivity.
- Wrote and implemented a comprehensive quality manual and standard operating procedures for compliance with FDA Quality System Regulations and ISO 13485:2003 requirements.
- Applied a knowledge of computer systems and software to establish a computer based management system for all operations of the company.
- Programmed an extensive database system to increase the accuracy and efficiency of company documentation, records, and regulatory compliance activities.
- Implemented and maintained a quality system to fulfill the requirements of the FDA Quality System regulation (QSR), DIN EN ISO 13485, and Annex II of Directive 93/42/EEC for class IIa medical devices.
- Serve as FDA and ISO contact. Prepared and played a primary role for submission of numerous regulatory documents including: 483 responses, 510(k) submissions, 515 Reclassification submissions, CE technical file updates, and FDA Medical Device Reports.
- Managed the daily operations and planning for an engineering department overseeing several new devices and major product enhancements.

2004 – 2006 *R. M. Baldwin, Inc.*, Grand Rapids, MI.

R. M. Baldwin, Inc. is a small engineering consulting firm involved in product development, regulatory compliance, and engineering.

Senior Project Manager

- Developed CAPA Facilitator – Corrective/Preventive software for regulatory compliance
- Wrote “Corrective and Preventive Action Guidelines” booklet.
- Provided Regulatory Compliance consulting to various clients.
- Created and maintain the company website (www.rmbimedical.com)
- Actively involved in marketing and customer service.
- Managed work on several medical product development projects.

1986 – 1988 *Industrial Training, Inc.*, Grand Rapids, MI.

Industrial Training developed technical training materials for industry.

Wrote, produced, and helped market successful training materials for industry.

1975 – 1986 *Modern Photographics, Modern Printing, Modern Photo Lab*, Lowell, MI. Owner and Operator.

1971 – 1976 *Saranac Community Schools*, Saranac, MI. Secondary Teacher.

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Other Activities / Recognition

1980 – 1996 *City of Lowell, MI.*

Member of City Council, 1980 – 1984 (elected, voluntary position)

Mayor, 1984 – 1996

- Actively participated in major development and growth in the city of Lowell, including: a new fire station, sewage treatment plant, cable television system, and significant retail growth.
 - Chaired city council meetings and helped set financial and operational policy for the city.
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- Person of the Year, Lowell, MI, 1995
 - Board of Directors, Lowell Light and Power & Cable TV, 2003 – 2007
 - Chairman: Lowell Building Authority, 1996 – 2007
 - Professional Advisory Board for Biomedical Engineering, Michigan Technological University, Houghton, MI, 2000 -2004