



Mr. Edward Walter LeMahieu [\[aH4L! Staff web\]](#)

President (*Chairman, Secretary, Treasurer, Founder*)

SUMMARY: Mr. Edward Walter LeMahieu is Founder and currently President and Chairman of aHAND4 Life!, a US Non-profit, Public Charity (tax-exempt). He also serves as Secretary and Chief Financial Officer. Ed is well-qualified in leadership, management, technology development and utilization, AND caregiving. These is a unique combination of skills that not only inspired aHAND4 Life!, but makes him we qualified to serve in the roles above, and as interim Tele-Counselor for

the various aH4L! Programs and Sub-Programs (until funding is achieved to hire a Full-Time (FT) Tele-Counselor). Ed successful provided caregiving, first as “parent” of a child with a chronic, Significant Physical Disability (PSPD, 6 to 18 yrs. of age), and then as an adult peer – for his son Brett Edward LeMahieu. Brett succumbed to a significant disease, Generalized Dystonia, and, at twenty-nine (29) years old is managing his condition and living successfully, semi-independently in “Supported Living” in Southern California. He is also an aH4L! Class A Member (PSPD), Director, and the Founding Ambassador. Ed earned a Bachelor of Science degree in Bio-Electronic Engineering, with a Math minor, Cum Laude, from Marquette University. He also completed the coursework for a Plan B Masters of Science in Bio-Electronic Engineering, Neuro-physiology minor, at the University of Minnesota. Ed has held progressively more responsible positions throughout his successful career in Medical Product Design & Development. He began his career as design engineer at Medtronic, a Fortune 200 Company. He promoted successful thru Principal EE/Systems Engineer in six (6) years, and moved to various Fortune 100/500 Companies, including Abbott Laboratories and Flextronics, as well as several Startups, including one that went IPO for Diabetes Management. Ed has held Project & Program Management titles, Engineering Department Manager, Director of Systems Engineering, and Vice President of Operations. Ed is expert in analog design, project & program management, business, and for many Product types: Hi-Rel, implantable, Consumer Diagnostic, Tele-homecare/ Telemedicine, Clinic-use, Bedside, ICU/CCU, Research to volume Manufacturing. Ed is multipreneuring, having founded and is acting as President another for-Profit corporation, [Walt Medical Product Services & Staffing, Inc.](#), which has contributed over \$15K in support in the formative years of aH4L! while 501 c 3 “tax-exempt” status was achieved. This company remains critical in bridge funding until a broad charitable giving base is established. Ed also formed and is General Manager, of [Names 'n Trade LLC](#), a company that develops and holds various Intellectual Property assets in its markets of expertise, and develops Corporate Identity and Branding solutions in these industries. This Company developed aH4L!’s Corporate ID, Program names, Slogans, and thus “Brand” as a unique, visionary non-profit Public Charity. Ed has personally been instrumental in the startup of aH4L!, personally contributing over \$10K in donations, and has suffered an opportunity cost in his career earnings of several hundred thousand dollars to-date while he is building the organization.

PRODUCT DEVELOPMENT – PRODUCT TYPES:

Design & Development of Medical, Pharma, and Cosmetic-use devices

- *Implantable* - Pacemakers, Defibrillators, and Sleep Apnea Monitors.
- *ICU/CCU* - Cardiac Monitors and Drug Delivery Systems, & Ambulatory Drug Delivery
- *Consumer* - Glucose Meters,
- *Telemedicine* - Physician Workstations/ Patient Stations/ Medical Monitor Peripherals.
- *Respirators* - Disposable and multi-use, Monitors, and Drug Inhalers
- *OTC Pharmaceuticals* – dermatological analgesics
- *Medical Dermatological devices* – acne, scarring, pigmentation, etc

PRODUCT DEVELOPMENT – MANAGEMENT:

- Program/Project Management – New product development, Project/ Program Management, Recruitment/Resourcing/Team-building, equipment planning, Concept to Production, multi-site, programs, Product Life-cycle management, Value Enhancement, Managed Obsolescence, Conversion of User Needs to Technical Specifications

- Executive/Department Management – Cross-functional management, Budgeting, Forecasting, PPM/Pro Forma development, Fundraising, Technical reports & presentations to Staff/ Management/ Investors, Strategic IP Planning, Patent Development.

PRODUCT DEVELOPMENT - ELECTRONICS:

- Electronic circuit Analysis/ Design – Spice simulation, worst-case/Monte Carlo analysis, mathematical modeling (undergrad mathematics minor), Bio-sensor interfacing (impedance, accelerometer, strain, infra-red, capacitive, intra-cardiac, skin), design w/ semiconductors, analog filters/amplifiers, electromagnetic, very low power, high/pulsed power, battery operated handheld devices, Specification authorship (Product, Electronic, Test, Component), Qualification, Verification, Validation.
- Embedded Digital Systems Analysis/ Design – Timing Analysis, State Machines, Micro-Processor/Controller, Digital Signal Processor (DSP), Field Programmable Gate Array (FPGA), communications (UART, RS-232).
- Biomedical Product Safety Design – Electrical, Mechanical, and SW systems, to industry-leading electro-medical device safety standard IEC60601-1, Edition 2 and 3, collaterals and particulars. Leakage/Risk current, micro electric shock, safety hazards, cardiac arrhythmias, tissue injury.
- Electronic Data Acquisition – Product, Bench, Lab systems, LabView G, BASIC programming

PRODUCT DEVELOPMENT - MANUFACTURING:

- Fabrication – Printed Circuit Boards/Assemblies, Auto-placement, Machine vision, SMT, hybrids, flex-circuit, ball grid, enclosures, cabling.
- Design for Test (DFT) – Product, Bench, Lab systems, LabView G, BASIC programming
- Design for Manufacturability (DFM)– V&V, Pilot, and Volume production, US, Mexico or China, with supply chain management, cost/profit, managed obsolescence.
- Design for Environmental Compliance – US Green/Sustainability initiatives. EU ROHS, WEEE

PRODUCT DEVELOPMENT - MECHANICAL:

- Enclosures – Implantable, Hand-held, Desktop, Mainframe. Plastics, Injection molding, rapid prototyping, metals, forming, welding, sealing, EMC/EMI, reliability, Use testing, Verification and Validation, Environmental materials – EU ROHS, WEEE, directives, US EPA, etc
- STERILE systems – Requirements analysis, factory setup, validation, sterile does determination, packaging validation, expiration dating, related Regulatory approvals.

PRODUCT DEVELOPMENT - QUALITY MANAGEMENT & SYSTEMS:

- Quality Management Systems – full documentation, implementation, certification, and inspection oversight for US FDA QSR and ISO13485 compliance (including ISO14971 for Risk Management). Authorship of 35 Standard Operating Procedures (SOPs) for Medical, OTC Pharma, Cosmetic
- Quality Management – Product Quality Management. Corporate SOP Training, Audit (FDA)/EU Medical Device Directive (MDD), Hazards Analysis, Failure Modes and Effects and Criticality Analysis (FMECA), Fault Tree Analysis (FTA).

PRODUCT DEVELOPMENT - REGULATORY MANAGEMENT:

- US & EU Regulatory Affairs Management – US Class I, II, III approvals to US FD&C Act, 21 cfr 820, US 510K Authorship, and EU Class I, IIa, IIb, III approvals to EU 93/42/EC Medical Device Directive (MDD) compliance, CE-Mark, Authorized Representative for Competent Authorities, etc.

PERSONAL MISSION/ PROFESSIONAL GOAL STATEMENTS

- I will remain a person of the highest integrity, energy, self-motivation, creativity, entrepreneurship, problem-solving and value creation.
 - I seek to build and lead organizations of high-impact, with innovative, dedicated individuals committed to excellence, for best-in-class biotechnology Products, Systems and Service to those in need.
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EXPERIENCE:

AHAND4 LIFE! INC **USA** **12/'08 – Present**
Founder, President **Marketing, Technology, Management, Quality, Regulatory**
▪ Founded, Drafted Articles. Marketing, Services, launching and growing as a 501c3 Public Charity.

WALT MEDICAL PRODUCT SERVICE & STAFFING, INC **Los Angeles, CA** **12/'08 – Present**
Founder, President **Engineering, Management, Quality, Regulatory**
▪ Founded, Drafted Articles. Cash-flow positive day one. Seven, 20+year Specialists and growing.
▪ Cosmetic Ultrasound, Derma Light Therapy, Derma Abrasion. Authored Walt Medical Editions! eBooks of Quality Management Systems and Engineering templates.
▪ Providing Expert and Advanced capability in a number of disciplines in Product Design & Development, CE-mark/ISO13485 QMS, EU Authorized Representative, etc. Party in several Joint Ventures.

NAMES 'N TRADE LLC **Reno, NV** **12/'08 – Present**
Founder, General Manager **Investment, Business, Corporate, Product Consulting**
▪ Founded, Drafted Letter of Organization, cash & asset positive day one. Growth-mode.
▪ Expertise in Investment & Business Analysis and Corporate and Product Identity, Branding & IP in areas of Expertise. Party in several Joint Ventures for IP development, R&D phase.

PAVAD MEDICAL, INC **Fremont, CA** **10/'06 – 10/'07**
Director, Systems Group **Electronics and Systems Engineering**
▪ Led Electronics, SW, & Systems Development. Advanced Concepts/IP/Regulatory contributor
▪ Re-designed oral implantable (Rx/Tx) for Battery life/NMR/size, for Obstructive Sleep Apnea

NEXT SAFETY, INC **W. Jefferson, NC** **4/'06 – 12/'06**
Vice President Operations **Product Concept, Design, and Development and Manufacturing**
▪ Was Flextronics Respirator PM for 1 yr, w/ 7 member engineering team.
▪ Led Product Definition/ IP –lead inventor two Patents pending, Respirator & w/ Drug Delivery
▪ Managed daily operations North Carolina HQ. Technical lead, Fundraising.

FLEXTRONICS INTERNATIONAL **San Jose, CA,** **12/'04 – 4/'06**
Lead Medical Program Manager **Product Development Group – Medical Segment**
▪ Medical Business Development. Engaged 6 strategic customers in 14 months, \$1M revenue growth. Proposals, DSA's, SOW's, Marketing Materials. Project Plans, Budgeting
▪ PM on multiple drug delivery, disposable, durable – Startup, Fortune medical
▪ US Manager Int'l Design Controls Committee – Med Centers of Excellence - w/ Italy & Austria

HOSPIRA **San Jose, CA,** **5/'04 – 12/'04 (ABBOTT SPINOFF)**
Program Manager **Core Engineering** **(12/'03 to 12/'04)**
▪ Defined program, led 15-member cross-functional team (EE, ME, SW, Marketing, Medical, RA, QA, PA, Manufacturing), multi-site (3US), root cause, design, V&V, scale-up, serviced field on telecommunications issues - GemStar® infusion pump & Connect™ SW
▪ Reported to Director of Program Management. Achieved schedule & cost in 12 mo., \$1M project
▪ Supported Regulatory weekly to achieve FDA strategy 510K for pump and not for Connect

ABBOTT LABORATORIES **San Jose, CA** **10/'01 - 5/'04 (SPUN OFF HOSPIRA)**
Project Leader **Systems Engineering Department** **(5/'02 - 12/'03)**
▪ Defined 18-month, \$750K upgrade to Optical/SO₂/Processor of Q2Plus Cardiac Monitor
▪ Participated with Senior Management to select Contract Design Partner-Plexus, Inc
▪ Significant contributor of contract and professional services agreement. Administrated contract
▪ Identified design opportunity & gained Senior Management support to save \$250K & 6 months
▪ Defined and implemented corrective action- eliminate component obsolescence to five years, increased MTTF 25%, \$2M cost savings over product life, 20% customer complaint reduction
▪ Led EE & SW root cause analysis – identified and resolved 3 electronics and 2 SW flaws

- Project Engineer** **Electronics Engineering Department** **(10/'01 - 5/'02)**
- Led 4 member EE team through V&V, launch, and Market adoption of Q2Plus Cardiac Monitor
 - Interfaced w/ Marketing for cost-benefit analysis, Regulatory assessments & FDA strategy

- AMERICAN TELECARE** **Minneapolis, MN** **5/'98 - 9/'01**
HW & Embedded Systems Engineering Manager, Technical Project Lead
- Built and managed 8 member Hardware Engineering Department of 5 year medical startup
 - Developed and maintained network of consultants, contractors, and service organizations
 - Developed and administered contracts and professional services agreements
 - Reported to VP Engineering, dotted-line to CEO for special medical projects
 - Worked daily with VP of Marketing and VP of Sales to identify product opportunities
 - Led focus groups, developed Marketing Descriptions, and conducted user studies
 - Led development of audio and ergonomics improvements of CareTone Steth and Aviva 1010
 - Conceived & championed development low-cost Patient (0505) and Central (1000) Stations.
 - Conceived & championed HiRes Snapshot capability for vertical market growth (wound care)

- INTEG** **St Paul, MN** **9/'94-5/'98**
Lead Electronic Engineer
- Led 18 month EE project to convert \$30K research system to \$150 LifeGuide Glucose Meter
 - Defined project. Participated w/ Senior Management to select Contract Design Partner-PLXS
 - Led 8 member team - internal and external, EE and SWE. 99% machine-built. 100K piece/year
 - Reported to VP Engineering. Developed Quality Manual with committee

- MEDTRONIC** **Minneapolis, MN** **5/'85 - 9/'94**
Systems-Principal Electrical -Senior Electrical -Electrical-Associate Electrical Engineer
Tachyarrhythmia Pacing- Instruments- Research, Pacing Research, Custom Devices Groups
- Led EE and Systems Design/Development of Model 5357 Defibrillation System Analyzer
 - Led EE and Systems Development of Model 5335 Electrophysiologic Systems Analyzer
 - Led Design & Development of clinical Models 2357 Pressure & 2379 Oxygen Sensor interfaces
 - Developed 1st Biphasic Defib circuit, and Model 2394 Biphasic Defibrillator
 - Developed 128 Channel Defib Mapping System, and Model 2705 Transthoracic Pacemaker
 - Developed Orthogonal Defibrillation system IP. Pacing lead/PCD studies. Custom pacers.

- MARQUETTE UNIVERSITY** **Milwaukee, WI** **9/'81 - 5/'85**
Bioelectrical Engineer Assistant **Dept. of Neurophysiology & Chronoendocrinology**
- Developed Inter-cranial brain stimulator. Developed circadian rhythm data acquisition system

EDUCATION:

- UNIVERSITY OF MINNESOTA** **Completed Plan B Coursework Option** **May 2000**
- *M.S. Biomedical Engineering, Minor Electrical Engineering, Minor Neuro-Physiology, 3.7 GPA*

- MARQUETTE UNIVERSITY** **Milwaukee, WI** **9/'81 - 5/'85**
- *B.S. Bioelectrical Engineering, Minor Mathematics, 3.6 GPA, Cum Laude*

- CONTINUING**
- ISO 13485 Quality '05
 - Program Management '04
 - ESD, FMEA, SMT, DOE, OP AMPs, SPICE ('89-02)
 - cGMP, annually, '94 to '04
 - IEC 14971 Risk Mngmnt '05
 - Executive Presentations '03
 - Effective Teams/Coaching '99
 - IEC/UL/CS601 biannually
 - Telecommunications '00
 - IEC 60601-1-6 Usability '05
 - Managing People '98
 - Effective Communications & Customer Encounters '95

INTELLECTUAL PROPERTY:

- US Trademarks "Walt Medical", "aHAND4Life!", "Supporting your living..." '09

- Lead Inventor Medi-Air-Port Respirator. '06.
- 3rd inventor Ultra Filtration, +ive Pressure Respirator '06.
- Creator "Pure Air Health™", Corporate/Respirator line trademark, Next Safety, '06
- Sole Inventor, US Patent 6,757,413 Low-cost Medical Image Transfer System/Method, ATI, '04
- Creator of "CarePort" Telemedicine trademark, American Telecare, '99

PUBLICATIONS, HONORS AND AWARDS:

- *Technical contributor*, "Revolutionary Glucose Meter ...", Portable Design, 10/98.
- '93 Medtronic Star of Excellence Design Team; '85 MU Biomedical Instrumentation Design

VOLUNTEER EXPERIENCE:

- [President, aHAND4Life!](#) '08 to Present – a 501 c 3 Tax Exempt Public Charity (Nov '12), serving capable, responsible significantly physically disabled adults in successful, supported living.
- **Board Member, Housing Choices, '03 to '08** – public charity for housing solutions for developmentally disabled - Community Council, Funding & Development Committees
- **Corporate Sponsor/Liaison - Center for Entrepreneurial Studies, University of Minnesota, Carlson School of Management, '01.** Joint lead with Faculty & MBA /MSBE students