Fremont, CA, USA
Las Vegas, NV, USA

Salvatore (Sam) C. Lazzara Jr.

+1 510 397 9739
Sam@MDQC.com

SUMMARY

- Over 40 years medical device industry experience
- Master of Science, Engineering
- Certified Biomedical Auditor (American Society for Quality)
- Trusted thought leader and decision maker regarding strategies for product design, quality assurance, regulatory affairs, manufacturing, distribution and post-market controls
- Established customer-focused and regulation-compliant quality systems at numerous companies ranging from early start-up to Fortune 500 market leader
- Technology experience: active and non-active devices including implants, vascular catheters and wires, gastroenterology devices, hearing devices, neurostimulators, orthopedic devices, and drug/device combination products

Areas of Expertise

- Biocompatibility: ISO 10993
- Design controls
- European CE marking: MDD, MDR
- FDA regulations: 21 CFR 800 series
- International standards
- Packaging and sterilization
- Process validation
- Quality systems: ISO 13485, FDA
- Regulatory compliance
- Risk management: EN ISO 14971
- Statistical techniques
- Supplier management
- Training programs

EDUCATION

Master of Science, Electrical Engineering and Applied Physics
Case Western Reserve University (Cleveland, Ohio)
Bachelor of Science, Engineering – Biomechanical and Electrical
Brown University (Providence, Rhode Island)

PROFESSIONAL AFFILIATIONS

American Society for Quality – Senior Member
Association for the Advancement of Medical Instrumentation
Regulatory Affairs Professionals Society

CERTIFICATIONS, TRAINING, CONTINUING EDUCATION

ASQ Certified Biomedical Auditor, Certificate 82 (since 2002)
ASQ Northern California Biomedical Discussion Group – Trainer
BSI Associate Consultant Program, ACP US 049 (2014 to Present)
BSI Medical Device Roadshows
Easy Medical Devices Europe MDR Green Belt Certificate
FDA CDRH Learn Program
GS1 FDA Unique Device Identification (UDI) Certification
ISO 13485 Lead Auditor Certificate (Excel Partnership)
Medical Device HQ Courses: ISO 14971, ISO 13485
NSF Medical Device Regulatory Requirements Certification – MDSAP, Australia, Brazil, Canada, Japan, United States

MEDICAL DEVICE CONFORMITY ASSESSMENT SYSTEM EXPERIENCE

- Studied, learned and continually applied requirements of Europe Medical Device Directive 93/42/EEC, Canada Medical Devices Regulation SOR 98/282 and associated guidance
- Directly managed Canada and Europe compliance programs at Concentric Medical from 2000 to 2009
- Designed and delivered numerous quality management systems, and guided implementation for clients to achieve US FDA approval, ISO 13485 registration, CE marking, and Canada licensing

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CONSULTING EXPERIENCE

Consultant, Quality Assurance and Regulatory Compliance 2002 to Present

- Provided quality and regulatory strategic planning advice to numerous start-up companies.
- Installed tailored quality systems to achieve CE marking with 7 different Notified Bodies.
- Clients for whom Sam Lazzara provided quality system documents as a consultant:

1. Archus Orthopedics (orthopedic implants) 2002-04
2. Vista Scientific (orthopedic implants) 2003-01
3. Crosstrees Medical (orthopedic vertebroplasty devices) 2005-06
4. Top Shelf Manufacturing (orthopedic soft goods and devices) 2006-06
5. Leptos Biomedical (neurostimulation active implant for obesity) 2005-01
6. BaroNOVA (gastrointestinal implant for obesity) 2006-08
7. r4 Vascular (vascular catheters) 2007-04
8. Nevro (neurostimulation devices for pain management) 2008-04
9. Autonomic Technologies (neurostimulation devices) 2009-04
10. Loma Vista Medical (valvuloplasty catheters) → CR Bard 2009-06
11. Nfocus Neuromedical (neurovascular implants) → Medtronic 2009-06
12. Anthem Orthopaedics (orthopedic implants for hip fractures) 2010-06
13. Embrace (newborn infant warmers) 2010-11
14. Brolex (C-section scalpel device) 2011-01
15. SpineAlign Medical (orthopedic spinal implants) 2011-02
16. Pulsar Vascular (neurovascular implants for aneurysms) 2011-07
17. NeuroPro Spinal Jaxx (orthopedic spinal implants) 2011-08
18. Fixes 4 Kids (orthopedic fracture treatment device) 2012-01
19. Biomimedica (orthopedic hip joint replacement implants) 2012-09
20. CardioKinetix (left heart ventricle partitioning implant) 2012-11
21. Healthcare Creations (orthopedic surgery devices) 2013-09
22. Medina Medical (neurovascular implants) → Medtronic 2013-10
23. Integrated Plasmonics (in vitro diagnostic nanotechnology) 2013-11
24. Allurion Technologies (gastrointestinal implant for obesity) 2013-11
25. Sharklet Technologies (surface patterned medical devices) 2014-04
26. BioTrace Medical (temporary cardiac pacing leads) 2014-05
27. Bioceptive (intrauterine device insertion system) 2014-06
28. EPIX Orthopaedics (orthopedic implants for hip fractures) 2014-06
29. CurvaFix (orthopedic implants for pelvic fractures) 2014-07
30. Cerus Endovascular (vascular implants) 2014-11
31. Ciel Medical (respiratory care devices) → Vyaire Medical (BD) 2015-01
32. Foldax (cardiac valves) 2015-02
33. Three Rivers Medical (neurovascular implants) 2015-04
34. Bionik Laboratories (robotic exoskeletons) 2015-04
35. Sano Intelligence (mobile medical devices) 2015-05
36. Avitus Orthopaedics (orthopaedic devices) 2015-09
37. Vestagen Technical Textiles (healthcare worker apparel) 2015-11
38. Beta Bionics (diabetes artificial pancreas system) 2016-02
39. Enzyme (electronic quality management system software) 2016-03
40. Urotronic (drug coated balloon catheters) 2016-04
41. MML Diagnostics Packaging (diagnostic specimen kits) 2016-05
42. Route 92 Medical (neurovascular devices) 2016-06
43. Drawbridge Health (blood sampling devices) 2016-09
44. Bonsano Medical (orthopaedic implants) 2017-01
45. Asahi-Intecc USA (vascular devices) 2017-03
46. PACSHealth (medical device software systems) 2017-03
47. CeQur (insulin infusion system for diabetes patients) 2017-05
48. Prospect Life Sciences (contract device design & manufacturing) 2017-06
49. Chinook Medical Gear (medical emergency convenience kits) 2017-07
50. Bayer Consumer Health (personal care devices) 2017-08
51. Labyrinth Devices (ear vestibular labyrinth treatment devices) 2017-09
52. Permobil TiSport (mechanical wheelchairs) 2017-10
53. Novonate (neonatal catheter securement devices) 2017-11
54. Neptune Medical (gastrointestinal access devices) 2017-12
55. Riverpoint Medical (surgical suture, needles and headlamps) 2018-03
56. Quool Therapeutics (therapeutic hypothermia devices) 2018-04
57. iSono Health (breast health ultrasonic imaging devices) 2018-05
58. Biorasis (continuous implantable glucose monitoring system) 2018-06
59. Camensys (health software design and development services) 2018-07
60. Foot Innovations (orthopedic devices) 2018-09
61. Lume Medical (vascular closure devices) 2018-10
62. Modular Bionics (neurostimulation devices) 2018-11
63. Respirogen (tissue oxygenation products) 2018-12
64. Vorso (neurostimulation devices for pain management) 2019-01
65. Revive Solutions (automated external defibrillators) 2019-02
66. Panther Orthopedics (bone fixation implants) 2019-08
67. SinoMed (drug coated coronary stent implants) 2019-09
68. Cerovations (neurosurgical shunt catheter) 2019-11
69. Cadence Digital/EMME (medication pill-case reminder system) 2020-04
70. Abiogenix (nasopharyngeal swabs for Covid-19 and other tests) 2020-05
71. Surgical Stabilization Technologies (spinal disk implants) 2020-05
72. Tampro DBA Sequel (novel menstrual tampons) 2020-07
73. BRIUS Technologies (behind-the-teeth orthodontic wire braces) 2020-10
74. ABC Filtration (respiratory protective devices) 2020-11
75. Pediatric Medical Devices (gastrointestinal stoma implant) 2021-01
76. FPrin (medical device contract design & manufacturing services) 2021-01
77. Applied VR (virtual reality digital therapeutic health products) 2021-06
78. 2Morrow (digital therapeutic health software products) 2021-12
79. Intergalactic Therapeutics (synthetic DNA gene therapy products) 2022-02
80. DIATIRO/UCSF (transplanted organ preservation devices) 2022-12
81. ZKR Orthopedics (knee implant system) 2023-01
82. Platform Innovations (minimally invasive surgical devices) 2023-04

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SELECTED CONSULTING CLIENT LOGOS

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EMPLOYEE EXPERIENCE

Vice President, Operations and Quality Assurance
Vice President, Quality Assurance
Concentric Medical (Mountain View, California) 2000 to 2009
Products: First FDA-cleared and CE marked thrombectomy devices for ischemic stroke patients.

- Established and maintained FDA/CE compliant and ISO 13485 registered quality system at 3 separate facilities as company progressed through start-up, clinical and commercialization stages.
- Driving force behind strong regulatory compliance record with FDA and CE Notified Body. FDA had no observations during September 2005 and April 2008 facility audits.
- Built Quality and Operations functions from the ground-up and guided product development and improvement activities based on customer feedback and company goals.
- Developed and maintained strong partnerships with key suppliers to meet quality requirements.

Director, Quality Assurance
Corvascular (Palo Alto, California) 1998 to 2000
Products: Pharmaceuticals and devices to control heart rhythm during coronary bypass surgery.

- Established clinical, quality and regulatory systems compliant with international pharmaceutical and device regulations and standards.
- Led company to zero-noncompliance ISO 13485 registration.
- Achieved CE Marking for Pacemaker Control Unit (active device).
- Prepared device regulatory documents including FDA submissions and Technical Files.

Director, Regulatory Affairs and Quality Assurance
Decibel Instruments (Fremont, California) 1997 to 1998
Products: Hearing aids and audiometers.

- Completely revamped quality system in 4 months.

Director, Regulatory Affairs and Quality Assurance
Symphonix Devices (San Jose, California) 1995 to 1997
Products: Implanted programmable middle ear hearing devices.

- Led company to zero-noncompliance ISO 9001 and EN 46001 registration.
- Established precision measurement laboratory for micro-miniature components.
- Authored design dossiers for submission to Notified Body to achieve CE marking.

Manager, Quality Control
Medtronic PS Medical (Santa Barbara, California) 1992 to 1995
Products: Neurosurgical implants including world leadership in hydrocephalus shunts.

- Led program to revamp quality system and achieve ISO 9001 certification.
- Introduced design control process for new products and design changes to ensure a well-documented and disciplined team approach.
- Reduced inspection lead times by over 50%.
- Successfully hosted two FDA inspections.

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EMPLOYEE EXPERIENCE (continued)

Manager, Regulatory Affairs and Quality Assurance
Du-MED (Rotterdam, The Netherlands) 1990 to 1992
Products: Endovascular ultrasonic imaging catheters and systems.

- Established quality system to comply with European requirements.
- Planned and submitted product registrations for European countries.
- Achieved safety certification for ultrasonic catheter imaging system.

Manager, Quality Engineering
Manager, Quality Assurance Testing Laboratory
Quality Engineer
CR Bard, USCI Division (Billerica, Massachusetts) 1983 to 1990
Products: Cardiovascular devices including angiography and angioplasty products.

- Spearheaded establishment of revamped multi-plant quality system to address FDA concerns. Trained over 500 employees at four facilities.
- Prepared non-clinical testing and manufacturing sections for balloon angioplasty catheter Premarket Approval Application.
- Staffed, equipped and developed procedures for laboratory to support design reviews, regulatory submissions, product complaint analysis and competitive product testing.

Sam Lazzara 26 Years Employee Experience Summary		Concentric Medical	Corvascular	Decibel	Symphonix	Medtronic PS Medical	Du-MED	CR Bard
Title		Vice President, Operations & QA	Director, QA	Director, RA & QA	Director, RA & QA	Manager, QC	Manager, RA & QA	Manager, QA/QE
Quality System Management Representative		✓	✓	✓				
Led ISO 9001/13485 Certification Effort		✓	✓		✓	✓		
Zero Nonconformity FDA Audit		✓✓ (2005, 2008)	No FDA audits	No FDA audits	No FDA audits		No FDA audits	
Zero Nonconformity ISO Certification Audit		✓	✓		✓			
Led Device CE Marking Effort		✓	✓		✓			
FDA Submission Experience		510(k), IDE	IND/IDE	510(k)	IDE, PMA	510(k), IDE	510(k)	510(k), PMA
Primary Escort for Regulatory Agency Auditors		✓	✓	✓	✓	✓		
Responsibilities	Corrective/Preventive Actions	✓	✓	✓	✓		✓	
	Document Control	✓	✓	✓	✓	✓	✓	✓
	Environmental Monitoring	✓	✓	✓	✓		✓	
	Equipment Calibration	✓	✓	✓	✓		✓	
	Internal Audits	✓	✓	✓	✓		✓	
	Manufacturing Engineering	✓						
	Material Control	✓						
	OSHA/EPA Compliance	✓						
	Production	✓						
	Quality Assurance/Control	✓	✓	✓	✓	✓	✓	✓
	Quality Engineering	✓	✓	✓	✓	✓	✓	✓
	Regulatory Affairs		✓	✓	✓		✓	
	Supplier Evaluation/Audits	✓	✓	✓	✓	✓	✓	
	Sterilization Validation	✓	✓		✓	✓	✓	
	Training	✓	✓	✓	✓	✓	✓	✓
Product Types	Highest Device Class	FDA - 2 EU MDD - III	FDA - 2 EU MDD - III	FDA - 2 EU MDD - IIa	FDA - 3 EU AIMD	FDA - 2 EU MDD - III	FDA - 2 EU MDD - IIb	FDA - 3 EU MDD - III
	Sterile Devices	✓	✓		✓	✓	✓	✓
	Implantable Devices	✓	✓		✓	✓		
	Active (Electronic) Devices		✓	✓	✓	✓	✓	✓
	Pharmaceuticals/Drug Delivery		✓			✓		

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American Society for Quality

Salvatore C. Lazzara

has satisfactorily fulfilled the requirements established by the Society for professional attainment in

Biomedical Auditing

and is, therefore, certified by the Society as a

Certified Biomedical Auditor

Certification Number 82
Certification Date 10/19/2002
Recertify By 6/30/2023

Chair, Certification Board

AMERICAN SOCIETY FOR QUALITY

Chair

Certified Biomedical Auditor Body of Knowledge Highlights

- Auditing Fundamentals
- Biomedical Quality Management System Requirements
  - Regulatory Laws and Requirements
    - USA FD&C Act, FDA Code of Federal Regulations Title including Part 11, 801, 803, 807, 820
    - USA FD&C Act, European Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC
    - Health Canada SOR/98/282
    - Japan Pharmaceutical Affairs Law (JPAL)
    - Australia TGA Requirements
    - Brazil ANVISA Requirements
  - International Standards for Quality Systems: ISO 9001, ISO 13485, ISO 17025
  - FDA Quality System Regulation 21 CFR 820
- Technical Biomedical Knowledge
  - Risk Management: ISO 14971, IEC 62366
  - Sterilization: ISO 11135, ISO 11137, ISO 11138, ISO 11737, ISO 17665
  - Biocompatibility: ISO 10993-1
  - Controlled Environments: ISO 14644
  - Software Development and Maintenance: IEC 62304, ISO 80002
  - Sources for New and Evolving Standards: FDA, Europe
  - Common Medical Device Directives and Standards: IEC 60601, IEC 80001, RoHS, REACH, WEEE
  - Packaging: ISO 11607, ASTM D4169, ASTM F1980

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CERTIFICATE OF SUCCESSFUL COMPLETION

NSF

PRESENTED TO:
Salvatore (Sam) Lazzara
FOR:
MDSAP and Regulatory Transitions - The Basics Virtual Training
AWARDED ON:
05/27/2018

Kimberly A. Trautman
Executive Vice President, Medical Device International Services

CERTIFICATE OF SUCCESSFUL COMPLETION

NSF

PRESENTED TO:
Salvatore (Sam) Lazzara
FOR:
Medical Device Regulatory Requirements - Australia
AWARDED ON:
05/24/2018

Kimberly A. Trautman
Executive Vice President, Medical Device International Services

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CERTIFICATE OF SUCCESSFUL COMPLETION

NSF

PRESENTED TO:
Salvatore (Sam) Lazzara
FOR:
Medical Device Regulatory Requirements - Brazil
AWARDED ON:
06/13/2018

Kimberly A. Trautman
Executive Vice President, Medical Device International Services

CERTIFICATE OF SUCCESSFUL COMPLETION

NSF

PRESENTED TO:
Salvatore (Sam) Lazzara
FOR:
Medical Device Regulatory Requirements - Canada
AWARDED ON:
06/09/2018

Kimberly A. Trautman
Executive Vice President, Medical Device International Services

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CERTIFICATE OF SUCCESSFUL COMPLETION

NSF

PRESENTED TO:
Salvatore (Sam) Lazzara
FOR:
Medical Device Regulatory Requirements - Japan
AWARDED ON:
06/16/2018

Kimberly A. Trautman
Executive Vice President, Medical Device International Services

CERTIFICATE OF SUCCESSFUL COMPLETION

NSF

PRESENTED TO:
Salvatore (Sam) Lazzara
FOR:
Medical Device Regulatory Requirements - United States
AWARDED ON:
05/28/2018

Kimberly A. Trautman
Executive Vice President, Medical Device International Services

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NSF

CERTIFICATE OF SUCCESSFUL COMPLETION

PRESENTED TO:

Salvatore (Sam) Lazzara

FOR:

European Union Medical Device Regulation – EU MDR (2 hours)

AWARDED ON:

30/11/2019

Kimberly A. Trautman
Executive Vice President, Medical Device International Services

GS1 US

The Global Language of Business

Certificate of Completion

This is to signify that

Sam Lazzara

has successfully completed

GS1 Standards for U.S. FDA UDI Online Certificate Course

10/14/2019 2:37:34 PM

This certificate acknowledges that the above named individual has completed four hours of GS1 US University online training covering the foundational aspects of GS1 product identification, barcoding, and sharing of information to the Global Unique Device Identification Database (GUDID). This certificate is valid for 3-years from the date of issue.

GS1 US
Princeton Pike Corporate Center
1009 Lenox Drive, Suite 202
Lawrenceville, NJ 08648 USA
T +1 937.435.3870
E info@gs1us.org
www.gs1us.org

Sandra D. Kozusko
Vice President, Education and Training

Fremont, CA, USA
Las Vegas, NV, USA

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Green Belt Certificate

We certify that

Sam Lazzara

completed the *Easy Medical Device Certifcation Program*
on the Medical Device Regulation (EU) MDR 2017/745
and suceeded at the final exam with the grade Green Belt

Student ID: 961

Instructor
Monir El Azzouzi

Date
February 03, 2021

GB8 - 2021-02-03 - Sam Lazzara - 961

Attestation of Training Completion

We certify that

SAM LAZZARA

has completed the online "Green Belt" Training Course delivered by Easy Medical Device GmbH covering the following subject:

EU MDR 2017/745

Content of the course:

- Module 1: General information on EU MDR 2017/745
  - Regulatory changes
  - Background
  - Timeline
- Module 2: Economic Operators
  - Responsibility of the manufacturer
  - Responsibility of the Authorized Representative
  - The PRRC
  - Responsibility of the Importer and Distributor
  - Summary on Economic Operators
- Module 3: 3 Steps to market
  - Notified Bodies
  - Medical Device Qualification
  - Medical Device Classification
  - Conformity Assessment
- Module 4: Technical Information
  - Technical Documentation
  - Clinical Evaluation
  - Post-marketing Surveillance
  - PMCF
- Module 5: UDI and EUDAMED
  - UDI
  - EUDAMED

Basel, 03-Feb-2021

Monir El Azzouzi
CEO Easy Medical Device

Fremont, CA, USA
Las Vegas, NV, USA

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medicaldeviceHQ

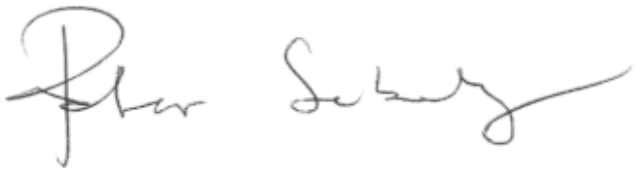
Course Certificate

Sam Lazzara

has attended and completed an online course
on Risk Management, titled:

Introduction to Risk Management for Medical Devices and ISO 14971:2019

On a registered final exam, the student has achieved
a score of 95.56% on the 6th March, 2021.



Peter Sebelius
CEO, Gantus AB

Course learning goals:
- Understand the overall process of risk management and how to create safe medical devices
- Be able to participate in performing risk analysis, risk evaluation and risk control according to ISO 14971:2019
- Be aware of different risk management tools, such as FMEA and P-FMEA.

The validity of this certificate and the qualifications of the course leader can be verified by contacting Gantus AB through medicaldevicehq.com.

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medicaldeviceHQ

Course Certificate

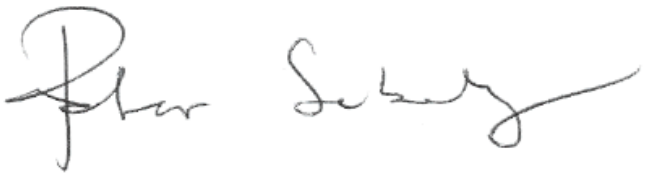
Sam Lazzara

(sam.lazzara@gmail.com)

has attended and completed an online course on Quality Management, titled:

Introduction to Quality Management for Medical Devices and ISO 13485

On a registered final exam, the student has achieved a score of 100% on the 13th May, 2022.



Peter Sebelius
CEO, Gantus AB

Course learning goals:

- Understand what quality management is and the benefits of it
- Work in a medical device company and meet ISO 13485 requirements
- Analyse if a requirement of the standard has been met or not

The validity of this certificate and the qualifications of the course leader can be verified by contacting Gantus AB through **medicaldevicehq.com**.