

# Sam Lazzara

## Medical Device Quality Consulting



Sam Lazzara is passionate about helping medical technology firms work smarter by providing tailored documents, training, mentoring and support based on 40 years of lessons learned

Master of Science, Engineering  
Case Western Reserve University



Bachelor of Science, Engineering  
Brown University



Certified Biomedical Auditor  
American Society for Quality



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# Sam Lazzara – Employee Work Experience

Full-time Employee: 26 years, 7 firms

Roles: Quality Assurance, Regulatory Affairs, Operations



<u>Position</u>	<u>Company</u>	<u>Product Types</u>
QA Lab Manager	CR Bard	Cardiology devices
QA/RA Manager	Du-MED	Intravascular ultrasound devices
QC Manager	PS Medical / Medtronic	Neurosurgical implants
RA/QA Director	Symphonix / MED-EL	Active implantable hearing devices
RA/QA Director	Decibel	Hearing aids
RA/QA Director	Corvascular	Drug/device combination for beating heart surgery
QA/Operations VP	Concentric Medical / Stryker	Neurovascular thrombectomy devices

# Sam Lazzara – Quality System Consulting Clients



82 medical device  
quality system  
clients since 2002

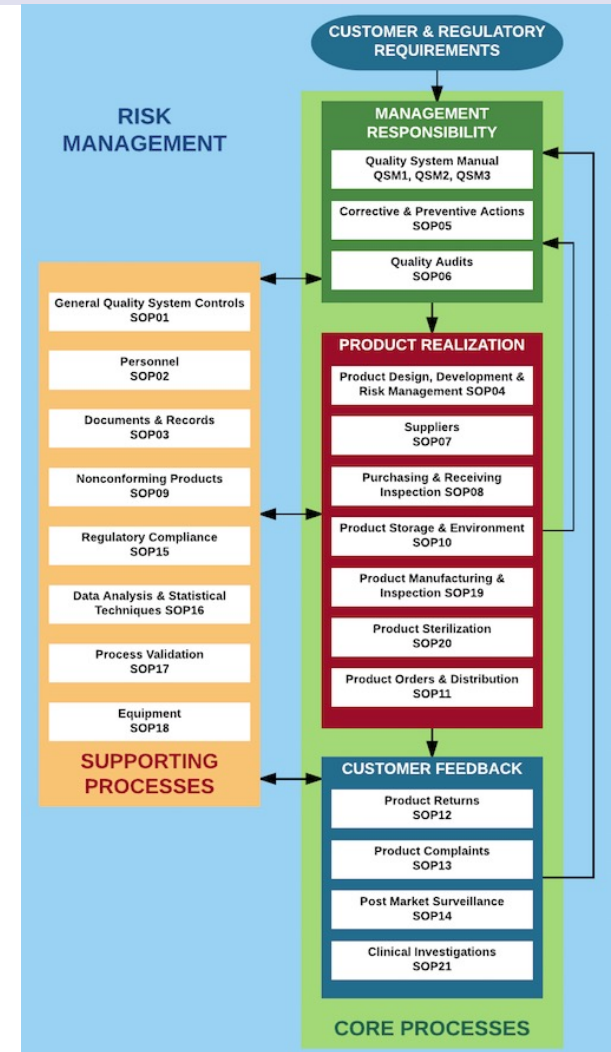
1. Archus Orthopedics (orthopedic implants)	2002-04	42. Route 92 Medical (neurovascular devices)	2016-06
2. Vista Scientific (orthopedic implants)	2003-01	43. Drawbridge Health (blood sampling devices)	2016-09
3. Crosstrees Medical (orthopedic vertebroplasty devices)	2005-06	44. Bonsano Medical (orthopaedic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

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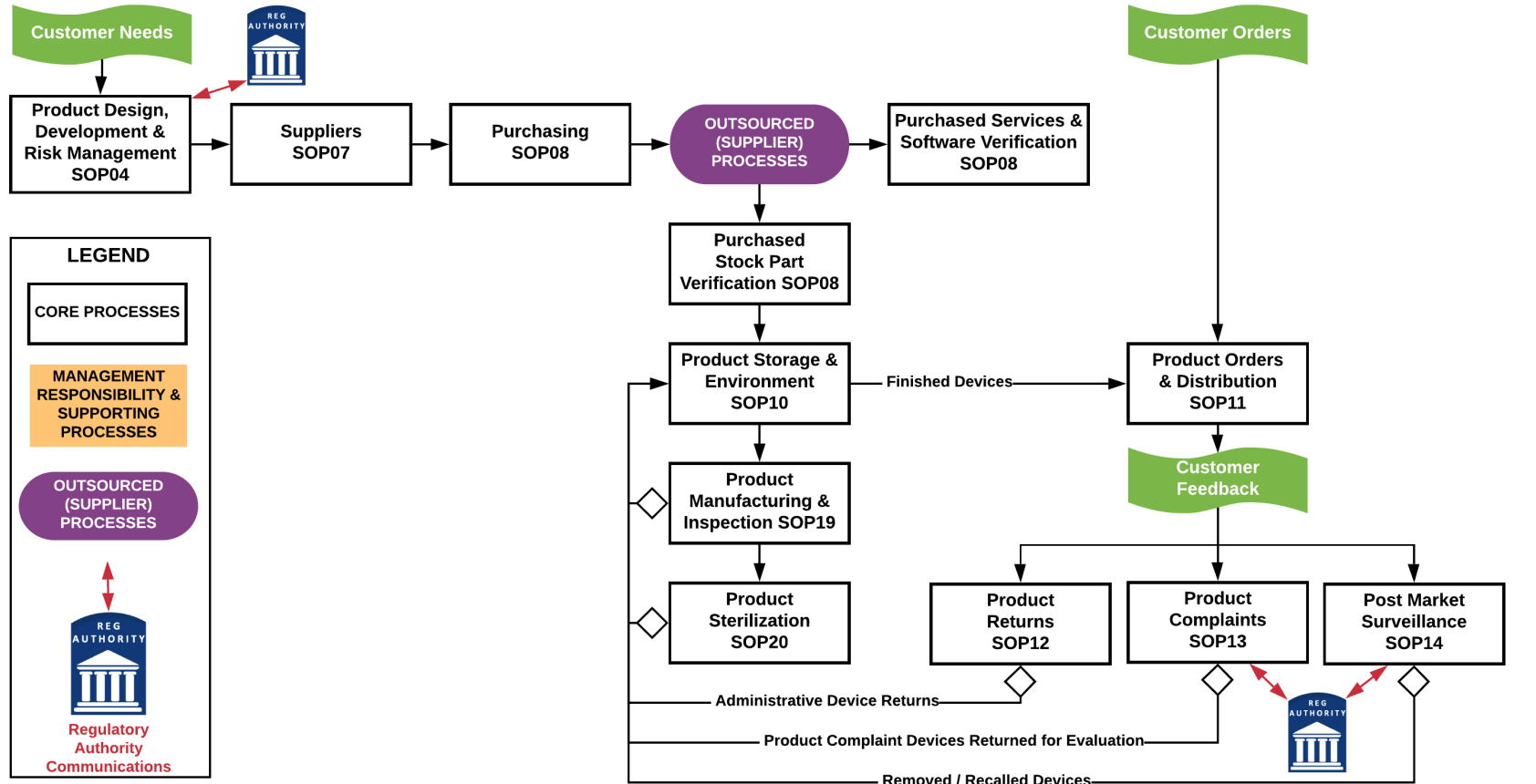
# Medical Device Quality System Documents & Services

- Culmination of Sam Lazzara's 40+ year medical device career, involving over 90 companies
- Streamlined for lean, efficient compliance with worldwide regulations and standards
  - ISO 13485 Medical Device Quality Management Systems
  - ISO 14971 Medical Device Risk Management
  - USA FDA 21 Part 820 Quality Management System Regulation
  - Europe Medical Device Regulation 2017/745
  - Canada Medical Devices Regulation SOR/98-282
- Continually improved after hundreds of internal audits, and dozens of external audits performed by the following regulatory bodies:
  - United States Food and Drug Administration (FDA)
  - California Department of Health, Food and Drug Branch (FDB)
  - European Notified Bodies: BSI, DEKRA, DQS, LNE/G-MED, NSAI, TÜV SÜD, Others
  - Japan Ministry of Health, Labor and Welfare (MHLW)
- Designed to be operated electronically via cloud-based storage



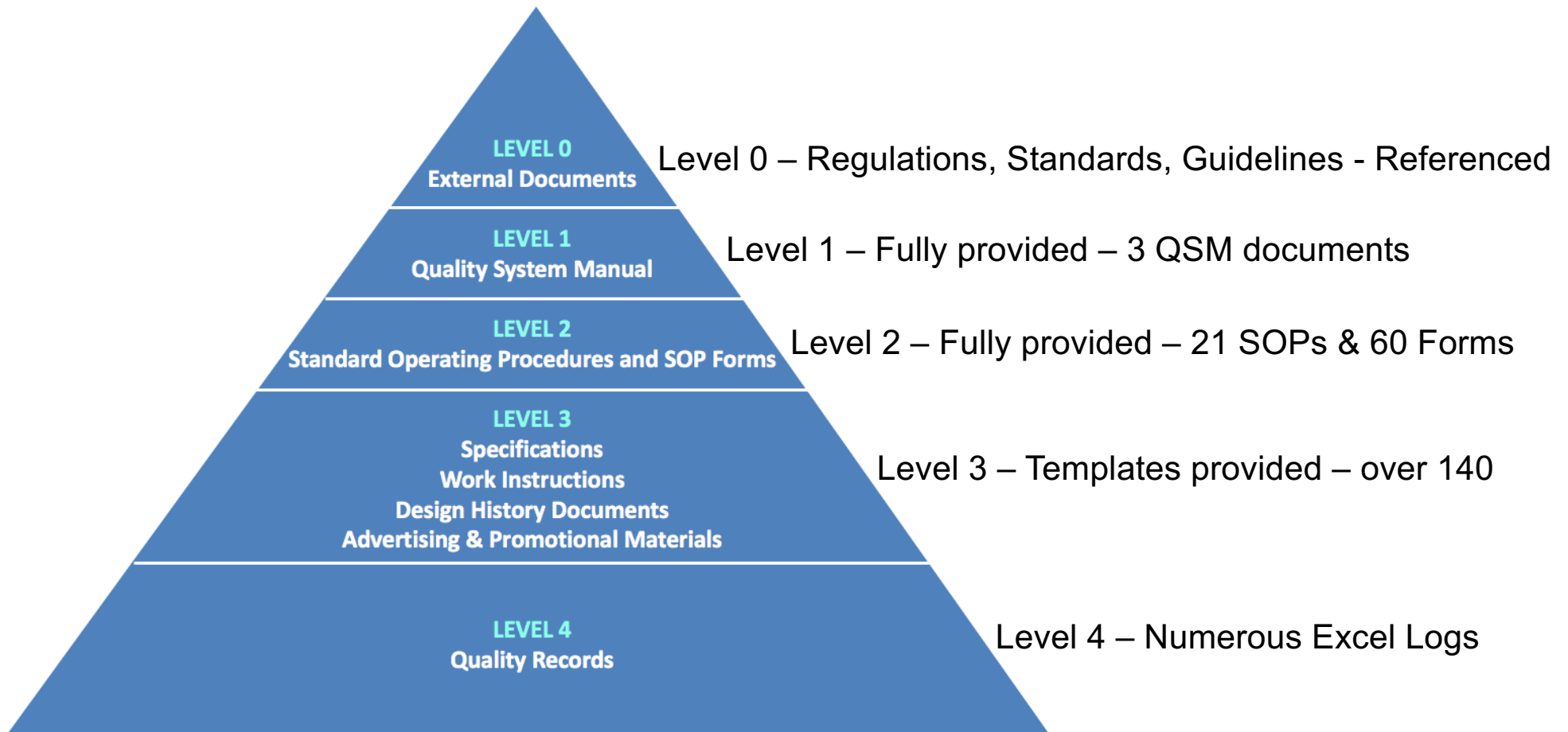
# Medical Device Quality System Documents & Services

QUALITY SYSTEM MANUAL: QSM1 - Quality System Overview    QSM2 - Quality System Glossary    QSM3 - Quality System Policy & Objectives



- General Quality System Controls SOP01
- Personnel SOP02
- Documents & Records SOP03
- Corrective & Preventive Actions SOP05
- Quality Audits SOP06
- Nonconforming Products SOP09
- Regulatory Requirements & Compliance SOP15
- Data Analysis & Statistical Techniques SOP16
- Process Validation SOP17
- Equipment SOP18
- Clinical Investigations SOP21

# Medical Device Quality System Documents & Services



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