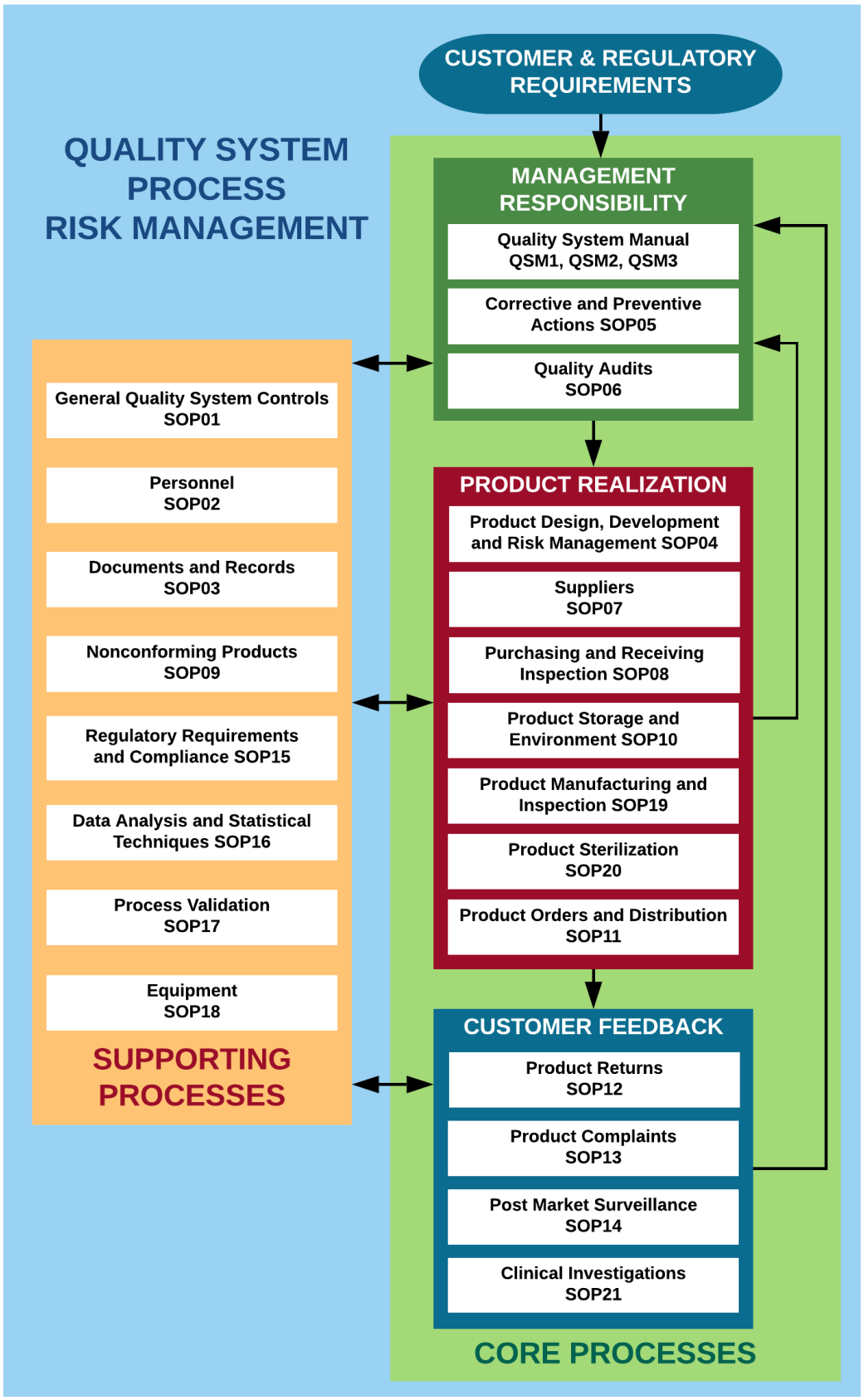


Medical Device Quality Central

MDQC is Sam Lazzara

40 years medical device quality assurance and regulatory compliance experience

Employee Experience
- 26 years
- 7 firms

Consulting Experience
- 2002 to Present
- Guided quality system implementation for over 80 medical device clients

ASQ Certified Biomedical Auditor
The Global Voice of Quality™

MS Engineering

CASE
CASE WESTERN RESERVE UNIVERSITY

BS Engineering

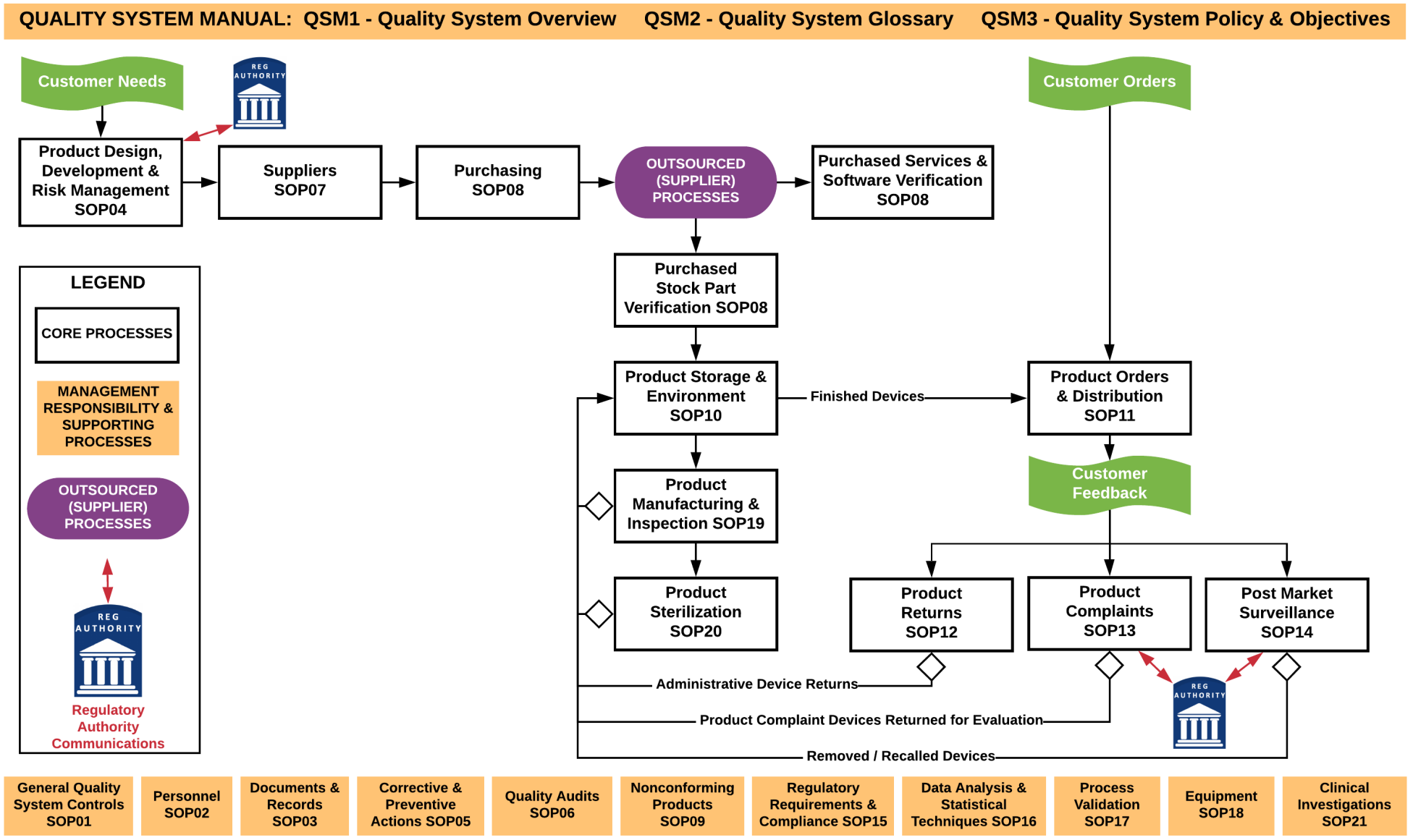
BROWN

Phone +1 510 397 9739

Email sam@mdqc.com

Website http://www.mdqc.com/

Address:
9557 Bachelors Fortune Street
Las Vegas, NV 89178 USA


QUALITY SYSTEM MANUAL: QSM1 - Quality System Overview QSM2 - Quality System Glossary QSM3 - Quality System Policy & Objectives
Customer Needs
REG AUTHORITY
Product Design, Development & Risk Management SOP04
Suppliers SOP07
Purchasing SOP08
OUTSOURCED (SUPPLIER) PROCESSES
Purchased Services & Software Verification SOP08
Customer Orders
LEGEND
CORE PROCESSES
MANAGEMENT RESPONSIBILITY & SUPPORTING PROCESSES
OUTSOURCED (SUPPLIER) PROCESSES
REG AUTHORITY
Regulatory Authority Communications
Purchased Stock Part Verification SOP08
Product Storage & Environment SOP10
Finished Devices
Product Orders & Distribution SOP11
Product Manufacturing & Inspection SOP19
Customer Feedback
Product Sterilization SOP20
Product Returns SOP12
Product Complaints SOP13
Post Market Surveillance SOP14
Administrative Device Returns
Product Complaint Devices Returned for Evaluation
Removed / Recalled Devices
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

- ✓ Culmination of Sam Lazzara's 40+ year career
  - Employee at 7 firms for 26 years
  - Consultant for 70+ firms

- ✓ Continually improved after hundreds of internal audits, and dozens of audits/inspections 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 NORD, TÜV SÜD
  - Japan Ministry of Health, Labor and Welfare (MHLW)

- ✓ Streamlined for lean, efficient compliance with worldwide regulations and standards.
- ✓ Easily tailored to meet the worldwide marketing requirements for any organization.
- ✓ Designed to be operated from the "cloud".
- ✓ State-of-the-art quality system documents conform to current regulations and standards.
  - ISO 13485:2016 and EN ISO 13485:2016 Quality management systems – Medical devices
  - ISO 14971:2019 and EN ISO 14971:2019 Medical devices – Application of risk management
  - Europe Medical Devices Regulation (EU) 2017/745 of 5 April 2017 (EU MDR)
  - USA 21 CFR Part 820 FDA Quality System Regulation for Medical Devices (and other applicable FDA regulations)
  - Canada Medical Devices Regulation
- ✓ Full Document Set includes the following:
  - Quality System Manual – 3 documents
  - Standard Operating Procedures (SOP) – 21
  - SOP Forms – 57
  - Templates – Over 100
  - Quality System Excel Logs (as required for system)
- ✓ Author and Qualifications
  - Salvatore C. Lazzara Jr. (Sam Lazzara)
  - Over 40 years' experience in medical device quality assurance and regulatory compliance positions
  - Certified Biomedical Auditor (American Society for Quality, Certificate 82)
  - MS Engineering – Case Western Reserve University (1983)
    BS Engineering – Brown University (1981)
  - Phone: +1 510 397 9739
  - Email: sam@mdqc.com
  - Website: http://www.mdqc.com/

Sam Lazzara MDQC Quality System Tailored Document Sets & Services Description (Rev 2023D)

State-of-the-Art Quality System Document Sets

Item	Deliverable(s) All documents sets include customization based on answers to provided tailoring questions.	Price $USD
STARTUP-PACK DOCUMENT SET 1: PRODUCT DEVELOPMENT (allows for product development and regulatory submissions, but does not allow device human use)		
1	• QSM2, SOP01, SOP02, SOP03, SOP04, SOP07, SOP08, SOP09, SOP16, SOP18 • Associated Forms, Templates and Quality System (Excel) Logs • Associated Quality System Electronic Folder Structure • One (1) hour post-delivery call to explain delivered documents	Provided upon request
STARTUP-PACK DOCUMENT SET 2: CLINICAL STUDY (allows device human clinical investigational use but does not allow device commercialization)		
2	• Startup-Pack Document Set 1 plus SOP05, SOP10, SOP11, SOP12, SOP13, SOP17, SOP19, SOP20, SOP21 • Associated Forms, Templates and Quality System (Excel) Logs • Associated Quality System Electronic Folder Structure • One (1) hour post-delivery call to explain delivered documents	Provided upon request
FULL DOCUMENT SET: COMMERCIALIZATION (allows device commercialization)		
3	• Quality System Manual – 3 documents (QSM1, QSM2, QSM3) • Standard Operating Procedures (SOP) – 21 (SOP01 through SOP21) • Associated Forms, Templates and Quality System (Excel) Logs • Associated Quality System Electronic Folder Structure • One (1) hour post-delivery call to explain delivered documents	Provided upon request

✓ Payment Terms: Prepaid (invoice will provide payment transmittal instructions)

✓ Document Set Delivery Time: Within 7 days of payment receipt and final answers to tailoring questions

✓ Post-Delivery Consulting Support
- System implementation guidance, coaching, mentoring
- Support for Management Reviews, internal quality audits, design reviews (independent reviewer)
- Ongoing quality system "Help Desk" for quick answers to questions

✓ Ongoing Consulting Support Compensation Options (A or B below) - requires formal Consulting Agreement

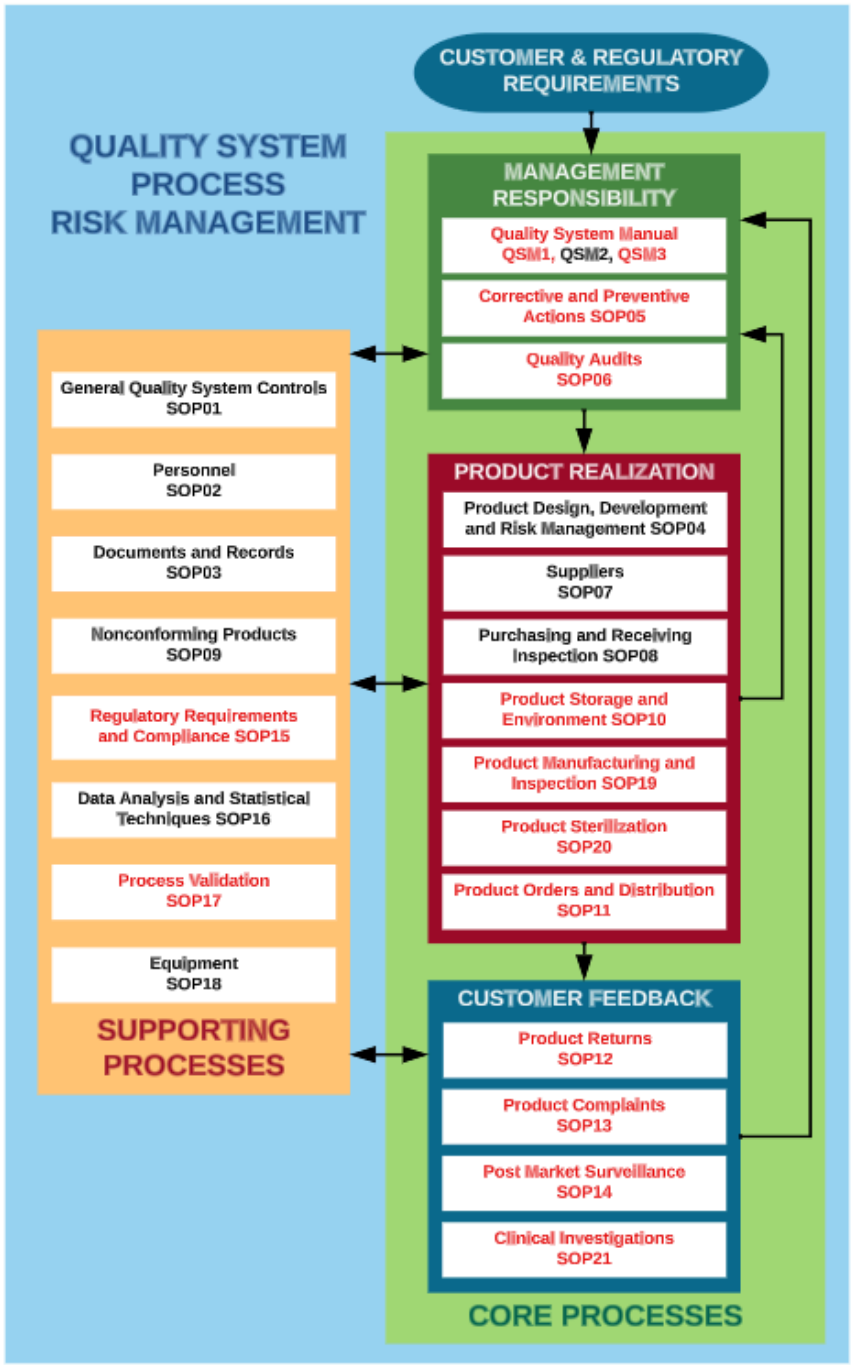
A. General Consulting Hourly Fees Payable Monthly Net 15 after work is performed (based on hours accrued at end of each month)
   - $Redacted per hour if total General Consulting hours for the month are 15 or less
   - $ Redacted per hour if total General Consulting hours for the month are over 15

B. Flat Fees Payable in Advance Net 5 after invoice (no expiration date, non-refundable)
   - $ Redacted for 30 hours (effective hourly rate is $ Redacted)
   - Statement detailing work type and hours to be provided each month services are rendered

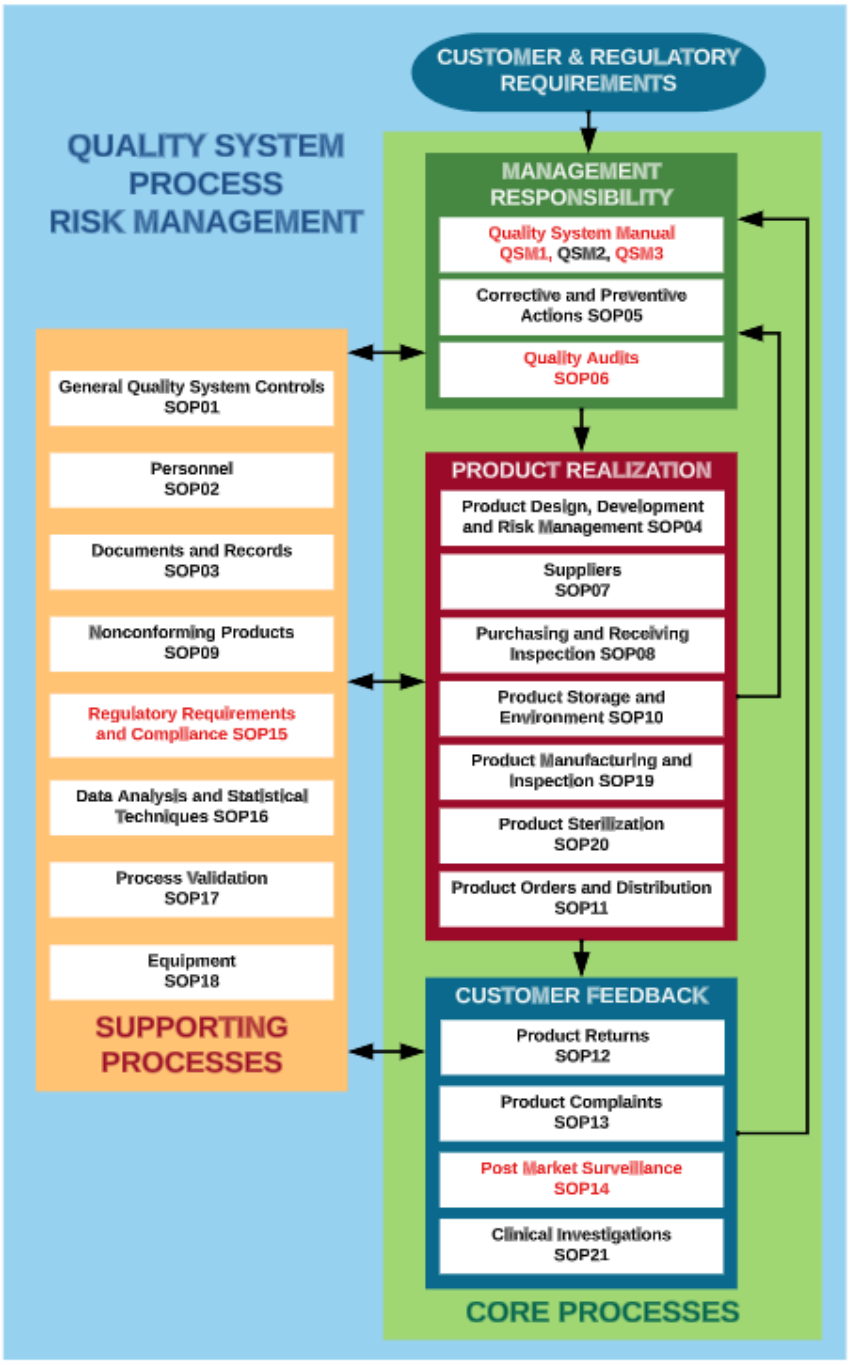
Document Set Procedure QSM/SOP Contents

Document Number	Document Title	Startup-Pack Document Set 1 "Development"	Startup-Pack Document Set 2 "Clinical Study"	Full Document Set "Commercial"
QSM1	Quality System Overview			Yes
QSM2	Quality System Glossary	Yes	Yes	Yes
QSM3	Quality System Policy and Objectives			Yes
SOP01	General Quality System Controls	Yes	Yes	Yes
SOP02	Personnel	Yes	Yes	Yes
SOP03	Documents and Records	Yes	Yes	Yes
SOP04	Product Design, Development and Risk Management	Yes	Yes	Yes
SOP05	Corrective and Preventive Actions		Yes	Yes
SOP06	Quality Audits			Yes
SOP07	Suppliers	Yes	Yes	Yes
SOP08	Product Purchasing and Verification	Yes	Yes	Yes
SOP09	Nonconforming Products	Yes	Yes	Yes
SOP10	Product Storage and Environment		Yes	Yes
SOP11	Product Orders and Distribution		Yes	Yes
SOP12	Product Returns		Yes	Yes
SOP13	Product Complaints		Yes	Yes
SOP14	Post Market Surveillance			Yes
SOP15	Regulatory Requirements and Compliance			Yes
SOP16	Data Analysis and Statistical Techniques	Yes	Yes	Yes
SOP17	Process Validation		Yes	Yes
SOP18	Equipment	Yes	Yes	Yes
SOP19	Product Manufacturing and Inspection		Yes	Yes
SOP20	Product Sterilization		Yes	Yes
SOP21	Clinical Investigations		Yes	Yes

Startup-Pack 1 (black font)



Startup-Pack 2 (black font)



EMPLOYERS

1. CR Bard (cardiology devices) 1983 to1990
2. Du-MED (intravascular ultrasound devices) 1990 to 1992
3. Medtronic PS Medical (neurosurgical implants) 1992 to 1995
4. Symphonix (active implantable hearing devices) 1995 to 1997
5. Decibel (hearing aids) 1997 to 1998
6. Corvascular (drug/device combination product for heart surgery) 1998 to 2000
7. Concentric Medical/Stryker Neuro (neurovascular thrombectomy devices) 2000 to 2009

CONSULTING CLIENTS

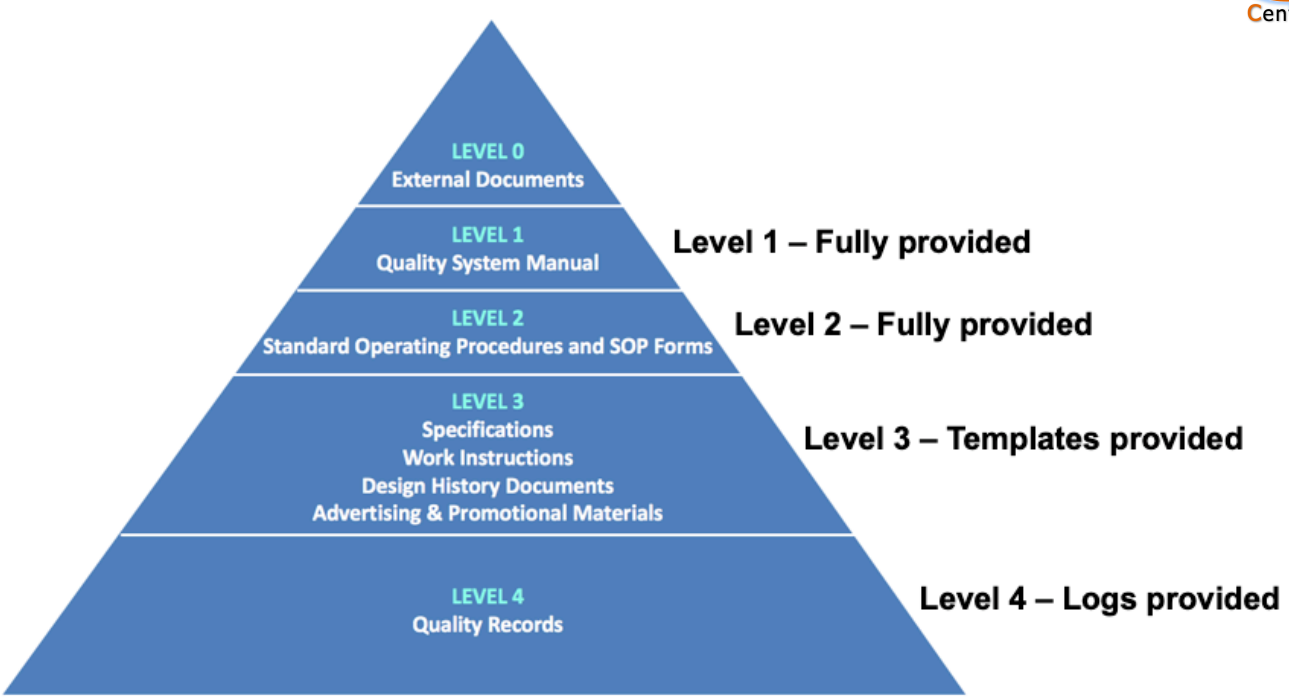
1. Archus Orthopedics (orthopedic implants) 2002-04
2. Vista Scientific (orthopedic implants) 2003-01
3. Crosstrees Medical (orthopedic vertebroplasty devices) 2005-06
4. Top Shelf Manufacturing (orthopedic soft goods and devices) 2006-06
5. Leptos Biomedical (neurostimulation active implant for obesity control) 2005-01
6. BaroNOVA (gastrointestinal implant for obesity control) 2006-08
7. r4 Vascular (vascular catheters) 2007-04
8. Nevro (neurostimulation devices for pain management) 2008-04
9. Autonomic Technologies (neurostimulation devices for pain management) 2009-04
10. Loma Vista Medical (cardiac valvuloplasty catheters) → acquired by CR Bard 2009-06
11. Nfocus Neuromedical (neurovascular implants) → acquired by Medtronic 2009-06
12. Anthem Orthopaedics VAN (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 devices) 2013-11
24. Allurion Technologies (gastrointestinal implant for obesity control) 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) → acquired by 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 (artificial pancreas system for diabetes treatment) 2016-02
39. Enzyme (electronic quality management system software provider) 2016-03
40. Urotronic (drug coated balloon catheter for non-vascular applications) 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 medical device designer and manufacturer) 2017-06
49. Chinook Medical Gear (pre-hospital medical emergency convenience kits) 2017-07
50. Bayer Consumer Health (personal care medical devices) 2017-08
51. Labyrinth Devices (inner 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 systems) 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 (lower gastrointestinal stomal repair implant) 2021-01
76. FPrin (medical device contract design and manufacturing services) 2021-02
77. Applied VR (virtual reality digital therapeutic health products) 2021-06
78. 2Morrow (digital therapeutic health software products) 2021-12
79. Intergalactic Therapeutics (non-viral 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


2Morrow
BRIUS
F Prin
PACSHealth
SPINAL STABILIZATION TECHNOLOGIES™
ABIOGENIX
CooperSurgical
INTEGRATED PLASMONICS
PANTHER
SpinalJaxx
Allurion
CAMENSYS
software for the future
INTERGALACTIC
PMD
Pediatric Medical Device Company LLC
SpineAlign
AppliedVR
CARDIOKINETIX
iSono Health
permobil
stryker
ASAHI INTECC
CeQur
Johnson & Johnson
Family of Companies
PLATFORM INNOVATIONS
3 RIVERS medical inc.
AUTONOMIC TECHNOLOGIES
CEROVATIONS
medtech development
Laborie
FOR DIGNITY. FOR LIFE.
PROSPECT
LIFE SCIENCES
TOP SHELF ORTHOPEDICS
AVITUS
Cerus Endovascular
Labyrinth Devices
PulsarVascular
UROTRONIC
Avive
Chinook Medical Gear, Inc.
Life Science Outsourcing
QooL THERAPEUTICS
VESTEX
BARD
Ciel Medical
LOMA VISTA MEDICAL
vyaire MEDICAL
BARONOVA
Crosstrees MEDICAL
MEDINA medical
RESPIROGEN
ZKR ORTHO
Bayer
CurvaFix
Medtronic
RVO
REVISION OPTICS
βeta βionics
DIATIRO
MML Diagnostics Packaging
RP RIVERPOINT
BIOCEPTIVE
Drawbridge™
HEALTH
MODULAR BIONICS
ROUTE 92
BIOMIMEDICA
embrace
Neptune MEDICAL
sano
BIONIK
InMotion Robotics
EMME
nēsos
SEQUEL™
Biorasis
EPIX Orthopaedics
nevro
Sharklet
BioTrace MEDICAL
fixes 4 KIDS
NFOCUS neuromedical
SILKROAD MEDICAL
Bonsano Medical
FOLDAX
novonate
SINOMED
Innovation for health

✓ Quality System Procedures – Compliance Cross Reference

Document Number and Title	*Applicable EN ISO 13485:2016 Clauses*	*Applicable USA 21 CFR 820 Clauses*
QSM1: Quality System Overview	1, 4.1, 4.2.2, 5, 6.1, 7.1, 8.1, 8.2.5, 8.4, 8.5.1	820.5, 820.20, 820.25, 820.186
QSM2: Quality System Glossary	2, 3, 4.2.2	820.3
QSM3: Quality System Policy and Objectives	4.2.2, 5.1, 5.2, 5.3, 5.4.1	820.20
SOP01: General Quality System Controls	4.2.5, 7.6, 8.2.1, 8.2.2, 8.5	820.100, 820.180, 820.198
SOP02: Personnel	5.5.1, 6.1, 6.2,	820.20, 820.25
SOP03: Documents and Records	4.2.1, 4.2.3, 4.2.4, 4.2.5, 7.1, 7.2.3, 7.3.4, 7.3.9, 7.4.2	820.20, 820.30, 820.40, 820.180, 820.181
SOP04: Product Design, Development and Risk Management	4.2.3, 5.2, 7.1, 7.2.1, 7.3, 8.2.6	820.30, 820.130, 820.181
SOP05: Corrective and Preventive Actions	8.5	820.100
SOP06: Quality Audits	8.2.4, 8.2.5	820.22
SOP07: Suppliers	4.1, 6.3, 7.4.1	820.50(a)
SOP08: Product Purchasing and Verification	4.1, 6.4, 7.4, 7.5.1, 7.5.2, 7.5.5, 7.5.8, 7.5.9, 7.5.11, 8.2.6	820.50, 820.60, 820.65, 820.70, 820.75, 820.80, 820.86, 820.120, 820.140, 820.150, 820.184
SOP09: Nonconforming Products	7.4.3, 7.5.8, 7.5.9, 7.5.11, 8.3	820.60, 820.65, 820.90, 820.140, 820.150
SOP10: Product Storage and Environment	6.3, 6.4, 7.5.8, 7.5.9, 7.5.11	820.60, 820.65, 820.70, 820.72, 820.80, 820.86, 820.140, 820.150
SOP11: Product Orders and Distribution	5.2, 7.2, 7.5.8, 7.5.9, 7.5.11	820.60, 820.65, 820.80, 820.86, 820.140, 820.150, 820.160
SOP12: Product Returns	6.4.2, 7.2, 7.5.8, 7.5.9, 7.5.11, 8.2.6	820.60, 820.65, 820.70, 820.80, 820.86, 820.140, 820.150
SOP13: Product Complaints	6.4.2, 7.2.3, 8.2.1, 8.2.2, 8.2.3	820.198
SOP14: Post Market Surveillance	7.2.3, 8.2.1, 8.2.3, 8.3.1, 8.3.3	820.100
SOP15: Regulatory Requirements and Compliance	4.1, 4.2.1, 7.2.3	All
SOP16: Data Analysis and Statistical Techniques	7.3.6, 7.3.7, 7.4.3, 8.1, 8.2.5, 8.2.6, 8.4	820.250
SOP17: Process Validations	4.1, 7.5.6, 7.5.7, 7.6	820.70(i), 820.75
SOP18: Equipment	6.3, 7.5.1, 7.6	820.70, 820.72
SOP19: Product Manufacturing and Inspection	6.4, 7.5.1, 7.5.2, 7.5.8, 7.5.9, 7.5.11, 8.2.6	820.60, 820.65, 820.70, 820.80, 820.120, 820.184
SOP20: Product Sterilization	6.4.2, 7.5.1, 7.5.5, 7.5.7, 7.5.8, 7.5.9, 7.5.11	820.60, 820.65, 820.70, 820.75
SOP21: Clinical Investigations	7.3.7, 8.2.1	820.30

✓ **Documents Provided: Level 1 and Level 2, and templates for Level 3**



✓ **Quality System Electronic Folder Structure Provided (suitable for cloud storage)**

- Quality System
  - QSM1 Management Review File
  - SOP01 Personnel Signature Record File
  - SOP02 Personnel File
  - SOP03 Document Change Order File
  - SOP03 Electronic Data Record File
  - SOP03 External Documents File
  - SOP03 Internal Documents File
  - SOP04 Design History File
  - SOP05 CAPA File
  - SOP06 Quality Audit File
  - SOP07 Supplier File
  - SOP08 Product Receiving Inspection File
  - SOP08 Purchase Order File
  - SOP09 Nonconforming Product File
  - SOP10 Product Storage and Environment File
  - SOP11 Product Orders and Distribution File
  - SOP12 Product Returns File
  - SOP13 Product Complaint File
  - SOP15 Regulatory Compliance File
  - SOP18 Equipment File
  - SOP19 Product Manufacturing File
  - SOP20 Product Sterilization File
  - SOP21 Essential Clinical Investigation Document File

✓ **Default Functional Groups (names can be changed before delivery)**

Clinical Affairs

Customer Service

Document Control

Finance

Manufacturing Engineering

Marketing

Materials

Production

Quality Assurance

Regulatory Affairs

Research & Development

✓ **Full Document Set Listing: Quality System Logs**

- !QSM1 Management Review Log.xlsx
- !SOP02 Job Description Log.xlsx
- !SOP03 Document Archiving Log, DCO Log, Internal Doc Log, QS Training Matrix.xlsx
- !SOP03 External Doc Log.xlsx
- !SOP04 Project Log.xlsx
- !SOP05 CAPA Log.xlsx
- !SOP06 External Quality Audit Log.xlsx
- !SOP06 Internal Quality Audit Log.xlsx
- !SOP07 Approved Supplier List.xlsx
- !SOP07 Supplier Quality Audit Log.xlsx
- !SOP08 Purchase Order Log.xlsx
- !SOP08 Receiving Lot Log.xlsx
- !SOP09 Nonconforming Product Log.xlsx
- !SOP10 Cleanroom Environmental Monitoring Log.xlsx
- !SOP11 Customer_User Training Log.xlsx
- !SOP11 Sales Order Log.xlsx
- !SOP12 Administrative Product Return Log.xlsx
- !SOP13 Product Complaint Log.xlsx
- !SOP18 Equipment Log.xlsx
- !SOP19 Engineering Lot Log.xlsx
- !SOP19 Production Lot Log.xlsx
- !SOP20 Product Bioburden Log.xlsx
- !SOP20 Sterile Lot Log.xlsx

✓ Full Document Set Listing: Quality Manual, Procedures, Forms

Document Number	Document Title
QSM1	Quality System Overview
QSM2	Quality System Glossary
QSM3	Quality System Policy and Objectives
SOP01	General Quality System Controls
SOP01-F1	Personnel Signature Record
SOP02	Personnel
SOP02-F1	Training Record
SOP02-F2	New Personnel Competence and Training Needs Assessment
SOP02-F3	Employee Performance Review
SOP03	Documents and Records
SOP03-F1	Document Change Order
SOP03-F2	Quality System Electronic Data Backup Record
SOP03-F3	Quality System Electronic Data Access Record
SOP03-F4	Internal Document Approval Matrix
SOP04	Product Design, Development and Risk Management
SOP04-F1	Design Review Record
SOP05	Corrective and Preventive Actions
SOP05-F1	CAPA Record
SOP06	Quality Audits
SOP06-F1	Quality Audit Review Record
SOP06-F2	Internal Quality Audit Leader Qualification Record
SOP07	Suppliers
SOP07-F1	Supplier Survey
SOP07-F2	Supplier Quality Agreement
SOP08	Product Purchasing and Verification
SOP08-F1	Purchase Order
SOP08-F2	Receiving Inspection Record
SOP08-F3	Inspection Data Record
SOP09	Nonconforming Products
SOP09-F1	Nonconforming Product Report
SOP10	Product Storage and Environment (2 versions: cleanroom, no cleanroom)
SOP10-F1	Material Transfer
SOP10-F2	Product Storage Area Signs
SOP10-F3	Product Processing Area Cleaning Record
SOP10-F4	Product Environment Inspection Record
SOP10-F5	Product Processing Area Map
SOP10-F6	Cleanroom Gowning and Work Practices (cleanroom version only)
SOP10-F7	Cleanroom Workday Conditions Record (cleanroom version only)
SOP11	Product Orders and Distribution
SOP11-F1	Product Distribution Request
SOP11-F2	Sales Order and Packing List (2 sheet document)
SOP12	Product Returns
SOP12-F1	Returned Product Inspection Record
SOP13	Product Complaints
SOP13-F1	Product Feedback Report
SOP13-F2	Product Complaint Report
SOP13-F3	European Vigilance Trend Report Determination Record
SOP14	Post Market Surveillance
SOP15	Regulatory Compliance
SOP16	Data Analysis and Statistical Techniques
SOP17	Process Validation
SOP18	Equipment
SOP18-F1	Equipment Service Record
SOP18-F2	Equipment Remedial Action Record

Document Number	Document Title
SOP18-F3	Equipment Modification Record
SOP18-F4	Equipment Status Change Record
SOP19	Product Manufacturing and Inspection
SOP19-F1	Production Quality Summary
SOP19-F2	Worksurface Cleaning Record
SOP19-F3	Type 1 Engineering Lot History Record Request
SOP19-F4	Type 2 Engineering Lot History Record Request
SOP20	Product Sterilization (3 versions: EO only, Radiation only, Both)
SOP20-F1	Radiation Sterilization Lot History Record
SOP20-F2	EO Sterilization Lot History Record
SOP20-F3	EO Sterilization Product Adoption Record
SOP21	Clinical Investigations
SOP21-F1	Clinical Site Visit Log
SOP21-F2	Clinical Site Qualification Report
SOP21-F3	Clinical Site Initiation Report
SOP21-F4	Clinical Site Interim Monitoring Report
SOP21-F5	Clinical Site Personnel Training Record
SOP21-F6	Clinical Site Delegation of Authority Log
SOP21-F7	Clinical Site Patient Screening and Subject Enrollment Log
SOP21-F8	Clinical Site Confidential Subject Identification Log
SOP21-F9	Clinical Site Device Accountability Log
SOP21-F10	Case Report Form Query Record
SOP21-F11	Clinical Site Close-Out Monitoring Report
SOP21-F12	Clinical Site Phone Contract Record
SOP21-F13	Clinical Study Responsibility Matrix
SOP21-F14	Essential Clinical Investigation Document File Index
SOP21-F15	Informed Consent Form Checklist

✓ Full Document Set Listing: Templates

- !QS Labels
- (QSM1 Template)DNP###.A Quality Plan and Report, Facility Move_EXAMPLE_SamV10.docx
- (QSM1 Template)Management Review INPUT YYYY-MM-DD_SamV12.pptx
- (QSM1 Template)Management Review OUTPUT YYYY-MM-DD_SamV10.pptx
- (SOP02 Template)DYY###.A Personnel Certification Plan, Manufacturing Work Instructions_SamV11.docx
- (SOP02 Template)DYY###.A Personnel Certification Plan, Product Inspection_Testing_SamV11.docx
- (SOP02 Template)Job Description, Manager, Clinical Affairs_SamV10.docx
- (SOP02 Template)Job Description, Manager, Customer Service_SamV10.docx
- (SOP02 Template)Job Description, Manager, Finance_SamV10.docx
- (SOP02 Template)Job Description, Manager, Marketing_SamV10.docx
- (SOP02 Template)Job Description, Manager, Materials_SamV10.docx
- (SOP02 Template)Job Description, Manager, Production_SamV10.docx
- (SOP02 Template)Job Description, Manager, Quality Assurance_SamV10.docx
- (SOP02 Template)Job Description, Manager, Regulatory Affairs_SamV10.docx
- (SOP02 Template)Job Description, Manager, Research & Development_SamV10.docx
- (SOP02 Template)Job Description, Position Title_SamV10.docx
- (SOP02 Template)Job Description, President & CEO_SamV10.docx
- (SOP02 Template)Job Description, Quality System Specialist_SamV10.docx
- (SOP02 Template)Organization Chart YYYY-MM-DD_SamV11.pptx
- (SOP02 Template)Personnel Certification Grandfathering Memo_SamV11.docx
- (SOP02 Template)Quality System Orientation Training_SamV11.pptx
- (SOP02 Template)Quality System Training Status Report (memo)_SamV10.docx
- (SOP03 Guideline)Part Specification (Drawing) Format and Style Guidelines_SamV10.docx
- (SOP03 Template)Attachment Slip Sheet_SamV10.docx
- (SOP03 Template)DNP003.A External Document State of the Art Review Report, YYYY-MM_SamV10.docx
- (SOP03 Template)DYY###.A Report, XXXXX (Outsourced Report)_SamV10.docx
- (SOP03 Template)IFU, CC###-01.A.YYYY-MM-DD IFU, XYZ Device_SamV11.docx
- (SOP03 Template)MPI###.A Title_SamV10.docx
- (SOP03 Template)Part Spec CCIFU, CC###-XX.A IFU, Product Name (Part Spec, IFU)_SamV10.docx
- (SOP03 Template)Part Spec FD##-XX.A Product Name, Packaged and Sterilized_Contract Manufactured_SamV10.docx
- (SOP03 Template)Part Spec FDIH, FD##-XX.A Product Name, Packaged and EO Sterilized (FD, In House Mfg)_SamV10.docx
- (SOP03 Template)Part Spec FDInHouse, FD10-XX.A Acme Device_EXAMPLE_SamV10.docx
- (SOP03 Template)Part Spec-CC###-XX.A Title (Component Custom)_SamV10.docx
- (SOP03 Template)Part Spec-CC###-XX.A Title (Component Custom2)_SamV10.docx
- (SOP03 Template)Part Spec-CC###-XX.A Title (Custom Assembly)_SamV10.docx
- (SOP03 Template)Part Spec-CS###-XX.A Title (Component Standard, Catalog Part)_SamV10.docx
- (SOP03 Template)Part Spec-CS###-XX.A Title (Component Standard, Packaging)_SamV10.docx
- (SOP03 Template)Part Spec-EQ###-XX.A Title (Equipment)_SamV10.docx
- (SOP03 Template)PSLHR FDInHouse, FD10-16.A PSLHR, Acme Device_EXAMPLE_SamV10.docx
- (SOP03 Template)PSLHR-FD##-01.A PSLHR, Title (embedded work instructions, no MPIs)_SamV10.docx
- (SOP03 Template)PSLHR-FD##-01.A PSLHR, Title (with MPIs referenced)_SamV10.docx

✓ Full Document Set Listing: Templates (continued)

- (SOP03 Template)RFS002.A General Requirements, Purchased Custom Parts (EXAMPLE)_SamV10.docx
- (SOP03 Template)Signature Designee Memo_SamV10.docx
- (SOP03 Template)STM###.A XXXX Testing_SamV10.docx
- (SOP03_SOP08 Template)QIP101.A General Parts_SamV10.docx
- (SOP03_SOP08 Template)QIP102.A Custom Parts_SamV10.docx
- (SOP03_SOP08 Template)QIP103.A Packaging Materials_SamV10.docx
- (SOP03_SOP08 Template)QIP104.A Product Labeling_SamV10.docx
- (SOP03_SOP08 Template)QIP105.A Sterile Finished Devices_SamV10.docx
- (SOP04 Template)Design Transfer Status Report (memo)_SamV11.docx
- (SOP04 Template)Design Transfer Status Report (memo)_SamV12.docx
- (SOP04 Template)Device Master Record and Medical Device File Status Report (memo)_SamV10.docx
- (SOP04 Template)DYY###.A Protocol, XXXX Testing, Product Name_SamV10.docx
- (SOP04 Template)DYY###.A Report, Animal Study_SamV10.docx
- (SOP04 Template)DYY###.A Report, Design Verification Analysis, DYY004, Trademark™ Generic_Device_Name_SamV10.docx
- (SOP04 Template)DYY###.A Report, XXXX Testing, Product Name [Attachment Style]_SamV10.docx
- (SOP04 Template)DYY###.A Report, XXXX Testing, Product Name_SamV10.docx
- (SOP04 Template)DYY001.A Product Specification, Trademark™ Generic_Device_Name_SamV13.docx
- (SOP04 Template)DYY002.A Risk Management Plan and Report, Trademark™ Generic_Device_Name_SamV14 (with FMEA).docx
- (SOP04 Template)DYY002.A Risk Management Plan and Report, Trademark™ Generic_Device_Name_SamV14 (without FMEA).docx
- (SOP04 Template)DYY003.A Essential Requirements Checklist, Europe 93_42_EEC, Trademark™ Generic_Device_Name_SamV10.docx
- (SOP04 Template)DYY003.A General Safety and Performance Requireme...lation 2017_745 (MDR), Trademark™ Generic_Device_Name_SamV10.docx
- (SOP04 Template)DYY004.A Verification and Validation Plan, Trademark™ Generic_Device_Name_SamV12.docx
- (SOP04 Template)DYY005.A Verification and Validation Report, Trademark™ Generic_Device_Name_SamV12.docx
- (SOP04 Template)Post Market Surveillance Plan (memo)_SamV11.docx
- (SOP04 Template)Prior DR Action Item Status Report (memo)_SamV10.docx
- (SOP04 Template)Project Plan (memo)_SamV10.docx
- (SOP04 Template)STM001.A Product Accelerated and Real Time Aging_SamV11.docx
- (SOP04 Template)STM002.A Packaged Product Simulated Distribution Testing_SamV11.docx
- (SOP04 Template)STM003.A Simulated Use Design Validation Testing, Product XYZ_SamV11.docx
- (SOP04 Template)Supplier Approval Status Report (memo)_SamV10.docx
- (SOP04_SOP15 Template)Regulatory Compliance Status Report (memo)_SamV11.docx
- (SOP05 Template)CAPA Effectiveness Memo, CAPA-####_SamV10.docx
- (SOP05 Template)CAPA Extension Memo, CAPA-####_SamV10.docx
- (SOP06 Template)Audit Response_SamV10.docx
- (SOP06 Template)Internal Quality Audit Report_SamV13.docx
- (SOP07 Template)DNP002.A Supplier Performance Report, YYYY-MM_SamV10.docx
- (SOP07 Template)Supplier Quality Audit Plan_SamV10.docx
- (SOP07 Template)Supplier Quality Audit Report_SamV10.docx
- (SOP08 Template)COC Template for Suppliers Who Need One_SamV10.docx
- (SOP08 Template)Purchasing Financial Authorization List_SamV10.docx
- (SOP10 Template)Product Environment Nonconformity Action Plan (memo)_SamV10.docx

✓ Full Document Set Listing: Templates (continued)

- (SOP11 Template)RFS001.A Finished Product Distribution List_EXAMPLE_SamV10.docx
- (SOP11 Template)RFS001.A Finished Product Distribution List_SamV10.docx
- (SOP14 Template)CAPA-#### (FSCA)_SamV10.docx
- (SOP14 Template)Correction_Removal Letter for Distributors, CAPA-####, YYYY-MM-DD_SamV10.docx
- (SOP14 Template)Correction_Removal Report, CAPA-####, YYYY-MM-DD_SamV10.docx
- (SOP14 Template)Correction_Removal Tracking Log, CAPA-####_SamV10.xlsx
- (SOP14 Template)Device Distribution Log, CAPA-####_SamV10.xlsx
- (SOP14 Template)DNP004.A Post Market Surveillance Report, YYYY-MM_SamV10.docx
- (SOP14 Template)DYY###.A PMS Plan_example_SamV10.docx
- (SOP14 Template)FDA Removal Report_SamV10.docx
- (SOP14 Template)Field Safety Notice, CAPA-####, YYYY-MM-DD_SamV10.docx
- (SOP14 Template)Health Hazard Evaluation_SamV12.docx
- (SOP14 Template)PMS Data Collection Table (EXAMPLE)_SamV10.docx
- (SOP15 Template)DYY006.A Clinical Literature Review Protocol, Product XYZ_SamV10.docx
- (SOP15 Template)DYY007.A Clinical Literature Review Report, Product XYZ_SamV10.docx
- (SOP15 Template)DYY008.A Clinical Evaluation Report, Product XYZ_SamV10.docx
- (SOP15 Template)DYY009.A Technical File_Design Dossier, Product Category Name (Part A)_SamV10.docx
- (SOP15 Template)DYY010.A Declaration of Conformity_SamV10.docx
- (SOP17 Template)DNP###.A Protocol, Software Validation, DocuSign Electronic Signature Service_SamV11.docx
- (SOP17 Template)DNP###.A Report, Software Validation, DocuSign Electronic Signature Service_SamV12.docx
- (SOP17 Template)DNP001.A Master Process Validation Plan and Report_SamV11.docx
- (SOP17 Template)DYY###.A Protocol, Packaging Validation and Pouch Heat Seal Process Validation, Product XYZ_SamV10.docx
- (SOP17 Template)DYY###.A Protocol, Process Validation, Catheter Hub Bonding (EXAMPLE)_SamV10.docx
- (SOP17 Template)DYY###.A Report, Process Validation, Catheter Hub Bonding (EXAMPLE)_SamV10.docx
- (SOP17 Template)RFS###.A Use Specification, DocuSign Electronic Signature Software Service_SamV11.docx
- (SOP19 Template)Production Trending Report_SamV10.docx
- (SOP20 Template)DYY###.A Protocol, EO Clinical Batch Release and Full Validation_SamV12.docx
- (SOP20 Template)DYY###.A Protocol, EO Clinical Batch Release and Full Validation, Product XYZ_SamV10.docx
- (SOP20 Template)QIP201.A Inspect Pre-Sterile Load, EO_SamV10.docx
- (SOP20 Template)QIP202.A Final Inspect Sterile Load, EO_SamV10.docx
- (SOP20 Template)QIP203.A Inspect Pre-Sterile Load, Radiation_SamV10.docx
- (SOP20 Template)QIP204.A Final Inspect Sterile Load, Radiation_SamV10.docx
- (SOP20 Template)RFS###.A EO Sterilization Cycle Specification_SamV10.docx
- (SOP21 Template)DYY###.A Clinical Investigation Plan_SamV10.docx

✓ Document Set Tailoring Questions (Client Needs Assessment)

Category	*Question / Answer (check as applicable)*
Name/ Facilities	1. Company Name: Facility Address: Company Logo: please provide image file
Nature of Device(s) and User(s)	2. Describe device(s): Check all that apply: ☐ Provided sterile ☐ Non-active ☐ Active ☐ Implantable (>30d) ☐ Reusable ☐ Resterilizable ☐ Single patient use ☐ Home/layperson user ☐ Professional user ☐ Software Describe users of device:
Markets	3. For which countries/regions do you want the quality system scope to facilitate marketing your devices? ☒ USA ☒ Europe ☒ Canada ☐ Other:
Risk Classes	4. What are the regulatory risk classes of devices the company plans to distribute? USA FDA: ☐ Class 1 ☐ Class 2 ☐ Class 3 FDA Product Code: Europe: ☐ Class I ☐ Class IIa ☐ Class IIb ☐ Class III ☐ IVD
Organization	5. Provide current/planned position titles and existing personnel names. Provide Organization Chart if available.
Lab Notebooks (SOP01)	6. Do you want to address the control of Laboratory Notebooks? ☐ Yes ☐ No
Personnel (SOP02)	7. Does the company want to have a quality system requirement for Job Descriptions? ☒ Yes ☐ No 8. Does the company want to mention employee performance reviews in Personnel SOP02? ☒ Yes ☐ No
Design (SOP04)	9. Does company plan to directly manage the product design process? ☒ Yes ☐ No
Clinical Investigation (SOP21)	10. Does company expect to sponsor clinical investigations to obtain regulatory clearance/approval or perform post-market studies in any of the planned markets? ☒ Yes (SOP21 addresses this) ☐ No
Measuring Equipment (SOP18)	11. Are there plans to perform "in-house" receiving inspection, in process inspection, final inspection, verification testing, validation testing, environmental monitoring, or other operations that require the use of company-owned measuring equipment to provide evidence of conformity to requirements? ☒ Yes ☐ No
Purchasing (SOP08)	12. Does company plan to purchase components and perform receiving inspections in-house? ☒ Yes ☐ No 13. Does company want to use require Purchase Requisitions in addition to Purchase Orders? ☐ Yes ☒ No
Suppliers/ Outsourcing (SOP07)	14. What major quality system functions is the company planning to substantially outsource to contractors? ☐ Design/Development ☐ Clinical Studies ☐ Manufacturing ☐ Sterilization ☐ Distribution ☐ Sales ☐ Returns/Complaints ☐ Other: _____
Customer Property (QSM1)	15. Will customers provide customer property for use or incorporation into company devices? ☐ Yes ☒ No Describe (if Yes): _____
Production (SOP19)	16. Does company plan to perform manufacturing operations "in-house" (Production function)? ☐ Yes ☐ No Describe (types of operations): _____
Environmental (SOP10)	17. Are special environmental controls needed to support device manufacturing? ☐ Yes ☐ No If Yes, indicate types of controls: ☐ Cleanroom ☐ Electrostatic Discharge ☐ Other: _____ 18. Are devices provided sterilized? ☐ Yes ☐ No 19. Will a controlled production environment (e.g., cleanroom) be established in-house? ☐ Yes ☐ No
Warehousing (SOP10/11)	20. Does company plan to store/distribute product from in-house warehouse (Materials function)? ☒ Yes ☐ No
Sales Orders (SOP11)	21. Does company plan to process customer orders for devices (Customer Service function)? ☒ Yes ☐ No
Installation	22. Do any of the planned devices require installation at customer sites before use by end users? ☐ Yes ☒ No
Servicing	23. Do any of the planned devices require post-distribution servicing operations (e.g. maintenance, repair, refurbishing, software updates)? ☐ Yes ☒ No
Product Sterilization Before Distribution (SOP20)	24. Will any of the planned devices be terminally sterilized before distribution? ☐ Yes ☐ No a. If Yes, indicate expected sterilization methods: ☐ Ethylene oxide ☐ Radiation (Gamma or Electron beam) ☐ Other: _____ b. If Yes, will sterilization processing be coordinated in-house or by contract manufacturers? ☐ Coordinated in-house ☐ Coordinated by contract manufacturers
Functional Group Names	25. Here are suggested functional group names: - Finance - Customer Service - Document Control - Marketing - Materials - Quality Assurance (QA) - Regulatory Affairs (RA) - Research & Development (R&D) - Clinical Affairs (typically needed if clinical investigations will be performed per SOP21) - Manufacturing Engineering (not needed if manufacturing is outsourced or if work is covered by QA/R&D) - Production (not needed if manufacturing is completely outsourced; is needed for SOP19 implementation) Are these groups and names appropriate, or do you wish to make additions, deletions, or other changes? ☐ Appropriate as shown above ☐ Changes: _____

Fremont, CA, USA
Las Vegas, NV, USA

Salvatore (Sam) C. Lazzara Jr.

+1 510 397 9739
Sam@MDQC.com

SUMMARY

- Over 39 years medical device 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
- FDA regulations
- 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)

BROWN

CASE
CASE WESTERN RESERVE UNIVERSITY

PROFESSIONAL AFFILIATIONS

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

ASQ
AAMI

RAPS

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
FDA CDRH Learn Program
GS1 FDA Unique Device Identification (UDI Certification
ISO 13485 Lead Auditor Certificate (Excel Partnership)
NSF Medical Device Regulatory Requirements Certification – MDSAP, Australia, Brazil, Canada, Japan, United States
RAPS San Francisco Chapter Updates

ASQ
Certified Biomedical Auditor
The Global Voice of Quality™

bsi.
ASSOCIATE CONSULTANT PROGRAM
ACP US 049

NSF

EXCEL PARTNERSHIP

GS1

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

FDA
CDRH Center for Devices and Radiological Health

European Union

Health Canada Santé Canada

Fremont, CA, USA
Las Vegas, NV, USA

Salvatore (Sam) C. Lazzara Jr.

+1 510 397 9739
Sam@MDQC.com

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 control)	2005-01
6.	BaroNOVA (gastrointestinal implant for obesity control)	2006-08
7.	r4 Vascular (vascular catheters)	2007-04
8.	Nevro (neurostimulation devices for pain management)	2008-04
9.	Autonomic Technologies (neurostimulation devices for pain management)	2009-04
10.	Loma Vista Medical (cardiac valvuloplasty catheters) → acquired by CR Bard	2009-06
11.	Nfocus Neuromedical (neurovascular implants) → acquired by Medtronic	2009-06
12.	Anthem Orthopaedics VAN (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 devices)	2013-11
24.	Allurion Technologies (gastrointestinal implant for obesity control)	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) → acquired by 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 (artificial pancreas system for diabetes treatment)	2016-02
39.	Enzyme (electronic quality management system software provider)	2016-03
40.	Urotronic (drug coated balloon catheter for non-vascular applications)	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 medical device designer and manufacturer)	2017-06
49.	Chinook Medical Gear (pre-hospital medical emergency convenience kits)	2017-07
50.	Bayer Consumer Health (personal care medical devices)	2017-08
51.	Labyrinth Devices (inner 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 systems)	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 (lower gastrointestinal stomal repair implant)	2021-01
76.	FPrin (medical device contract design and manufacturing services)	2021-01
77.	Applied VR (virtual reality therapy for various medical conditions)	2021-06
78.	2Morrow (digital therapeutic health software products)	2021-12
79.	Intergalactic Therapeutics (digital therapeutic health software 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

Fremont, CA, USA
Las Vegas, NV, USA
Salvatore (Sam) C. Lazzara Jr.
+1 510 397 9739
Sam@MDQC.com

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.

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.

EMPLOYEE EXPERIENCE (continued)

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		✓			✓		

Fremont, CA, USA
Las Vegas, NV, USA

Salvatore (Sam) C. Lazzara Jr.

+1 510 397 9739
Sam@MDQC.com

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
    - European Medical Device Directive (MDD) and Medical Devices Regulation (MDR)
    - 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

Fremont, CA, USA
Las Vegas, NV, USA

Salvatore (Sam) C. Lazzara Jr.

+1 510 397 9739
Sam@MDQC.com

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

Fremont, CA, USA
Las Vegas, NV, USA

Salvatore (Sam) C. Lazzara Jr.

+1 510 397 9739
Sam@MDQC.com

Fremont, CA, USA
Las Vegas, NV, USA

Salvatore (Sam) C. Lazzara Jr.

+1 510 397 9739
Sam@MDQC.com

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

Fremont, CA, USA
Las Vegas, NV, USA

Salvatore (Sam) C. Lazzara Jr.

+1 510 397 9739
Sam@MDQC.com

NSF

CERTIFICATE OF SUCCESSFUL COMPLETION

PRESENTED TO:

Salvatore (Sam) Lazzara

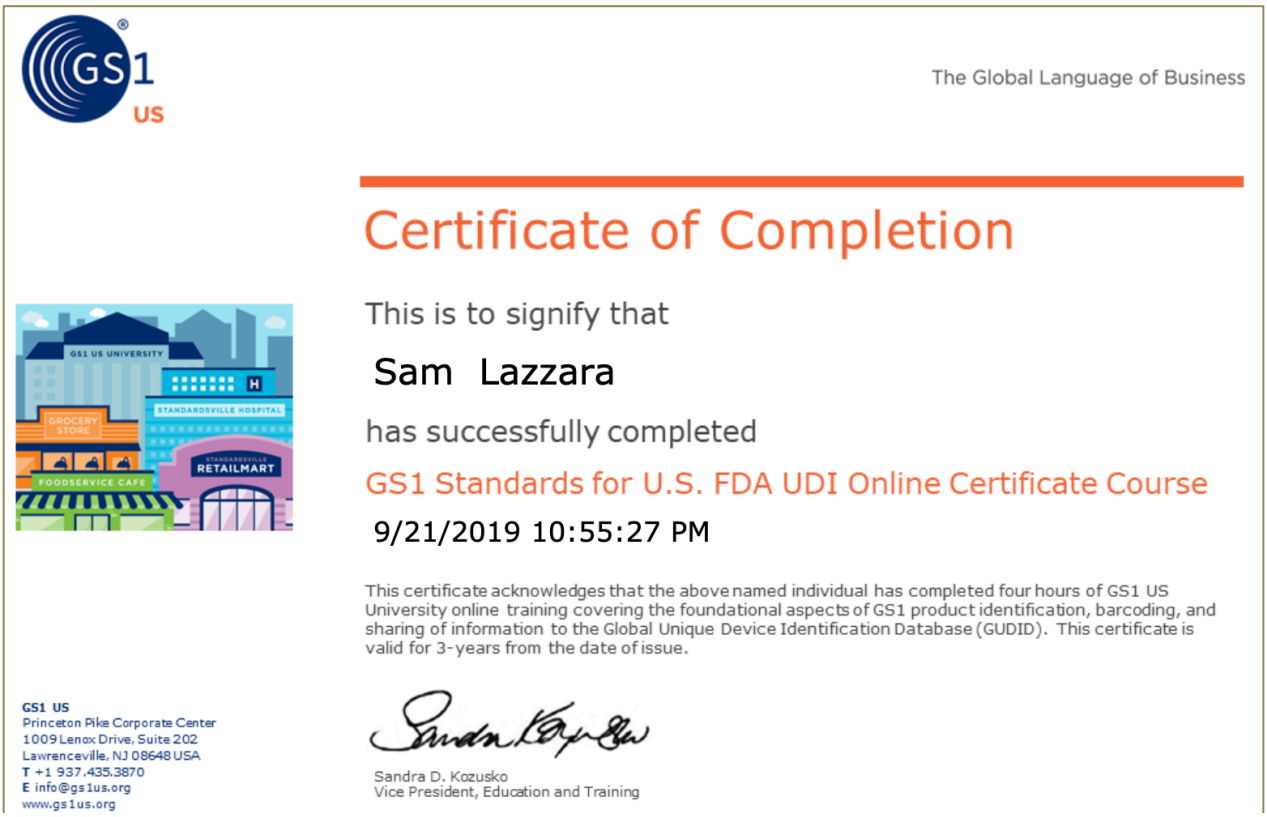
FOR:

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

9/21/2019 10:55:27 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.

Sandra D. Kozusko
Vice President, Education and Training

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

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

Salvatore (Sam) C. Lazzara Jr.

+1 510 397 9739
Sam@MDQC.com

medicaldeviceHQ

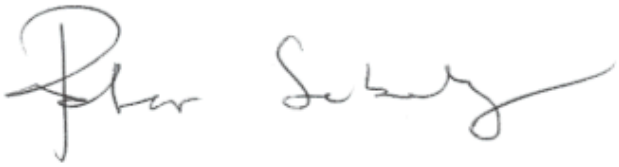
Course Certificate

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.