Ronald J. Makar

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Auditor / Assessor Credentials

- Audit Period: September 2007 through December 2023
- Approved as an independent auditor for DEKRA Business Assurance (www.dekra.com), Feb. 2018

Active Certifications

AMERICAN SOCIETY FOR QUALITY (ASQ)

- Certified Biomedical Auditor (CBA), Cert. No. 772
- Certified Hazard Analysis and Critical Control Point (HACCP) Auditor (CHA), Cert. No. 787
- Certified Manager of Quality & Organizational Excellence (CMQ/OE), Cert. No. 3187
- Certified Supplier Quality Professional (CSQP), Cert. No. 574
- Certified Quality Auditor (CQA), Cert. No. 10,459
- Certified Quality Engineer (CQE), Cert. No. 35,016

VILLANOVA UNIVERSITY

- Certified Lean Sensei, Villanova University – Lean Six Sigma (Cert. No. VU2019216, Nov. 2019)

EXEMPLAR GLOBAL

- Qualification Based Medical Device Lead Auditor: Medical Device (ISO 13485:2016) Auditor (Cert. No. 207821, July 2020)
- Qualification Based Lead Internal Auditor: Medical Device Single Audit Program Internal Auditor (Cert. No. 207821, July 2020)

Relevant Training

- 36-Hour QMS Lead Auditor Course (ISO 9001:2015) inclusive of ISO 13485:2016, Oriel Stat A Matrix, 15 Jun. 2020 – 25 Jun. 2020
- Conducting a Remote Medical Device QMS Audit, Oriel Stat A Matrix, 1 Jul. 2020 – 2 Jul. 2020
- EU In Vitro Diagnostic Regulation 2017/746 Training for Auditors, Oriel Stat A Matrix, 9 Sept. 2021 – 10 Oct. 2021
- EU MDR Auditor Training 2017/745, Quality Auditing, 6 Jan. 2023
- EU MDR Auditor Training 2017/745, Oriel Stat A Matrix, 24 Aug. 2020 – 28 Aug. 2020
- ISO 14971 Medical Device Risk Management Training, Oriel Stat A Matrix, 20 Jul. 2020 – 24 Jul. 2020
- MDSAP criteria from ISO 13485:2016 and Device Regulations for MDSAP Jurisdictions, Oriel Stat A Matrix, 5 Jun. 2020

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
74	2/28/2024	Charlottesville, VA	Sterilization of vials, stoppers, and/or seals for sterile filling. Aseptic filling and terminal sterilization for liquid products.	Supplier Audit	1 (On-site Audit)	Audit Team Leader	Criteria: • 21 CFR Part 211 Audit Scope: • Full QMS
73	2/16/2024	Everett, PA	Polyclonal and monoclonal antibody development, cell culture services, and blood-derived products.	Supplier Audit	1 (Remote Audit)	Audit Team Leader	Criteria: • ISO 13485:2016 Audit Scope: • Full QMS
72	1/23/2024	Boothwyn, PA	Medical Device Service Repair Operations – Oxygen Ventilator Equipment	Supplier Audit	1 (On-site Audit)	Audit Team Leader	Criteria: • ISO 13485:2016 Audit Scope: • Full QMS
71	12/21/2023	Conshohocken, PA	Medical Device Software Development and Services	3rd party audit (Quality Management System)	2 (Remote Audit)	Audit Team Leader	Criteria: • ISO 13485:2016 Audit Scope: • Full QMS

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
70	12/20/2023	Sparta, NJ	Designs, manufactures and distributes single-use components and systems to transfer and/or store fluid or other media.	3rd party audit (Quality Management System)	1 (On-site Audit)	Audit Team Leader	Criteria: • ISO 9001:2015 Audit Scope: • Full QMS
69	12/14/2023	New Britain, PA	The manufacture of sterile barrier systems and packaging for the medical device industry.	Supplier Audit	1 (On-site Audit)	Audit Team Leader	Criteria: • ISO 13485:2016 Audit Scope: • Full QMS

68	12/11/2023	Golden, CO	Design and development, distribution and production of software used for visualization and study of changes of tissue perfusion and diffusion in CT and MRI digital images	3rd party audit
				(Quality Management System)
					4
					(Remote Audit)
						Audit Team Leader	Criteria:
							• 21 CFR Part 820
							• ISO 13485:2016
							• MDSAP, including
							  ○ Australia
							  ○ Brazil
							  ○ Canada
							  ○ Japan
							  ○ United States
							• EU MDR 2017/745
							
							Audit Scope:
							• Full QMS

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
67	12/06/2023	West Chester, PA	Contract design and development organization providing design services to the medical device industry	3rd party audit (Quality Management System)	2 (On-site Audit)	Audit Team Leader	Criteria: • 21 CFR Part 820 • ISO 13485:2016 Audit Scope: • Full QMS
66	11/30/2023	Easton, PA	The design, manufacture, and distribution of cryosurgical devices intended for the surgical destruction of target tissue by applying cryogenic gasses	Suppler Audit	2 (On-site Audit)	Audit Team Leader	Criteria: • 21 CFR Part 820 • ISO 13485:2016 Audit Scope: • Full QMS
65	11/14/2023	Lancaster, PA	Contract manufacturer of metal and plastic orthopaedic implants and instrumentation	3rd party audit (Quality Management System)	2 (On-site Audit)	Audit Team Leader	Criteria: • 21 CFR Part 820 • ISO 13485:2016 Audit Scope: • Full QMS
64	11/07/2023	Wesmont, IL	Design and manufacturer of non-sterile medical devices for spinal surgery	3rd party audit (Quality Management System)	2 (Remote Audit)	Audit Team Leader	Criteria: • 21 CFR Part 820 • ISO 13485:2016 Audit Scope: • Full QMS

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
63	11/02/2023	Newark, DE	Manufacturer of monomaterial bulk liquid packaging, capable of shipping hazardous chemicals, disinfectants and industrial chemicals	3rd party audit (Quality Management System)	2 (On-site Audit)	Audit Team Leader	Criteria: • ISO 9001:2015 Audit Scope: • Full QMS
62	10/16/2023	North Brunswick, NJ	Class III medical device manufacturer of FDA approved vascular graft	3rd party audit (Quality Management System)	2 (On-site Audit)	Audit Team Leader	Criteria: • 21 CFR Part 820 • ISO 13485:2016 Audit Scope: • Full QMS
61	10/11/2023	Harleysville, PA	Manufacturer of sterile catheter locking solution and packager of catheter kits	3rd party audit (Quality Management System)	2 (On-site Audit)	Audit Team Leader	Criteria: • 21 CFR Part 820 • ISO 13485:2016 Audit Scope: • Full QMS

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
60	9/27/2023	Rosedale, MD	Design manufactures and distributes mechanical springs including compression, extension and torsion springs, washers, wire forms, stampings, assemblies and related products	3rd party audit (Quality Management System)	1 (On-site Audit)	Audit Team Leader	Criteria: • ISO 9001:2015 Audit Scope: • Full QMS
59	7/25/2023	Charlottesville, VA	Producer of pre-sterilized vials for commercial drug products	3rd party audit (Quality Management System)	1 (On-site Audit)	Audit Team Leader	Criteria: • 21CFR Part 211 Audit Scope: • Full QMS
58	7/10/2023	Harleysville, PA	Manufacturer of sterile catheter locking solution and packager of catheter kits	3rd party audit (Quality Management System)	3 (On-site Audit)	Audit Team Leader	Criteria: • 21 CFR Part 820 • ISO 13485:2016 Audit Scope: • Full QMS
57	6/07/2023	North Brunswick, NJ	Class III medical device manufacturer of FDA approved vascular graft	3rd party audit (Quality Management System)	2 (On-site Audit)	Audit Team Leader	Criteria: • 21 CFR Part 820 • ISO 13485:2016 Audit Scope: • Full QMS

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
56	5/18/2023	Reading, PA	Supplier of packaging for medical device manufacturers	Supplier Audit	1 (Remote Audit)	Audit Team Leader	Criteria: • ISO 13485:2016 Audit Scope: • Full QMS
55	4/18/2023	St. Louis, MO	A division of a global medical device company dedicated the design, manufacture and service of endoscopy equipment	Internal QMS Audit	3 (Remote Audit)	Audit Team Member	Criteria: • 21 CFR Part 820 • ISO 13485:2016 • MDSAP AU P0002.007 (Rev. 2022-04-15) Audit Scope: • Full QMS
54	4/11/2023	San Diego, CA	A developer and manufacturer of diagnostic testing technologies across the continuum of healthcare testing needs	Internal QMS Audit	2 (Remote Audit)	Audit Team Leader	Audit Criteria: • BS EN ISO 14971:2019 standard (Medical devices – Application of risk management to medical devices). Audit Scope: • This audit was targeted to audit two (2) recently marketed diagnostic test kits.

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
53	3/20/2023	Center Valley, PA	A global medical device company dedicated the design, manufacture and service of endoscopy equipment	Internal QMS Audit	2 (Remote Audit)	Audit Team Member	Criteria: • 21 CFR Part 820 • ISO 13485:2016 • MDSAP AU P0002.007 (Rev. 2022-04-15) Audit Scope: • Full QMS
52	3/01/2023	Richmond, Ontario	A global medical device company dedicated the design, manufacture and service of endoscopy equipment	Internal QMS Audit	4 (Remote Audit	Audit Team Member	Criteria: • 21 CFR Part 820 • ISO 13485:2016 • MDSAP AU P0002.007 (Rev. 2022-04-15) Audit Scope: • Full QMS
51	11/09/2022	Millville, NJ	Global packaging solutions supplying a broad range of rigid and flexible packaging products for the food, beverage, healthcare, medical-device, home, and personal care and tobacco industries	Internal QMS Audit	2 (On-site audit)	Lead Auditor	Criteria: • ISO 1385:2016 Audit Scope: • Full QMS

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
50	9/20/2022	Center Valley, PA	A global medical device company dedicated the design, manufacture and service of endoscopy equipment	3rd party audit (Quality Management System)	2 (Remote Audit)	Lead Auditor	Criteria: • ISO 13485:2016 • FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Audit Scope: • Measurement, Analysis and Improvement • Medical Device Adverse Events and Advisory Notices Reporting • Production and Service Controls
49	6/14/2023	Harleysville, PA	Manufacturer of sterile catheter locking solution and packager of catheter kits	3rd party audit (Quality Management System)	5 2 days (on-site) 3 days (remote)	Lead Auditor	Criteria: • 21 CFR Part 820 • ISO 13485:2016 Audit Scope: • Full QMS
48	6//07/2023	Lancaster, PA	Contract manufacturer of metal and plastic orthopaedic implants and instrumentation	3rd party audit (Quality Management System)	3 (On-site Audit)	Audit Team Leader	Criteria: • 21 CFR Part 820 • ISO 13485:2016 Audit Scope: • Full QMS

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
47	5/12/2022	Pennsauken, NJ	A manufacturer of rubber and aluminum primary and secondary packaging components for pharmaceutical, medical, dental and animal health applications	Supplier Monitoring Audit	1 (Remote Audit)	Lead Auditor	Criteria: • ISO 9001:2015 Audit Scope: • Sterilization Validations • Complaint Handling • Control of Non-conforming Product • Corrective and Preventive Action • End to end QC/QA process
46	3/29/2022	Center Valley, PA	A global medical device company dedicated the design, manufacture and service of endoscopy equipment	3rd party audit (Quality Management System)	2 (Remote Audit)	Lead Auditor	Criteria: • ISO 13485:2016, • FDA Quality System Regulation (U.S. CFR Title 21 Part 820) • MDSAP Audit Model Audit Scope: • Market Quality

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
45	2/28/2022	St. Louis, MO	A medical device supplier that develops and commercializes an accessory for a CT system, utilizing electromagnetic tracking technology to locate and navigate endoscopic tools, catheters and guidewires relative to a CT-based model of the tracheobronchial tree	Supplier Monitoring	3 (Remote Audit)	Lead Auditor	Criteria: • ISO 13485:2016 • FDA Quality System Regulation (U.S. CFR Title 21 Part 820) • MDSAP audit model, • Medical Device Directive (MDD) 93/42/EEC Annex II Audit Scope: • Full QMS
44	3/25/2021	Mansfield, MA	Class II and Class III contract manufacturer offering design, development, validation and contract manufacturing services for the medical device industry	Supplier Qualification Assessment	1 (Remote Audit)	Lead Auditor	Criteria: • ISO 13485:2016 • FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Audit Scope: • Design Controls • Risk Management • Project Management

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
43	3/25/2021	Center Valley, PA	A global medical device company dedicated the design, manufacture and service of endoscopy equipment	3rd party audit (Quality Management System)	1 (Remote Audit)	Lead Auditor	Criteria: • ISO 13485:2016, • FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Audit Scope Areas: • Product Realization
42	3/18/2021	Center Valley, PA	A global medical device company dedicated the design, manufacture and service of endoscopy equipment	3rd party audit (Quality Management System)	1 (Remote Audit)	Lead Auditor	Criteria: • ISO 13485:2016 • FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Audit Scope: • Field Service

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
41	12/15,16/2020	Exton, PA	A global medical device company dedicated to offering innovative orthopedic medical devices and joint replacement products	3rd party audit (Quality Management System)	2 (Remote Audit)	Lead Auditor	Criteria: • ISO 13485:2016 • FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Audit Scope: • Document, Data and Record Controls • Management Controls • Customer Requirements • Design Controls • Risk Management • Purchasing Controls • Production and Process Controls • Distribution Controls • Post Market Controls • Corrective and Preventive Action • Statistical Techniques
40	12/17/2020	Center Valley, PA	A global medical device company dedicated the design, manufacture and service of endoscopy equipment	3rd party audit (Quality Management System)	1 (Remote Audit)	Lead Auditor	Criteria: • ISO 13485:2016 • FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Audit Scope: • Software Validation

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
39	3/17/2020	Center Valley, PA	A global medical device company dedicated the design, manufacture and service of endoscopy equipment	3rd party audit (Quality Management System)	1 (Remote Audit)	Lead Auditor	Criteria: • ISO 13485:2016 • FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Audit Scope: • Product Realization
38	12/16/2019	Langhorne, PA	A provider of software services on an outsourced basis to leading medical device and imaging equipment manufacturers	Supplier Qualification	1 (On-site Audit)	Lead Auditor	Criteria: • BS EN ISO 13485:2016 Medical devices – quality management systems – requirements for regulatory purposes • BS EN 62304:2006 +A1:2015 Medical device software – Software life-cycle processes • BS EN 14971:2015 Medical devices – Application of risk management to medical devices Audit Scope: • Full QMS

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
37	4/18/2019	Center Valley, PA	A global medical device company dedicated the design, manufacture and service of endoscopy equipment	3rd party audit (Quality Management System)	1 (On-site Audit)	Lead Auditor	Criteria: • ISO 13485:2016 • FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Audit Scope: • Measurement, Analysis and Improvement
36	10/15,16/2018	Center Valley, PA	A global medical device company dedicated the design, manufacture and service of endoscopy equipment	3rd party audit (Quality Management System)	2 (On-site Audit)	Lead Auditor	Criteria: • ISO 13485:2016 • FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Audit Scope: • Inventory Controls (10/15) • Complaint Handling (10/16)
35	9/20,21/2018	North Wales, PA	A provider of Quality Management Standards ISO auditing services that are accurate & professional	3rd party audit (Process Audit)	2 (On-site Audit)	Lead Auditor	Criteria: • ISO 17021-1:2015 (Requirements for bodies providing audit and certification of management systems) Audit Scope: • Full QMS

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
34	9/27,28/2018	Center Valley, PA	A global medical device company dedicated the design, manufacture and service of endoscopy equipment	3rd party audit (Quality Management System)	2 (On-site Audit)	Lead Auditor	Criteria: • ISO 13485:2016 • FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Audit Scope: • Document & Change Control (9/27) • Purchasing & Supplier Mgt. (9/28)
33	May 2018	Granby, QC, Canada	Design and manufacturer of medical device imaging software	Supplier Qualification Audit	2 (On-site Audit)	Lead Auditor	Criteria: • ISO 13485:2016 • FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Target Area: • New Product Design and Development
32	May 2018	Leander, TX	Contract manufacturer of precision machined components	Quality Management System audit (Stage II Registration Audit)	3 (On-site Audit)	DEKRA Audit Team Leader (DEKRA Business Assurance)	ISO 13485:2016

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
31	April 2018	Bellefontaine, OH	Service and repair operations of medical device equipment	Quality Management System audit (Stage I Registration Audit)	1 (On-site Audit)	DEKRA Audit Team Leader (DEKRA Business Assurance)	Criteria: • ISO 13485:2016 • FDA Quality System Regulation (U.S. CFR Title 21 Part 820)
30	Feb 2018	Coal City, PA	Provider of electronic contract manufacturing services (PCBAs and Electro-mechanical assembly) to original equipment manufacturers for the non-active, non-implantable device market	Quality Management System audit (Stage II Registration Audit)	1 (On-site Audit)	DEKRA Audit Team Member (DEKRA Business Assurance)	Criteria: • ISO 13485:2016 • FDA Quality System Regulation (U.S. CFR Title 21 Part 820)
29	Nov 2017	Center Valley, PA	A global medical device company dedicated the design, manufacture and service of endoscopy equipment	Quality Management System audit	2 (On-site Audit)	Lead Auditor	Determine compliance to ISO 13485:2016 and the FDA Quality System Regulation (U.S. CFR Title 21 Part 820)

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
28	May 2017	Denver, CO	A global medical device company dedicated to the design and manufacture of hearing implant devices	Quality Management System audit	3 (On-site Audit)	Lead Auditor	Determine compliance to ISO 13485:2003, and the FDA Quality System Regulation (U.S. CFR Title 21 Part 820)
27	Mar 2017	Sumter, SC	A global medical technology company that manufactures medical supplies, devices, laboratory equipment and diagnostic	Quality Management System audit	4 (On-site Audit)	Lead Auditor	Determine compliance to ISO 13485:2012, and the FDA Quality System Regulation (U.S. CFR Title 21 Part 820)
26	Jan 2017	Quebec City, Quebec	A global medical technology company that manufactures medical supplies, devices, laboratory equipment and diagnostic	Quality Management System audit	4 (On-site Audit)	Lead Auditor	Determine compliance to ISO 13485:2012, and the FDA Quality System Regulation (U.S. CFR Title 21 Part 820)

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
25	Oct - Nov 2016	Zelienople, PA	A global medical device company dedicated advancing the delivery of healthcare by creating innovative products and services	Not an audit, per se, but a contract consulting assignment	N/A	Project Team Lead	As project team lead, was responsible for creating a process map of the organizations service and repair operation, and proposing solutions to streamline the process, as well as assure compliance to FDA 21 CFR Part 820 and ISO 13485:2003
24	Oct 2015 - Oct 2016	Round Lake, IL	A global medical device company dedicated to the production of IV solutions and delivery systems	Not an audit, per se, but a contract consulting assignment	N/A	Project Team Lead	As project lead, was responsible for guiding this company in the consolidation of 13 global design control systems into a single design control system, compliant to ISO 13485:2003
23	July - Sept, 2015	Kaisei, Japan	A global medical device company who is a manufacture of endoscopes	Not an audit, per se, but an FDA remediation project	N/A	Project Team Member	As project team member, responsible for review of and improvements to client's purchasing and supplier controls operations, complaint to ISO 13485:2003
22	Dec 2014	Exton, PA	A global science-based company active in health, nutrition and materials	Affiliate company contracted to provide aseptic formulation, syringe filling, packaging and distribution operations.	1 (On-site Audit)	Lead Auditor	Determine compliance to ISO 13485:2012, ISO 14971:2012, and the FDA Quality System Regulation (U.S. CFR Title 21 Part 820)

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
21	Sept 2014	Alachua, FL	CMO for polymer formulation and aseptic syringe filling and packaging operations	Existing supplier audit	4 (On-site Audit)	Lead Auditor	External audit of a CMO manufacturing facility and assess readiness and compliance to ISO 13485:2003, U.S. CFR Title 21 Part 820 to meet business
20	Feb 2014	Rotkreuz, Switzerland	OEM manufacturer of mixing, delivery and application systems for multi-component biomaterial	Supplier Qualification Audit	2 (On-site Audit)	Lead Auditor	External audit of a medical device company to determine compliance to ISO 13485:2003, U.S. CFR Title 21 Part 820, ISO 14971:2007
19	Nov 2013	St. Paul, MN	Medical device manufacturer of precision dispensing systems for delivery of biomaterials	Existing supplier audit	2 (On-site Audit)	Lead Auditor	External audit of a medical device company to determine compliance to ISO 13485:2003, U.S. CFR Title 21 Part 820 and to perform CAPA and customer complaint effectiveness verification.
18	Aug 2013	Allentown, PA	Provider of strategies and distribution services to support clinical trials	Supplier Qualification Audit	2 (On-site Audit)	Lead Auditor	Determine compliance to meet internal company requirements to provide clinical trial materials and distribution services.
17	Aug 2012	Minneapolis, MN	Contract sterilization facility	Supplier Qualification Audit	1 (On-site Audit)	Lead Auditor	External audit of a medical device company to determine compliance to ISO 13485:2003, U.S. CFR Title 21 Part 820

No.	Audit Start Date	Auditee Location	Company Offerings	Audit Type	# Audit days	Audit Role	Audit Scope
16	May 2012	Berkeley, CA	A global science-based company active in health, nutrition and materials	External supplier qualification audit	1 (On-site Audit)	Lead Auditor	External audit of a medical device company to determine compliance to ISO 13485:2003, U.S. CFR Title 21 Part 820, ISO 14971:2007
15	May 2012	San Diego, CA	A provider of clinical trials materials distribution management	Supplier Selection Audit	1 (On-site Audit)	Lead Auditor	External audit of a medical device company to determine compliance to ISO 13485:2003, U.S. CFR Title 21 Part 820.
14	May 2012	San Diego, CA	A CMO under consideration for aseptic formulation and filling of bio-polymer for surgical applications	Supplier Selection Audit	1 (On-site Audit)	Lead Auditor	External audit of a medical device company to determine compliance to ISO 13485:2003, U.S. CFR Title 21 Part 820, ISO 14971:2007
13	Apr 2012	Durham, NC	A CMO under consideration for aseptic formulation and filling of bio-polymer for surgical applications	Supplier Selection Audit	1 (On-site Audit)	Lead Auditor	External audit of a medical device company to determine compliance to ISO 13485:2003, U.S. CFR Title 21 Part 820, ISO 14971:2007
12	Sept 2011	Riverside, PA	CMO providing fermentation products	Existing supplier audit	1 (On-site Audit)	Lead Auditor	Quality management system audit to determine compliance to quality agreement in place.

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11	Aug 2011	Wilmington, DE	Company focus: Develop products for adhesion prevention, tissue sealing, hemostasis, and other surgical applications	Quality Management System	1 (On-site Audit)	Lead Auditor	External audit of a medical device company to determine compliance to ISO 13485:2003, U.S. CFR Title 21 Part 820, ISO 14971:2007
10	May 2010	Riverside, PA	Fermentation, API facility	Readiness to initiate commercial fermentation, extrusion and pelletization operations.	1 (On-site Audit)	Lead Auditor	Assess supplier compliance to FDA cGMP [U.S. CFR Title 21 Part 110: Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food] as guidance.
9	Jan 2010	Lawrence, MA	Supercritical fluid extraction process	Supplier Qualification Audit	1 (On-site Audit)	Lead Auditor	Review FDA cGMP requirements for applicable sections of the dietary supplement regulation [U.S. CFR Title 21 Part 111: CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS].

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8	July 2009	City of Industry, CA	CMO of nutritional supplements including softgels, tablets, capsules, etc.	Supplier Qualification Audit	1 (On-site Audit)	Lead Auditor	Assess supplier compliance to U.S. CFR Title 21 Part 111 (Current GMP in Manufacturing, Packaging, Labeling or Holding Operations for Dietary Supplements)
7	May 2009	San Diego, CA	Pilot plant operations to develop a commercial process for the production of biomass	Supplier Qualification Audit	2 (On-site Audit)	Lead Auditor	Assess supplier compliance to FDA cGMP [U.S. CFR Title 21 Part 110: Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food] as guidance.
6	Feb 2009	Riverside, PA	Fermentation, API facility	Supplier Qualification Audit	1 (On-site Audit)	Lead Auditor	Assess supplier compliance to FDA cGMP [U.S. CFR Title 21 Part 110: Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food] as guidance.
5	May 2008	Northwood, OH	Conducts pre-clinical studies under GLP conditions	Supplier Selection Audit	1 (On-site Audit)	Lead Auditor	To assess this facility for compliance to DuPont standards and FDA GLP regulations (U.S. CFR Title 21 Part 58) as a potential supplier to DuPont to perform pre-clinical studies under GLP conditions.

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4	Apr 2008	Cambridge, MA	Contract polymer testing, research and development facility	Supplier Selection Audit	1 (On-site Audit)	Lead Auditor	Assess candidate supplier for compliance to FDA cGLP (U.S. CFR Title 21 Part 58 (GLP for Nonclinical Studies)
3	Mar 2008	Lexington, MA	Conducts pre-clinical studies under GLP conditions	Supplier Selection Audit	1 (On-site Audit)	Lead Auditor	To assess this facility for compliance to DuPont standards and FDA GLP regulations (U.S. CFR Title 21 Part 58) as a potential supplier to DuPont to perform pre-clinical studies under GLP conditions.
2	Oct 2007	Mattawan, MI	Conducts pre-clinical studies under GLP conditions	Supplier Selection Audit	1 (On-site Audit)	Lead Auditor	To assess this facility for compliance to DuPont standards and FDA GLP regulations (U.S. CFR Title 21 Part 58) as a potential supplier to DuPont to perform pre-clinical studies under GLP conditions.
1	Sept 2007	Denver, PA	Conducts pre-clinical studies under GLP conditions	Supplier Selection Audit	1 (On-site Audit)	Lead Auditor	To assess this facility for compliance to DuPont standards and FDA GLP regulations (U.S. CFR Title 21 Part 58) as a potential supplier to DuPont to perform pre-clinical studies under GLP conditions.