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Auditor / Assessor Credentials

- Audit Period: September 2007 through March 2021
- Approved as an independent auditor for **DEKRA Business Assurance** (www.dekra.com), Feb. 2018

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)

No.	Date	Auditee Client Location	Company Offerings	Audit Type	# of Audit days	Audit Role	Audit Scope
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	Lead auditor (Remote Audit)	Determine compliance to ISO 13485:2016, and the FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Audit Scope Areas: Design Controls Risk Management Project Management
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	Lead auditor (Remote Audit)	Determine compliance to ISO 13485:2016, and the FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Audit Scope Areas: Product Realization

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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	Lead auditor (Remote Audit)	Determine compliance to ISO 13485:2016, and the FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Audit Scope Areas: Field Service

No.	Date	Auditee Client Location	Company Offerings	Audit Type	# of 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	Lead auditor (Remote Audit)	Determine compliance to ISO 13485:2016, and the FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Complete QMS Audit: • 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

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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	Lead auditor (Remote Audit)	Determine compliance to ISO 13485:2016, and the FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Audit Scope Areas: Software Validation
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	Lead auditor (Remote Audit)	Determine compliance to ISO 13485:2016, and the FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Audit Scope Areas: • Product Realization

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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	Lead auditor	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
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	Lead auditor	Determine compliance to ISO 13485:2016, and the FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Audit Scope Areas: Measurement,37 Analysis and Improvement

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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 total (1 day each audit area)	Lead auditor	Determine compliance to ISO 13485:2016, and the FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Audit Scope Areas: • 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	Lead auditor	Determine compliance to company procedures and to ISO 17021-1:2015 (Requirements for bodies providing audit and certification of management systems)
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 total (1 day each audit area)	Lead auditor	Determine compliance to ISO 13485:2016, and the FDA Quality System Regulation (U.S. CFR Title 21 Part 820) Audit Scope Areas: • Document & Change Control (9/27) • Purchasing & Supplier Mgt. (9/28)

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33	May 2018	Granby, QC, Canada	Design and manufacturer of medical device imaging software	Supplier Qualification Audit	2	Lead Auditor	Determine compliance to ISO 13485:2016, and the 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	DEKRA Audit Team Leader (DEKRA Business Assurance)	ISO 13485:2016
31	April 2018	Bellefontaine, OH	Service and repair operations of medical device equipment	Quality Management System audit (Stage I Registration Audit)	1	DEKRA Audit Team Leader (DEKRA Business Assurance)	ISO 13485:2016

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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	DEKRA Audit Team Member (DEKRA Business Assurance)	ISO 13485:2016
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	Lead Auditor	Determine compliance to ISO 13485:2016 and the FDA Quality System Regulation (U.S. CFR Title 21 Part 820)

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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	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	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	Lead Auditor	Determine compliance to ISO 13485:2012, and the FDA Quality System Regulation (U.S. CFR Title 21 Part 820)

No.	Date	Auditee Client Location	Company Offerings	Audit Type	# of 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

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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	Lead Auditor	Determine compliance to ISO 13485:2012, ISO 14971:2012, and the FDA Quality System Regulation (U.S. CFR Title 21 Part 820)
21	Sept 2014	Alachua, FL	CMO for polymer formulation and aseptic syringe filling and packaging operations.	Existing supplier audit	4	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	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

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19	Nov 2013	St. Paul, MN	Medical device manufacturer of precision dispensing systems for delivery of biomaterials.	Existing supplier audit	2	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	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	Lead Auditor	External audit of a medical device company to determine compliance to ISO 13485:2003, U.S. CFR Title 21 Part 820
16	May 2012	Berkeley, CA	A global science-based company active in health, nutrition and materials.	External supplier qualification audit	1	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

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15	May 2012	San Diego, CA	A provider of clinical trials materials distribution management.	Supplier Selection Audit	1	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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.