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MEDICAL DEVICE EXPERIENCE

- 35 YEARS: INDUSTRY EXPERIENCE
- 5 YEARS: INDEPENDENT CONSULTANT

FOCUS AREAS:

1. QMS MANAGEMENT
2. SUPPLER QUALIFICATION & QA
3. AUDITING
4. FDA REMEDIATION

1. QMS MANAGEMENT (DUPONT, HOLOGIC, INDEPENDENT CONSULTANT, 1990 – CURRENT)

- PROVIDED QUALITY MANAGEMENT SYSTEM PROCESS IMPROVEMENT GUIDANCE AND TRAINING TO AN INTERNATIONAL MEDICAL DEVICE COMPANY TO U.S. TITLE 21 CFR PART 820 AND FDA QSIT AUDIT TECHNIQUE.
- CONSULTANT TEAM LEADER, RESPONSIBLE FOR SIMPLIFICATION AND HARMONIZATION OF A WORLD-WIDE MEDICAL DEVICE PRODUCT DEVELOPMENT AND DESIGN CONTROL PROCESS OF AN INTERNATIONAL MEDICAL DEVICE COMPANY ACROSS THIRTEEN (13) GLOBAL PRODUCT DESIGN CENTERS.
- AS QMS MANAGEMENT REPRESENTATIVE (DUPONT, HOLOGIC, 1990 – 2014), ESTABLISHED AND MAINTAINED SEVERAL QUALITY MANAGEMENT SYSTEMS TO ENABLE THE DEVELOPMENT AND COMMERCIALIZATION OF MEDICAL DEVICE PRODUCTS COMPLIANT TO U.S. FDA QUALITY SYSTEM REGULATION (U.S. CFR TITLE 21 PART 820), ISO 13485 (2003, 2012), MEDICAL DEVICE QUALITY SYSTEM REQUIREMENTS AND ISO 14971 (2000, 2007, 2012), APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICE.
- IDENTIFIED AND ESTABLISHED A MECHANISM TO MANAGE DOCUMENTS (STANDARDS AND REGULATIONS) OF AN EXTERNAL ORIGIN.
- MANAGED RESOLUTION OF CUSTOMER COMPLAINTS WITH DIVERSE BUSINESS OPERATIONS GROUPS, INCLUDING DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE AND PREVENTIVE ACTIONS.
- MANAGED QUALITY MANAGEMENT SYSTEM COMPLIANCE OF A MEDICAL DEVICE MANUFACTURER'S R&D DIVISION TO ISO 9001:1994, THE FDA QUALITY SYSTEM REGULATION, AND EN46001.
- DEVELOPED AND IMPLEMENTED A PRODUCT DEVELOPMENT AND COMMERCIALIZATION SYSTEM COMPLIANT WITH FDA FOOD (21 CFR PART 110) AND DIETARY SUPPLEMENT (21 CFR PART 111) REGULATIONS.
- IMPLEMENTED AN ESTABLISHED QUALITY MANAGEMENT SYSTEM IN MICROSOFT® SHAREPOINT.

2. SUPPLER QUALIFICATION & QA (DUPONT APPLIED BIOSCIENCES, INDUSTRIAL BIOSCIENCES, INDEPENDENT CONSULTANT, 2007 – CURRENT)

- MANAGED SUPPLIER SELECTION, QUALIFICATION AND APPROVAL ACTIVITIES OF CRITICAL CONTRACT MANUFACTURING OPERATIONS. THIS INCLUDED DEMONSTRATING SUPPLIER CAPABILITY AND OBTAINING ASSURANCE THAT SELECTED CRITICAL SUPPLIERS WERE COMPLIANT TO APPLICABLE FDA AND ISO QUALITY SYSTEM REGULATIONS AND REQUIREMENTS.
- MANAGED EFFORTS IN THE DEVELOPMENT AND EXECUTION OF QUALITY AGREEMENTS WITH CRITICAL SUPPLIERS.
- INTERFACED DIRECTLY WITH CRITICAL CONTRACT MANUFACTURING OPERATIONS (CMO) ON A REGULAR BASIS, TO REVIEW, APPROVE AND RELEASE PRODUCTION LOTS.
- IN PARTNERSHIPS WITH CRITICAL CONTRACT MANUFACTURING OPERATIONS, ENSURED THAT THE CMO HAD PERFORMED ADEQUATE AND EFFECTIVE RISK ANALYSIS OF THEIR MANUFACTURING PROCESSES.

3. AUDITING (DUPONT, HOLOGIC, INDEPENDENT CONSULTANT, 1990 – CURRENT)

- LEAD AUDITOR, 3RD PARTY FDA 21 CFR PART 820, ISO 13485, ISO 14971 AND FDA QSIT AUDIT, INCLUDING A REVIEW OF PRODUCT, PROCESS, SYSTEM AND SOFTWARE VALIDATION ACTIVITY.
- LEAD AUDITOR (MEDICAL DEVICES), DEKRA BUSINESS ASSURANCE (WWW.DEKRA.COM): ISO 9001:2015, ISO 13485:2016.
- PERFORMED INTERNAL COMPANY AUDITS IN R&D, MANUFACTURING (CONSUMABLES, INSTRUMENTATION, SERVICE, SOFTWARE) FOR DUPONT MEDICAL PRODUCTS, DADE BEHRING, W.L. GORE MEDICAL PRODUCTS, HOLOGIC, INC. – (1990 – 2007).
- MANAGED INTERNAL AUDIT PROGRAMS, INCLUDING TRAINING OF AUDITORS, AS A PART OF QUALITY MANAGER RESPONSIBILITIES (1990 – 2014).
- PERFORMED VARIOUS BIOTECH AND MEDICAL DEVICE SUPPLIER AND CONTRACT MANUFACTURING AUDITS DURING ROLES AS GLOBAL QUALITY MANAGER (DUPONT INDUSTRIAL BIOSCIENCES) AND QUALITY SYSTEMS DIRECTOR (ACTAMAX SURGICAL MATERIALS) – (2008 – 2014).
- PERFORMED VARIOUS MEDICAL DEVICE AUDITS AS INDEPENDENT CONSULTANT FOR INTERNATIONAL MEDICAL DEVICE COMPANIES – (2015 – 2018).

4. FDA REMEDIATION (INDEPENDENT CONSULTANT)

- AS A MEMBER OF A SIXTEEN (16) PERSON FDA QUALITY SYSTEMS REGULATION (QSR) REMEDIATION TEAM, LED CORRECTIVE ACTION EFFORT TO BRING INTO QSR COMPLIANCE SUPPLIER AND PURCHASING CONTROLS OF AN INTERNATIONAL MEDICAL DEVICE COMPANY HEADQUARTERED IN JAPAN.