DAHLFELTCONSULTING

CONSULTANT WITHIN QA, QC, RISK, RA, IT, STERILISATION & PROJECT MANAGEMENT

Name	Phat Huynh
Nationality	Danish
Gender	Male
Domicile	Denmark

CONTACT INFORMATION

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PHAT HUYNH | CURRICULUM VITAE

PERSONAL LETTER

Detail-oriented medical device & Pharma professional with great analytical skills and with an ability to work in teams. Possess 15+ years' experience from Pharma & medical device working for organizations and clients. Gained expertise in various medical device standards and products regarding Quality Assurance, Regulatory standards, design & development, risk management, process validation, manufacturing and sterilization.

Looking to utilize my existing skill set to support clients in both small and large projects.

STRENGTHS

- Honesty
- Integrity
- Respectful
- Desire for self-improvement by learning new abilities and being self-critical
- Good listener
- Good to sense a given situation

EXPERTISE

- Regulatory Compliance: Extensive knowledge of ISO 13485, 21 CFR Part 820, and EU MDR, ensuring compliance across all stages of product development and manufacturing.
- Design Control: Proficient in establishing and managing design control processes, ensuring that medical devices meet user needs and intended uses while complying with regulatory requirements.
- Risk Management: Skilled in identifying, assessing, and mitigating risks throughout the product lifecycle, aligning with ISO 14971 standards.
- Process Validation: Expertise in process validation, including installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) to ensure consistent product quality.
- Sterilization Validation: In-depth experience with sterilization validation methods including e-beam, gamma irradiation, and ethylene oxide (EO), ensuring the sterility of medical devices.
- Software Validation: Knowledge in validating software used in medical devices, ensuring compliance with standards and regulatory requirements.

IT SKILLS

- MS Office 365
- MS Visio
- MS Projects

EDUCATION AND DEGREES

CAND. SCIENT. MOLECULAR BIOLOGY

University of Aarhus

1997 – 2008

CERTIFICATIONS AND COURSES

2024	Implementation of Medical Device Regulation (MDR) for CE marking
2022	PRODUCTION & QUALITY SOFTWARE - AAMI
2022	FMEA WITHOUT TEARS - AAMI
2021	INTEGRATING RISK MANAGEMENT INTO THE PRODUCT LIFE CYCLE - AAMI
2019	THE QUALITY SYSTEM REGULATION 21 CFR 820 AND ANSI/AAMI/ISO 13485: NAVIGATING REGULATORY REQUIREMENTS - AAMI
2019	SOFTWARE VALIDATION WORKSHOP: PRACTICAL TOOLS & TECHNIQUES - AAMI
2018	GAMP5 - COMPUTER SYSTEM VALIDATION - ECA
2017	MEDICAL DEVICE REGULATION 2017 - PRESAFE/PREVENTIA
2017	PROCESS VALIDATION REQUIREMENTS AND INDUSTRY PRACTICE - AAMI
2016	ETHYLENE OXIDE STERILIZATION FOR MEDICAL DEVICES - AAMI
2015	ISO 14971 RISK MANAGEMENT - MAETRICS
2014	21 CFR 820.30 DESIGN CONTROL - AAMI
2013	ISO 14971 MEDICAL DEVICES – APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES GANTUS.COM
2012	STERILIZATION - ETHYLENE OXIDE ADVANCED - HIGHEDGE CONSULT
2011	LEAN - PRACTICAL PROCESS IMPROVEMENTS (PPI) (6 WEEKS PROJECT) - THERMO FISHER SCIENTIFIC
2010	DOSIMETRY - PANEL ON GAMMA AND ELECTRON IRRADIATION
2010	LEAN - PRACTICAL PROCESS IMPROVEMENTS (PPI) (6 WEEKS PROJECT) - THERMO FISHER SCIENTIFIC
2010	LEAD AUDITOR EDUCATION – ISO 9001-2008 - ISO CONSULT
2008	LEAN - PRACTICAL PROCESS IMPROVEMENTS (PPI) (6 WEEKS PROJECT) - THERMO FISHER SCIENTIFIC
2008	VALIDATION AND PROCESS CONTROL FOR ELECTRON BEAM STERILIZATION - RISØ/DTU
2007	VALIDATION AND PROCESS CONTROL FOR ELECTRON BEAM STERILIZATION - RISØ/DTU

LANGUAGE SKILLS

Danish	Written and spoken	Fluent
English	Written and spoken	Fluent
Chinese	Spoken	Fluent

PROFESSIONAL BACKGROUND

Feb. 2023 - present

DahlfeltConsulting | Senior Consultant

Senior Consultant Sterilization expert, Validation, Design & Risk management & Quality Assurance.

- Managed CAPA (Corrective and Preventive Actions) to address quality issues and improve processes.
- Oversaw change request activities, review and approval, including workshop for optimization of the process.
- Sparring-partner for management regarding design control and ISO 13485 compliance.
- Conducted change assessments for medical software and developed change notification for notifying body.
- Managed medical device development project, including review and approval of test documentation.

Jan. 2020 - Feb. 2023

Sigma Connectivity | Senior Consultant

- Project manager at a medical device manufacturer developing a class II, sterile convenience kit. Overseeing activities from initial user needs and design development planning, risk management and design inputs to choosing of manufacturing strategy, process validation, sterilization validation, design verification/validation.
- Gap analysis of a QMS system aiming for an ISO 13485 certification.

Jan. 2012 - Dec. 2019

Al Engineering | Senior Consultant

As a Senior Consultant within the medical device industry, I have had the pleasure to work with the major medical device companies that manufacture devices ranging from Class I to Class III in the Copenhagen area and abroad. The durations of these contracts have ranged from a few months to 2,5 years with returning clients.

The assignments include the following working areas:

- Qualification of manufacturing equipment – establishment of a user requirements specification and test protocols. Execution of test plans, Fill/Finish.
- Process validation – establishment of test protocols and execution of test plans and reporting.
- EO sterilization validation – review and approval of protocol and report established by sub-contractor.
- Software validation – establishment of a user requirements specification, functional requirement specification, risk analysis and test protocols.
- Test method validation – establishment of test protocol and reporting.
- Validation activities in production equipment IQ, OQ, PQ, FAT & SAT
- GAP analysis – reporting of gaps between areas of a client's QMS compared to the ISO 13485/21 CFR Part 820.
- QA role responsible for review and approval of design control -, risk management – and usability documentation in a R&D development project. Review and approval of

test documentation, change requests and CAPA. Participation in certification audit and supplier audit.

- Advisory role regarding design control, process validation and sterilization validation.
- Compliance issues with ISO 13485 and 21 CFR Part 820.

2008-2012

Thermo Fisher Scientific | Quality Assurance Specialist

The role as a Quality specialist and as the person responsible for the quality/compliance aspects of the gamma facility, it has provided me an in-depth knowledge of how such a facility works and hands-on experience with dose mapping issues, validation issues and dosimeter calibration issues. During the years I have managed to implement several initiatives that have lifted the compliance level of the gamma facility. Besides the facility I was also participating in site improvement and lean projects.

The assignments include the following working areas:

- Sterilization validation of an in-house gamma facility to comply with ISO 11137 following an annual source replenishment.
- Performance of dose mapping of products and reporting.
- Performance of calibration of purchased dosimeter batches.
- Review and approval of daily sterilization reports for release of sterilized products.
- Review and approval of e-beam/gamma sterilization documentation from sub supplier.
- Review and approval of sterilization reports for release of sterilized products performed at sterilization sub supplier.
- Audit of sterilization supplier.
- Participation in certification audit and customer audit.
- Compliance projects to ensure that the gamma facility and its processes comply with ISO 11137

Achievements:

- Implementation of max. dose.
- Implementation of family groups.
- Implementation and standardization of PQ dose mapping for family groups.
- Implementation of in-house dosimeter calibration.
- Determination of dosimeter uncertainty for use in OQ and PQ.
- Implementation of dummy material for use during OQ for reduction of process variation.
- Implementation of differentiated sterilization cycles for sterile vs. non-sterile products that are sterilized for other purposes.
- Implementation of barcode system and sterilization batch release by measurement of a reference dosimeter.
- Site improvement and lean projects such as implementation of a vision system for QC and a software system for measurement of dosimeters and release of sterilized goods.
- Internal audits and supplier audit.

⁘ Handling of CAPA, complaints and change requests.

2007-2008

Thermo Fisher Scientific | Irradiation Expert

As an Irradiation technician the responsibilities have been mainly about the daily operations of the gamma facility and the sterilization validation following the annual gamma source replenishment.

The assignments include the following working areas:

⁘ Sterilization validation of an in-house gamma facility to comply with ISO 11137 following an annual source replenishment.

⁘ Performance of dose mapping of products and reporting.

⁘ Review and approval of daily sterilization reports for release of sterilized products.

⁘ Review and approval of e-beam/gamma sterilization documentation from sub supplier.

⁘ Review and approval of sterilization reports for release of sterilized products performed at sterilization sub supplier.

Achievements:

⁘ Technical file ready for submission to authorities within planned deadline

⁘ Design control documentation / technical file in compliance for several device projects

⁘ Creation of RM plan, RM analysis and RM report for several device projects

⁘ Review of Usability reports, Requirement Engineering reports, Development Plan, Verification plan and report

⁘ Knowledge on device standards and regulations FDA QSR part 820, MDR, ISO 14971, ISO 11608-1, ISO 13485

⁘ Consultancy work for customers within medical device / pharma industry ⁘ ISO 13485, FDA part 820 QSR, MDD, MDR, ISO 14971, EU GMP, GXP, GAMP5.