DAHLFELTCONSULTING

CONSULTANT WITHIN RA, QA, R&D AND SUBMISSION

Name	Lisbeth Sejer
Nationality	Danish
Gender	Female
Domicil	Denmark

CONTACT INFORMATION

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LISBETH SEJER - CURRICULUM VITAE

PERSONAL LETTER

+25 years of experience within Medical Devices industry, In Vitro Diagnostic and. Pharmaceutical. Worked in a number of different areas such as: Quality Assurance, Regulatory Affairs/ CMC, Research & Development and Laboratory.

Throughout her career, she has conducted registration worldwide of Medical Devices (MD), In Vitro Diagnostics (IVD) and Pharmaceuticals including EU, US, Canada, China etc. by contact with authorities and stakeholders (Consultant and Distributors).

Furthermore, she has been Responsible for overall compliance with registered product accordingly to new regulations or new/updated standards. Additional maintain regulated product listing.

She has participated in MDR/IVDR transition activities. Performed review of the Technical Files and the corresponding Regulatory documentations, created or updated Standard Operational Procedures (SOP) to reflect worldwide legalization.

Experience with handling complaints, Non Conformities (NC), CAPA and support Post-Market Surveillance (PMS) Periodic Safety Update Reports (PSUR).

Conducted Vigilance activities, including submitting reports to authorities, ex. FDA, EU, UK.

Review and approve of labeling.

Knowledge for legalization of documents ex. Company created documents, Free Sales certificate (FSC) ISO-certificates etc.

Experience working with GMP/GXP, ISO-13485, FDA 21CFR, MDD/MDR, IVD/IVDR, IEC/EN 60601-1, ISO 10993, ISO 14971.

Heavy knowledge from working within, RA and QA.

Communicating on all levels – internally as well as externally.

STRENGTHS

- Result oriented
- Proactive
- Innovative
- Team player
- High energy level
- Excellent interpersonal skills
- Dedicated, Focused and Structured

MEDTECH/PHARMA

- Medical Device +25 yrs. experience Quality Assurance and regulatory
- Pharma + 15yrs experience Regulatory and Quality Assurance
- 20 yrs. experience in Laboratory
- 20 Yrs. experience FDA approval, Medical Device and Pharma
- 10 yrs. experience MDD/MDR
- 10 yrs. experience IVD/IVDR
- 9 years' experience SOP/CAPA
- 10 yrs. experience Complaint handling (NC)
- 4 yrs. Experience Risk Management
- 5 yrs. experience 510K

EXPERTISE

- Large Expertise in Various aspects of Regulatory and QA assets
- World Wide submission experience
- Broad RA/QA knowledge from various countries World wide
- Experienced in clinical trials
- Experienced with vigilance activities
- Experienced in analyzing of Specimen
- Have a technical and hands-on personality
- Lean optimization and change management mindset
- Result oriented mindset
- Contributes to a great team atmosphere

IT SKILLS

- Microsoft Office / Outlook / Excel / Word /Power Point
- Data Bases (Registrations database CDM and MDM)
- SharePoint (Administrator)
- Document Control System (Agile)
- Lotus Note • Data Base (SAP)
- Contempus (Invoicing)
- TimeSite (Editing Intranet)

EDUCATION AND DEGREES

1984 - 1987	Biomedical Laboratory Scientism / B.SC Med
1983 - 1986	Laboratory Technician, Roskilde Denmark

CERTIFICATIONS AND COURSES

- Medical Devices Periodic Safety Update Report (PSUR)
- Integrating Risk Management into the product Life Cycle (Risk Management – ISO 14971; 2019 and FDA regulations)
- Pharma, R&D, Packaging material, IFU Label etc
- QS/ISO13485 requirements for IVD
- Introduction to Regulatory Affairs for IVD's
- CE marking of Medical Devices

- ASIA Pacific Device Summit
- Design Control – in a Nutshell
- Maintenance of marketing authorizations products
- eCTD Electronic Common Technical Document
- Theoynex Robot Course

LANGUAGE SKILLS

Danish	Written and spoken	Native
English	Written and spoken	Fluent
German	Written and spoken	Business

PROFESSIONAL BACKGROUND

Apr. 2022 – Present

DahlfeltConsulting | Regulatory Senior expert / Specialist

- Supporting companies for being in compliance within MDR and IVDR regulations for both Regulatory Affairs and Quality Assurance
- Submitted Technical File (MDR and IVDR) to Notify Body for review
- Registration worldwide of Medical Devices and In Vitro Diagnostic
- Overview of legalization for Medical Devices and In Vitro Diagnostic worldwide
- Communications with Notify Body and Authorities
- Conducted vigilance activities, including submitting reports to authorities ex. FDA, EU
- Coordination and conduct recall
- Support Post-Market Surveillance (PMS) and Periodic Safety Update Reports (PSUR)
- Handling of CAPA
- Complaint handling
- Non-conformity
- Change request
- Perform regulatory assessment of new and changed products
- Review and approve of labeling
- Overview of Standards and GAP assessment for new/updated standards

Apr. 2020 – Mar. 2022

Sigma Connectivity | Regulatory Senior expert

- Supporting companies being in compliance within MDD, MDR and IVDR regulations for both Regulatory Affairs and Quality Assurance
- Registration worldwide of Medical Devices and In Vitro Diagnostic / IVD
- Overview of legalization for Medical Devices and In Vitro Diagnostic worldwide
- Communications with Notify Body, FDA and Authorities
- Coordination and conduct recall
- Support post-market surveillance and vigilance activities, including submitting reports to authorities
- Handling of CAPA
- Complaint handling
- Non-conformity

- Change request
- Perform regulatory assessment of new and changed products
- Review and approve of labeling
- Overview of Standards and GAP assessment for new/updated standards
- Headed up a RA department for one year

2017 - 2020

Otometrics Natus medical Denmark | Regulatory affairs specialist

- Responsible for registration of Electro Medical Device worldwide
- Responsible for being in compliance with registration in China and APAC
- Responsible for maintain regulated product list within EU, US (FDA), Canada etc.
- Responsible for FDA listing
- Responsible for registration in Canada
- Responsible for Renewal of Canada Licenses
- Responsible for review and approve of labeling
- Responsible for issue UDI numbers for new products
- Responsible for GUDID database
- Communication with stakeholders worldwide (ex. Internal colleagues, Distributors and Consultants)
- Communications with Notify Body and Authorities
- Vigilance
- CAPA
- Coordination of Recall
- Legalizes documents (ex. ISO Certificates, Free Sales Certificates, other Company's documents)
- Review of SOP's Responsible for maintenance "database" of relevant standards (IEC, EN, ANSI etc.)

2013 - 2017

DAKO An Agilent Technologies Company | Regulatory affairs specialist

- Final set up of FDA Submissions, Annual reports, 30-day Notice, 510(k) etc.
- Handles close contact to various external stakeholders
- Renewal of Canada Licenses
- R&D documentation, compliance
- Support for registration in China, Korea and Australia
- Responsible for obtaining relevant documentation for registration in RoW
- Legalizes different documents (ISO Certificates, Free Sales Certificates etc.)
- Tracking of feedback for recall for international market
- Procurement – approval of invoices
- Plans and coordinates submissions to FDA

2006 - 2013

Actavis A/S | Head of Regulatory Department

- Development of documentation needed for securing national regulatory variations within EU (Life Cycle Management)
- Created system and process to ensure compliance with Certificate of suitability for API's (CEP)
- Securing close contact to local authorities within EU
- Handled close contact to various external stakeholders
- Responsible for obtaining relevant documentation/Certificates from 3rd party manufacturers
- Successfully participated in the transfer of all regulatory tasks to units in Bulgaria, Sweden and Iceland.
- Worked as business partner
- Successfully detected areas of saving costs and ensured compliance with SOP's
- Co-responsible for optimizing product range for saving fees
- Proactively saved 10-20% on translation of regulatory documents

1997 – 2006

H. Lundbeck A/S | Coordinator to HR R&D Laboratory Technician

- Supported 180 colleagues within procurement of office and laboratory supplies
- Handled negotiations with and secured discounts from external vendors • Coordinated internal and external courses
- Handled contact to and negotiations with external third part suppliers
- Facilitated evaluation of all courses
- Update of intranet • Procurement, installation and start-up of Robot – for analyzing of enzymes
- Successfully developed various methods (Chromatography and Enzyme Assays)
- Analyzed specimens from Clinical studies
- Analyzed and processed data with high quality

1996 – 1997

Danish Veterinary and Food Administration | R&D Laboratory Technician

- Developed assays for identifying Estrogen activity in different products/drugs
- Worked with cell cultures and microsomes incubations

1988 - 1997

Novo Nordisk A/S | R&D Laboratory Technician

- Developed methods and assays to test industrial use of enzymes within animal food and detergent
- Achieved an enzyme purity of more than 80% • Analyzed and processed data with high quality

- Successfully optimized processes

1987 - 1988

DAK-Laboratoriet (Nycomed now Takeda) | Laboratory Technician

- Responsible for finished product control - Infusions and injections
- batch documents review and approval

1987

Slagelse Hospital, Clinical-Chemical Laboratory | Biomedical Laboratory Scientist

- Responsible for blood sampling
- Maintenance and calibration of laboratory equipment
- Analyzed and processed data with high quality