DAHLFELTCONSULTING

Name	Lisbeth Sejer
Nationality	Danish
Gender	Female
Domicile	Albertslund

Contact information

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Personal Letter

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

Throughout my career I have conducted registration worldwide of MD, IVD and pharmaceuticals including EU, US, Canada, China etc. by contact with authorities and stakeholders (Consultant and Distributors), further more I have been responsibility for being in compliance with registered product accordingly to new regulations or new/updated standards. Additional maintain regulated product listing

Experience with handling complaints, Non conformities, CAPA and support post-market surveillance and vigilance activities, including submitting reports to authorities.

Review and approve of labeling, review of SOPs/Procedures and legalization of documents and certificates ex. Free Sales certificate (FSC) ISO-certificates etc.

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

Efficiency improvements and general cost savings.

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

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Medtech / Pharma:

- Medical Device +25 yrs experience Regulatory and Quality Assurance
- Pharma + 10yrs experience Regulatory and Quality Assurance
- 13 yrs experience Laboratory
- 30 Yrs experience FDA approval, Medical Device and Pharma
- 10 yrs experience MDD/MDR
- 6 yrs experience 510K
- 4 years' experience SOP/CAPA
- 10 yrs experience Complaint handling

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
- Has 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 Scientis
- 1983 - 1986 Laboratory Technician, Roskilde Denmark

Certifications

- ASIA Pacific Device Summit
- Design Control – in a Nutshell
- QS/ISO13485 requirements for IVD
- Introduction to Regulatory Affairs for IVD's
- CE marking of Medical Devices
- Maintenance of marketing authorisations products

- eCTD Electronic Common Technical Document
- Theoynex Robot Course

Language skills — Level

• Danish, Written and spoken	Fluent
• English – Written and spoken	Fluent
• German – Written and spoken	Business

Professional background

DahlfeltConsulting
Apr 2022 –
Regulatory Senior expert / Specialist

- Supporting companies for being in compliance within MDR and IVDR regulations for both Regulatory Affairs and Quality Assurance
- 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
- Coordination and conduct recall
- Support post-market surveillance and vigilance activities, including submitting reports to authorities

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Sigma Connectivity
2020-04 – 2022-03
Regulatory Senior expert

- Supporting companies for being in compliance within MDR and IVDR regulations for both Regulatory Affairs and Quality Assurance
- 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
- 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

Otometrics

Natus medical Denmark

2017 – 2020

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 Licences
- 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)

DAKO

An Agilent Technologies Company

2013 – 2017

Regulatory affairs specialist

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

Actavis A/S

2006 – 2013

PA, Head of Department Regulatory

Global Regulatory Affairs Assistant

PA

- Worked as business partner
- Provided support and sparring to Regulatory Department
- Responsible for securing salary and absence portal
- Developed performance tools, job descriptions and salary benchmarking
- Procurement – approval of invoices
- Planned and coordinated local and international meetings and seminars
- 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

Global Regulatory Affairs Assistant

- 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.

H. Lundbeck A/S
1997 – 2006
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

Danish Veterinary and Food Administration
1996 – 1997
R&D Laboratory Technician

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

Novo Nordisk A/S
1988 - 1997
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

DAK-Laboratoriet (Nycomed now Takeda)

1987 - 1988

Laboratory Technician

• Responsible for finished product control - Infusions and injections

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Slagelse Hospital, Clinical-Chemical Laboratory

09.1987 –11.1987

Biomedical Laboratory Scientist

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