

# DAHLFELTCONSULTING

## CONSULTANT WITHIN QA, RISK, PRODUCT/PROJECT MANAGEMENT

Name Alexandra Torres Sommer  
Nationality Danish  
Gender Female  
Domicile Denmark

## CONTACT INFORMATION

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## ALEXANDRA TORRES SOMMER - CURRICULUM VITAE

### PERSONAL LETTER

Alexandra has a comprehensive experience within Pharma and MedTech and has worked with Risk management, quality assurance, regulatory affairs, product management, etc.

She has a strong technical insight with both hardware and software and extensive knowledge with complaint handling, which has made her able to set up complaint systems, solve technical complaints, and compose successful project proposals as Product Manager.

Furthermore, Alexandra has extensive experience with documenting deviations, driving CAPAs, change controls, SOPs, batch reviews, managing QMS systems, etc.

She studied Global Engineering and after graduating held different roles involving the Pharmaceutical and Medical Device industries. Her insight to software as well as laboratory controls, combined with project and product management, gives Alexandra a unique profile and she has hands-on experiences within all areas.

She has a high technical understanding for the whole chain and are familiar in taking the lead in teams and show the way to find the optimal solution in a short time. Alexandra always strives for good documentation and high quality in her work.

As a person, Alexandra is very social, loves working with new colleagues, and has no problems to adapt to new groups. She always gives 110% and contributes with energy to the group. She has been training CrossFit for many years, play strategic board games like a pro. and knows the importance of team spirit. She is very competitive and sees every challenge as a new opportunity to learn something new.

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### STRENGTHS

- ❖ Highly QA/RA skilled and experienced
- ❖ R&D and product knowledge
- ❖ Deep insight to technical problem solving and hands-on
- ❖ Driven & responsible
- ❖ Team Leader/Team Player
- ❖ Creative and energetic
- ❖ Eager to learn

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### EXPERTISE

- ❖ Quality assurance
- ❖ Regulatory affairs
- ❖ Risk Management

- ❖ Product management
- ❖ Process management
- ❖ Project management

#### IT SKILLS

- ❖ Vault QualityDocs
- ❖ TrackWise
- ❖ Microsoft Office
- ❖ Microsoft Visio etc.

#### EDUCATION AND DEGREES

2008-2013      B.Sc. Global Business Engineering      DTU

#### CERTIFICATIONS AND COURSES

2021      Integrating Risk Management into the Product Life Cycle, ISO: 14971

#### LANGUAGE SKILLS

Danish	Written & spoken	Native
English	Written & spoken	Fluent
Spanish	Written & spoken	Native

#### PROFESSIONAL BACKGROUND

Mar. 2023 – Present  
[DahlfeltConsulting](#) | Senior Consultant Quality Assurance and Regulatory affairs  
 Consultancy tasks within Pharma and medical Device regulatory affairs - QA, Risk, Product and Project management

2020 - Mar. 2023  
[Sigma Connectivity Denmark](#) | QA and RA Systems Quality Engineer  
 Senior Consultant Quality Assurance and Regulatory affairs

At costumers within MedTech:

- ❖ Redesign of an existing product
- ❖ Responsible for the QA part
- ❖ Design control
- ❖ Risk management
- ❖ At a customer within Pharma:
- ❖ Batch review after production to make ready for release
- ❖ Handling of CAPAs
- ❖ Handling deviations in production in regards to GMP
- ❖ Updating and contributing to new processes/procedures

2019 - 2020

[Natus Medical Incorporated](#) | Quality Assurance Engineer

Reporting directly to the QA Manager I was responsible for the following tasks but is not limited to:

- ❖ Facilitate and assist as a team member in new product introduction and/or
- ❖ Design transfer projects
- ❖ Provide input and support to the corrective and preventive action program
- ❖ (CAPAs)
- ❖ Complaint handling, Non-Conforming Product and MRB Process
- ❖ Updating the whole QMS from the former company to Natus. Getting ready for the upcoming audits, both internal and external

2018 - 2019

[Natus Medical Incorporated | Complaint Specialist](#)

Reporting directly to the QA Manager. Responsible for the following tasks:

- ❖ Ensure that complaint files are completed and reviewed in a timely manner
- ❖ Identify and escalate issues for safety review and for product investigation
- ❖ Support potential adverse event investigations

**Main achievements:**

Trained the current complaint team sitting in Gort, implemented the trending meetings reports, which, are used as benchmark for the entire Natus company.

2017 - 2018

[Agilent Technologies Denmark | Global Product Manager](#)

Reporting directly to the Director & Head of Global Product Marketing. Involved in the following but not limited to:

- ❖ Tracking of market share and profitability
- ❖ Development of sales forecast
- ❖ Implementation of product life cycle plans
- ❖ Business case development for new development projects
- ❖ Define stakeholder requirements, and interface between marketing and R&D
- ❖ Prepare product roadmaps
- ❖ Develop product training material and concept

**Main achievements:**

Various project proposals for both Hardware & Software approved by Top Management.

2015 - 2017

[Agilent Technologies Denmark | Complaint investigator and Quality Engineer Specialist](#)

Reporting directly to the QA Manager she had the following areas of responsibilities:

- ❖ Cross Platform Complaint investigation and trending, identifying CAPAs and NCRs etc.
- ❖ Training and mentoring new employees in complaint investigation, CAPAs and NCRs

- ❖ Participation in PIM as investigator.
- ❖ Updated quality control standards, methods, and procedures to meet compliance requirements
- ❖ Main achievements: Successfully trained the complaint team in log file analyses
- ❖ Managed to improve the complaint trending process.

2015-2017

[Agilent Technologies Denmark](#) | [Research Scientist](#)

Reporting directly to the R&D Team Lead & Customer Interface Manager:

- ❖ The goal of this position was to collect and collate data from customers' complaints and feedback in a systematic way to map the performance of the installed instrument base.
- ❖ This information was used to prioritize and flag concerning issues for the Global Product Manager
- ❖ Collected and recorded data at various field sites for later assessment and log file analyses
- ❖ Main achievement: Established process development to make sure that all log files from a given platform could be retrieved remotely and onsite.

2014-2015

[Agilent Technologies Denmark](#) | [Spanish Tender Coordinator](#)

Reporting directly to the Global Sales Support Manager.

The purpose of this position was to streamline the tender process for Spanish speaking markets:

- ❖ Ensuring a standardized tender offer across the markets
- ❖ Single point of contact between the Key Account Managers in the specific Markets and the product development team/R&D
- ❖ Main achievements: Implemented the process across teams in Spain, France & Italy.

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