

Contact

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Top Skills

Process Engineering

Process Validation

Project Commissioning

Shady Harpel

Technical Product Manager | Research | Instruments and machine design | Life science | Pharma | Medical devices

Austria

Summary

I am a performance-driven Mechanical constructor and team leader with more than 16 years' solid experience and success in mechanics, testing and verification, Including design and documentation, specific in the medical device and pharma industry.

Experience

Croda

Croda Pharma, Qualification and design engineer

October 2022 - Present (1 year 4 months)

Denmark

Empowering drug delivery, with the highest purity excipients and solutions.

Croda Pharma is a leading partner for the development of excipients and the supply of high purity materials for pharmaceutical formulations. The company is focused on empowering biologics drug delivery, through its adjuvant systems, small molecule, protein, and nucleic acid delivery platforms. With a wide range of solutions for both human and animal health markets, the pharmaceutical portfolio is unsurpassed in its excellence. Croda Pharma's products, along with its in-house formulation and regulatory expertise, allows the company to meet its customers' most demanding formulation needs. The company is committed to enabling the next generation of drug delivery systems.

Projects:

New HVAC for GMP production, November 2022

Meng Design

Mechanical Engineering Consultant

2022 - 2023 (1 year)

Copenhagen, Capital Region, Denmark

Consultant within the fields of:

* Design laboratory Instruments

- * Design Medical devices
- * Design for manufacturing
- * Validation
- * GMP documentation
- * Technical documentation
- * Risk analysis

Spectro Inlets

Production Engineer

March 2022 - October 2022 (8 months)

Austria

Spectro Inlets allows researchers and product developers to measure real-time chemical reactions on electrodes, in batteries, bioreactors and chemical production systems. We deliver a microchip interface for mass spectrometer systems allowing for millisecond response time and the ability to detect minute changes in chemical reactions. This data allows R&D engineers to develop better batteries, monitor biochemical reactions and produce better chemical catalysts.

Participate in the roll-out of additional prototype devices for field testing including assembly, testing and installation

-Participate in supporting the systems out in the field, including troubleshooting, servicing, etc.

-Participate in improving and overhauling the design of our core technology

-Participate in design for manufacturing

Projects:

- Assembly LGA103, May 2022, Done

FOM Technologies

Technical Product Manager

2019 - 2021 (2 years)

Copenhagen, Capital Region, Denmark

To help professionals around the world to discover, develop & commercialize new, innovative functional materials, through FOM Technologies equipment, technology & knowledge.

Design for Assembly and Design for Manufacturing

Lifecycle Management

Projects:

ArcR2R development, Februar 2021

Project Charles concept development. Januar 2021 Done

Product development, AlphaSC with Oven, Januar 2021

Implementation of PDM, August 2020, Done

Product development custom project RWTH on platform Vektor SC. June 2020, Done

Product development, new platform for Vektor SC, January 2020, Done

Product development, redesign our Nano RC, December 2019 Done

Andreasen & Elmggaard A/S

Senior Consulent

2018 - 2019 (1 year)

Søborg, Denmark

Andreasen & Elmggaard A/S provide highly qualified engineering consultancy within all disciplines relating to project management, GMP compliance, technical advice, production efficiency and process verification in the pharmaceutical-, biotechnological-, medical device- and food industry.

Projects:

Blusense Diagnostics Aps

- Quality agreement and identify critical process steps
- Starting up a ECO documentation system
- Identifying gaps in GPS specifications

Xellia pharmaceuticals Aps

Project management

- Responsible for qualification Spray drier, new drying chamber, Primary Purification
- Conducted day-to-day QDR for Xellia project.
- Validation templates documents for intern use at A&E

LaboGene A/S

Mechanical engineering, Team leader and PDM administrator

2015 - 2018 (3 years)

Allerød, Denmark

LaboGene ApS

Medical devices. development, test and construction of products, I have experienced in the late stages of the development process where the product transfer to production. I'm good to working cross-functional and with different cultures. I'm quick to Adapting to New Challenges and is a good teamplayer.

Projects:

Product development, new platform for Fortuna, september 2017, Done

Product development, redesign our filter fittings equipment to ScanLaf Mars Pro, LAF2016, april 2017 Done.

Product design, design our new series of ScanLaf Mars LAF2016 , december 2016 Done

Specialties:

- Design for manufacturing
- Test and verification
- Experiment
- Product development
- Life time mangement
- Design tranfere from R&D to production
- Financial system C5
- ISO13485 Medical devices
- Design controle
- Lean produktion
- PDM Administrator

Kivex Biotec, K-Systems

Mechanical engineering, head of PTA.

2012 - 2015 (3 years)

Birkerød

K-SYSTEMS Kivex Biotec A/S is the market leader within development, manufacturing and sale of innovative and well designed equipment to the professional In Vitro Fertilization (IVF) Clinics. All our equipment is developed and produced at our premises in Denmark. Our range of equipment enable laboratory technicians to perform IVF techniques in safe and ergonomical conditions.

- ISO13485 implemtering of control, incoming product

- Design for manufacturing
- Design of special customized solutions for IVF Clinics
- Validation, devices
- Design tranfere of new incubator from R&D to production

ProInvent A/S

Mechanical engineering, machine design

2012 - 2012 (less than a year)

Hørsholm

Technology development, concept development machine design.

Novo Nordisk A/S

4 years

Mechanical engineering, Novo nordisk device R&D

2011 - 2011 (less than a year)

Hillerød

Work on concept development of equipment for administration of insulin.

Project PDS 265

2007 - 2011 (4 years)

Hillerød

Insulin patch pump project

Part of projekt team for a highly innovative prefilled insulin patch pump with a wireless remote control and PC-interface for patient data management and analysis.

- Part design and optimization
- Test equipment, design and construction
- Testing and verification
- Design verification protocol for test setup

Radiometer Medical

Development and PTA-engineering

2003 - 2007 (4 years)

- Work with biochemical sensores in production, as PTA-staff supporter.
- Participate in development a new biochemical sensor. Focus on projects where process development is required in both the areas of product development as well as Research projects. The devices include optical sensor or thick film sensor. Project group consists of people with technical or chemical of operational background.

Technologi transfer from R&D to production
Mechanical reviews, tolerance stack up calculations
Process development and validation,
Specification and purchasing of process equipment
General support to production
Lean manufacturing

Education

DTU - Technical University of Denmark
Access course for diploma engineer · (1992 - 1993)

Copenhagen Technical Academy
Production technologist, (machine technician) machine design · (1993 - 1995)