



Jens Ulrik Poulsen

MSc Mechanical Engineering

R&D Program Management and Design Control

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Medical Device Development

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Competences

- Medical Device Development
 - Program and project management including usability and clinical trials
 - Syringes, injectors, pumps, IVD and monitoring systems including reagents, surgical instruments
 - Mechanics, electronics, software and connectivity
 - Design Control and QA: MDR, ISO 13485, 21 CFR 820.30
 - Risk analysis: ISO 14971 - FMEA
 - Experience with Root Cause Analysis, datamining and trend spotting
 - Lab testing and analysis, Design of Experiments
 - Test methods and measurement uncertainty: ISO 2859, ISO 3951, ISO 17025, BIPM, GUM
 - Basic plastic material knowledge
- Extensive experience working cross functionally with pharmacist and chemists to find solutions crossing the border between device physics and chemistry and quality compliance
- Thorough understanding of injection molding, its strengths and limitations
- Extensive experience working internationally with suppliers including CMOs and test houses including data review

Software, Standards & Regulation

- Software
 - SAP, skilled user
 - Veeva Vault, skilled user
 - Excel, experienced user
- Standards & Regulation
Extensive experience working according to and under:
 - ISO 13485 (Design Control), ISO 14971 (Risk) and related standards
 - MDR, FDA 21 CFR 820.30

References

- **Medicologic: 2021 – present**
Senior Consultant
 - Medical Device Design Control
 - Novo Nordisk: Technology Project Manager - Digital Health product
 - Coloplast: Senior Project Manager - Wound Healing product
- **LEO Pharma**
Manager
 - R&D Line Management
- **LiNA Medical**
R&D Engineer & Project Manager
 - Development of portfolio of endoscopic surgical instrument
- **Aston Life Sciences. CH**
Consulting: R&D Engineering, Project Manager
 - For clients: DFM/DFA concepts developed, and patent granted, strategy for outsourcing vs in house production adopted by customer.
- **Phillips Medisize. NL**
 - Managing Medical Device development and DFM/DFA for clients
 - Business target and budgets
- **Novo Nordisk**
R&D Engineer, Project Manager, Manager
 - Smartphone app for receiving and presenting insulin data.
 - Concept developed, documented and usability tested.
 - Prediction of blood glucose and automated advice to patients with diabetes. Driving device and scientific model development, quality assurance and coordinating clinical trials with ~200 patients
 - Complex electro-mechanical medical device: System integration and system performance specifications, industrial and Man Machine Interface design
 - Primary Packaging: comprehensive revision of primary packaging specifications and processes regarding all mass-produced insulin vials and cartridges.
 - Optical device for IVD and monitoring of patients' coagulation status: development from concept to launch. Involving delicate injection moulded parts and electronics.
 - Electro-mechanical insulin pump: scale-up, launch and support to Production.

Key results

- Program Management:
 - Established consortium of 13 partners, was awarded 7.3 M€ EU funding and led the project from concept to clinical validation
- Decision support system:
 - Device and SW concept, design and verification
 - Clinical data structure, set up, coordination and analysis
 - QA responsible
- Complex electro-mechanical inhalation drug delivery system:
 - Specification, risk management, system integration, testing, data analysis and design adaptations
 - Industrial and Man Machine Interface design
- Comprehensive revision of mass-produced Primary Packaging
 - Revision of specifications, design control, quality specifications/agreements, risk management and test methods to comply with user needs, process capability, quality and regulation
 - Major cost savings achieved
- IVD blood testing regarding coagulation
 - Device design and commercial launch. Danish Design Award
- Dosing test method for pen injectors and infusion pumps
 - Invented test method
 - Used in ISO 11608 Needle-based injection systems

Personal Characteristics

- Jens is systematic, analytic, QA minded and has an innovative and proactive mindset
- He is a perfectionist with an eye for details and correctness, however pragmatic regarding what is needed to achieve objectives
- He has a strong system understanding and of the physics involved
- Jens meet people with positive expectations and establish respectful, productive, and efficient relationships.