



**René Pihl**  
M.Sc.ME R&D and QC, DTU

Senior Projekt Manager

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Medical Device Development

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## Competences

- Expertise in General / Vendor / Project Management, Project Engineering and Consultancy
- Specification and installation of equipment and facility systems under GMP regulations.
- Product development, specification, production design and implementation.
- Stakeholder and client relations management.
- Validation of production and products, also with statistical methods
- Lean 6 sigma and hands on experience with analysis systems (JMP (SAS) and Minitab)
- Problem solving and roadblock removal.

## Software/Standards

- Certified Project Manager with Siemens
- Certified Green Belt – Six Sigma, 12 weeks
- NNE Pharmaplan Project Management. PMP
- Personal Power, Syntax A/S, Reach your goals

### Extensive knowledge in:

- ISO9001
- ISO13485
- FDA regulation [CFR part 820]

## References

### Medicologic A/S (Present - )

Senior Project Manager

### Novo Nordisk

Senior Project Manager for completion and improvement of inline printer (Ink jet printing with UV curing ink to produce entire label print and subsequent vision inspection) for injection pens. New technology and validation support for laser decoration machines for medical plastic components. FMECA (risk analysis) for injection device for diabetes treatment.

### Fujifilm

CQV Lead for Buffer Prep and Hold vessels in connection with a major expansion of an API (active pharmaceutical ingredients) production facility.

### Radiometer Medical

As a consultant for Radiometer, I validated a heat welder for device production and authored the necessary documentation, including URS, FAT, IQ/OQ/PQ protocols, and user manuals. I also prepared qualification documentation for a prototype robotic gluing system.

### Thermo Fisher

Program Manager for FDA Readiness program: Managing 16 tracks with improving compliance within Documentation, Training, Maintenance etc. to live up to FDA regulations as well as ISO 13485 and introduction of MDD.

## Key results

A highly motivated and adaptable project manager and senior mechanical engineer with over 20 years' extensive experience in the Pharmaceutical, Solar & Wind Power, Steel Construction and Food industries, on major projects (worldwide).

Long track record in both large Pharma like Novo Nordisk, Fujifilm and in Medical Devices like Novo Nordisk, Radiometer and Thermo Fischer

## Personal Characteristics

Known for their approachable and easygoing nature, the consultant fosters collaboration and adaptability in any professional setting. With strong negotiation skills and a hands-on approach, they excel at developing innovative products and equipment to enhance efficiency and profitability. Their logical and creative mindset ensures effective solutions in production processes, and as a motivating team leader, they guide projects smoothly to successful completion.

Project manager and technical advisor for developing single use equipment with configured set up for vaccine manufacturing combined with developing integrity test based on helium trace gas.

### Xellia, Cleveland

Validation & start up project manager for installation of filling line incl. vial washer, depyrogenation tunnel and handling equipment to freeze dryers

### NNE Pharmaplan, USA – Project Manager for Novo Nordisk

In **Clayton, North Carolina**, I managed the high-volume FlexPen Assembly Line, overseeing equipment specifications, SCADA coordination, and logistics for introducing a new product. I ensured UL compliance for European equipment and developed maintenance and spare parts programs. The project achieved the fastest FlexPen optimization, became the first UL-approved line, and delivered four weeks early.

In **Hayward, California**, I coordinated materials for inhalable insulin strip development, integrating logistics across work packages using Lean methods. I transitioned materials from R&D to GMP standards and optimized material flow between buildings. A unified logistics system was established despite differing objectives.