Steen G. Petersen
MSc. Ph.D. Molecular Genetics
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QA and RA, Medical Device Expert

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Competences

- Project management; Prince2 certified
- Design control, requirements, design gates
- Verification, production transfer, validation
- Quality management
- Risk management
- Design FMEA
- Molecular biology, biochemistry, surface modification
- GAP analysis: MDD/MDR; IVD/IVDR
- Usability

Key results

2015:
Six medical devices (Class III device and Class I devices) developed and marketed

2009:
Three different disposable columns for recombinant IgG purification developed and marketed

2004:
SpotOn™ DNA Micro Array Slide and SpotOn™ Protein Micro Array Slide developed and marketed

Regulations/Standards

- 21 CFR part 820
- ISO 13485
- ISO 14971
- Dir. 1998/98/79 EU (IVD)
- Reg. 2017/746 EU (IVDR)
- Dir. 1993/93/42 EEC MDD)
- Reg. 2017/745 EU (MDR)
- ISO 62366-1

Personal Characteristics

As a Project manager and Design responsible Steen timely handle and prioritize project challenges in order to ensure the right delivery and product quality is achieved and validated, according to plan and stakeholder expectations.
Extensive experience, analytical abilities and commercial understanding combined with teamwork in a positive atmosphere have delivered impressive results. Steen is motivated by ambitious goals, proactive decision making in a busy interdisciplinary QMS and GMP regulated environment and he always see possibilities

References

Medicologic A/S

Senior consultant

Sigma Connectivity

Senior consultant
Products: Medical devices: Subjects: Risk management, usability, biological evaluation and performance evaluation

AlfaNordic A/S

Senior consultant
Products: Medical devices, Cosmetics and Medical device - Drug combination product. Subject: Designs control, risk management, QA, test protocols, validation and polymer chemistry

Dako/Agilent

Design responsible, Senior scientist
Development, planning and design control of *in vitro* diagnostic medical devices. Responsibility for requirements, risk management, IFU, verification/validation (external testing in UK, Italy and US) production transfer and for design gate passing

Upfront Chromatography A/S

Project manager
Development and design control of columns for recombinant IgG purification. responsibility for planning, product requirements, risk management, toxicological testing, QA, IFU, validation and reporting

Millimed A/S

Project manager, Senior scientist
Development of catheters for intravascular drug delivery. Responsibility for design control, requirements and risk management. Establishment of formulation for controlled intra vascular drug release. In relation to its clinical evaluation: Preparation and completion of: Clinical rationale, drug dose estimate, pharmaco dynamics, and pharmaco kinetics

Scandinavian Micro Biodevices Aps

Project manager, Department leader
Company upstart with two more people. Responsibility for DNA and Protein micro array technologies and for modification of surfaces and analysing their interaction with human cells