Steen Guldager Petersen
M.Sc., Ph.D. certified project manager

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PROFILE:

As a Project manager and Design responsible I 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 financial results. I am motivated by ambitious goals, proactive decision making in a busy interdisciplinary QMS and GMP regulated environment and I always see possibilities.

CONSULTANT TASKS AND PROJECTS:

Client F:

Medical device – drug combination product, low blood sugar drug delivery device

- Definition of requirements for secondary packaging and user communication
- Product verification and validation activities:
  - Verification of product requirements
  - Product validation report
- Biological evaluation activities:
  - Device sub-part identification and characterization (purpose, material composition, sub-part history and supplier)
  - Assessment of device parts for biological/toxicological testing
  - Achievement of material compliance/compatibility statements
- Interpretation of FDA guidelines for ensuring compliance via device requirement definition

Client E:

Medical device – new blood gas production line project

- IQ, OQ and PQ protocols for more process equipment and evaluation of FAT and SAT requirements

Client D:

Medical device – QA department

- Assessment of production documentation and QC release of multiple products including class I & III medical devices
  - QC release of re-packed products for China
- Input to QA processes

Client C:

Food culture & enzymes – new starter culture production line project

- Utility verification: identification, documentation and GAP analysis of utilities for a new production line

Client B:

Development of cosmetics

- Planning of experiments revealing chemical ingredients affecting the stability of sun factor creams
- Conclusion on experiments leading to a new product

Client A:

Medical Device – QA department

- Steering procedure for Process validation master plans
- Definition of upper management responsibility in accordance with ISO 13485
- Assessment of open CAPA's including re-classification, merge and closure
- Independent reviewer of process documents

EMPLYMENTS:

2020 – Life Science Progress, Owner, Senior consultant

Life Science Progress is part of Life Science Konsulenter which collects experienced consultants at one site

- Currently working at Novo Nordisk A/S.

2015 – AlfaNordic A/S, Senior consultant – time limited project contracts.

AlfaNordic A/S is a consulting house with more than 60 employees working in the medical device and pharmaceutical industry

- **Tasks**: Medical devices, cosmetics and medical device - drug combination product: designs control, validation, test protocols, QA, quality manual according to ISO 13485, polymer chemistry and project management. Companies: Novo Nordisk A/S, Chr. Hansen A/S, Dako / Agilent, Radiometer, Riemann, MLJ and ThermoFisher Scientific.

2010 – 2015 Dako / Agilent. Design responsible / Project leader

Dako acquired by Agilent in 2012, is a world leader in cancer diagnosis

- **Responsibility**: 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 design gates.
- **Results**: Six medical devices (Class III device and Class I devices) were successfully developed and marketed. Furthermore, have participated in the development of the "Dako Omnis Platform" for cancer diagnosis that was awarded the "Product Price 2014" by the Confederation of Danish Industry.

2007 – 2009 Upfront Chromatography A/S. Project manager

Upfront is a biotech company with world class expertise in protein separation processes

- **Responsibility**: Development and design control of columns for recombinant IgG purification. Responsibility for overall planning, risk management, reporting, product requirements, toxicological testing, QA / QC, IFU and validation.
- **Results**: Four columns were successfully developed and marketed.

2004 – 2007 Millimed A/S. Project leader

Millimed A/S was a medical company focused on development of intra vascular drug releasing solutions

- **Responsibility:** Micro catheters for intravascular drug delivery. Establishment of formulation for controlled drug release. Responsibility for design control, requirements and risk management. Furthermore in relation to clinical testing of intravascular drug release, responsibility for clinical rational, drug dose estimates, pharmaco dynamics, and pharmaco kinetics.

- **Results:** Production of micro catheters prototypes and development of drug formulation with controlled intravascular drug release. Together with the "Drug-device project group", application of drug formulation onto intra vascular devices which subsequently were analysed in pre-clinical and clinical trials.

2000 – 2004 Scandinavian Micro Biodevices Aps (SMB). Project leader / group leader
SMB established by NKT A/S and profitably sold to Inverness Medical Innovation in 2003

- **Responsibility:** Start up the company with two more people. Development of DNA and protein micro array technologies. Furthermore development of human cell interaction assays.
- **Results:** Succesfully development of marketed micro arrays slides: SpotOn™ DNA Micro Array Slide and SpotOn™ Protein Micro Array Slide. In addition, development of surface preventing human cell attachment.

1997 – 2000 Chr. Hansen A/S. Project leader
Chr. Hansen is the largest producer of calf chymosin (the cheese making enzyme) and of dietary starter cultures

- **Responsibility:** Genetic improvement of calf chymosin expression in *Aspergillus*. Design, mutagenesis and growth of chymosin variants with increased enzyme activity/stability. Development of PCR based method for detection of recombinant DNA trace amounts, for FDA approval of a novel chymosin purification method.
- **Results:** FDA approval of PCR method for the detection of chymosin impurity. Mutated and patented chymosin variants with increased stability and enzymatic activity.

1991 – 1997 Danisco Biotechnology, Danisco. Research scientist
Danisco acquired by DuPont in 2011, was a world leader in seeds, sugar, enzymes and food ingredients

- **Responsibility:** Cloning of several plant genes and the development of a novel, environmentally friendly genetic plant transformation system based on a natural metabolizing plant gene as selection marker. Implementation of the *in situ* hybridization techniques.
- **Results:** Development of a novel efficient and environmentally friendly genetic plant transformation system, sold to Novartis for > 7 million Euros. Cloning of self-incompatibility genes from sugar beet and cloning of genes and promoters for modification of plant based food ingredients. Implementation of the *in situ* hybridization technique.

1988 – 1991 Ph.D. student: Dept. of Genetics. University of Copenhagen, Faculty of Life Sciences
Title of the Ph.D. thesis: Molecular analyses of the genome of pea early browning virus (PEBV) and transformation of plants with the PEBV coat protein gene in sense and anti sense orientation.

1987 Employed master student: Biochemical Laboratory, Danisco Biotechnology, Danisco
Title of master project: Transformation of sugar beet with *Agrobacterium rhizogenes* - and isolation, purification and growth of transgenic protoplasts.

EDUCATION:

1991 **Ph.D**. Molecular Genetics and with biochemistry as auxiliary subject. Faculty of Life Sciences University of Copenhagen

1988 **M.Sc**. Food science. Faculty of Life Sciences, University of Copenhagen

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COURSES:

2019	Prince 2 Project management certification. The Leaders Competence Center
2019	Basic project management. The Leaders Competence Center
2016	Presentation technique – tools for the excellent presentation. Danish Technological Institute
2012	Applied statistics Course using JMP from SAS by Per Vase, NNE Pharmaplan
2010	Project management. Copenhagen Business College
2004	Risk analysis of Medical Devices. Danish Medical Device Industry
2004	Process validation, Danish Medical Device Industry
2003	Introduction course to the medical device industry, Danish Medical Device Industry
2003	Biocompatible polymers, Danish Society for Polymer Technology
2001	Adhesion science and technology. YKI, Institute for Surface Chemistry
2001	IPR Conference, The Danish Patent and Trademark Office
1996	The leader role. Danish Industry
1993	Isotope technique and health physics. University of Copenhagen, Faculty of Life Sciences The course allows purchase, handling and disposal of radioactive nuclides.

LANGUAGES:

English and Danish (written and spoken)

IT SKILLS:

MS Office (Word, Excel, Power Point)
Agile Lifecycle Management
HPQC

OTHER ACTIVITIES:

Censor at the Technical University of Denmark (currently not active).

REFERENCES:

Steen Petersen, Arman Vahebzadeh, and Bent Pedersen (2014): Method and apparatus for reagent mixing. U.S. Provisional Patent Application, International Application Number: P255US01 09138.6068.00000.

Kent Nielsen, Lars Niklas Larson, Frederik Enemark Poulsen, Steen Guldager Petersen and Christian Jensen (2008): Medical device with pH dependent drug release. Patent Application, International Application Number: PCT/DK2007/000030. World Intellectual Property Organization.

Kent Nielsen, Frederik Enemark Poulsen, Christian Jensen, Lars Niklas Larsson and Steen Guldager Petersen (2008): Medical device capable of releasing NO. Patent Application, International Application Number: PCT/EP2007/057779. World Intellectual Property Organization.

van den Brink J.M., Petersen S.G., Rahbek-Nielsen H., Hellmuth K. and Harboe M. (2006): Increased production of chymosin by glycosylation. J. Biotechnol., **125,** 304 – 310.

S. Bouaidat, C. Berendsen , P. Thomsen, S. Guldager Petersen, A. Wolff and J. Jonsmann (2004): Micro patterning of cell and protein non-adhesive plasma polymerized coatings for biochip applications. Lab Chip, **0**, 1 – 7.

Johannes Maarten van den Brink, Marianne K. Harboe, Henrik Rahbek-Nielsen and Steen Guldager Petersen (2003): Improved method of producing an aspartic protease polypeptide in a recombinant host organism. Patent Application, International Application Number: PCT/DK2003/000398. World Intellectual Property Organization.

Poul Erik Høiby, Ulrich Krühne, Rachel Kahn, Tina Kristensen, Svend Erik Rasmussen, Steen Guldager Petersen, Dorte Lauritsen, Pernille Skouboe, Trine Møller, Thomas Brevig, Michael Beyer, Thomas Ahl, Lars Hagsholm Pedersen and Kim Holmstrøm (2002): Development of tools for DNA chip, protein array and microfluidic. 29th Annual Meeting Danish Society for Biochemistry and Molecular Biology, Ebberup, 28 – 30 October.

Steen Guldager Petersen, Niels E. Magnussen, Søren Flygenring Christensen and Peter Thomsen (2002): SpotOn™ DNA MicroArray Slide, a new composite microarray slide with a new chemistry, manufactured by Softplasma™ technology. The Second Bi-Annual Symposium, Array Technology in Research and Diagnostics, Aarhus, 25 - 26 October.

S. Bouaidat, S.G. Petersen, S.F. Christensen, J. Jonsmann, C. B. Nielsen and S. Bartling (2002): Plasma-polymerized coatings for biochip applications. Medicon Valley Bio Conference 2002, Malmö, 8 - 10 October.

Søren Flygenring Christensen, Steen Guldager Petersen, and Bjørn Winther-Jensen (2002): A method for the preparation of a substrate for immobilising chemical compounds and the substrate and the use thereof. Patent Application, International Application Number: PCT/DK01/00870. World Intellectual Property Organization.

Steen G. Petersen (2000): High-sensitivity testing for recombinant DNA in fermentation-produced chymosin using the polymerase chain reaction (PCR). Research News. **5**, January, 4 - 6.

Morten Joersbo, Steen Guldager Petersen, Finn T. Okkels (1999): Parameters interacting with mannose selection employed for the production of transgenic sugar beet.
Physiologia Plantarum, **105,** 109.

Joersbo M., Petersen S.G., Nielsen J.E., Marcussen J. and Brunstedt J. (1999): Isolation and expression of two cDNA clones encoding UDP-galactose epimerase expressed in developing seeds of the endospermous legume guar, Plant Science**, 142**, 147-154.

Joersbo M., Donaldson I., Kreiberg J., Petersen S.G., Brunstedt J. and Okkels F.T., (1998): Analysis of Mannose selection used for transformation of sugar beet. Molecular Breeding, **4**, 111-117.

Anna Haldrup, Steen G. Petersen and Finn T. Okkels (1998): The xylose isomerase gene from *Thermo-anaerobacterium thermosulfurigenes* allows effective selection of transgenic plant cells using D-xylose as a substrate. Plant Molecular Biology **37**, 287-296.

Joersboe M., Brunstedt J. and Petersen S.G. (1998): Cloning of UDP-galactose epimerase. Patent Application, International Application Number: PCT/IB98/00886. World Intellectual Property Organization.

Joersboe M., Brunstedt J. and Petersen S.G. (1998): In vivo modification of galactomannans in guar by expression of UDP-galactose epimerase antisense RNA. Patent Application, International Application Number: PCT/IB98/00891. World Intellectual Property Organization.

Anna Haldrup, Steen G. Petersen and Finn T. Okkels (1998): Positive selection: a plant selection principle based on xylose isomerase, an enzyme used in the food industry. Plant Cell Reports **18**, 76-81.

Steen G. Petersen, A. Haldrup, L. Bruun, R.D. Thompson and F.T. Okkels (1997): Expression of an S receptor-like protein kinase gene in sugar beet styles. 5th International Congress of Plant Molecular Biology. Singapore, 21-27 September.

S.G. Petersen, A. Haldrup, L. Bruun, F.T. Okkels and R.D. Thompson (1996): A cDNA from sugar beet flower styles with similarity to self-incompatible genes of *Brassica*. 10th International Biotechnology Symposium. Sydney, Australia, 25 - 30 August.

L. Bruun, A. Haldrup, S.G. Petersen, L. Frese, Th.S.M. de Bock and W. Lange (1995): Self-incompatibility reactions in wild species of the genus *Beta* and their relation to taxonomical classification and geographical origin. Genetic Resources and Crop Evolution **42**, 293 - 301.

Bojsen K., Donaldson I., Haldrup A., Joersboe, M., Kreiberg, J.D., Nielsen J., Okkels F.T., and Petersen S.G. (1994): Mannose or xylose based positive selection. Patent Application, International Application Number: PCT/EP94/00575. World Intellectual Property Organization.

Steen Guldager Petersen, Lone Bruun og Anna Haldrup (1991): Forskning i selvuforenelighed - et fremtidigt værktøj i planteforædlingen ?. Spiren, december, nr. 232, 5 - 8.

Steen Guldager Petersen and Bernhard Borkhardt (1990): Establishment of resistance to Pea Early Browning Virus strain SP6 in plants. VIIIth International Congress of Virology. Berlin, Germany, 26 - 31 August.

Steen Guldager Petersen and Bernhard Borkhardt (1990): Establishment of resistance to Pea Early Browning Virus in plants. Workshop on Genome Expression and Pathogenesis of Plant RNA Viruses. Madrid, Spain, 7 - 10 May.

Steen G. Petersen, Jan Lehmbeck and Bernhard Borkhardt (1989): Analysis of RNA2 of Pea Early Browning Virus strain SP6. Plant Molecular Biology **13,** 735 - 737.

Steen G. Petersen, Bjarne M. Stummann, Peter Olesen and Knud W. Henningsen (1989): Structure and function of root-inducing (Ri) plasmids and their relation to tumour-inducing (Ti) plasmids. Physiologia Plantarum **77**, 427 - 435.

Steen G. Petersen, Bernhard Borkhardt and Jan Lehmbeck (1989): Molecular characterization of RNA2 from Pea Early Browning Virus in relation to plant/virus interaction. The Molecular Biology of Plant Virus Pathogenicity, EMBO Workshop. Kent, UK, 16 - 19 July.