Summary Mette Hansen

A motivated
innovator, which is my insight profile and from my years in elite sport I know the importance of being a team player.

I possess a strong Quality Mindset and a solid experience within compliance and Quality related processes (GMP) and Quality Management Systems (QMS), Quality Management Review, handling Audit and inspections findings as well as signals, Validation, Quality Risk Management, including risk-based approach to the mentioned.

I thrive on simplicity, setting direction and development of systems and method to enable fulfilment of requirement, balancing the level of effort to the level of risk.

I am a good facilitator and communicator of complicated topics, also support in developing of corporate procedures, interpretation and assuring regulatory references and requirements, including development of tools and systems.
To mention implementation ICH Q9 across the whole Novo Nordisk organisation, tools for risk-based evaluation of cross contamination, participating in implementing FDA PV guide in 2011, and lately in the task force behind developing Science and Risk based Validation together with establishing of design Standards on SVP and Corporate level.

I am an experienced and recognised educator and lecture for both larger groups and classroom (or virtual) courses for a wide range of participants (from operators to upper management) - both internal and external.

Through my last +20 years my assignments have given me the opportunity to work both cross organisational, and cross cultural within DFP/IFP, working with colleagues from Europe, South America, China and North America.

I have since 2007 been an active member of ISPE, working with the subgroup PQLI, and since 2017 member of the board for ISPE Nordic, where I now hold the Chair.

As a former elite rower, I enjoy spending time in my rowing club, enjoying the good exercise with good friends. Through the sport I know the importance of being a team player, but also to perform as an individual.
I now contributing to the club by being member of the board, focusing on getting young people enrolled in the sport. Coordination of activities, participation during regattas and supporting and passing my experience on to the young talents.

Professional experience

Feb 2022- **Quality Risk Specialist for Fujifilm Diosynth Biotechnologies**
Developing the QRM setup, support to processes.

April 2019-February 2022 **Compliance and QA Specialist for DFP and ManDev**

As part of the Corporate Science and Risk based Validation (SRV) project, I support and facilitate implementation of the developed principles, mainly in development and innovation projects.
As recognised Subject Matter Expert in QRM, I introduce by facilitation risk-based approach and risk-based decisions, across core processes and support processes.

Part of the team who developed QA oversight, as a different way of being a QA, from the more reactive activities, to approve and review, toward more proactive, being a compliance partner, supportin developing quality and validation documents.

Creating awareness of Good Engineering Practice, to strengthen the benefit of Science and Risk based Validation. and conduct competence gap analysis for the Engineering responsible in Line of Business. Identify need for training and develop courses together with Engineering Management.
Support the development of design Standard together with relevant Subject Matter Experts.

Subject Matter Expert for following DFP Process groups:
Quality Risk management
Quality oversight
Design and facility
Validation
Representing DFP in the corporate process groups.

DFP ManDev Novo Nordisk A/S, Bagsværd, Denmark

April 2014-april 2019 **Compliance Specialist for Diabetes Finished Product (DFP)**
Subject Matter Expert for following DFP Process groups:
Quality Risk management
Validation
QA oversight and Audit and Inspection

Been part of the corporate Lean Qualification (LQ) project to define Science and Risk Based validation concept and supporting the implementation across DFP.
Sharing findings and interpretation of GMP and cGMP and supporting and setting a way to solve the issues.
Support to all 7 DFP sites regarding Quality Risk Management, by facilitating risk assessment.
Training in validation across all sites, and general support in relation to validation.
Representing DFP in the Corporate Process group

DFP Compliance Support Novo Nordisk A/S, Bagsværd, Denmark

May. 2010 –Apr. 2014 **QRM Process Expert – Implementation of Quality Risk Management and Validation concept based on the 2011 FDA Guide**

Interpretation of external requirements, author of global SOP's and support and coaching in Audit and Inspections
Develop and facilitate the use of tools for risk assessment, and risk-based decisions.
Develop Risk Facilitator Course and establish a QRM facilitator network.

Establish training courses in QRM and validation across Novo Nordisk

Developed and conduct training courses for basic and advanced QRM. Training of MHRA in UK for application for QRM to the GDP (Good Distribution Practices).

Chair of Novo Nordisk QRM focus group and member of Novo Nordisk Validation focus group, Contributing by my external representative in ISPE, and prior ASTM E55

Corporate Quality, Novo Nordisk A/S, Bagsværd, Denmark

Apr 2005- May 2010 **Principle Scientist and Quality Risk Management Process Expert**
Support to all of Novo Nordisk, affiliates, Drug Product, Drug Substance and Device and Sourcing
Head of collecting external requirements together with the external representatives and distributing to relevant Focus groups, for implementation.
Special assistance with quality issues, especially QRM, and validation.
Interpretation of ICH Q9, and implementation across Novo Nordisk.

Conduct several risk assessments workshops as certified QRM facilitator using a wide range of risk assessment tools (incl. FMECA, Fault Tree Analysis, HAZOP, HACCP).
Development of a method of for an easy way to conduct local process FMECAs at the production sits to support the product transfer plans.

Quality Process Technologies, Manufacturing Science & Quality, Global Quality, Novo Nordisk A/S, Gentofte, Denmark

Feb 2000- Apr 2005 **QA professional for Medical Devise**
QA support for pen production, support to injection moulding dept, and to development and optimization of pen systems, (Novo Pen, Flex Pen and Innolet).
Interpretation of authorities' requirements, and ISO standards.
Member of the Devise Focus groups, and Medico Industrien Risk Managemnet Group

Diabetes Disposable Pens, Novo Nordisk A/S Hillerød and Værløse

Oct 1995- Feb 2000 **Development Engineer**
Egalet, is an injection moulded controlled release tablet, water soluble polymers were used, together with special design, so a constant release profile was obtained
Process responsible for establishing pilot production, including design of clean room and formulation facilities. purchase of manufacturing equipment assists in qualification with vendor, and final validation.
Drug product formulation responsible, and develop formulation recipes for different API, and test set-up for approving starting materials and excipients
.
Egalet A/S, Kirke Værløse

Jun 1993-jul 1994	**Student at RMIT and SCIRO** PhD prework Mathematical model for lifetime prediction of plast and polymers, by comparing real-time aging to accelerated degradation Melbourne Australia
1991-1992	**Project Engineer at levnedmiddelstyrrelsen** Investigating the effect pollution from central Europa has on the arctic marine conditions. Levnedsmiddelstyrrelsen Gladsaxe
Sep 1987 Jul 1990	**Consultant for building projects**, Building project with focus on surface coatings adhesive abilities, conducting test for clients, and advice regarding coatings Surface Technical Department Technological Institut Tåstrup
Sep 1986-Sep 1987	**Development and Rotation Engineer** Research and development of binders for plast coating Sadolin & Holmblad Amager

Educational background

Aug 1993-jul 1994	**Pre PhD work** at Melbourne University in cooperation with CSIRO, simulation of polymer degradation
jun. 1986	**Chemical Engineer / MSc Chem. Eng.** (Major in Polymer Tecnology) Danish technical Univercity of Denmark
June 1979	**High school graduation (Student/ STX)** (Math/Fysics line**)** Øregård Gymnasium, Hellerup, Denmark

Publications

As member of the PQLI team (ISPE)e	Part 1 product Realization Using Quality by Design (QbD) **Concepts and Principles** ISBN 978-1-936379-20-**0**
As member of the PQLI team (ISPE)e	Part 2- product Realization Using Quality by Design (QbD) **Illustrative Examples** ISBN 978-1-936379-21-7

External Presentations and Lectures

Nov. 2018 International Society for Pharmaceutical Engineering/ISPE Nordic Annual Meeting: *Risk Based Approach for Evaluation of Cross Contamination*
Copenhagen, Denmark

June 2013 On behalf of ISPE for MHRA (Medicines and Healthcare Products Regulatory Agency): *QRM and Good Distribution Practises (GDP) –a two day training session with a combination of lecture and workshop.*
London, England

Feb. 2012 PDA conference
Risk based approach and Quality by Design
Frankfurt Germany

Conferences

2011 Sep	**ISPE QbD conference. 2 days conference**
ISPE	Arranged with Mette Bryder Ferring
Europe	**Brussel Belgium**
ISPE	Arranged ISPE Nordic Conference
Nordic Nov	Quality Risk management
2018	ISPE Nordic Annual Meeting, Copenhagen