

Curriculum Vitae

Work experience

Personal information Henriette Vindmar

• Dec, 2023 - present: Medicines Inspector, Danish Medicines Agency, Denmark • Aug, 2020 - Nov, 2023: Inspector of Medical Devices, Danish Medicines Agency, Denmark • Jul, 2017 - Jul, 2020: Director QA&QC, pK Chemicals A/S, Denmark Overall responsible for QA and QC activities in relation to chemical and biological API. Furthermore for components for medidical devices. Quality activities related to a CEP for a chemical API. Regulation: EU GMP part I and II and MDR, US CFR part 820. • May, 2016 - Jun, 2017: QA Director, Ferrosan Medical Devices A/S, Denmark

Overall responsible for QA and

Qualified Person. Class III Medical

devices. Regulation: EU GMP part I,

MDR, US CFR part 210, 21

and 820.

• Jun, 2014 - Apr, 2016: Senior specialist, Amgros I/S, Denmark National auditor for the Danish Hospital Pharmacies. Regulation:

EU GMP part I and II.

• Aug, 2012 - May, 2014: QA Operations Manager, Qualified Person, Ferrosan A/S.

Regulation: EU GMP part I and II.

• Jul, 2011 - Jul, 2012: Senior GMP Specialist, Pharmagile, Denmark

> Various GMP consultancy task related to medicinal products, API

> > and medical devices. Regulation: EU GMP part I and part II, EU req. medical devices, US CFR part 210, 211 and 820.

• Jan, 2010 - Jun, 2011: Partner, Consulting, NNE A/S, Denmark Various GMP consultancy task related

to medicinal products, API
and medical devices. Regulation: EU
GMP part I and part II, EU req. medical
devices, US CFR part 210, 211 and 820.
• Oct, 2007 - Dec, 2009: Quality Director, Qualified Person,
Nomeco A/S, Denmark
Overall responsible for QA activities in
relation to wholesale of
medicinal products. QP related to
secondary packaging of IMP.
• Nov, 2001 - Sep, 2007: Manager GMP & Qualification/Validation,
NNE A/S, Denmark
Various GMP consultancy task related
to medicinal products, API
and medical devices. Regulation: EU
GMP part I and part II, EU req. medical
devices, US CFR part 210, 211 and 820.
• Oct, 2010 - Oct, 2001: GMP Specialist, NNE A/S, Denmark
Various GMP consultancy task related
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to medicinal products, API
and medical devices. Regulation: EU
GMP part I and part II, EU req. medical
devices, US CFR part 210, 211 and 820.
• Jan, 1998 - Sep, 2000: Medicines Inspector, Danish Medicines
Agency, Denmark
Various inspections: Sterile and non-
sterile medicinal products in
Denmark and 3 rd countries.
• Jan, 1993 - Dec, 1997: Cand.Pharm. Quality Coordination,
Lundbeck A/S, Denmark
Quality agreements with CMO of
medicinal products. Audit of
CMO and suppliers of API, Quality
projects.
• Jan, 1992 - Dec, 1992: Cand.Pharm. QA, Nycomed-Pharma-
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Medica A/S, Denmark
Review of batch documentation etc.
• Mar, 1991 - Sep, 1991: Cand.Pharm., Silkeborg Ørne Apotek
(Pharmacy), Denmark

Education and training

May 2024,

Authorisation as Medicines Inspector, Danish Medicines Agency.

In relation to GMP: Medicinal products incl IMP (sterile, non-sterile), computerized systems, chemical lab, microbiological lab, biological lab, PAT + QbD and Pharmacies with production of medicinal products, API (Chemical and biological).

In relation to GDP: Wholesaler, inprot and distribution of API and inspektion of computerized systems

Juli 1990,

Cand.Pharm. Copenhagen University, Denmark

Additional information

Publications

Projects Memberships Other Relevant Information