



Curriculum Vitae

Personal information **Malene Weis**

Work experience

Start date - end date: 01-04-2024 -

Position: Inspector

Employer: DKMA

Country of employment: Denmark

Main activities: GCP inspections

Start date - end date: 01-06-2023 - 31-03-2024

Position: CPM

Employer: Synklino

Country of employment: Denmark

Main activities: establishing QMS, build Clinical Operations, vendor selection, core project team member.

Start date - end date: 01-10-2017 - 30-05-2023

Position: independent consultant

Employer: self-employed

Country of employment: Denmark

Main activities: CPM roles

Start date - end date: 01-06-2013 - 30-09-2017

Position: CPM

Employer: Orphazyme and Cytovac

Country of employment: Denmark

Main activities: CPM, writing SOPs

Start date - end date: 01-04-2011 - 30-10-2012

Position: Director Clinical operations

Employer: CRO (Encorium/Ergomed)

Country of employment: Denmark

Main activities: Managing clinops teams, training, budgets, proposals.

Start date - end date: 01-06-2008 - 30-04-2010

Position: Director Clinical Operations

Employer: Neurokey

Country of employment: Denmark

Main activities: establishing QMS, establish ClinOps, prepare for FIH clinical, vendor selection.

Start date - end date: 01-08-2004 - 28-02-2008

Position: Director clinical operations

Employer: Osteologix

Country of employment: Denmark

Main activities: establishing QMS, establish ClinOps, oversight early phase studies, vendor selection.

Start date - end date: 01-09-2001 - 30-04-2003

Position: CPM

Employer: Leo Pharma

Country of employment: Denmark

Main activities: Oversight late phase studies.

Start date - end date: 01-09-1997 - 31-08-2001

Position: CRA/senior CRA

Employer: Covance/Aventis

Country of employment: Denmark

Main activities: monitoring, leading CRAs

Education and training

2012, 30 days , lean management, Management course Copenhagen, Denmark

1993 M.Sci. Pharm. Copenhagen University, Denmark

Additional information

Publications

2007	Improved strontium bioavailability in a new tablet formulated strontium salt. Results of a phase 1 study of a novel DABA (NB101)
1993	Bioavailability of four oral coenzyme Q10 formulations in healthy volunteers.

Projects

None

Memberships

None

Other Relevant Information

None