

PERSONAL INFORMATION

Helena Lindberg

WORK EXPERIENCE

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- August 2021- Present **Manager GCP/GVP Inspections**
Swedish Medical Product Agency (Sweden)
Manager position at the Drug Inspectorate, with responsibility for GCP and GVP inspection areas.
- June 2019-August 2021 **Director Clinical and CMC Compliance**
Sobi AB (Sweden)
Director within the Global Quality Department. Initially with responsibility for QA GCP audits and audit processes and since Nov 2020 responsible for managing the international team Clinical and CMC Compliance within the same department.
- April 2018-May 2019 **Director Quality Assurance and Compliance**
LINK Medical (Sweden)
Evaluate and ensure internal compliance and perform external audits and other quality related assessments for customers. Since Jul 2018 managing the Swedish QA team.
- June 2010-April 2018 **Pharmaceutical Inspector GCP**
Swedish Medical Products Agency (Sweden)
Plan and lead GCP inspections nationally in Sweden, and internationally on behalf of EMA. Including also normative work and mentoring new inspectors.
- September 2008-June 2010 **Clinical Project Manager**
OxThera AB (Sweden)
Responsible for an international orphan drug clinical program.
- April 2006-October 2008 **Director Clinical Research and Project Manager**
Resistentia Pharmaceuticals AB (Sweden)
Responsible for the international clinical program and since Sep 2007 Project Manager and Manager of a team of CRMs.
- January 2000-March 2006 **Clinical Program Leader**
Q-Med AB (Sweden)
Responsible for international medical device clinical programs and since Mar 2003 Manager of a team of CRMs.
- February 1990-December 1999 **Clinical Research Manager**
Pharmacia Corporation (Sweden)
Joined the company as Laboratory Engineer, but since Nov 1991 worked with international clinical study management within several different therapeutic areas.

EDUCATION AND TRAINING

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- January 1986-January 1990 **M Sc Pharmacy**
Uppsala University (Sweden)

ADDITIONAL INFORMATION

Expertise GCP, GCLP, GMP for IMP, Medical device clinical trials, GVP

Publications
Projects

Memberships
Other Relevant Information