# Curriculum Vitae

## Personal information

Helena Cavieses

## Work experience

1. Employer: Swedish Medical Products Agency
   - Start date: 060123
   - End date:
   - Position: Senior Expert Pharmacovigilance, Operations Pharmacovigilance System, Office of Division of Use and Information
   - Activities: Responsible to maintain the PSMF of the Swedish Medical Products Agency (SMPA); strategic and tactic planning and development of pharmacovigilance of the SMPA and nationally - such as reporting and monitoring of pharmacovigilance data, signal management, regulatory actions, communications and follow up, interpretation and implementation of legislations, input to new/updated legislations (national and EU-level); Quality Manager of the Office of the Division of Use and Information; Quality Lead of units in the Division of Use and Information; Chair of Assessors quality assurance team for issues of national interest; representative in national and international patient safety groups (e.g. the International Medical Safety Network, and the Patientsafety group within the National health care regions' Collaboration for Knowledge Management; Project management
   - Country: Sweden
2. Employer: Swedish Medical Products Agency
   - Start date: 010922
   - End date: 310523
   - Position: Deputy Team Leader Veterinary medicine group, Department of Drug Safety
   - Activities: Team Leader of the Veterinary medicine group, 6 persons, and part of the Managment group of the Drug Safety Department. Overseeing the daily veterinary case handling and signal management work, currently including implementation of a new national database system. Ensuring national legislation and processes per current legislation and both European and national implementation of new veterinary pharmacovigilance legislation. Supporting and providing expert input to the teams active involvement in European work groups such as PhVWP, HMA subgruop ESS, CVMP VedDRA_subgroup and from next year also the P_SMEG group.
   - Country: Sweden
3. Employer: Swedish Medical Products Agency
   - Start date: 042021
   - End date:
   - Position: Senior Assessor, Department of Drug Safety
   - Activities: Co-project lead for the government assignment of an investigative studie for developing national snapshot information on status of availability, access, demand and localisation of medicinal products and medical devices; coordingating the departments development of Business Contingency Plans, Lead auditor of the SMPA's Pharmacovigilance System; Supporting and providing experties in the area of pharmacovigilance to the department and other areas of the SMPA.
   - Country: Sweden
4. Employer: Swedish Medical Products Agency
   - Start date: 092017
   - End date: 032021
   - Position: Pharmacovigilance Inspector
   - Activities: Areas of responsibility: _ Inspection of pharmacovigilance systems and safety surveillance of market authorisation holders with market authorisations of medicinal products granted for the Swedish market, in accordance with national and European regulations guidelines. _ Normative work and providing guidance and advise, with special focus on pharmacovigilance in relation to traditional herbal medical products, and veterinary medical products. _ Functioning as inspector with responsibility for veterinary pharmacovigilance inspections. Other activities and achievements: _ Participating in the MPA’s work group for implementation of the pharmacovigilance parts of new veterinary legislation Regulation (EU) 2019/6. _ Responsible for the managing a national project to suggest actions to reinstate nationally controlled distribution of medicines and materials for risk minimising programmes. _ Representing the Inspections department in the Medical Product Agency’s (MPA) internal Values group, promoting the national good governmental value principals at the MPA. _ Handling cases of product information exemption requests, as internal support during the Covid_19 pandemic.
   - Country: Sweden
5. Employer: Astra Zeneca UK Ltd
   - Start date: 102015
   - End date: 082017
   - Position: Pharmacovigilance and Regulatory Complianc (PVRC) Principal, within Global Patient Safety Oncology Therapeutic Area, Global Regulatory Affairs, Patient Safety and Quality Assurance (GRAPSQA), Development and Enabling (D&E)
   - Activities: Responsibilities included: Process Owner: _ Signal Management area, Jan’ 17 – date _ Global Standard on Case Handling for Individual Case Reports (ICSR), and Collection of ICSRs from Organised Data Collection Programmes (ODCP), Websites and Digital Listening Activities Achievements included: _ Implemented a new SOP on Safety Management for Externally Sponsored Research _ As lead of a workgroup within the GMA project Optimising Medical Evidence Generating Activities (OMEGA) I drove the creation of an AZ standardised classification of types of Real World Evidence sources, as applicable to safety reporting regulations. _ As part of a cross_functional governance advisory group linked to the GMA Patient Centricity group (gPace) I ensured that adverse event reporting is one of seven mandatory principles of a fist in industry global standard on patient interactions. _ Within a year built up a

network and good relations with functions applicable to my Process Owner areas, across Global Medical Department (GMD) and Global Medical Affairs (GMA).
    - Country: United Kingdom
6. Employer: Astra Zeneca UK Ltd
    - Start date: 112014
    - End date: 102015
    - Position: Consulting Senior Pharmacovigilance Scientist, within Global Patient Safety Oncology Therapeutic Area, GRAPSQA
    - Activities: Responsibilities included: _ Risk Management activities, Signal Detection and Evaluation, Labelling activities, and support of Regulatory Reports and Submissions. _ Conducting both routine and ad hoc safety signal surveillance/evaluation for Cediranib and AZD5363, including preparing material for SERM Achievements included: _ Timely called for monthly and ad hoc SSaMT meetings, authored SSaMT minutes and followed up on safety preparations action log to ensure timely input to for the Cediranib MAA submission _ Timely produced assigned responses to Health Authority Questions _ Contributed to the production of DSURs _ Prepared Maestro hand over for Cediranib
    - Country: United Kingdom
7. Employer: Boehringer Ingelheim Ltd
    - Start date: 062013
    - End date: 122013
    - Position: Consulting Pharmacovigilance Manager, within Drug Safety Unit UK and Ireland department (part time)
    - Activities: Responsibilities included: Supporting the marketing company's Head of Drug Safety UK and Ireland Achievements included: _ Finalised about 5 outstanding PVA negotiations with Licence Partners in collaboration with the local legal department _ Reviewed and updated approx. 10 local PV working instructions and SOPs affected by changed global SOPs (following the new EU legislation in 2012). _ Reviewed the department structure and drafted new job descriptions for the Pharmacovigilance roles.
    - Country: United Kingdom
8. Employer: Boehringer Ingelheim AB
    - Start date: 072008
    - End date: 052013
    - Position: Head Nordic Drug Safety Unit (NDSU)
    - Activities: Responsibilities included: _ As part of the Nordic marketing companies' medical management team: Responsible for the pharmacovigilance operations in the marketing companies of Sweden, Norway, Denmark, Finland and Iceland, working towards the company's Nordic clinical and marketing departments. (In Iceland only Vendor representation for marketing). _ Line management of the team in Stockholm, and dotted line to three part time safety associates in Norway, Denmark and Finland (reporting to the regulatory affairs heads of their countries). _ Setting and monitoring the Unit's budget and staff resources _ Participating in corporate global working groups for process enhancement. _ Perform routine PV operations Achievements included: _ Building a strong case for negotiating the need of increased staff resources, I built the local tem in Stockholm over three years from initially one part time safety manager reporting to me to four FTE safety managers and two FTE consulting assistants. _ Created a library of local SOPs and Working Instructions for all local Nordic PV activities ranging from; case entry into the company's global database; regulatory reporting in all Nordic countries; setting up, maintaining and tracking local PVAs; QA of case handling and other PV processes; preparing training schedules and material and performing PV training for the Nordic marketing companies, including investigator training. _ Set up a quality management system implementing processes for capturing quality issues and following up on CAPAs. _ Built up a new process to ensure safety awareness and tracking of Non_Trial Activities. _ Set up a local process ensuring safety reporting from Compassionate Use Programmes. _ Implemented portal SAE reporting to the company's Nordic investigators. (Sabbatical Sep_2012 – May _2013)
    - Country: Sweden
9. Employer: Boehringer Ingelheim AB
    - Start date: 032008
    - End date: 072008
    - Position: Drug Safety Manager, within NDSU
    - Activities: Responsibilities included: _ Case handling (receipt, triage, data entry, regulatory reporting) _ Provide PV training Nordic clinical staff (approx. 60 FTE) Achievements included: _ Within 7 weeks of employment, I was at first attempt certified as case entry manager with highest score at the mandatory global case entry_training course _ After three months on the job, I was promoted as Head of the Nordic Drug Safety Unit.
    - Country: Sweden
10. Employer: Uppsala Monitoring Centre/WHO Collaborating Centre for International Drug Monitoring
    - Start date: 012000
    - End date: 052006
    - Position: Senior Expert Pharmacovigilance/Programme Leader WHO Databases
    - Activities: Senior Expert Pharmacovigilance: Responsibilities included: _ Provide in_house and external expert advice on pharmacovigilance _ Assisting the UMC sales manager with technical expertise at international conferences _ Provide training: Lecturing as invited speaker at international meetings and courses held at National Centres, on PV in general and WHO activities specifically _ Participating in work groups for international harmonisation. Programme Leader WHO Databases (Jan '00_ Sept '03 ) Line Management: _ Cross departmental collaboration with the Signal work team and the WHO Programme Lead. Project Management Achievements included: _ I authored the world's first guideline describing the format required to transfer ICSRs in E2B format. It was provided to the first National Centres transmitting ICSRs in E2B_XML_files. _ A seamless transfer of the WHO ADR database from INTDIS to the world's first database in/on an E2B compatible structure and platform, with no down time of activities: WHO DD and WHOART were still produced in time and signal detection runs and development continued on schedule. As project manager, I authored system descriptions, E2B guidelines, and processes for quality assuring the transfer of data; was in charge for quality assuring the database function; and ensured cross_departmental oversight for implications and timing. _ The new structure of WHO DD facilitating storage and retrieval of information regarding herbal medicines was built using my thesis for bachelor's degree in pharmacy. _ Completed a bachelor's degree in pharmacy at the Uppsala University, the thesis was published in the DIA journal. _ Contributed to the 'WHO Guidelines to Reporting of Traditional Medicines' (2002) _ Initiated closer collaboration with Adis Press, publisher of Reactions Weekly, linking up this newsletter on global adverse drug reaction news and news bulletins received by UMC from the National Centres of the WHO Programme.
    - Country: Sweden
11. Employer: Uppsala Monitoring Centre/WHO Collaborating Centre for International Drug Monitoring
    - Start date: 011991
    - End date: 121999
    - Position: Pharmaceutical Officer
    - Activities: Responsibilities included: _ Quality assuring and uploading batches of ICSRs from National Centres into the WHO ADR Database _ Updating the WHO Drug Dictionnary (the register of medicinal products in the WHO ADR database, these days known as WHODrug
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Global), and WHOART (the WHO Adverse Drug Reaction Terminology). _ Signal coordinator Aug '93_ Jan '99 _ Participating in work groups for international harmonisation _ Assisting the UMC sales manager with technical expertise at international conferences _ Provide training in PV: o Lecturing as invited speaker at international meetings and courses held at National Centres, on PV in general and WHO activities specifically. Including lecturing at the Pharmacy School of Uppsala University, about the WHO activities in the area of pharmacovigilance. o On_line search training for subscribers of access to the WHO Adverse Reactions Database Achievements included: _ As part of a cross functional team, I contributed to develop a refined process for signal detection which was first in the world to use neural network technology (Bayesian disproportionality methods). This work resulted in a published article. _ Contributed to the document 'the Erice declaration' (1997) _ Edited the 'WHO SIGNAL' documents '94_'99 _ Reviewed and updated the WHO Always Serious list within WHOART. (Jun '91 – Nov '92 Maternity leave)
    - Country: Sweden
12. Employer: Uppsala Academic Hospital
    - Start date: 081990
    - End date: 121990
    - Position: Wards assistant at Oncology ward
    - Activities:
    - Country: Sweden
13. Employer: Apoteket AB/National Pharmacy
    - Start date: 081989
    - End date: 121990
    - Position: Receptarie/Dispencing Pharmacist at Pharmacy Gripen in Stockholm
    - Activities: (Sabbatical Aug 1990 until Dec 1990)
    - Country: Sweden

## Education and training

1. Subject: Department of pharmaceutical chemistry, Pharmaceutical faculty, Uppsala University
    - Start date: 081999
    - End date: 062001
    - Qualification: Bachelor of Pharmacy
    - Organisation: pharmacognosy and pharmacoepidemiology
    - Country: Sweden
2. Subject: Pharmaceutical faculty, Uppsala University
    - Start date: 081987
    - End date: 061989
    - Qualification: Dispensing Pharmacist
    - Organisation:
    - Country: Sweden
3. Subject: Medical Products Agency
    - Start date: 052019
    - End date: 052019
    - Qualification: National Pharmacovigilance Day
    - Organisation:
    - Country: Sweden
4. Subject: Swedish Medical Products Agency
    - Start date: 052018
    - End date: 052018
    - Qualification: National Pharmacovigilance Day
    - Organisation:
    - Country: Sweden
5. Subject: EMA Inspectorates Working Group
    - Start date: 102017
    - End date: 102017
    - Qualification: PhV IWG Training course
    - Organisation:
    - Country: United Kingdom
6. Subject: Drug Safety Research Unit (DSRU)
    - Start date: 062017
    - End date: 062017
    - Qualification: 9th Biennial Signal Detection Conference
    - Organisation: News and future in signal management, use of social media and big data screening
    - Country: United Kingdom
7. Subject: Internal Astra Zeneca UK training
    - Start date: 062016
    - End date: 062016
    - Qualification: Business Relationship Management
    - Organisation:
    - Country: United Kingdom
8. Subject: Internal training (Astra Zeneca, global)
    - Start date: 122014
    - End date: 122014
    - Qualification: Signal Management System Training
    - Organisation:
    - Country: United Kingdom
9. Subject: Internal training (Boeheringer Ingelheim AB)
    - Start date: 052012
    - End date: 052012
    - Qualification: Introduction to Diabetes
    - Organisation: Internal medicine and pharmaceutical developments
    - Country:
10. Subject: Pharma Package
    - Start date: 102011
    - End date: 102011
    - Qualification: Pharmacovigilance in the Nordics beyond 2012
    - Organisation:
    - Country: Sweden
11. Subject: Internal training (Boeheringer Ingelheim AB)
    - Start date: 042011
    - End date: 042011
    - Qualification: Introduction to Oncology
    - Organisation:
    - Country: Sweden

12. Subject: Internal training (Boeheringer Ingelheim AB)
    - Start date: 112010
    - End date: 112010
    - Qualification: Finance workshop
    - Organisation: Setting budgets and keeping targets
    - Country: Sweden
13. Subject: IQPC
    - Start date: 062010
    - End date: 062010
    - Qualification: Pharmacovigilance conference
    - Organisation: Focus inspections and RMPs
    - Country: United Kingdom
14. Subject: Internal training Boehringer Ingelheim (global)
    - Start date: 092009
    - End date: 092009
    - Qualification: World Class Leadership
    - Organisation:
    - Country: France
15. Subject: DiSC
    - Start date: 092009
    - End date: 092009
    - Qualification: Leadership training
    - Organisation:
    - Country: Sweden
16. Subject:
    - Start date: 012009
    - End date: 012009
    - Qualification: Work environment, training for leaders
    - Organisation:
    - Country: Sweden
17. Subject: EMA
    - Start date: 122008
    - End date: 122008
    - Qualification: EU Qualified Person for Pharmacovigilance
    - Organisation:
    - Country: Sweden
18. Subject: Diamond
    - Start date: 092003
    - End date: 092003
    - Qualification: Leadership workshop
    - Organisation:
    - Country: Sweden
19. Subject: Chef.
    - Start date: 112002
    - End date: 112002
    - Qualification: Kvinna, ledare och chef/Woman, leader and boss
    - Organisation:
    - Country: Sweden
20. Subject: Forum SQL
    - Start date: 012002
    - End date: 012002
    - Qualification: SQL for database han
    - Organisation: Building queries using SQL
    - Country:
21. Subject: DIA
    - Start date: 102001
    - End date: 102001
    - Qualification: A clinical approach to ADRs
    - Organisation: "The Benichou ADR training", ADRs in clinical practice
    - Country: France
22. Subject: Swedish Pharmaceutical Union (SFF)
    - Start date: 091999
    - End date: 091999
    - Qualification: Förhandlingsteknik för unga farmaceuter/Negotiation techniques for young pharmacists
    - Organisation:
    - Country: Finland
23. Subject: CIOMS
    - Start date: 091997
    - End date: 091997
    - Qualification: Erice Conference on Good Communication in Pharmacovigilance
    - Organisation:
    - Country: Italy
24. Subject: WHO Programme for International Drug Monitoring
    - Start date: 121995
    - End date: 121995
    - Qualification: National Centre meeting
    - Organisation:
    - Country: Thailand
25. Subject: ISPE
    - Start date: 081994
    - End date: 081994
    - Qualification: Seminar at International Conference on Pharmacoepidemiolog
    - Organisation:
    - Country: Sweden

## Additional information

### Publications

Own: _ Fucik H, A Backlund, Farah M Building a Computerized Herbal Substance Register for Implementation and Use in The World Health Organisation International Drug Monitoring Programme. Drug Information Journal 2002; 36: 839_ 854 _ Fucik H et al Herbal Adverse Drug Reactions from the UMC Database Focus Bolletino di Farmacovigilanza 2001 _ Fucik H, Edwards IR Impact and Credibility of the WHO Adverse Reaction Signals. Drug Information Journal 1996; 30: 461_464 Co_author: _ WHO_UMC Publication; Guideline on Reporting Adverse Events in E2b format (2002) _ Lindquist M, Edwards IR, Bate A, Fucik H, Nunes A_M, Ståhl M. From Signal to Alerts – A Revised Approach to International Signal Analysis. Pharmacoepidemiology and Drug Safety 1999; 8: S15_S25 _ Meyboom RHB, Fucik H, Edwards IR Thrombocytopenia reported in association with Hepatitis B and A vaccines. Lancet 1995; 345: 1638

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| Projects | * Implementing Portal reporting to the Company's Nordic Clinical Research investigators 2012 * Implementing streamlined and more efficient SAE reporting from all Nordic Clinical Research sites to the Company 2012 * Implementing PV e_learning for all Nordic Staff 2011_12 * Implementing process for secure e_mail SAE reporting to the Company's Nordic Clinical Research investigators 2010 * Transfer of the WHO ADR database from the original WHO format (INTDIS, International Drug Information System) to a new structure and platform (Vigibase, ICH E2B compatible). (Aug '00_ Sept '03). * Restructuring the register of the medicinal products in the WHO ADR database (know as the WHO Drug Dictionnary), to facilitate storage and retrieval of information regarding herbal medicines (today a separate product called HDD, Herbal WHO Drug Dictionnary). 2000_2003 |
| Memberships | |
| Other Relevant Information | TRAINING AND SUPPORT * Several local and Nordic investigator trainings (2008_2012) * PV training of Boehringer_Ingelheim's Nordic staff and Vendors (2008_2012) * Acting as UMC Senior Pharmacovigilance Expert giving in_house and external advise on pharmacovigilance (2003_2006) * Assisting the UMC sales manager with technical expertise at several international conferences (1993_2003) * Lectures at the pharmacy school of Uppsala University, about the WHO activities in the area of pharmacovigilance * On_line search training for subscribers of access to the WHO Adverse Reactions Database (1995_2001) * In_house training of UMC staff (1993_2006) * Lecturing as invited speaker at international meetings, or courses at National Centres, on PV in general and WHO activities specifically (1993_2003) MEETINGS Participating as speaker: _ Adverse Reactions and Adverse Reaction Monitoring International Training Course, Uppsala May 2003, 2001, 1999, 1996, 1995, and 1994. _ National Pharmacovigilance Day, Uppsala, Sweden, May 2003, 1996 and the first one in 1991 _ Swedish Medical Products Agency workshop on ADRs (Läkemedelsverkets biverkningsnämnd), Uppsala Nov 2002 _ National pharmacovigilance symposium, Nicosia, Cyprus, Oct 2002 _ National pharmacovigilance training course, Kuala Lumpur, Malaysia, May 2002 _ Annual meeting of International Society of Pharmacovigilance, Tunis, Tunisia, Nov 2001 _ Graduation seminar at Uppsala Universitet, Juni 2000 _ Signal Review team meeting, Uppsala, Aug 1998 _ Swedish Drug Information centers' annual meeting (Läkemedelsinformationscentralernas årsmöte), Umeå, Feb 1999 _ The Impact of IT on the Drug Regulatory Process, Uppsala, Apr 1997 _ Drug Information Association 31st Annual Meeting, Orlando, Florida, USA, Jun 1995 Participating in work groups for international harmonisation: _ 24th Annual meeting of National Centres in the WHO Drug Monitoring Programme, Tunis, Tunisia, Nov 2000 _ CIOMS Workshop 'Communications in Pharmacovigilance', Erice, Italy, Sep 1997 _ CIOMS Workshop 'Communications in Pharmacovigilance', Verona, Italy, Sep 1996 _ 17th Annual meeting of National Centres in the WHO Drug Monitoring Programme, Bangkok, Thailand, Nov 1995 _ MEDDRA Working group, London, UK, Jul 1994 |