



Curriculum Vitae

Personal information **Irene Agerkvist**

Work experience

1. Employer: Medical Product Agency
 - Start date: 052022
 - End date:
 - Position: Senior Assessor
 - Activities: Scientific and regulatory support within quality (CMC) matters
 - Country: Sweden
2. Employer: Medical Products Agency
 - Start date: 052016
 - End date: 042022
 - Position: Scientific Director Pharmaceuticals and Biotechnology
 - Activities: Scientific support responsibilities within quality (CMC) matters in the scientific advice procedures and regulatory assessment for marketing authorization applications e.g. heading quality assurance meetings peer_reviewing assessment reports and giving supervisory support to assessors.
 - Country: Sweden
3. Employer: REGA Consulting AB
 - Start date: 012011
 - End date: 042015
 - Position: Senior Consultant
 - Activities: Independent Consultant in various CMC management roles
 - Country: Sweden
4. Employer: Octapharma AB
 - Start date: 092003
 - End date: 122010
 - Position: Head of Biopharmaceutical Development
 - Activities: Management of a department for development and industrialization of recombinant protein products for hemophilia treatments.
 - Country: Sweden
5. Employer: Octapharma AB
 - Start date: 012001
 - End date: 122004
 - Position: Head Engineering & Process Development
 - Activities: Management of a department for the scientific and technical support functions to the commercial manufacturing of Plasma Protein Products.
 - Country: Sweden
6. Employer: AGA AB
 - Start date: 111997
 - End date: 122000
 - Position: Corporate Director Product Quality Development
 - Activities: Quality upgrading and GMP implementation of traditional Medical Gas Products to comply with medicinal products legislation regarding quality systems and documentation for authority registration of the products.
 - Country: Sweden
7. Employer: Nycomed Imaging AS
 - Start date: 111992
 - End date: 071997
 - Position: Senior Scientist and Department Manager
 - Activities: Senior Scientist and Department Management positions within formulation development, API as well as DP process development and upscaling to commercial manufacturing for Medical Contrast Agents.
 - Country: Norway
8. Employer: Institute of Surface and Colloid Chemistry
 - Start date: 091985
 - End date: 101992
 - Position: Research Scientist
 - Activities: Academic studies and experimental research work leading to PhD degree
 - Country: Sweden
9. Employer: Kabi Vitrum AB
 - Start date: 081984
 - End date: 081985
 - Position: Process Scientist
 - Activities: Experimental work for process development of lipid substances to be used in Parenteral Lipid Emulsions
 - Country: Sweden
10. Employer: ACO Läkemedel AB
 - Start date: 071982
 - End date: 081984
 - Position: Process Scientist
 - Activities: Experimental laboratory and manufacturing work for process development and implementation for Parenteral Infusion Solutions.
 - Country: Sweden

Education and training

1. Subject: The Royal Institute of Technology
 - Start date: 091985
 - End date: 101992
 - Qualification: PhD Biotechnology
 - Organisation: Biotechnology, Biochemistry, Surface and Colloid Chemistr. Thesis Title: "Characterization of and flocculation in Escherichia coli cell disintegrates".
 - Country: Sweden
2. Subject: Biotechnology
 - Start date: 091976
 - End date: 061982
 - Qualification: MSc
 - Organisation: Biochemical Engineering and Biochemistry
 - Country: Sweden

Additional information

Publications

20 peer reviewed scientific publications

PUBLICATION LIST

1. Selective flocculation with Chitosan in E. coli cellhomogenates. [I Agerkvist](#), L Eriksson, S-O Enfors. *Chitin and Chitosan*, Ed. G. Skjåk-Bræk, T. Anthonsen and P. Sandford, Elsevier, London, 543-557 (1989)
2. Characterization of E.coli cell disintegrates from a Bead Mill and High Pressure Homogenizers. [I Agerkvist](#), S-O Enfors. *Biotechnology and Bioengineering*,36, 1083-1089 (1990)
3. Selective flocculation with Chitosan in Escherichia coli cell disintegrates: Effects of pH and nuclease treatment. [I Agerkvist](#), L Eriksson, S-O Enfors. *Enzyme Microbial Technology*, 12, 584-589 (1990)
4. Selective flocculation with Chitosan in Escherichia coli cell disintegrates: Effects of inonic strength and multivalent cations. [I Agerkvist](#), L Eriksson. *Journal of Dispersion Science and Technology*, Vo.14, No.3, 269-293 (1993)
5. Mechanisms of flocculation with chitosan in escherichia coli cell disintegrates: Effects of urea and chitosan characteristics. [I Agerkvist](#), *Colloids and Surfaces*, 69, 173-187 (1992)
6. Characterization of and flocculation in Escherichia coli cell disintegrates. [I Agerkvist](#). *PhD Thesis*, Royal Institute of Technology, Stockholm, Sweden (1992)
7. Preparation of polymeric microbubbles: formulation studies and product characterisation. K Bjercknes, J Undheim Braenden, R Skurtveit, G Smistad, I. Agerkvist. *International Journal of Pharmaceutics*, 158, 129-136 (1997)
8. Preparation of polymeric microcapsules: formulation studies. K Bjercknes, K Dyrstad, G Smistad, [I Agerkvist](#). *Drug development and industrial pharmacy*, 26(8), 847-856 (2000)
9. Air-filled polymeric microcapsules from emulsions containing different organic phases. K. Bjercknes, J Undheim Braenden, J E Braenden, R Skurtveit, G Smistad, [I Agerkvist](#). *Journal of microencapsulation* 18(2), 159-71 (2001)
10. Evaluation of different formulation studies on air-filled polymeric microcapsules by multivariate analysis. K Bjercknes, J Undheim Braenden, G Smistad, [I Agerkvist](#). *International journal of pharmaceutics* 257(1-2),1-14 (2003)
11. Micro-organisms in medicinal gases. A Lofter, B Wesen, I Fält, L Hamilton, [I Agerkvist](#). *Pharmeuropa* 14.1, 59 (Jan 2002)
12. A novel B-domain-deleted recombinant factor VIII expressed in a human cell line. H Sandberg, [I Agerkvist](#), E Lindner, K Martinelle, S Winge. *Journal of Thrombosis and Haemostasis* 2007; Volume 5, Supplement 2, P-T-027
13. A Novel Recombinant Factor VIII Expressed In a Human Cell Line. H Sandberg, [I Agerkvist](#), E Lindner, K Martinelle, S Winge, C Cordula, M Dadaian, S Sebring, S Stenlund. "Hämostaselogi im Kindes und Jugendalter" der Gesellschaft für Thrombose und Hämostaseforschung (GTH), 2008
14. Properties of a novel recombinant factor VIII expressed in a human cell line. H Sandberg, [I Agerkvist](#), C Cordula, M Dadaian, S Sebring, S Stenlund. *World Federation of Hemophilia (WHF)*, 2008 World Congress
15. Manufacturing of the first human cell line derived recombinant FVIII. [I Agerkvist](#), K Martinelle, S Winge, T Åslund, H Sandberg. *53rd Annual Meeting of the Society of Thrombosis and Haemostasis*, Gesellschaft für Thrombose- und Hämostaseforschung (GTH), 2009, FC6-3
16. The product characteristics of human cell line recombinant factor VIII (Human-cl rhFVIII). H Sandberg, [I Agerkvist](#), M Ramström, S Sebring, P Stenlund. *53rd Annual Meeting of the Society of Thrombosis and Haemostasis*, Gesellschaft für Thrombose- und Hämostaseforschung (GTH), 2009.
17. Characteristics of the first recombinant factor VIII derived from a human cell line (Human-cl rhFVIII). H Sandberg, [I Agerkvist](#), C Kannicht, M Ramström, P Stenlund, U Oswaldsson, T Brunberg. *Journal of Thrombosis and Haemostasis* 2009; Volume 7, Supplement 2, PP-MO-574
18. The first human cell line recombinant factor VIII (Human-cl rhFVIII) – Functional properties and differences from currently available recombinant factor VIII products. H Sandberg, [I Agerkvist](#), C Kannicht, M Ramström, P. Stenlund, U. Oswaldsson, T Brunberg. *Blood (ASH Annual Meeting Abstracts)*, Nov 2009; 114: 1298
19. Product characteristics of human cell line recombinant factor VIII (Human-cl rhFVIII). H Sandberg, M Ramström, P Stenlund, C Kannicht, [I Agerkvist](#). *World Federation of Hemophilia (WHF)*, 2010 World Congress
20. Product characteristics of human cell line recombinant Factor VIII, (human-cl rhFVIII). H Sandberg, M Jonsson Ramström, P Stenlund, C Kannicht, [I Agerkvist](#). *55rd Annual Meeting of the Society of Thrombosis and Haemostasis*, Gesellschaft für Thrombose- und Hämostaseforschung (GTH), 2011, P02-13

PATENTS

1. STABILIZED COMPOSITIONS FOR RECOMBINANTLY PRODUCED FACTOR VIII, *Granted Patent*, EP 2337580 B1
2. NEW STABILIZING AGENT FOR PHARMACEUTICAL PROTEINS, *Patent Application*, WO 2011131720
3. A METHOD OF INCREASING THE PRODUCTIVITY OF EUKARYOTIC CELLS IN THE PRODUCTION OF RECOMBINANT FVIII, *Patent Application*, WO 2012156356

Projects

Memberships

PDA
ISPE

Other Relevant Information