

**PERSONAL INFORMATION** **Marjo-Riitta Helle****WORK EXPERIENCE**

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- February 2001-August 2006 **Quality manager / Pharmaceutical Production**  
University Pharmacy (Finland)  
QP activities
- June 1995-January 2001 **Consulting assessor / quality**  
National Agency for Medicines (Finland)  
Evaluation of marketing authorisation dossiers / quality
- September 1992-March 1994 **Laboratory manager**  
University Pharmacy (Finland)  
Quality assurance of the pharmaceutical production
- April 1988-December 1990 **Head of Department**  
Oy Leiras Ab (Finland)  
Tablet production
- April 1986-August 1987 **Qualified Person**  
KabiVitrum AB (Sweden)  
Parenteral production
- June 1980-September 1985 **Laboratory assistant**  
Leiras Oy (Finland)  
Quality control, Pharmaceutical production
- June 1982-August 1982 **Laboratory assistant**  
Astra Läkemedel AB (Sweden)  
Pharmaceutical development
- June 1983-August 1983 **Laboratory assistant**  
B.Braun Melsungen AG (Germany)  
Quality assurance / Infusions
- August 2006- Present **Head of Unit**  
Finnish Medicines Agency FIMEA (Finland)  
Marketing authorisations

**EDUCATION AND TRAINING**

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- January 1998-April 2003 **Licenciate of Pharmacy**  
Helsinki University (+ Danish School of Pharmacy / DK) (Finland)  
Industrial Pharmacy
- August 1981-November 1985 **Master of Science (Pharm.)**  
Helsinki University (Finland)  
Pharmaceutical Chemistry (main), Pharmaceutical Technology (second)

## ADDITIONAL INFORMATION

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**Expertise** Pharmaceutical Quality Assurance, Pharmaceutical Chemistry, Pharmaceutical Technology, Industrial Pharmacy, GMP, Marketing authorisations, leadership

**Publications** Helle, M-R, Yliruusi, J. and Mannermaa, J-P. , 2003, A Literature Review of Pharmaceutical Process Validation, Pharm.Technol.Eur., 15(3), 52-57.  
Helle, M-R., Reijonen, M. and Mannermaa, J-P., 2003, Using a Delphi Survey to Assess the Value of Pharmaceutical Process Validation, Part 1: Survey Methodology, Pharm.Technol.Eur., 15(4), 43-48.  
Helle, M-R., Heinämäki, J. and Mannermaa, J-P., 2003, Using a Delphi Survey to Assess the Value of Pharmaceutical Process Validation, Part 2: Expert Opinions, Pharm.Technol.Eur., 15(8), 21-30.  
Helle, M-R., 2004, To Outsource or not to Outsource?, Pharmaceutical Outsourcing Decisions, PriceWaterHouseCoopers, London 2004, 81-83.

### Projects

**Memberships** Finnish Pharmaceutical Association 1985 -  
Association of Physical Pharmacy / Finland 1989-

### Other Relevant Information