Siri H. Segalstad
Curriculum Vitae

Date of Birth: 14th March 1954
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Qualifications

- **Oslo Tekniske Skole / Oslo Ingeniørhøgskole:** Degree in Chemical engineering and analytical chemistry
- **University of Cambridge:** Proficiency in English
- **IQA-IRCA:** TickIT auditor exam
- Approved auditor for Norwegian Accreditation (ISO 45001 / 17025 / GLP)

Job History

From 1995	**Segalstad Consulting (from 1997 Segalstad Consulting as)** Principal
1987 - 1995	**Nycomed Imaging AS (Pharmaceutical company – currently GE Health)** Analytical engineer in R&D lab 1987 - 1990 Quality Assurance Associate R&D 1990-1995 Application manager for chromatography and LIMS systems 1989-1995 Quality assurance of computer systems 1990-1995
1986 - 1987	**Project, Ullevål Hospital** Analytical engineer
1983 - 1986	**Norwegian YMCA Scouts** Clerical officer
1980	**Pennsylvania State University, USA** Dept. of Geosciences, Analytical Engineer
1976 - 1978	**University of Oslo** Department of Geology, Analytical Engineer

Key Experience

Siri Segalstad has over 15 years of experience working as an analytical chemist and engineer, including 8 years of experience in one multinational pharmaceutical company. From 1989 to 1995 she worked as an application manager for the chromatography- and laboratory information management (LIMS) systems, and with quality assurance where she has been responsible for the quality assurance of information systems.

She formed Segalstad Consulting AS in 1995, which is an independent company working with quality assurance and validation, specializing in applying different standards, including 21 CFR Part 11, to various computerized systems, and with all aspects of IT projects, implementation and validation. Since the start of her company she has been involved in many LIMS projects, and also in many validation activities for LIMS, chromatography systems, MRP systems, Document Management Systems, clinical and non-clinical protocol-driven systems. She is also involved with suppliers for implementation of Part 11 and quality management systems.

Experience as an employee in Nycomed 1987-1995 (Currently GE Health)

Quality Assurance: As an employed quality assurance associate with background in analytical chemistry and information systems Siri took active part in developing the quality systems in these fields for Nycomed. She has performed numerous first and second party audits. She had the responsibility for interpreting the GMP/GLP/GCP and ISO 9001 standards for quality assurance of information systems within the company she worked for, and she developed the strategies and internal requirements for the handling of such systems. This included writing Standard Operating Procedures (SOPs) for all phases of the system life cycle, and subsequent training of personnel.

Application manager LIMS and Chromatography system: As an application manager for the chromatography and LIMS systems she developed these information systems to suit the needs of the laboratories, first within the R&D, and later including three different production sites in 2 countries. She wrote the company's LIMS handbook (approximately 250 pages), first in Norwegian and later updated and translated into English. She regards training as a major road to a successful implementation, and developed her own training program for new users. She gave nearly 40 2-4 day training classes. The training efforts were acknowledged by the company by awarding her the Education Award 1991.

Relevant consulting practice

Knowledge
Siri has extensive knowledge of quality standards like Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Clinical Practice (GCP), 21 CFR Part 11, and relevant ASTM, IEEE and ISO standards. She has specialized in quality assurance / validation of computer systems. She has passed her TickIT auditor exam for ISO 9001, which utilizes the ISO 90003 guideline for developing and manufacturing computer programs. Siri is an approved auditor for Norwegian Accreditation, in the fields of EN 45001 / 17025 and GLP in the pharmaceutical industry.

Consulting
Siri has headed system project groups for new applications in several companies. This includes writing the user requirements specifications for operations and quality, evaluating supplier answers, supplier audits, in-house testing of systems, implementing systems, and training new users. It also includes complete system validation, which comprise creating validation plans, executing these plans, writing reports, and creating the standard operating procedures for ongoing validation activities. She has been working mostly in the highly regulated pharmaceutical industry and pharmaceutical supply chain, including medical devices, but also in other industry like computer system suppliers, oil, hospital, metals, logistics, and accredited laboratories.

Classes and conference papers

Siri has given papers at several international conferences, and has written many publications on the issues. This has been acknowledged by receiving more invitations to give presentations in other conferences, seminars, classes, and training courses in over a dozen countries in three continents over the past years. Siri was the appointed Program Chairman for the 11th International LIMS conference held in The Netherlands June 1997. She was an invited speaker and teacher at Pittcon 1997, 1999, 2001, 2010 and 2011. She has given several classes on computer validation, 21 CFR Part 11, supplier audits, and LIMS issues at various conferences, as internal training in companies, as well as independent classes open to the public.

Standards Organizations

ASTM: Siri was a member of the American Standards of Testing and Materials (ASTM) from 1994 to 2002 where she took active part in developing standards for LIMS and LIMS Validation.

GAMP Nordic: She has been a Steering Committee member of GAMP Nordic since it was formed in 2002, and has taken part in creating and assessing position papers and guidelines through various Special Interest Groups.

Consulting experience

Norwegian Chemical Supplier No. 1 1995 and Norwegian Chemical Supplier No. 2 1996
Total quality management system: Written all parts of the TQM comprising quality manual and SOPs, covering all aspects of quality of products and service, and legal requirements from the Working Environments Act.

Royal Pharmaceutical Society of Great Britain 1995, 1996, and 1997
Teaching team for 3-day classes in "Practical Computer Validation".

Swedish Pharmaceutical Company No. 1 1995
LIMS: Written User Requirements Specification (URS) for a new LIMS.

Swedish Pharmaceutical Company No. 2 1995-98
- *Computer Systems Validation Handbook*: Reviewed and suggested corrections.
- *LIMS:* Supplier audit, co-project leader for implementation, responsible for SOPs and validation.
- *Clinical system 1*: Supplier audit, SOPs, validation.
- *Clinical system 2*: Retrospective validation. Supplier audit.
- *Chromatography system*: Prospective and retrospective validation. Supplier audit.
- *1 day seminar*: Quality assuring the IT systems according to GMP and GLP.
- *Internal audits* of several types of IT systems' validation protocols, validation documentation and reports.

Swedish Pharmaceutical Company No. 3 1995-96
- *Chromatography system*: System validation and SOPs, 3 Supplier audits.

Swedish Medical Device Company No. 1 1996-99
- *2 x 1 day seminar*: Quality assuring the lab computer, and what standards to apply in this industry
- *2 short seminars:* What is LIMS, *and* Quality Assurance for an IT department
- *LIMS*: 2 Supplier audits, implementation, validation, SOPs

Swedish Pharmaceutical Company No. 4 1997-98
- *LIMS*: Implementation, validation, SOPs

Swedish Pharmaceutical Company No. 5 1997-98
- *LIMS*: Assessment of Supplier replies to URS, Supplier audit, validation and SOPs
- *2 day seminar*: Validation of LIMS in the pharmaceutical industry

Norwegian Pharmaceutical Raw Material Company No. 1 1997-98 and 2000-2001
- *Seminar*: Validation of computer systems
- *SAP*: Supplier audit
- *LIMS*: URS, in-house test plan, Supplier audits

Danish Pharmaceutical Company No. 1 1998-2003
- *LIMS* Project team member with 50% time for nearly 2 years: URS, in-house test plans, quality/validation plan, Supplier selection, SOPs, system validation, implementation & qualification of static data in system.
- *3 Seminars:* 21 CFR Part 11 & Validation of LIMS, tailored to the company's internal requirements and the chosen LIMS
- *Toxicology LIMS:* URS, assessing Supplier answers to URS, validation plan
- *Drug analysis LIMS:* Assessing documentation
- *21 CFR Part 11 project:* Checklists, class, assessment of approx. 30 systems with action suggestions
- *Batch documentation management system:* Validation plan

Norwegian Governmental Agency No. 1 1998-1999
- *Seminar*: Validation of LIMS in the EN 45001 accredited environment
- *LIMS:* implementation, validation, Standard operating procedures (SOP)

Norwegian Accreditation 1998
- *Seminar:* Year 2000 problem in the accredited laboratory

Norwegian Pharmaceutical Company No. 1 1999-2001
- *LIMS:* Feasibility study
- *MRP:* URS, Supplier audit

Norwegian Pharmaceutical Company No. 2 2000
- *Seminar:* LIMS project and system validation
- *LIMS:* Quality/validation plan

Swedish Medical Device Company No. 2 2000-2002
- *Seminar:* LIMS project and system validation
- *LIMS:* URS, assessment of Supplier answers, Supplier audit, leading the validation process
- *Class:* LIMS validation, 21 CFR 11 and GMP requirements

Norwegian Pharmaceutical Company No. 3 2001-2003
- ***Short seminar:* 21 CFR Part 11**
- *Class for 100 employees:* 21 CFR Part 11
- *Workshop:* LIMS validation, status and plans
- *2 day workshop:* validation of computer systems used in production and laboratories, special emphasis on instruments
- *Maintenance software:* Validation

Finnish LIMS Supplier No. 1 2001-2002 and 2005
- *Seminar for their user group 2001:* Validation of LIMS, requirements according to various standards
- *Review of their LIMS system and service:* Assessment according to 21 CFR Part 11, GMP and ISO 17025

- *2 Seminars for their user groups 2002:* Electronic signatures and electronic records
- *1 seminar for their user group 2005: Validation of IT systems*

Open Classes Norway 2001
- *21 CFR Part 11:* Interpretation of the regulations, and practical implementation
- *Validation of IT system:* Which activities are included, and how to handle them

Open Classes Finland 2001
- *21 CFR Part 11:* Interpretation of the regulations, and practical implementation
- *Validation of IT system:* Which activities are included, and how to handle them

Swiss Pharmaceutical Company No. 1 2001-2002
- *Chromatography system:* Supplier audit
- *LIMS system:* Supplier audit, OQ protocol / plans
- *MRP system:* Supplier audit

Norwegian Pharmaceutical Company No. 4 2001
- *Documentation system:* Supplier audit

Norwegian Medical Device Company No. 1 2001
- *Medical device:* OQ/PQ plan, testing and report

Norwegian Pharmaceutical Company No. 5 2001
- *MRP system:* Supplier audit
- *Internal audit of IT systems and their handling according to GMP, 21 CFR Part 11 and internal quality system*

Norwegian Pharmaceutical Company No. 6 2001 – 2006
- *QA system top level:* SOPs for IT systems, plus review and rewriting later on risk-based approach
- *Acting as QA manager for IT systems for 1 month 2003*
- *Document Management system:* SOPs and 21CFR11 status and test plans
- *SAP rollout:* Review of validation (IQ, OQ, PQ) documentation
- *Acting as Senior QA officer 50% for 6 months 2005:* Responsible for creating IT SOPs
- *ECTD:* Supplier audit and QA responsible
- *ECTD:* Supplier re-audit
- *Acting as QA officer 40% for 2 months 2006*
- *2 Supplier audits*

Norwegian Computer Systems Supplier No. 1 2001
- *Seminar:* Build in quality according to 21 CFR Part 11 and ISO 9000-3

Norwegian Pharmaceutical Company No. 7 2001
- *Internal audit of IT systems used for API production*

British Laboratory Instruments Supplier No. 1 2002
- *3 Seminars:* 21 CFR Part 11, and Validation of computer systems

Norwegian Medical Device Company No. 2 2002-2003
- *LIMS:* URS, SOPs, validation

Norwegian Governmental Accredited Laboratory No. 2 2002 – 2005
- *LIMS:* URS, validation

Norwegian Medical Device Company No. 3 2002 – 2003
- *21 CFR Part 11:* Interpretation, checklist, system check
- *21 CFR Part 11* inclusion of requirements in URS

Norwegian Pharmaceutical Producer and Supplier No. 1 2002-2004
Distribution system: Validation

GAMP Nordic 2002- now (in process)
- *Board member of GAMP Nordic, and Organizing committee and speaker at various meetings since 2002*

- *Participating in Position Paper on Validation of Building Management Systems (2005)*
- *Participating in project for updating GAMP 5 documents (2007)*
- *Leader Special Interest Group for Supplier assessments and cooperation (2009)*

US LIMS Supplier No. 1 2003
- *Key note speaker at Seminar:* Corrective Action – Preventive Action
- Report on functionality in LIMS versus SAP-QM

Norwegian Computer Systems Supplier No. 2 2003
- *Seminar:* Build in quality according to 21 CFR Part 11 and ISO 9000-3
- *Assessment of their system for technical compliance with 21 CFR Part 11.*

German Pharmaceutical Company No. 1 2003
- *LIMS:* Supplier audit and project audit

Norwegian Computer Systems Supplier No. 3 2003 - 2006
- Total Quality Management system

Norwegian Pharmaceutical Producer and Supplier No. 2 2003 - 2006
- Specification of LIMS functionality in existing MRP system
- Validation of MRP system

EU Leonardo da Vinci Project – Gent University, Belgium 2003 – 2006
- Creating a curriculum for a Masters degree in IT validation. In charge of 4 graduate courses.

Icelandic Pharmaceutical Company No. 1 2003 – 2004
- *LIMS:* Validation, SOPs

Norwegian / Belgian Chemical Company No. 1 2005
- *LIMS / PIMS:* Assessment of documents, recommendations of global vs. local systems

Norwegian Pharmaceutical Supplier No. 3 2006
- *Supplier audit*

Norwegian Oil Company No. 1 2006
- *LIMS / PIMS:* User Requirements Specification for R&D

Belgian Pharmaceutical Company No.1 2006
- *LIMS:* Independent reviewer of documents, presentation at project meeting

Danish Pharmaceutical Company No. 2 2006
- *Supplier audit*

Ecoman, United Arab Emirates, May 2007
- *5 day LIMS Class*

Hospital, Norway 2007-2012 (in process)
- *Building Management System:* Validation in new R&D Building
- *LIMS:* User Requirements Specification, Validation plan, Implementation, IQ-OQ-PQ plan, testing and reports, Validation report in Department of Cellular Therapy

US/EU LIMS Supplier No. 2 2008
- *REACH Directive Report:* Implications for LIMS

Norwegian Metal Industry No. 1 2008 - 2009
- *LIMS:* User Requirements Specification and assessment of answers from the suppliers, Validation plan, Implementation

Swedish Oil Company No 1 2008 - 2009
- *LIMS:* User Requirements Specification and assessment of supplier answers

Norwegian/Swiss Pharmaceutical Company No. 1 2009
- *Supplier audit:* GCP supplier

Norwegian/Danish Logistics Company No. 1 2009-2012 - ongoing
- *Supplier audits:* 2 GDP supplier audits
- *Warehouse Management System (WMS):* Validation plan / report, User Requirements Specification, OQ/PQ plan / testing and report, 10 SOPs
- *WMS: N*ew version revalidation

Norwegian Pharmaceutical Company No. 8 2009
- *Supplier audits:* 3 GCP supplier audits

Hogeschool Gent, Belgium, Academic year 2010-2012 (Ongoing)
- *Teaching class for Master's degree* "Quality Management Systems" (Curriculum created for the Leonardo da Vinci project, see above). 2010-2011
- *Teaching class for Master's degree* "Quality Management Systems - Validation" (Curriculum created for the Leonardo da Vinci project, see above). 2012

Ecoman, United Arab Emirates, October 2010
- *5 day ISO 17025 Class (Laboratory Accreditation standard)*

Latvian pharmaceutical company, 2011-2012
- *1 day class on What is LIMS?*
- *LIMS: User Requirements Specification*

Veterinary University, Norway, 2011-2012
- *2 day class: How to handle LIMS within the ISO 17025 accreditation standard*
- *Internal audit if implemented LIMS*

Danish Pharmaceutical company No 3 2011
- *LIMS Validation: Internal audit of validation documents*

Ecoman, Malaysia, 2012
- *5 day LIMS Class*

Publications

BOOKS:

Segalstad: Agility 1-2-3, Book 180 pages, ISBN 978-82-529-3365-9, Tun Forlag *November 2011*

Segalstad: International IT Regulations and Compliance, Book 344 pages, ISBN 978-0-470-75882-3, Wiley-Blackwell, *October 2008*.

PAPERS:

Segalstad, Kierulf, Langseth-Manrique, and Storstein: Free Digitoxin in Normal and Albumin-Deficient Serum as estimated by Centrifugal Ultrafiltration, Clinical Chemistry 4 (1988) 766-777.

Segalstad and Synnevåg: A practical guide to validating LIMS, Laboratory Information Management 26 (1994) 1-12 (Tutorial).

Segalstad: Quality Assurance of Computer Systems What is needed to comply with ISO 9000, GMP, GLP, and GCP?, Laboratory Automation and Information Management 31 (1995) 11-24.

Segalstad: Quality Assurance of Computer Systems Compliance with GMP, GLP, GCP and ISO Standards, LIMS Letter Vol II - Issue I, Spring 1996.

Segalstad: LIMS 95 - LIMS 1995 - A delegate's view, Laboratory Automation and Information Management 31 (1995) 151-153.

Segalstad: Vendor audits for Computer Systems: An ISO 9000-3 approach, Laboratory Automation and Information Management 32 (1996) 23-31.

Segalstad: Validation of computer databases for GxP. Chapter in book Good Research Practices, edited by Nigel Dent, Butterworth and Heineman (1996) 475-485.

Segalstad: Book review, Laboratory Automation and Information Management, 1996.

Segalstad: Supplier Auditing and Software, European Pharmaceutical Review Vol. 1 Issue 3, (1996) 37-44.

Segalstad: Quality Assuring the Laboratory Computer - keeping it in compliance. Proceedings from 18th Nordic Conference on Measuring Techniques, November 1996.
Segalstad: Outsourcing work in the pharmaceutical industry - a challenge to quality, European Pharmaceutical Review Vol.1 Issue 4, (1996) 59-63.
Segalstad: Validation Issues Update, LIMS/Letter Spring 1997, 6-7.
Segalstad: Can You Rely on Your Information Technology, Inside Laboratory Management, Vol. 1 No. 4 (May 1997) 16-17.
Segalstad: Kvalitetssikring av laboratorier - Ufullstendig uten validering av IT-systemer. (Quality assurance of laboratories - incomplete without validation of IT systems), Kjemi 8, 1997, 16-18.
Segalstad: Software validation according to EU GMP Annex 11, European Pharmaceutical Review, Vol. 2 Issue 4, (1997) 55-64.
Segalstad, Florén, Nilsson: Choosing and installing the right LIMS, Scientific Computing World, Issue 39 June 1998, 25-26. (Re-written by the journal's editor without authors' approvals)
Segalstad: År 2000-problemet: Datakaos slett ikke umulig (Year 2000: Data chaos not inconceivable), Kjemi 6, 1998, 11.
Segalstad: LIMS: M is for Management, Process Information Technology, June 2000 54-56.
Segalstad: The WWW (Who-Why-What) of 21 CFR Part 11 Electronic Records and Electronic Signatures, European Pharmaceutical Review Vol. 5 Issue 2 (2000) 69-74.
Segalstad: The User Requirements Specification – The most Important Tool in the Validation, Scientific Computing and Instrumentation, Fall 2000 (24-25)
Segalstad: Development Qualification: Selecting the right LIMS vendor, European Pharmaceutical Review, Vol. 5 Issue 4 (2000) 58-61 *Also published in:*
American Pharmaceutical Review, Vol. 3, Issue 4 Winter 2000-2001 (84-87)
Segalstad: Instrument validation, Managing the Modern Laboratory Vol.5 No.3 2001 (57-61)
Segalstad: Elektroniske data og elektronisk signatur, (electronic data and electronic signatures) Kjemi, April 2001 (9-12)
Segalstad: Arvelighet av pelsfarver hos collie (Heredity of fur colors in the collie dog), Norsk Collieblad No.1, 2002 (60-64). Also revised and published in "Compendium for judging the collie", Norwegian Collie Association, 2002.
Segalstad: How to use and misuse a consultant, Scientific Computing LIMS Issue January 2003 (14-19)
Segalstad: Testing for technical compliance with 21 CFR Part 11, International Validation Technology, August 2004 (342-350)
Segalstad: Laboratory Information Management Systems - LIMS, 5000 words in Marcel Dekker's Online encyclopedia, Marcel Dekker Publisher, Contracted paper 2004
Segalstad: Risikovurdering og risikohåndtering (Risk assessment and risk management), Kjemi 4, 2004
Segalstad: Hvilken LIMS skal vi velge? (Which LIMS shall we choose?) Kjemi 7, September 2004 (10-14)
Segalstad: Contributor to GAMP Special Interest Group position paper: Use of Building Management Systems and Environmental Monitoring Systems in Regulated Environments, Pharmaceutical Engineering, September / October 2005 (28-78)
Segalstad: Pharmaceutical Standards for Computerized Systems. ISPE Pharmaceutical Engineering March-April 2007 (94-101)
Segalstad: Contributor to GAMP5 chapter on Testing, 2008
Segalstad: Standards for LIMS. Scientific Computing and Instrumentation January 2007 (1-2 and 19-24)
Segalstad: International IT Regulations and Compliance, Book 344 pages, ISBN 978-0-470-75882-3, Wiley-Blackwell, October 2008.
Segalstad: The Many Ways of Implementing LIMS But are some Ways better than Others? American Pharmaceutical Review, February 2009 (28-31)
Segalstad: Which LIMS is the best? Scientific Computing and Instrumentation May/June 2009 (6-8)
Segalstad: Do we really understand risks? Scientific Computing and Instrumentation July 2009 http://www.scientificcomputing.com/article-in-Do-We-Really-Understand-Risks-071009.aspx
Segalstad: Quality Assurance and Quality Control. Scientific Computing and Instrumentation. July 2009 *http://www.scientificcomputing.com/article-in-quality-thinking-072809.aspx*
Segalstad: Use of consultants. Scientific Computing and Instrumentation. *July 2009.*
Segalstad: IT Supplier Audits for the Regulated Industries, Computer Validation Digest *July 2009*
Segalstad: Instrument qualification, Scientific Computing and Instrumentation. *July 2009.*
Segalstad: What does a LIMS really cost? Scientific Computing and Instrumentation, *September/October 2010* (6-8)
Segalstad: Data management consideration for the environmental lab. Scientific Computing and Instrumentation, *March 2011*, (6-9)
Segalstad: Validation of IT systems. Scientific Computing and Instrumentation (Submitted March 2012)

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