CONSULTANT PROFILE SUSAN BALLEGAARD
(LIFE SCIENCES ADVISORY)

Full Name:
Susan Agerholm Ballegaard

Title / Role:
Director | Quality & Regulatory Advisor | Qualified Person (QP)

Areas of Expertise:

- Quality Assurance & GMP Compliance
- Qualified Person (QP) Oversight & Batch Certification
- Quality Management Systems (GMP, ISO 13485, ISO 9001)
- Regulatory Affairs & Authority Interaction
- Organizational Development & Quality Leadership
- Digital QMS & Process Optimization

Professional Summary:
Experienced life science leader and Qualified Person (QP) with more than 25 years of experience across pharmaceuticals, biopharmaceuticals and medical devices. Susan brings a strong track record in quality management, regulatory compliance and executive leadership, including establishing and scaling full value-chain life science businesses.

She combines deep regulatory expertise with a pragmatic and people-centered leadership style, enabling organizations to build robust, inspection-ready quality systems while supporting business growth. Susan has extensive experience working with regulatory authorities, leading GMP environments, and driving digital transformation of quality systems.

Key Competencies:

GMP Quality Systems & Compliance	QP Certification & Regulatory Oversight	Quality Oversight
Inspection Readiness & Authority Interaction	Deviation Management & Root Cause Analysis	Supplier Quality & Global Supply Chain Oversight
Digital QMS Transformation	Leadership & Organizational Development	

Industry Experience:

- Pharmaceuticals & Biopharmaceuticals
- Medical Devices
- Advanced Therapies (ATMPs)
- Regulatory Authorities
- Life Science Consulting

Selected Achievements / Project Experience:

- Established two full value-chain life science businesses, including QMS design, manufacturing setup, and regulatory approvals
- Led implementation of GMP-compliant digital Quality Management Systems and global quality processes
- Achieved manufacturing and importation authorizations and supported successful regulatory inspections
- Extensive experience in QP batch certification and release of investigational medicinal products (ATMPs)

Education & Certifications:

- MSc in Pharmacy, Royal Danish School of Pharmacy
- Project Management (Academy Level)
- Sustainable Leadership, Master Class
- Authorized Qualified Person (QP) – Danish Medicines Agency

Regulatory / Technical Expertise (if relevant):

- EU GMP (EudraLex Volume 4)
- EU Medical Device Regulation (MDR)
- ISO 13485, ISO 9001, ISO 17025
- ATMP and investigational medicinal products
- Regulatory submissions and marketing authorization support

Languages:

- Danish – Native
- English – Full professional proficiency
- German – Basic

Availability:

Available for project-based, interim, and advisory engagements
QP roles, quality leadership, and regulatory support

Location / Willingness to Travel:
Based in Denmark. Available for EU and global projects

Contact / Booking:

Email: sb@plenumconsult.com

Mobile: +45 26 81 12 22

LinkedIn: www.linkedin.com/in/susan-ballegaard-a4376338/