

# HIGH SUN GxP CONSULTING

## GMP Consulting & GxP Compliance Services

Transparent quality · Strategic Compliance · Regulatory expertise · Operational Excellence

### Personal Branding



**DI (FH) Klaus Hajszan**  
Founder &  
Qualified Person (QP)

### Who I Am and What I Stand For

**Profile:** Leadership and technical expertise across all areas of GxP management (QC, QA, QP, GMP/GLP/GCP). Interdisciplinary know-how for strategic concepts and practical implementation.

**Passion:** Quality is not an obligation but an opportunity. I view compliance as a competitive advantage that makes processes more efficient, safer, and more sustainable.

**Mission:** My goal is to align compliance, operational excellence, and business competitiveness to achieve long-term stability, sustainable growth, and measurable success.

### How I Work With You

**Empathetic:** I listen carefully, take perspectives seriously, and develop solutions on equal footing that build trust.

**Experienced:** I bring over 15 years of leadership experience in the life-science sector and possess solid regulatory expertise.

**Results-oriented:** I focus on pragmatic solutions instead of bureaucracy — efficient, inspection-ready, and delivering lasting value.

### Education & Professional Experience

- Bioengineering – Focus on Quality Management (FH Campus Vienna)
- University Program in Pharmaceutical Quality Management (University of Vienna)
- Over 15 years in senior leadership roles, including Quality Management, Quality Assurance, Quality Control, Test Site Management, and Trial Facility Management, as well as Authorized Representative and Managing Director.
- AGES-certified Qualified Person (QP) since 2012.
- Proven expertise in GMP compliance, audits, and project support from development to market authorization

### Services

HIGH SUN GxP CONSULTING provides tailored compliance services for the life-science industry.

- GxP Compliance Consulting (GMP, GLP, GCP, GCLP)
- Interim Management
- QP-Services
- GxP Audits & Inspection Support
- Regulatory Affairs
- Project & Process Management
- Training & Workshops
- Validation & Qualification
- Documents & Documentation
- Risk Management
- Change Management
- Operational Excellence

In addition, we offer individual services that we are happy to tailor to your specific needs in a personal discussion.

### Project Highlights (Selection)

- Implementation and harmonization of integrated GxP systems for analytical laboratories
- Organization of quality improvements across all company departments
- Representation of the company in > 100 customer and regulatory audits (incl. FDA, AGES, BASG)
- Design and implementation of an ISO 17025-compliant QMS from scratch
- Development of strategies for validation, transfer, and outsourcing
- Management of business expansions, mergers, and post-acquisition integrations
- Leadership in successfully extending operational licenses to include microbiological testing
- Obtained GLP certification for the facility
- Continuous improvement of quality, laboratory systems, and business processes

Contact us for a no-obligation initial consultation. Together, we'll strengthen your competitive edge.



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