HALFMANN GOETSCH A PARTNER G

Healthcare Industry Partners

HGP Asia

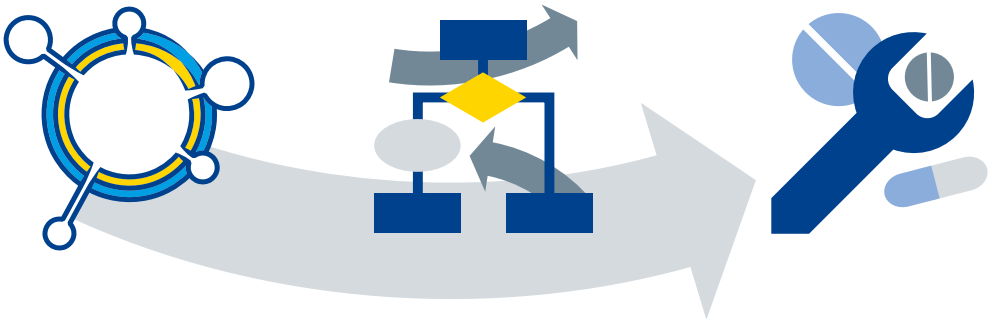
We speak Pharma, just like you.

About Us

HGP Asia is part of the Halfmann Goetsch Partner AG Consulting Group of companies. Based in Singapore we provide business consultancy services for all aspects of Manufacturing Operations Management for the Pharma, Medical Device, Biotech and related industries, focusing on pharma manufacturing, governance, risk and compliance. Our parent company is based in Switzerland, from which we have close working and personal relationships with the global headquarters of many of the world's leading pharmaceutical companies. These relationships and well-established networks give us the advantages of understanding our global objectives while we deliver our services locally.

Our Focus

PEOPLE — **PROCESS** — **TECHNOLOGY**



Our Goal

To translate your company's qualities into measurable success together with you and securing your position in the market place.

Our Vision

To achieve what appears impossible by making efficient use of human capital, technologies, lean processes and standardization – increasing quality while reducing costs.

Governance, Risk & Compliance

IT Quality and Management

- IT, Business and Quality partnership
- Creation and implementation of IT procedures
- Business process alignment and optimization
- CSV Management and Data Integrity assessments
- Digital Compliance Management for static and mobile solutions
- Regulatory audit preparation support
- IT audit readiness

Information Risk Management

- Governance, policy & strategy
- Secure architecture & infrastructure management
- Secure IT baseline
- Training and Awareness
- Data Integrity

Computer System Validation

- CSV audit: auditing the validation status
- CSV strategy: producing and implementing a validation strategy subject to the risk-based approach (GAMP 5)
- CSV implementation: implementing validation projects for IT systems, laboratory systems and automation systems.
- Cloud Validation: Cloud validation strategy, implementation and validation lifecycle management

Pharma Manufacturing

Technical and GMP Consulting

- Qualification and Validation
- Process development, optimization and troubleshooting
- Analytical method development and validation
- Validation life cycle management

Quality Risk Management

- Applying risk assessment tools (FMEA, FMECA, FTA, HACCP and HAZOP)
- Development and implementation
  of structured and customized risk management methodologies
- Risk management, mitigation and control process optimization

Supply Chain Management

- Workflow optimization
- Technical Project Management
- Cold chain process development and qualification

Paperless Manufacturing (MES / EBR)

- Analysis and design of processes that are GMP compliant and fit for MES
- Strategic planning of system roll-outs
- Integration into the existing IT landscape according to ISA-95
- Conception and conducting of trainings for specific user groups
- MES project implementation and project management
- MES recipe management and authoring

Product Safety (Track & Trace / Serialization)

- Project and Program Management
- System Qualification and Validation

Technology Transfer

- Technical consulting for process scale up
- Quality and compliance reviews and process development

Training

Our experts can customize training programs tailored to your organization's needs or contact us for one of our ready to go training modules including:

- Introduction to cGMP
- Introduction to Pharmaceutical Quality Management System (QMS)
- Introduction to Quality Risk Management
- Validation Lifecycle Management
- Introduction to Computer System Validation
- Deviation Handling and Root Cause Analysis (RCA)
- Managing Non-Conformances (NC) and Corrective and Preventive Actions (CAPA)
- Technical Writing
- Good Documentation Practice
- Quality Control Operations
- Data Integrity
- Good Laboratory Practice

What Makes Us Different

HGP Asia is a leader in addressing operational and project challenges.

- Team with excellent knowledge and understanding of pharmaceutical processes
- Broad experience and competence in applying a science and risk-based approach to address multiple operational and compliance challenges
- In depth understanding of technical and regulatory requirements and the ability to align these with client's business requirements
- Experience in successful delivering projects utilizing a range of project management methodologies
- Ability to successfully perform knowledge transfer to client following project completion
- We take a big picture approach, and all projects & assignments are delivered with a program to ensure quality of delivery

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