CONSULTANCY SERVICES

PCS offers a comprehensive package of services to assist you in achieving compliance with current Good Manufacturing Practices. In addition to our standard services, a network of experienced and reliable associates allows PCS to provide a number of specialised services, which include: business consulting, CSV consulting, interim management, microbiological services, project management, inspections and preparations for regulatory inspections and regulatory affairs, including the set-up of a Quality Culture based Quality Management System.

TRAINING, AUDITING, INTERIM MANAGEMENT AND CONSULTANCY

PCS was founded in 1990 with one simple mission: help companies struggling with GMP in achieving regulatory compliance. We have maintained this philosophy throughout the years. Our team consists of experienced, enthusiastic experts who share a common goal of making GMP easy to implement, maintain and comprehend. This allows us to think, operate and be different from other organizations.

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Self-Inspection & Auditing

Current GMPs call for a comprehensive programme of self-inspection and auditing as part of the Quality Management System.

PCS performs such audits against published GMP guidelines, both as part of pre-inspection preparations or as part of the ongoing self-inspection programme. In addition, PCS will carry out third party audits and inspections of suppliers, including APIs, excipients and other starting materials.
Quality Assurance

PCS will review, update or advise on QA and QM systems. If necessary, an entire QA concept can be developed; support can be provided for its implementation, maintenance and monitoring. In particular, PCS are able to assist in the preparation of Quality Assurance handbooks, which can be either custom-designed or modelled on the requirements of ISO 9000. Specific support for key QMS elements can be provided, e.g.

- CAPA
- Failure investigations
- Root cause analysis
- Managing deviations
- Change control

WHO Pre-Qualification

PCS assists pharmaceutical companies worldwide in achieving WHO Pre-Qualification and WHO approval.

Pharmaceutical Engineering Projects

PCS provides a full service from initial facility design, through project consulting, project management, installation and validation, all to recognised Regulatory requirements.

PCS can arrange for the purchase, installation and validation of pharmaceutical equipment.

Documentation

PCS advises on all aspects of control and manufacturing documentation. This includes the initial planning of a basic documentation system, through to actual preparation of documents required by the client.

FDA/EMA Approval

PCS performs pre-regulatory inspections and GMP upgrade trajectories for companies seeking FDA or EMA approval. PCS has experts worldwide who have practical experience in implementing these regulatory requirements.

(Sterile) Production Processes

PCS has significant practical, theoretical and Regulatory experience in the manufacture and control of pharmaceutical products. PCS has process experts helping companies worldwide.

PCS advises on equipment requirements, environmental matters, personnel training, process design and regulatory requirements.

Validation

PCS develops qualification programmes for all critical pharmaceutical equipment and installations, as well as process validation approaches to meet cGMP requirements.

PCS supervises the implementation of validation programs and provides practical support to complete the work in the most cost-effective and timely manner.
PCS Recent Clients:

• AMT (Amsterdam, the Netherlands), Interim QP from start up to Clinical Study Manufacturing for a biotech product.
• Serum Institute of India (Pune). Support in the design and construction and implementation of quality systems for 3 new buildings including 2 vaccines and one sterile finished dosage form. FDA Approved.
• Assistance during construction of Transgene TUP (Strasbourg, France). Design, project-support and start-up.
• Assistance in start-up and quality systems for Protein Sciences, (Meriden U.S.). FDA approved.
• Long term support for Boehringer Ingelheim IT, (Biberach, Germany). FDA approved.
• Long Term QA support for Roche (Mannheim, Germany). FDA approved.
• Phoenix Chemicals, (Bromborough UK). Support to API pilot plant from construction to production of clinical trial lots (for UK Ministry of Defense). To MHRA standard (EU).
• Acambis, (Cambridge U.S.) QA support in startup and operation of a vaccine manufacturing plant. FDA approved.
• Design Qualification of a Biotech Facility in South Korea.
• Bilthoven Biologicals, (Bilthoven, the Netherlands). Interim Quality System Management.
• Sovereign Pharma, (Gujarat, India). Design qualification of Sterile WFI facility. EU approved.
• Genibet, (Lisbon, Portugal). Design Qualification of a Biotech Manufacturing facility and QA support to Licensing (EU approved).
• China Vaccine Project, Design Qualification, QA support and training for 3 vaccine and biotech manufacturing plants in China.
Risk Management

ICH Q 8, 9 and 10 identify risk management as a key element of the QMS for the whole life cycle of a pharmaceutical product. PCS provides support in developing appropriate strategies for implementing risk management principles, both in Development and Manufacture. PCS has significant experience in the application of techniques such as FMEA and HACCP to pharmaceutical processes in order to establish acceptable risk profiles.

Contract Service Evaluation

The use of contract services, either for manufacture or testing, is increasing. Current GMPs place the responsibility for assuring the quality of such activities on the Contract Giver.

PCS evaluates contractors for compliance to GMP/GCLP and will provide an independent assessment of the quality of the services on offer from initial due diligence inspections through pre-award visits to compliance audits. This can also include establishing GMP compliant Technical and Quality Agreements.

Interim Management & QP Services

PCS has extensive experience in providing interim management and QP services for both multinationals and SMEs, both long term and short term, in various areas of expertise.

The PCS team

The PCS partners and associates include pharmacists, microbiologists, chemists, engineers and IT specialists with significant senior industrial and regulatory authority experience.

Training

PCS specialise in providing practical training on all aspects of GMP and Quality Assurance at all levels of the organisation.

With our experienced team of trainers, we develop custom made in house courses for operators, middle and senior management. Examples include; Quality Culture, Auditor Certification Programs, the Quality Management System, Risk Management, WHO/FDA/EMA Requirements and their Practical Applications and many more.