

GMP Compliance

*Industry experts in audit support
and compliance*



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Smart Consulting Group – Industry Experts in Audit Support and Compliance

GMP Compliance

Whether you need audit support or a comprehensive rebuild of your compliance program, Smart Consulting Group can provide you with the expert experience you need to meet your compliance requirements.

Compliance today is a growing challenge as the regulatory expectations and industry standards continue to expand and broaden both domestically and globally. That's why you need an experienced partner that has its finger on the pulse and is in touch with what the major regulatory authorities are thinking.

At Smart Consulting Group, we bring decades of experience in the development and manufacturing of drugs and other medical products.

To us, each client's problems are unique and our approach to this is to build client-specific consulting teams with a cross functional blend of skill sets that enable us to produce remarkable solutions that generate superior results.

Vision

Our teams are challenged to generate a wider vision of opportunities and possibilities while keeping a sharp focus on the specifics of the job at hand. The rapidly expanding medical products market is providing numerous challenges, but the bottom line is to establish a series of measures and practices that result in a state of sustainable compliance.

3 Stages of Lean Success

Our goal is always to produce sustainable, lean compliance solutions that are delivered on time and on budget. Our success results from your success, so to assure this we have developed a three stage approach to deliver measurable change.

Our approach involves:

- 1 program design**
- 2 customer driven program management**
- 3 use of process excellence tools**

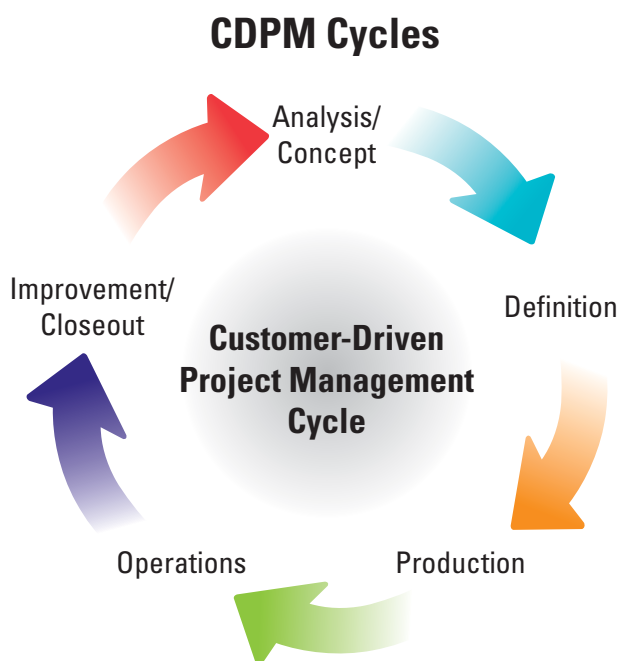


1 Program design

Working together with your team, or independently, we can craft an approach that will meet your compliance goals and match your timeline. We are very system-oriented and will apply the latest regulatory input to develop a winning formula that will provide the competitive edge to elevate you to market leader status. For example, through our innovative approaches to quality system design, use of risk analysis and risk mitigation strategies and quality by design philosophy, we develop gap analyses, and generate innovative workflows and execute work breakdown structures to produce sustainable lean compliance solutions that are delivered on time and on budget

2 Program management

Through our customer driven project management process, Smart Consulting Group integrates the vision of the program design with the practical execution of the multiple tasks involved in delivering the program to generate a seamless transition to the desired future state condition.



In the CDPM model, customer-driven teams go through five stages of project development.



3 Operational excellence

Using our innovative approach, together with good program management, the solution is generated by Smart Consulting Group to provide guaranteed success because of the application of process excellence tools at all phases of the program. These tools are assuring that our approach and solutions are always streamlined and efficient, in addition to being effective and compliant.

Some of the tools used in our process excellence program include, but are not limited to:

- Lean, six Sigma methodologies
- Cycle time reduction methodologies
- Risk analysis/mitigation strategies
- Quality by design

Our goal is to work smarter rather than harder to arrive at the future state.

Smart Consulting Group – GMP Compliance

Smart Consulting Group provides a full range of GMP compliance services including, but not limited to, the following:

- Quality system design
- Quality system strategy
- Quality system implementation
- Risk management analyses
- Statistical analyses
- Quality audits
- Vendor qualification program
- Vendor audits
- Internal audits
- Document systems change management
- Investigations at a specifications
- Corrective action preventative action
- Sample return policy
- cGMP training shadow coaching
- Electronic GMP systems support
- Documentum track wise LIMS
- Documents design
- SOPs.policy documents/validation
- Quality plans
- Quality agreements

Call us at **610-344-9218**
to discuss your program
requirements.

