Introduction

ScienTech is part of ScientiCal group, an international consulting, engineering and validation company providing a full spectrum of professional and field services, primarily to the Pharmaceutical industry based in Basel, Switzerland with proven expertise in providing integrated strategies and solutions throughout the product lifecycle in supporting Quality Management Organizations in their Quality, Compliance and Validation activities.

We have extensive and proven experience in all major Quality areas like Work Instructions & SOPs, Organization buildup (Quality Assurance, Quality Control, Audit & Inspection, Validation Department etc.) then Compliance (Change Management & Change Control, CAPA, Product Release etc.) and Validation (Process & Line Production Validation, Facility & Cleaning Validation, CSV etc.). We are dedicated to ensuring that quality of the task is executed to the highest possible standards.

GXP/GMP Compliance

Pharmaceuticals - Our GMP consultants can offer practical knowledge, based on a proven track record and experience on how to implement or enhance Quality Systems aligned with the EU/FDA GMP requirements and ICH Q10 / ISO 9001 for Pharmaceuticals. **S**cienti**C**al will work from a series of templates and past projects and quickly install Policies, Procedures, Work Instructions and Forms.

Pharmaceuticals GMP GAP audits / assessments and remediation plans.

Engineering Consulting Services

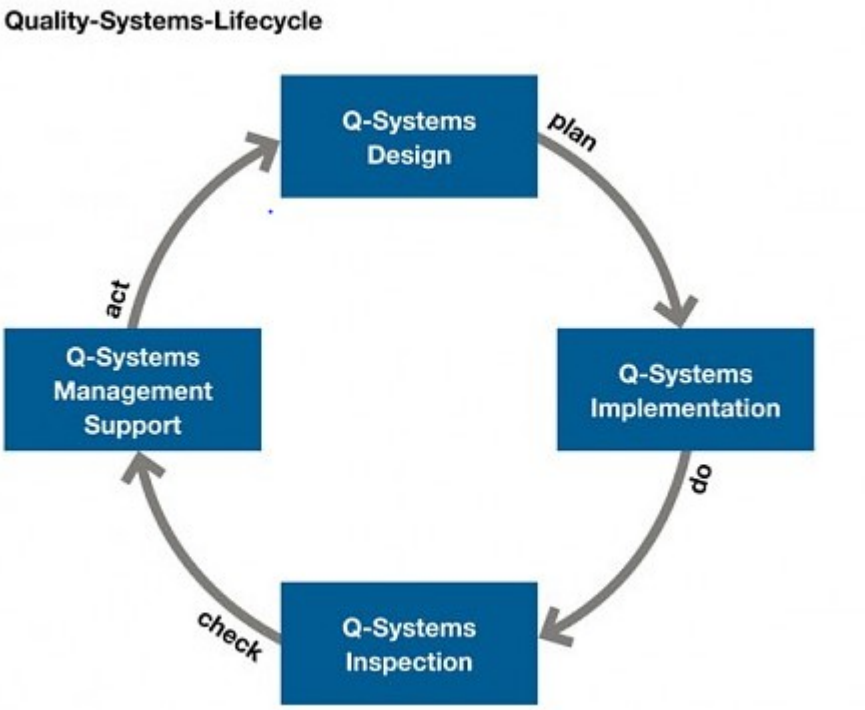
- We offer a wide range of engineering consulting services across the six stages of engineering projects.
- Our GMP and Engineering staffs are experts in facility and clean room design and classification. They will ensure that work done on clean rooms adheres to the correct standards helping to avoid costly mistakes.

Training to the Pharmaceutical, Medical Device & Veterinary industries

- We offer a wide range of Validation and GMP training.
- Our extensive range of training courses include GAMP® 5 training, ISO 13485 training and Q9 / ISO 14971 quality risk management training courses.

Quality Management Systems

ScientiCal experienced quality assurance and technical document writers can quickly write a quality management systems for virtually any industry sector and have written documents for the following industries - pharmaceutical, medical device, laboratories, research, pesticide testing and (oncology) compounding pharmacies to ensure GMP compliance.



Quality System Design

For pharmaceutical quality systems, the requirements of regulatory bodies on the one hand but also of company management on the other hand have significantly changed in recent years.

Quality Systems Implementation

Even well-designed quality systems have yet to be implemented and internalized.

Quality System Management Support

Your systems are running fine, in general. However, some important subjects will always drop out due to lack of time.

Do it yourself Templates

For smaller companies **S**cienti**C**al offers a starter set of Quality Management System templates for Pharmaceutical manufacturers; these documents include policies, procedures and forms commonly used within a manufacturing company.

These can be purchased and downloaded from this website by following the link to the right. In addition, there are sets of validation templates, mainly aimed at equipment qualification and computer system validation (GAMP 5) to be used in a pharmaceutical manufacturing application.

Occasional Expert Guidance

Using the templates above, or modifying exiting documents, our GMP Consultants and / or Technical Document Writers will redraft or only perform a final review.

It is critical to lay a solid foundation, before commencing a Quality Management System The development of templates, style guide, ensuring the appropriate review dates and control of the electronic versions of the documents should be determined before the QMS project is started.

Often, **S**cienit**C**al consultants and / or Technical Document writers provide assistance to multinational companies in enhancing systems and providing essential relief to busy line staff.

Turn-key solution

We strongly recommend that the company staff write their own Quality System Documentation, however often busy Quality Assurance professionals simply do not have the time to dedicate to "SOP writing". Our experience is that the project timelines slip as the line staff deal with other important and urgent priorities. Dedicated resources without this distraction ensure that project remains on target and within budget.

Our writers are professionally trained with great interviewing skills to ensure that the information is clearly, sequentially and logically laid out; and facilitating both training and operator. Their training includes looking for business process improvements ensuring that obvious productivity gains are included to the systems.

As our writers engage and work with site staff, we can discuss options and ensure that the alternatives are evaluated and the best operating practice is adopted; our writers can often draw on the depth of past projects in the office to get the best solution.

Industry solution

Pharmaceuticals

Scienti**C**al helps pharmaceutical manufacturers with EU legislations or FDA regulatory requirements.

Our services include:

GxP compliance consulting

We provide GMP compliance advice that is based on cost-effective and practical compliance, not just compliance without regard to business demands

GxP compliance contracting

If you are resource-poor and need experienced GMP professionals to get a job done or a project completed, then we can supply contractors with a range of GMP skills and knowledge. _

GMP Compliance Audits - Pharmaceuticals

If you have an impending audit, our auditors can do a mock audit to determine if you are ready or need to make improvements.

Audit findings responses

If you've just been audited, we can help you formulate your response to the regulator's audit or compliance report (CAPA Action)

Facility design reviews

Before you spend capital on new facilities make sure the design will make GMP compliance easy.

Supplier audits

Scienti**C**al offers a third party GMP audit service that allows several customers of a specific supplier to share the costs of an audit.

QMS development

If you need a new Quality Management System (QMS) or updates to an existing one, **S**cienti**C**al can provide the resources and expertise

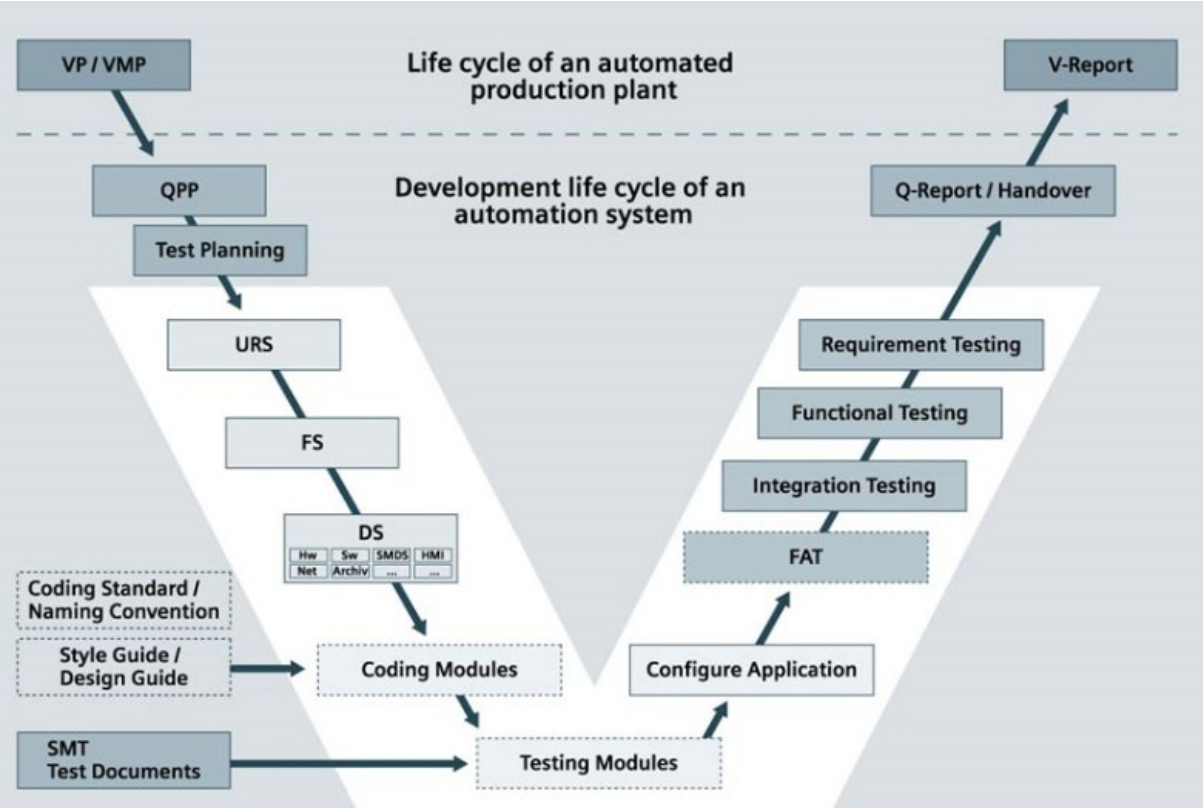
Pharmaceutical Process Validation Services

Pharmaceutical process validation according to the most recent regulations

Validation - Process, Equipment, Cleaning & Computer

- Pharmaceutical and Medical Device Process Validation to EU and FDA regulations.
- Pharmaceutical Equipment Validation to international regulatory standards and in accordance with current Good Manufacturing Practice.
- Cleaning Validation for pharmaceutical and medical device manufacturing facilities.
- Computer Systems Validation to FDA Part 11 regulations, EU Annex 11.
- Temperature mapping of warehouses and cold rooms.

We offer a full range of validation services, from cleaning validation and process validation to computer systems validation.



Validation V-Model

Validation Training

Scienti**C**al provides interactive team workshops and class discussions that focus on typical ways manufacturers prepare for and carry out process validations. Course participants will obtain hands-on practical application experience involving planning, execution, and reporting of process validation activities as part of the integrated requirements of a quality management system that meets FDA/EU and ISO requirements.

On-Site Support & Training

Scienti**C**al supports you in all aspects of GMP and Compliance with experienced experts and specialists from industry and regulatory bodies. Within our Life Cycle Management for Quality Systems we can support you in designing a modern Quality System or a single Quality Module like risk management.

Of course we also help with the implementation at the site. Using established Mock-Audit approaches we check and evaluate your systems prior to authority inspections. We help with set-up and implementation of CAPAs from QC-lab to (continued) process validation and guide you through the inspection, whether local or e.g. by FDA.

In any case of bottlenecks, be it subject matter specific or simply due to work load, we can support you with specialists for subjects like sterile production, GDP, PiP or interim management. The performance of your supplier qualification as 3rd party auditors completes our service portfolio.