Efficient Qualification – with SIQC (Smart Integrated Qualification Concept)

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SIQC is an intelligent, integrated concept for efficient qualification, which is needed today more than ever.

Despite, or perhaps because of, the Corona pandemic, the activities of the pharmaceutical industry have gained considerable momentum. Conversion or new construction in connection with the creation of production capacities for vaccines is at the top of the list. But it's not just about vaccines. It is also about the survival of the pharmaceutical industry in an increasingly fierce global competition, in which not only costs, but predominantly time play a decisive role. Namely, the time it takes for a successfully tested product to be manufactured and brought to market. This time span is made up of the planning and construction period as well as the final qualification of the manufacturing plant in compliance with the regulations.

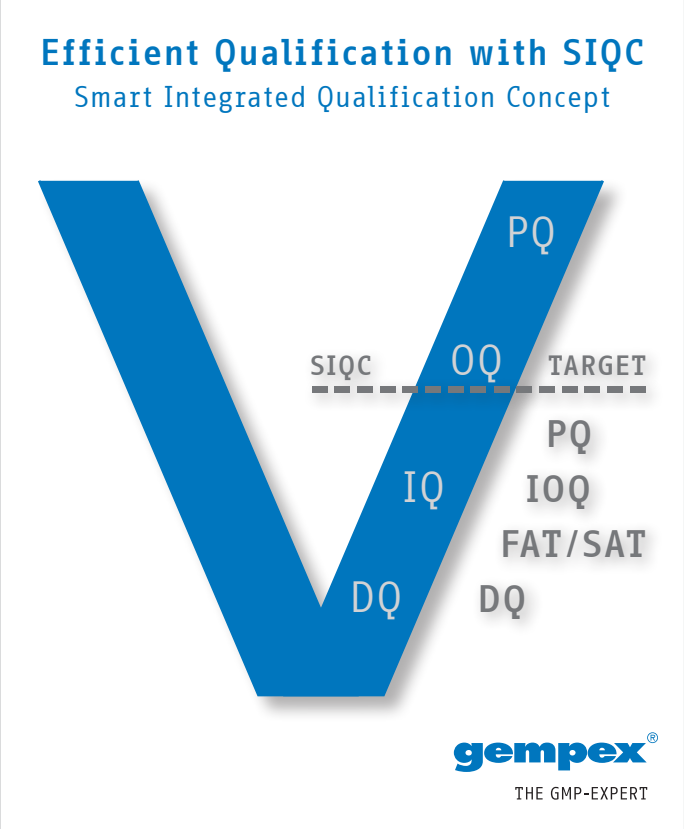
At the heart of the measures is qualification – an important quality assurance tool that has been required in the GMP-regulated environment for a very long time and is intended to ensure that technical equipment and systems are «suitable for their intended use». What sounds simple is actually quite complex, especially in the case of a new construction project, and involves a great deal of formalism, paperwork and testing. It is not uncommon for especially these activities to delay the final deadline and thus the timely completion of the manufacturing plant; often by several months. In many cases, however, this could be avoided, especially since the authorities have been working for years to ensure that the necessary activities are carried out in a flexible, targeted and selective manner (risk-based).

The solution lies in an intelligent and integrated approach, whereby «integrated» represents much more than mere «consideration»:

- Timely start together with the actual project initiation
- Project schedules that take into account all activities, including qualification, from the very beginning
- Early decision which technical systems will be qualified according to GMP and which will be technically accepted according to GEP
- Early decision on a qualification approach that relies on basic technical testing by equipment suppliers and engineers wherever possible
- Involvement of the suppliers in the risk analyses to be carried out at an early stage, in order to limit the qualification to the necessary content from the outset
- Qualification of the suppliers through training to be carried out at the start of the project; combined with timely review of the test documents from the supplier that are intended for use (FAT, SAT, commissioning tests)

In order to remain competitive, however, an integrated solution alone is often no longer sufficient. The combination with an «intelligent approach» creates the desired advantage. An intelligent system is characterized by the fact that the qualification documents created for the critical systems are simple, logical and clearly structured. Bloating the documents with lengthy definitions, explanations and duplications, combined with prettified tables, boxes and checkboxes, is inefficient and does not lead to the desired results. The number of reviewers and circulators should also be reduced to the experts and responsible persons who can and must have a say in the matter. Not every specialist department has to co-sign on the documents.

The focus of all activities is the quality of the plant. The documents are a means to an end and should be used in a pragmatic and targeted manner, as in the case of plant safety and environmental protection.



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The GMP experts at gempex have been dealing with this topic for more than 20 years. They know the tricks and pitfalls, especially those related to qualification. It is worthwhile to have a discussion about intelligent and integrated solutions before starting a project. An introductory workshop with all stakeholders before the start of the project can be a small step towards great success.

The journal «Die pharmazeutische Industrie» (pharmind), Editio Cantor Verlag für Medizin und Naturwissenschaften GmbH, Aulendorf (D), has published a four-part series of articles on «Basic principles of an effective and efficient qualification» (German language only). Author is Ralf Gengenbach.

gempex GmbH is an independent, internationally oriented service company specializing in consulting and implementation of GMP requirements in the life sciences industry. With a branch office in Sisseln, Switzerland, the GMP experts support leading companies – not only in the cross-border environment.

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