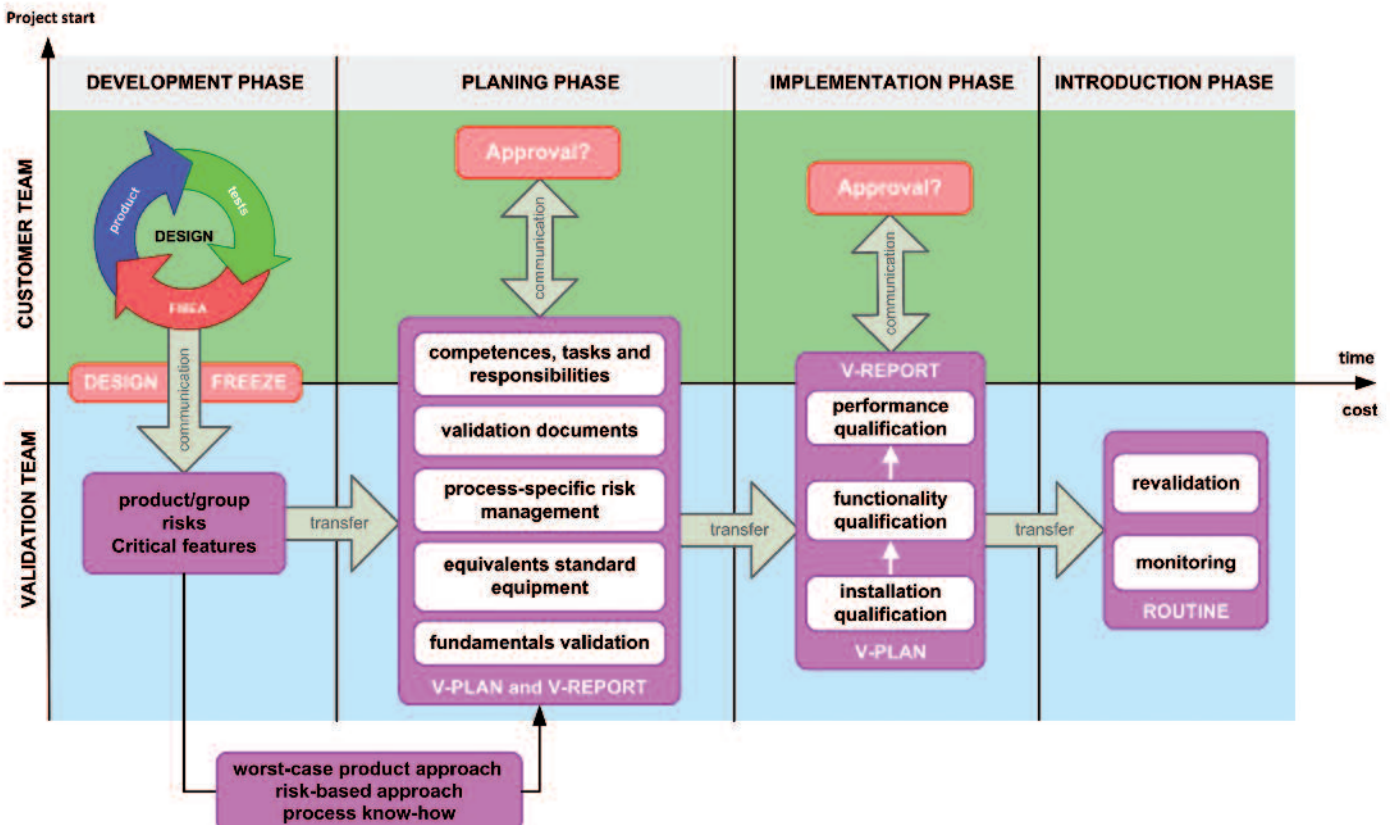
In this way, “process validation” in medicinal product manufacture is economical for everyone



An approach which is state of the art at SAMAPLAST AG.

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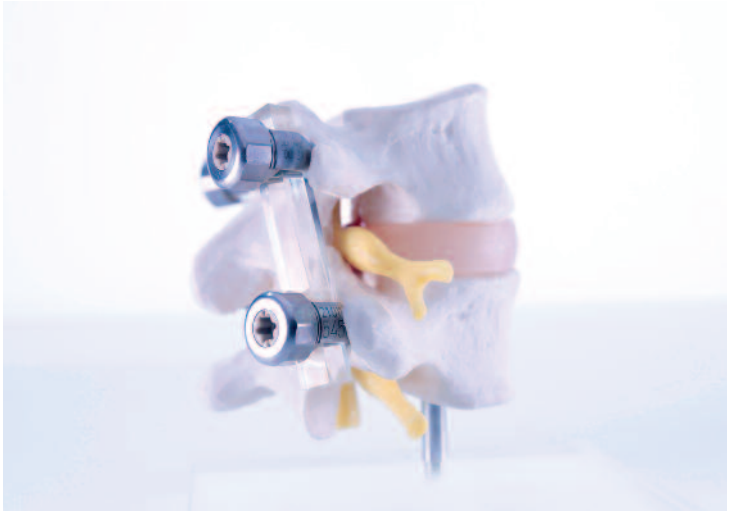
The sector is battling with this problem

Various laws and harmonised norms (e.g. MDD 93/42 EEC or 21 CFR Part 820) have to be adhered to in the manufacture of medicinal products . Here, a particularly important aspect is process validation, i.e. proof of suitability in the production of medicinal products for processes such as injection moulding, packaging (sealing) and gamma-sterilisation.

Experience has shown that the fundamental requirements are the creation of framework conditions such as the implementation of a GxP-environment, the qualification of the machines and facilities, the validation of the implemented software and the calibration of the respective instruments and measuring systems applied. In addition, personnel needs to have a high level of knowledge, significant experience and know-how and and an immense personnel expenditure is necessary.



Picture: medicinal product - Implant

The resulting problem that many medicinal product manufacturers have are the high costs which occur from process validation due to significant time, personnel and material costs. But who carries these costs? In most cases, the medical customer is not willing to pay the costs in their entirety which means that such costs are carried by the product itself. The consequence: price increases and reduced competitiveness.

Even today, there is neither guidelines nor a manual which regulates process validation economically and therefore keeps costs within limits. Therefore, the SMEs active in this field need to have a great deal of creativity and the will to innovate in order to develop economic and practical models for the adherence to standard requirements in process validation which result from the existing regulatory environment, i.e. laws and norms.

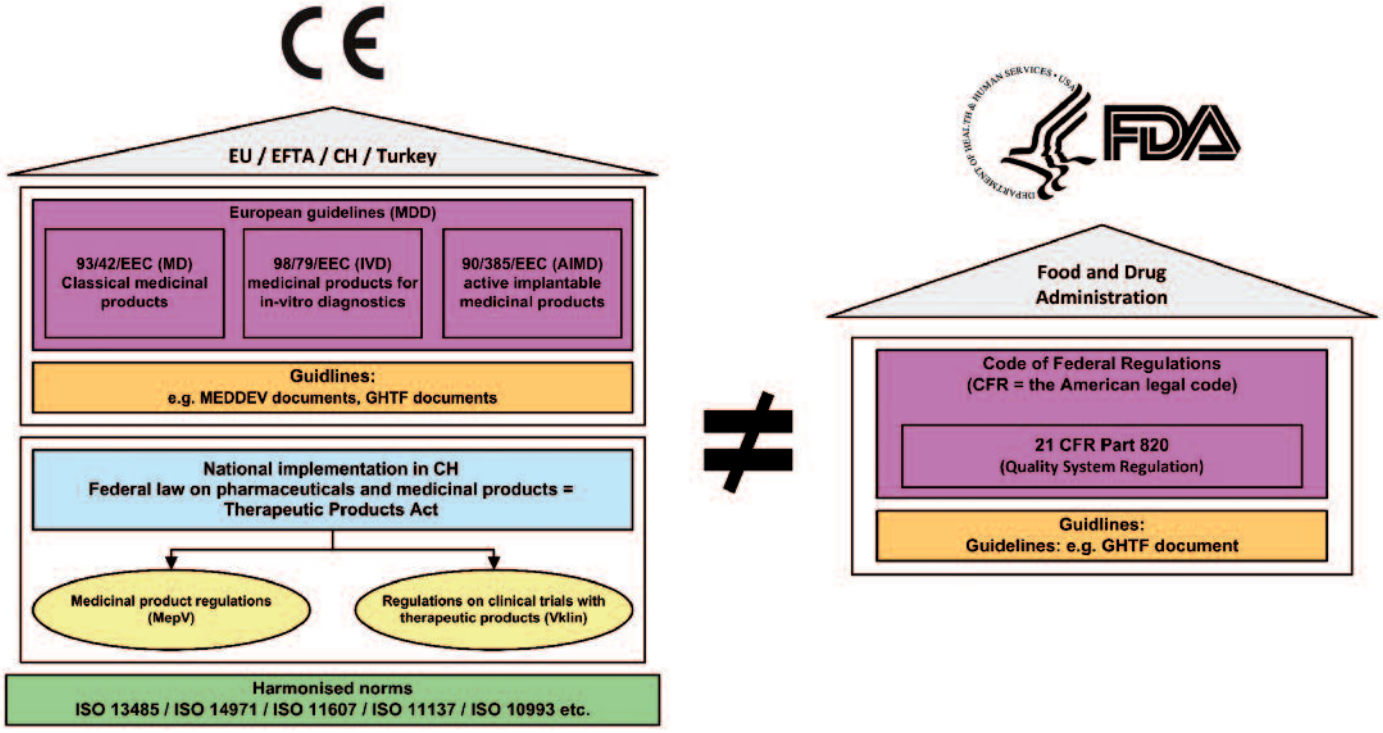


Figure: Legal basis EU and USA[1]

[1] from master thesis, An economic, practice-oriented approach for the implementation of standard requirements "Process validation" in medicinal product manufacture, Scheffknecht B., 2012.

This is how we solve this problem at SAMAPLAST AG

At this juncture, we can offer a solution: Based upon the objective that the validation of medicinal products has to be economical, the author of the study, Boris Scheffknecht, places the existing guidelines under a microscope and puts together a compendium which includes the legal requirements and norms. The study provides a representative overview of the must-criteria.

Subsequently, the practice was investigated in that numerous questionnaires were sent to customers, suppliers and renowned experts. A matrix was created using the analysis of current practices. This enabled the current situation to be visualised and made comprehensible.

In a further, decisive step, the author derived 15 starting points and divided his recommendations into general and process oriented parts.

Amongst other things, a standardisation of procedures and documents such as ergonomic templates or SOPs as well as the equipment – equivalence proof –, of the resources and materials is an indispensable precondition for particular economic efficiency. A further important step on the way to cost reductions for the customer are timely planning and communication – both external and internal – and a well-trained and experienced validation team which is – not only – working in this area.

Vital milestones on the way towards cost optimisation in project/product specific process validation is a timely design-freeze, the validation in process know-how, a risk based approach with the focus on patient risk, the criticality of the components or the process influences as well as a worst-case-product approach and the referencing on a fundamentals/basis validation.

In the final section of the paper, the potential for improved efficiency in relation to the phases for the process validation which lies in the development and planning phases is examined. If the company is already in the implementation phase or even in the introduction phase, then the opportunities for improvement are often gone. The following model, based on the insights obtained by this paper, illustrates an economic implementation of the process "injection moulding".

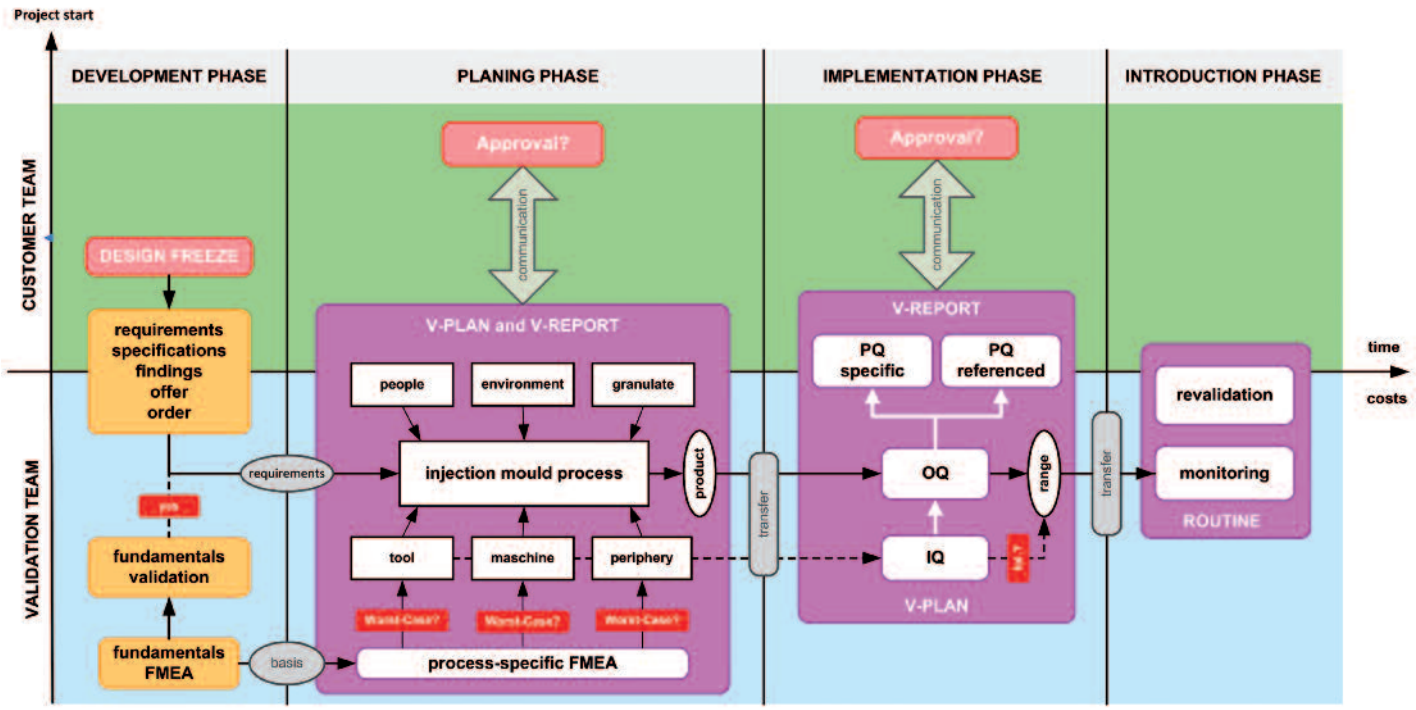


Figure: implementation model – injection moulding process[1]

SAMAPLAST AG
KUNSTSTOFFWERK

SAMAPLAST AG – Pioneer in the area of optimisation

SAMAPLAST AG has practised efficiency in the implementation of process validation for the benefit of its customers for many years.

It has already standardised the procedure and the documentation throughout and implemented ergonomic templates. The equivalence of the machines, facilities and equipment has been practised for a long time.

Planning and communication – both internal and external – takes place very early during the design phase of the medicinal product, beginning with the drafting of the offer and the implementation of design and process FMEAs working together with the customer.

A cross-process, well trained and experienced validation team is just as standard at SAMAPLAST AG as a longstanding, sound industrial process know-how especially in the injection moulding process, but also in follow- on processes such as e.g. packaging – sealing –, US-welding, adhesion, gamma-sterilisation, etc.

Picture: medicinal product

The list of the implemented starting points is supplemented with the application of the worst-case product approach in all processes and the referencing on a fundamentals/basis validation (see SAMAPLAST flyer 17) which has been implemented and applied in a risk-based manner on many occasions in the core competence injection moulding.

The knowledge gained with the master thesis, together with the experience already made at SAMAPLAST AG, enables us to offer all our customers a methodical foundation for the procedure of process validation. The result is always the same. Reliably high quality, time savings and enormous cost savings.

In this way, SAMAPLAST AG possesses a practical instrument to increase the efficiency of the process validation of medicinal products so that the customer can be saved time, money and worry. This is built upon standards which have been state of the art in our company for a long time.

You can benefit as a customer from this know-how!

Picture: cleanroom production