



Good Manufacturing Practice (GMP) Qualified for More Quality

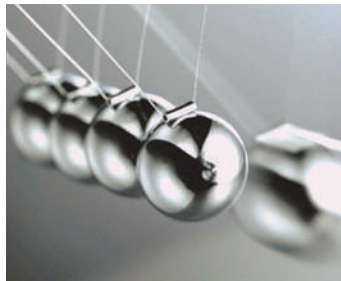
Quality can be checked on the finished product. However, Westfalia Separator Engineering becomes involved at a much earlier stage: We plan, produce, check and document your installation quality – right from the very beginning and right through to the smallest detail.

GMP – an abbreviation which stands for maximum requirements for a manufacturer or supplier. This is because the rules of “Good Manufacturing Practice” specify that the quality of a product must not be assured exclusively by means of a final check. Instead, GMP specifies that quality is monitored before, during and after the production process of your installation.

The focus is on detailed documentation of each relevant stage in the production process and every test which is carried out. In this way, it is possible to demonstrate that the design and execution of the installation are consistent with the previously defined documents.

Effective quality control

Westfalia Separator Engineering has set up a separate GMP team in order to meet these extensive and constantly changing requirements. The objective of our quality commitment is to



reduce the amount of qualification work for our customers and also to ensure that the customer's specifications are implemented in project processing in a manner which is as effective as possible and also in a manner which is consistent with cGMP.

Westfalia Separator Engineering accordingly provides you with most of the qualification work which is normally carried out by the client – a further example of the high added value of our services for you.

Your added value:

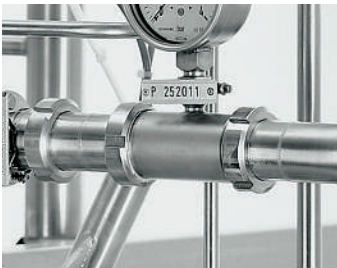
- Clearly defined processes
- cGMP conformity
- Ideal document management
- Constantly high product quality
- Delivery of a mainly qualified installation
- Minimum qualification costs



Production of Sterile Weld Seams Clean Performance

The pipework systems of hygienic or sterile installations pose particularly stringent quality requirements on weld seams. Westfalia Separator Engineering is your reliable partner for this task – because we ensure perfect connections everywhere.

As a result of our specially developed welding procedures, we guarantee constantly high surface quality, annealing colours and reproducibility – entirely without the use of welding additives. Chemical treatment of the weld seams which come into contact with products is thus no longer necessary.



We also guarantee continuous and pore-free quality of the seams. The know-how and experience of our specialist welders enable us to meet the quality requirements which are becoming more and more numerous. One example in this respect is our ability to guarantee a limited ferrite content, which we of course also document.

However, the ability to use orbital welding technology is not sufficient for this purpose. It is essential to be in a position to carry out weld seams in such a way that they meet the requirements of a sterile and compact pipework system with minimum dead legs. This requires manual welds in addition to orbital welds.

Your added value:

- Generally 100% endoscopy
- Complete weld seam documentation is possible
- Video documentation is possible (photos, videos)
- X-ray testing is possible
- Ferrite content measurement is possible
- Third party acceptance is possible

Your contact:

Ralph Desel
Phone +49 2522 77-2806
Fax +49 2522 77-3-2806
desel.ralph@gea-westfalia.de