GMP Design: Guidelines

1. Heat Exchanger Operation

1.1 Process Side

The heat exchangers must be operated so that surfaces coming in contact with the

- basic media
- in-process material
- final products or
- components thereof

are not

- reactive
- adhesive
- absorptive

in order to avoid changes in

- the security
- the identity
- the strength
- the quality or
- the purity

of the drug products that may result in license revocation or operation outside of the established rules and regulations.

1.2 Service Side

All auxiliary media e.g.

Cooling- or heating media

mustn‘t come into contact with the process media so that the a.m. properties of the drug products are not influenced beyond the allowable amounts.

2. Cleaning and Maintenance

2.1 Cleaning and Maintenance

Heat exchangers and the tools must be cleaned and maintained regularly to avoid

- faulty operation or
- contamination

relating to the a.m. characteristics.

2.2 Written Instructions

Written instructions for cleaning and maintenance must be provided and respected; these instructions must at least include

- Competence and Responsibility
- Plans for cleaning and maintenance
- Detailed description of the process and the (dis-) mounting
- Removal or destruction of preceding batch identification
- Protection of the cleaned heat exchanger against contamination
- Cleanliness inspection immediately before use
- Records of archived measurements