

Validation - New and Existing Facilities

Validation implications for new and ongoing operations are different and are considered separately.

New Facilities

For new capital projects validation activities come at the end of the construction and commissioning of the new facility. As a consequence these activities are on the critical path so that any reduction in validation effort will shorten the project timeline. Therefore using Sartorius Stedim Biotech Systems reduces the extent of cleaning and steam in place validation activities. This has two benefits:

- Reduced cost of validation
- Reduced timeline means that the plant can be up and running quicker

These costs are offset by validation of extractables from the product contact plastics used in the single-use disposables. These costs can be minimised by use of generic data and by careful bracketing of the validation studies for multi product facilities. In general the more extensive the use of single-use disposables the greater the potential savings.

Existing Facilities

In existing operations it is a regulatory requirement that the cleaning and sterilization regimes are revalidated at regular intervals. For many facilities this is carried out annually. Again by reducing the amount of cleaning and sterilization within a process, single-use disposables will reduce the extent of the revalidation requirements.