

# TUNING FOR SINGLE-USE EQUIPMENT

CUSTOMER-SPECIFIC AND GMP-COMPLIANT REFINEMENT



**BILFINGER**



Single-use or stainless steel – a choice you no longer have to make. Many companies would like to enjoy the advantages of both worlds, therefore setting store by hybrid solutions. However, this requires having the right partner as single-use solutions are not normally tailored to the customer's specific requirements. This is precisely what Bilfinger Industrietechnik Salzburg (ITS) offers with tuning for single-use equipment: It refines systems such as these to satisfy specific customer requirements and produce in a GMP-compliant way.

Single-use systems have become a fixed feature in biotech/pharmaceutical production operations over the past few decades. The shorter time-to-market over stainless steel equipment is viewed as a major ad-

## KEY FACTS

- Given their degree of standardisation, single-use solutions are often too rigid if customer-specific (company) standards need to be satisfied in a GMP-compliant production environment.
- Bilfinger tuning enables pharmaceutical and biotech companies to employ single-use equipment while at the same time maintaining their established (company) standards.
- Bilfinger tuning 'refines' the single-use equipment to reflect the customer's requirements, i.e. Bilfinger adapts single-use solutions to satisfy customer specifications and GMP requirements.
- Bilfinger ITS has decades of experience, with tried-and-tested engineering and fabrication methods in place to bring individual systems and individual solutions to life.

## Technologies

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vantage. Single-use technology may cost less and offers greater flexibility. There is no longer any need for cleaning and sterilisation steps with corresponding validation. Single-use equipment has since found its way into the entire process chain. Our customers also rely on it, for example, as the first step in the seed train for cell cultures. Single-use systems are integrated into stainless steel equipment (hybrid equipment) and incorporated into the equipment control system.

Single-use technology does have its limits however – especially when customer-specific (company) standards are involved.

## What works is customer-specific solutions with single-use components

Single-use equipment is highly standardised, and this is precisely what often causes the most problems when it comes to GMP-compliant production operations. This is because many pharmaceutical/biotech companies want to retain their established (company) standards even when employing single-use equipment and components used in production, such as valves or measuring instruments. It is however very rare for manufacturers of single-use equipment to support such customer-specific solutions because making such adaptations causes a high qualification effort for them.

In contrast, the core business of Bilfinger Industrietechnik Salzburg focuses on the engineering and fabricating of customer-specific equipment and systems. Our company specialises in creating individualised equipment and tailored solutions with a focus on the problem to be solved, possessing the requisite expertise together with tried-and-tested engineering and fabrication methods.

## Tuning for single-use equipment

Bilfinger tuning refines the single-use equipment for the customer's specific use, i.e. Bilfinger ITS adapts single-use solutions to satisfy customer specifications and GMP requirements.

Here is an example of a successfully customised system: A single-use downstream mixer tank based on single-use bags was retrofitted with state-of-the-art sensors, measuring instruments and control cabinet, as well as with pumps for dosing and with load cells – all in line with the company's in-house standard. It was also possible to refine certain aspects of the equipment itself (e.g. temperature measurement, insulation, lid). The tubing connections – often a vulnerable point in terms of safety in single-use systems – are fed through 'conduits', so-called tube supports, holding them properly and protecting them against breakage or bending. Managing the tubing in this way makes single-use systems more user-friendly and reliable.

With its tuning for single-use equipment, Bilfinger ITS has positioned itself as a problem solver when it comes to adapting single-use solutions to satisfy customer and GMP requirements in biotech and pharmaceutical production operations.

## Tuning for single-use equipment Examples of application



*Single-use bag in a single-use mixer tank skid. The secure way in which the tubing of the stainless steel skid has been managed improves the user-friendliness and reliability of the single-use components during operation.*



*Bilfinger has integrated control of the single-use reactor (in the foreground) into the PCS7-based control system of the entire plant. The connection was established and programmed via two interfaces: The reactor transmits process data (batch reports etc.) via a data interface, while basic functions of the reactor are centrally controlled (start/stop etc.) via a control interface.*



*Ultra-/diafiltration skid with an integrated bag holder skid and scale as well as customised boxes and lift for the product bags to be transported safely.*