

# cGMP AutoVessel™

## Automatic cGMP Vessel Systems



The Ultimate Versatile Vessel system providing repeatable, critical processing with Integrated Clean In Place and Sterilising In Place

### Overview

Following extensive client collaboration, we have developed a range of vessels, that can incorporate differing technologies and methodologies to provide the optimum solution to your process critical needs as well as an automatic Cleaning In Place and Sterilising In Place facility.

The resultant cGMP AutoVessel™ Systems provide an Automatic, Validatable, Verifiable, Versatile, customisable, Vessel system providing repeatable, critical processing, cleaning and sterilising.

Our cGMP AutoVessel™ systems are high specification units, built to comply with ASME BPE Bioprocessing Equipment with optional construction from alloys such as AL6XN and C22/C276 (Hastelloy), combining regulated biopharma automation systems, developed to comply with FDA 21 CFR Part 11 -- Electronic Records and Electronic Signatures.

Developed to the GAMP 'V' model (Verification and Validation), system life cycle approach, which links the three main qualification activities (installation, operation and performance) back to the design process with validation being key to every stage of the development process, including Factory Acceptance Testing (FAT), SAT and Qualification.

### Applications

- ✓ BioPharma
- ✓ Life Science
- ✓ Medical
- ✓ Research
- ✓ Critical Processing
- ✓ Custom Applications

### GMP Construction

- ✓ FDA approved components with no threads and triclamp connections
- ✓ ASME BPE 316L no dead legs, fully drainable, material & weld traceability
- ✓ GAMP5 Control and instrumentation
- ✓ Repeatable, validatable client configurable sequences
- ✓ Riboflavin proof of coverage

# GMP AutoVessel™ DATASHEET

VERSION 2.05



## Welcome

Since our foundation in 1961, Suncombe has pioneered the development of innovative solutions for Cleaning In Place, BioWaste decontamination, GMP Washers, GMP skids, Sanitary Tanks and Vessels. The business continues to be privately owned and managed day to day by Dave Adams and Steve Overton.

Supporting Dave and Steve is a close-knit, dedicated, highly motivated and long-standing team encompassing a wealth of technical experience and knowledge in all relevant disciplines, including design, manufacture, testing, installation, validation, documentation and after-sales support. All of our work is carried out across our own facilities north of London near Stansted Airport.

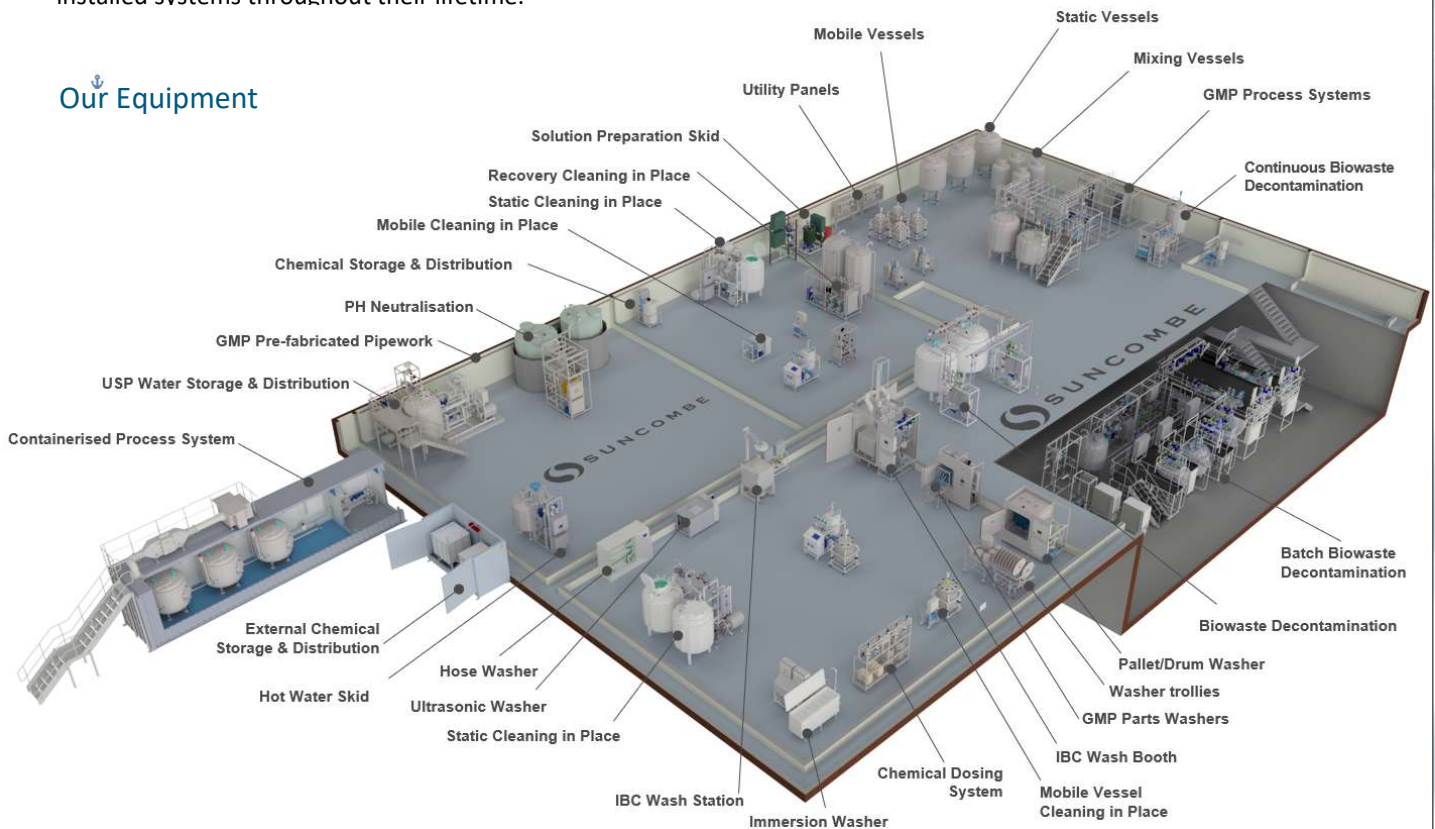
The team employ the very latest techniques, standards and best in class solutions. Having such a strong team allows us to offer the ability to carry out all of our work in-house, under our direct control and quality management systems, ensuring that we own and preserve all the knowledge and experience gained with every project and offer continued support for all our installed systems throughout their lifetime.

Our policy is to re-invest much of our profits into continuous development of our staff and our facilities, together with Research and Development to provide the optimum technical solutions for our clients requirements.

## Our Clientele



## Our Equipment



### Suncombe Ltd

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Key Technologies	Benefits
Capacities	Available with vessel capacities from 20 to 500 litre as mobile vessels and 20 to 2,000 litre as static vessel
Applications	Biopharma mobile and static process applications incorporating differing technologies and methodologies to provide the optimum solution to your process critical needs as well as an automatic Cleaning In Place and Sterilising In Place facility.
Available technologies and methodologies	Mixing/Agitation/Powder Addition/Filtration/Powder Incorporation/Heating/Cooling/Blending/Aerating/Dosing.
Material of Construction	Systems are constructed to the highest sanitary standards with 3.1/2.2 material traceability and welding dossier. This ensures a fully validatable and cleanable treatment environment.
Various Instrumentation	Instruments including temperature, pressure, flow, pH, DO, TOC, Load Cells, Conductivity, Level, Head Lift, Pressure Relief, Zero Dead Valve Legs Valves, Magnetic Mixers etc.
Cleaning In Place	Integrated Cleaning In Place Facilities
Sterilising In Place	Integrated Sterilising In Place Facilities
Continuous monitoring of key parameters	Process is highly repeatable and validatable.
Safety	Alarms, interlocks and fail-safe design prevent waste discharge in the event of an unsuccessful treatment. This encompasses scenarios such as power loss and under-temperature events.
Siemens PLC and 12" colour HMI with options for larger HMIs	Control hardware is industry standard and supported worldwide by Siemens. Ethernet interface included for transfer of critical operating variables to other systems. Designed to enable integration to third party equipment or higher level control system.
Suncombe ControlSuite software	Control software specification has been developed and proven over many years for critical applications and includes a wide range of user or administrator configurable parameters to enable customised decontamination profiles. User passwords, Active Directory, Audit Trails, Electronic batch reports for local or network storage are possible. User interface screens and

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 Tel +44(0) 208-443-3454 Fax +44(0) 208-443-3969 E-Mail: mail@suncombe.com Web: www.suncombe.com  
**Designers, manufacturers & installers of quality, hygienic processing and cleaning systems and Equipment**

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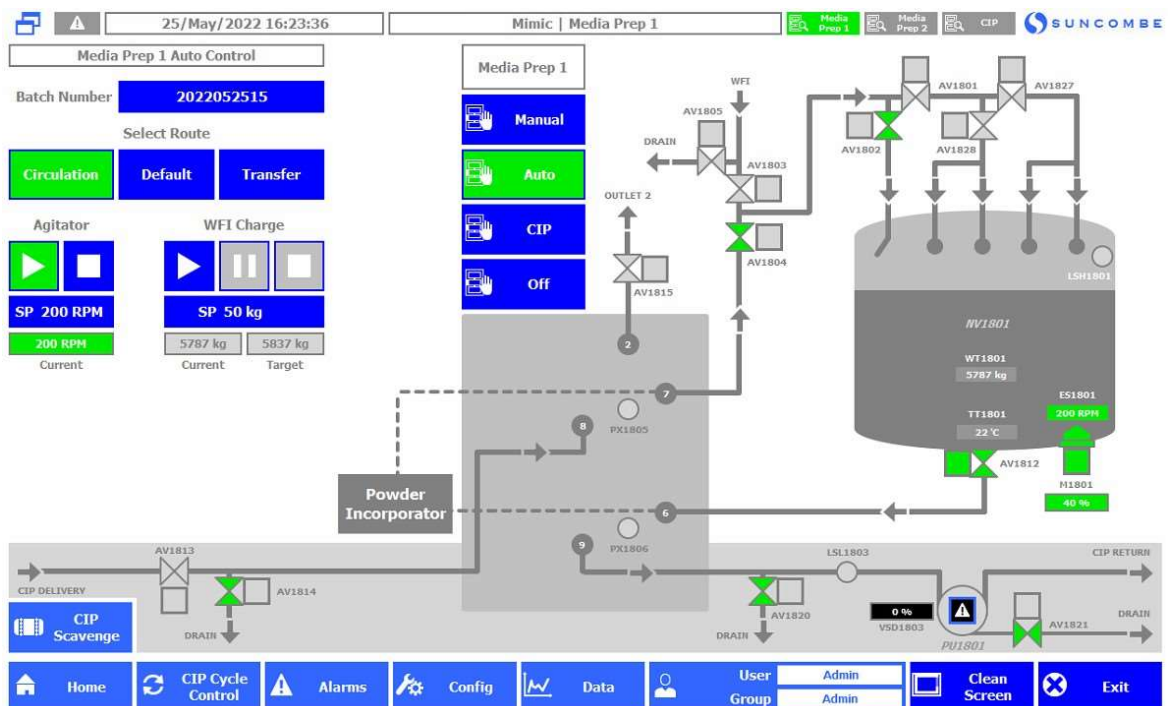
## cGMP AutoVessel™ Systems Examples

Suncombe cGMP AutoVessel™ System Examples with Mixing, Agitation, Powder Addition, Filtration, Powder Incorporation, Heating, Cooling, Blending, Aerating, Dosing etc.



## cGMP AutoVessel™ Systems Examples

Suncombe cGMP AutoVessel™ System Examples with HMI including Automatic, Manual, Batch, Continuous Operation, User Management, Operation, maintenance, reporting, Audit Trail etc.



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## Control and Automation System

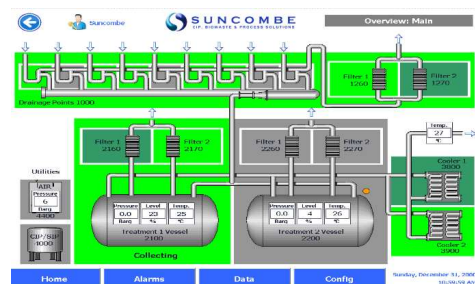
Renowned for their ease of operation and versatility, Suncombe systems are designed and manufactured for reliability, repeatability and longevity, whilst complying with the highest international regulatory standards. With dedicated in-house automation personnel for control design and software, Suncombe engineers have tremendous experience in incorporating a broad range of control solutions to suit your specific control requirements.

Developed to the GAMP 'V' model (Verification and Validation), system life cycle approach, which links the three main qualification activities (installation, operation and performance) back to the design process, the system software is produced in house by qualified software engineers, encompassing software development standards, quality control systems and change control during and post development.



## Standards and Guidelines

- ✓ GAMP Guidelines
- ✓ FDA 21CFR11 Compliance
- ✓ ASME BPE
- ✓ EU Machinery Directive
- ✓ EU Low Voltage Directive
- ✓ EU cGMP Guidelines
- ✓ EU EMC Electromagnetic Compatibility Directive
- ✓ IEC 61131 for PLCs
- ✓ EN 60204 Safety of machinery
- ✓ EN 60439 Low Voltage Switchgear
- ✓ CE and UKCA Marks



Typical Operator Interface



