Professionals in Process /Product Technologies

SM Biosystems

We are '*Professionals in Process/ Product Technologies*' with following expertise-

- **Conceptualization and Engineering of Projects**
- **Module and skid building**
- **Custom-built solutions**
- **Innovative hygiene Products for Pharma/ Dairy Industry**
- **Expertise in Pharma, Food, Natural resource based projects**
- **Business partners of world class products from Europe and USA**

Our Offerings-

- **Bio-Reactors And Fermenters**
- **Bio - Waste Decontamination Systems / Sterilization Systems / Inactivation Systems**
- **PWDS, WFIDS, CSDS Systems**
- **CIP Plants**
- **Pharmaceutical Machinery and Bio-pharma Custom Built Modules**
- **Mixing And Blending Vessels**
- **Dairy/Starch Projects**
- **Drying And Evaporation Projects**
- **Biorefineries**
- **Piping Engineering**
- **Plug-in Temperature / Brix / pH / Pressure/ Flow Control Modules**
- **Electrical And Automation Engineering**
- **Flow Control Equipment**
- **All Types Of Valves And Valve Automation**

Bio-Reactors and Fermenters

SM Biosystems

At the heart of life science manufacturing operations lie bioreactors and fermenters.

SM Biosystems offer a complete range of skid-mounted cell culture reactors and fermenters for the life science industry. Coupled with extensive offerings both upstream and downstream of the biological core of the process, these bioreactors and fermenters form the nucleus of a fully integrated bioprocess suite.

Designs for both mammalian and prokaryotic system range from a working volume of 20 to 25000 L. The systems are supplied as completely tested units, with all instruments, controls and accessories necessary for installation. This "**plug-and-play**" approach to the heart of the manufacturing process ensures that the culture systems are ready to go when the rest of the project is complete.

SM Biosystems process experts ensure the integration of the biological portion of a manufacturing process with both the facility design and surrounding process operation. SM Biosystems' bioreactors and fermenters are designed to interface with support operations such as media preparation and clean-in-place (CIP) systems.

SM Biosystems specializes in design and fabrication techniques mandated by the regulatory demands on the life science industry.

Features

- Complete control and traceability of design and fabrication life- cycle.
- GAMP- compliant automation systems
- Material certifications and test reports for all process contact components.
- Fabrication testing, including boroscope weld records.

Standard design

Cleanablity

SM Biosystems culture systems are designed with the understanding of the need of cleaning and sterilization process in fermentation. Whether the

system is a 20L inoculums fermenter intended for clean-out-of-place (COP) service, or 20000L production bioreactor with fully automated CIP, the vessel and all process contact components are designed to be readily and repeatedly cleaned.

The system incorporates a unique design feature, the use of a common header to supply clean steam for clean-in-place (CIP) operations and CIP solutions for cleaning operations. This dual-use header reduces system complexity as well as the number of valves in fully automated CIP operations.

Completely integrated CIP capability is available by integrating **SM Biosystems' CIP system** with the reactors. This feature enables complete CIP testing during factory acceptance testing (FAT) and ensures that the vital integration between process equipment and cleaning system supply equipment is done right.

SM Biosystems designs systems with building blocks such as:

- Vessel assembly
- Agitation system
- Inlet gas handling and exhaust system
- Temperature control system
- Liquid addition system
- Instrumentation system and control

The process requirements dictate the selection of the appropriate functional blocks. SM Biosystems' technical specialists are experts in configuring and customizing a reactor to meet a wide range of operational requirements.

Vessel assembly

The vessel assembly is the core of the system. It consists of a jacketed pressure vessel, vessel internals and fittings. It is designed to be completely cleanable and freely drain all process fluids. Standard bioreactors built with 1.5:1 nominal aspect ratio to facilitate good mixing, and bacterial vessels are built with a 2.5:1or higher aspect ratio to meet the high mass transfer demands on these processes.

Agitation system

SM Biosystems offers both top and bottom drive agitators, although we encourage the use of bottom drive agitators wherever possible. The bottom drive system provides complete drainability of the vessel and frees significant space on the top head for piping and instruments. A bottom drive also permits the use of a short shaft which allows for smaller shaft diameters and

eliminates the need for steady bearings.

SM Biosystems' shaft seal is a cartridge-type, clean-steam lubricated, doubled mechanical seal with silicon carbide seal faces. The seal faces are oriented in a "back-to-back" arrangement that increase sealing force as the pressure increases. This permits the seal to be sterilized independently from the vessel and eliminates seal pressure adjustments. The seal cartridge assembly can be completely assembled and tested before installation on the vessel, thereby greatly reducing seal change time. The complete shaft assembly fits directly through the seal, eliminating the need for an in-vessel coupling.

Impeller types are process-dependent. Typical recommendations for different processes are shown below:

	Mammalian cell culture Vessel	Bacterial Fermentation Vessel
Design Code	ASME, PED or Other	ASME, PED, or other
Design conditions	45 psig/ FV@ 300°F	45 psig/ FV@ 300°F
Aspect ratio	1.5:1 nominal	2.5:1 minimum
Jacket standard	Dimpled standard*	Dimpled standard*
Material of construction		
Process contact:	SS316L	SS316L
Jackets:	SS304	304SS
Insulation:	Mineral wool	Mineral wool
Finish	20 microinch Ra, EP internals 35 microinch external**	20 microinch Ra, EP internals 35 microinch external**
Typical ports & penetration	Manway (full opening head 500L and below)	

Unique Features of SM Biosystems' Fermenters

- Available in varying sizes
- High Aspect Ratios
- *In-situ* Sterilizable
- Piping Skid, Modular in Design
- Steam Sterilizable Drain & Sampling Valves
- Designed as per ASME Codes

- User choice Control packages like Temperature, pH, DO2, Motor Speed, Foam, Cell Density, Exhaust Gas composition, O2 Supplementation etc.,
- Unique sampling systems
- cGMP compliant Design
- PLC Based Process Control with SCADA

FOR MORE DETAILS CONTACT

Office & Works : -SM BIOSYSTEMS
S. No. 28 / 27, Dhayari, Narhe - Dhayari Road,
Behind Oneness Controls, Dhayari,
Pune - 411041.
Maharashtra INDIA

Tel.-020 64701545, 020 24690018
Fax-020 24690655
Email- mktg@smbiosystems.com
response@smbiosystems.com
Visit us at www.smbiosystems.com