

Virus Production Facility

MAAK supplied an integrated process control system and instrumentation package for multiple bioreactors (3 x 2000 litre) and their utility support systems, including:

- Media Preparation
- Clean-In-Place
- Harvest System

The system is used in the production of a vaccine product.

The scope of supply included design, fabrication (control panels), instrumentation, software development, integration, installation, commissioning, FAT and SAT for each system. System design adhered to the GAMP (Good Automated Manufacturing Practice) life-cycle approach for the development and validation of automated systems. MAAK also supplied detailed and comprehensive design and test documentation.



Process Description

The bioreactors are the central pieces of equipment in the facility. All other systems in the facility either directly support the operation of the bioreactors or further process the viral product. The bioreactors provide an environment that allows contained and controlled proliferation of the virus population and their cellular hosts. Automatic control over several bioreactor process variables is provided, including weight, pressure, agitation, temperature, dissolved oxygen and pH.

The following major operations are provided:

- Sterilization
- Cultivation
- Harvest
- Decontamination
- CIP

Automation

The system controls all aspects of the process including sterilization, media preparation, cultivation, product collection (harvest), decontamination and equipment cleaning. As per client requirements, automated batch control is provided consisting of over 70 process steps.

The control system equipment consists of a Programmable Logic Controller (PLC), Operator Interface Terminal (OIT) and process analysers (DO, pH, conductivity, etc.) for each bioreactor. The systems are assembled in 19" rack mounted mobile tower enclosures. These tower systems provide compact control systems that can be moved for ease of cleaning as typically required in highly clean pharmaceutical environments.

MAAK also provided installation and commissioning services for the project. MAAK provided all required documentation including Functional Requirements Specification, Detailed Design Specification, Operating & Maintenance manuals, drawings and software documentation.

