

Polio Production Facility

MAAK supplied an integrated process control system and instrumentation package for multiple mammalian cell culture bioreactors (3 x 1000 litre). The system is used in the production of a polio 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 used for the production of polio virus in MRC-5 cells. The cells are grown for a specified time, followed by virus growth. The process requires manual addition and removal of various media.

The process requires control of temperature, pH, DO and agitation throughout the various stages of fermentation. Weight is also controlled. The vessel is sterilized before use, and decontaminated (by sterilization) after use.

The overall process is non-linear and multi-variable. Further, there are multiple ways of controlling some parameters, while some parameters need to have defined limits, which must be controlled within minimum and maximum limits due to the effect on the living cell and micro-carrier.

The basic process functions are sterilization, cultivation, hold, & decontamination.

Automation

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.

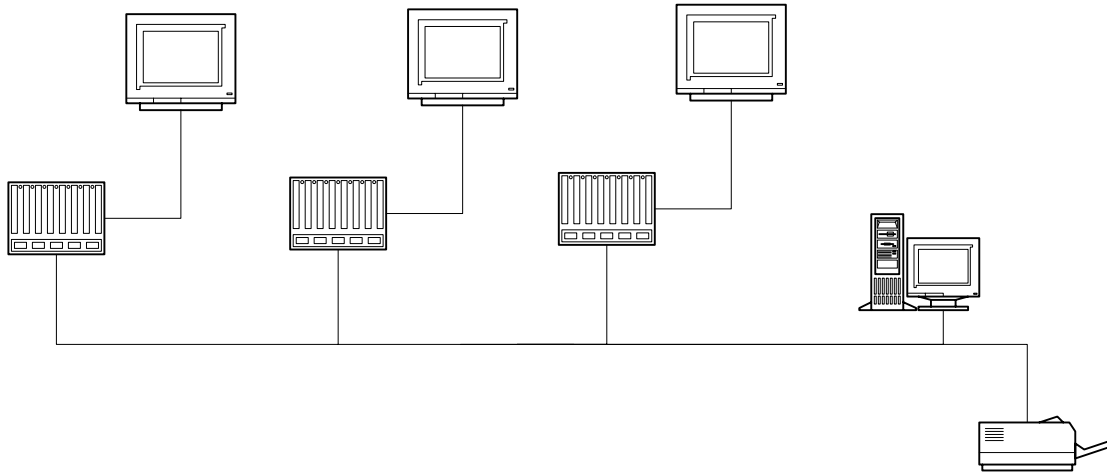
The system controls all aspects of the process including sterilization, cultivation, product collection and decontamination. As per client requirements, automated batch control is



provided consisting of over 20 process steps. The ability for operator interaction to confirm process steps and operate manual equipment is provided.

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.

All control systems supplied by MAAK Technologies Group Inc. for fermentation and cultivation applications are validated for use in GMP facilities.



Bioreactor 1 C

Bioreactor 1 PLC