One Fermenter Control for All

By:
Geert Deschamps GENimmune

Dick van der Geest Eurotherm
Who is Eurotherm

Invensys

Eurotherm

APV

Process Systems

Rail Systems

Invensys Controls

Drayton

EBERLE

CEWELL

invensys
EUROTERM

invensys
APV

invensys
FOXBORO

invensys
TRICONEX

invensys
SINISCI-ESSCOR

invensys
AVANTIS

invensys
WESTINGHOUSE

Rail systems
Our Vision:

 Duis Eurotherm will be the leading supplier of automation solutions and services in our chosen markets, harnessing the passion that people feel for Eurotherm.

We will constantly search for competitive advantage and innovation to create value for our customers, employees and shareholders.
Industries served

- Boiler Control
- Environmental Testing and Monitoring
- Food and Beverages
- Glass
- Heat Treatment
- Hospitals and Healthcare
- Life Sciences
- Metals
- Power Generation
- Plastics
- Semiconductor Fabrication
- Water

Invensys®
Scalable Lab-pilot-Production
21 CFR Part 11 Compliant
Standalone or integrated in bigger systems
Complete application available including CIP/SIP
Easy to Use, Auto/Semi/Manual operation
Recipe driven Multi-product (Batch as per S88)
Improve quality, reduce trash
Reduce rework by identifying abnormal conditions rapidly
On-line monitoring & control
Batch record with full audit trail (21CFR Part 11)
Batch Report
Multiple language support
Reduce validation
Integrated Audit trail
Audit trail on sequence
Introduction GENimmune

Geert Deschamps

Functional Unit manager cell culture and fermentation

GEN immune
Single fermentation control system for R&D and Biomanufacturing

Geert Deschamps
Functional Unit Manager Cell Culture and Fermentation
GENimmune NV
## About Innogenetics Group

### INNOGENETICS NV DIAGNOSTICS
- HLA testing
- Genetic testing
- Infectious diseases
- Neurodegeneration
- Oncology

Vertically integrated

### GENimmune NV THERAPEUTICS
- Therapeutic vaccines
  - Hepatitis B virus
  - Hepatitis C virus
  - Human papillomavirus
- Other immune therapeutics
- Biomanufacturing

Development focussed
Biomanufacturing Unit

- Multipurpose unit with segregated production lines
  - Microbial production
  - Eukaryotic production
- Formulation and filling
- Biosafety level 2
- EU 98/81 compliant
- cGMP compliant
- ISO 9001/2000 certified Quality System
- Authorization No 641 from Belgian Ministry of Health to produce API’s
- Biomanufacturing partnerships with third parties
Contract Manufacturing

Services offered

• Microbial expression systems
• Eukaryotic expression systems
• Virus production
• Production of cell banks / virus seeds
• Fermentation
• Purification
• Formulation and filling (BL-2)
• Process development
• Scale up
• Analytical methods
Fermentation control systems at GENimmune

Historical situation

• R&D:
  – In-house built control system
    • Product line discontinued: no technical support
  – Standard off-the-shelf control units
    • limited flexibility

• Biomanufacturing:
  – In-house built control system:
    • not 21 CFR part 11 compliant
    • multiple validation issues

Need for upgrade and uniformity
System upgrade “Wish list”

• Uniform platform for Biomanufacturing and R&D
  – Minimized operator training
  – Facilitated process transfer

• Fixed system in Biomanufacturing
  – 21 CFR part 11 compliant
  – Fully validated
  – Fixed production batch, recipe driven
  – In-house tools available for future system adaptations

• Flexible system in R&D
  – Interaction with ongoing processes
  – Design and implementation of new control strategies

• Use of same automation/control platform for different applications
Overall project roadmap

Quality and Project Plan

Risk Assessment + User Requirement Specification

Functional design spec. Hardware design spec.

Facility Qualification

System acceptance tests

Operational Qualification

Site System acceptance tests

Validation Report

Table of Compliance
Eurotherm control system architecture

Heart of the control system

Visual supervisor

Remote PC

Fermentor

Courtesy of Eurotherm
Visual supervisor system

- Control database: Eurotherm Process Automation Local Instrument Network (LINTools)
  - Pre-programmed function blocks (e.g. I/O function blocks, PID control block, etc.)

- I/O communication: I-Tools

- Batch parameters fixed in recipes and profiles
Operator access

- Different access levels
  - Operator, R&D Engineer, Calibrator, Administrator
  - Access level as defined

- Full audit trail

- Operator signature and authorization
  - Activated for Biomanufacturing only
  - Open access in R&D
User interface

• Visual supervisor: touch screen control
  – Standard features
  – User-defined screens
  – Intuitive navigation through screens
User interface

[Diagram of a user interface with various components such as Batch ID, State, Phase, Temperature control, Agitation control, pH, CO2, and menu options.]
Training

• In-depth (administrator/engineer/operator level) training in:
  – LIN-Tools: Control database
  – I-Tools: I/O module configuration
  – User screen editor: user interface screen building
  – Review: data analysis

In-house flexibility for adaptation towards new control strategies
Conclusion: Project evaluation

**Strong points**

- Fully compliant production control system
- High flexibility achieved
- Uniform system
- User-friendly Interface

**Points to consider**

- High time investment system administrator
- High input internal engineering department
- Document nomenclature (e.g. System Acceptance test – IQ OQ protocol)
Questions ???

You find us at stand 9 for detailed information

www.genimmune.com
www.innogenetics.com
www.eurotherm.com