

REFERENCE CASE STUDY

Biotechnology – Mammalian cell fermentation production

Fully automated greenfield plant at Gedeon Richter, Hungary



01 Gedeon Richter,
Debrecen Biotech
Plant, Hungary

Gedeon Richter commissioned a fully automated, integrated and validated production, building management and environmental monitoring system for a multipurpose and flexible batch manufacturing greenfield facility dedicated to mammalian cell fermentation. Richter selected ABB System 800xA technology and the engineering team, supported by international expertise and experience, to successfully deliver the project.

Gedeon Richter's biotechnology production plant in Debrecen, Hungary is designed to produce mammalian cell fermentation based biopharmaceuticals. The plant will supply the international pharmaceutical market and complies to regulated market authority requirements. Gedeon Richter needed a partner that would provide the technology and engineering capability to deliver a complete automation solution for this multipurpose facility.

The plant is designed for fully automated batch production with minimal operator intervention. Gedeon Richter required a technology providing a single platform for integrated batch manufacturing, building management and environmental monitoring system. Manufacturing efficiency is achieved through full operator visualization of all process and environmental information and data, complete batch reports and alarms and events audit trail. Engineering and maintenance efficiency is achieved through common hardware and software design for the entire plant.

ABB's scope of supply

Fully validated and integrated batch control, environmental monitoring and facility management system

Biotechnology requirements

- Recipe-based production management (S88)
- FDA 21 CFR Part 11 compliance
- GAMP 5 based project execution complying with best practices in the life sciences industries
- All process control functions by a single DCS

Basics

- Gedeon Richter – New biopharmaceutical facility in Debrecen, Hungary
- Project Type: Biopharmaceutical facility
- Output chemicals: Therapeutic proteins
- Construction started: 2008
- Commissioned: 2013

Benefits for Gedeon Richter plc

- Process Automation is an essential requirement for a modern biotechnology manufacturing facility
- Microbiological & environmental safety is paramount and hence an effective EMS system is a key
- Certain elements of the technology can only be enabled by an appropriate and overarching PAS system, like the one ABB has delivered
- PAS system allows for the necessary integration of technology steps
- The PAS system drives effectiveness and effi-

ciency, allows for the required remote control of the process technology

- The PAS system is a key element that makes the Gedeon Richter plc Debrecen biotechnology plant a “world class” facility.

Scope of supply

- Process Automation System (PAS):
 - System 800xA DCS with Batch Management
 - 27 Operator Workplaces
 - 5000 I/O signals
- Building Management System (BMS)
 - 50 Air Handling Units
 - Utility and Energy Monitoring
 - 6200 I/O signals
- Environmental Monitoring System (EMS)
 - 95 Room monitoring objects
- Project management
- Application engineering and testing
- Installation and commissioning

02 Fully automated batch control for upstream media preparation and fermentation and harvest



03 Fully automated batch control for downstream purification, buffer preparation and distribution

