DOC NUMBER: **569-DB07-AIC-110-006**	CLIENT NUMBER: **PRD-AIC-TSP-026**
CLIENT: **TAKEDA/BAXALTA**	
PROJECT **BURITI EPCMV PROJECT**	

AUTOMATION EMS

DESIGN BASIS

0	30JU2021	ISSUE FOR CONSTRUCTION	MAV	MAF	RSP
A	16JUN2021	90% DD ISSUE	MAV	MAF	RSP

REV	DATE	DESCRIPTION	EXEC	CHECK	APPROV.

INDEX

1. REVISION HISTORY

Rev.	Reason for change
A	90% DD ISSUE
0	ISSUE FOR CONSTRUCTION • THIS DOCUMENT HAS BEEN REPLACED BY DOCUMENT CQV-DOC-URS-105_A_Environmental Monitoring System

2. PROJECT DESCRIPTION

2.1 Takeda has re-negotiated a licensing and tech transfer agreement (LTTA) with the Brazilian state- owned company Hemobrás (HB) to transfer the technology of Takeda's recombinant FVIII (rFVIII) product ADVATE from Takeda to Hemobrás. Hemobrás is planning to construct a vertically integrated facility for manufacturing of rFVIII at the Hemobrás owned site at Goiana, Pernambuco (PE), Brazil (Project Buriti).

2.2 The scope of Project Buriti is to design, build and qualify a new vertically integrated rFVIII Manufacturing facility, and includes implementation of all needed support buildings and Systems (Boilers, Emergency Generators and Wastewater Treatment) on an existing brownfield site. It is expected that the new facility is completely self-contained and the existing Goiana site provides only basic utility supply (city water, gas, power) and logistics (access road, site security). The project also must account for operation's waste management (specifically process waste). The site's capacity layout for ADVATE manufacturing shall be based on three 2500L chemostat bioreactors, even though only equipment for a two bioreactor operation should be implemented at first.

2.3 In order to guarantee an optimal integration with current facility operations, a complete functional telecommunications systems connection between the new building and the existing buildings will be designed.

3. SCOPE.

3.1 This document is a technical guideline to design EMS Automation systems considered for the Hemobrás Project (Phase 2, 3 & 4) – building B07A and building B07B:

a) EMS system (for any room considered as GMP impact on a validated platform)

3.2 This document has the minimum engineering requirements to be considered to integrate a complete and functional Automation systems to the Site's/Campus system. Compatibility with already existing systems at Goiana site is preferred.

4. ABBREVIATIONS.

AHU	Air Handler Unit
API	Active Pharmaceutical Ingredients
APS	Advanced Planning Schedule
BAS	Building Automation System
BMS	Building Management System
BU	Black Utilities
CCTV	Closed Circuit Television
CIP	Clean-in-Place
CU	Clean Utilities
DCS	Distributed Control System
DHS	Data Historian System
EBR	Electronic Batch Record
ERP	Enterprise Resource Planning
EMS	Environment Monitoring System
GAMP	Good Automated Manufacturing Practice
HMI	Human Machine Interface
HVAC	Heating Ventilating and Air Conditioning
I&EC	Instrumentation & Electrical Controls
IT	Information Technology
LIMS	Laboratory Information Management System
MBR	Master Batch Record
MES	Manufacturing Execution System
MOM	Manufacturing Operation System
NTG	Nitrogen (gas)
OEE	Overall Equipment Effectiveness
OEM	Original Equipment Manufacturer
OI	Operational Intelligence
OXG	Oxygen (gas)
PAA	Plant Automation Accelerator
PAT	Process Analytical Technology
PCS	Process Control System
PLC	Programmable Logic Controller
ROW	Reverse Osmosis Water
SIP	Steam-in-Place
UPS	Uninterruptible Power Supply
W&D	Weighing and Dispenser
WFI	Water for Injection
WMS	Warehouse Management System

5. REGULATIONS AND STANDARDS.

5.1 Systems design, equipment, materials, and procedures, considered in this project, have to fulfill the next regulations and standards:

Brazilian standards	NBR & ABNT
International Electrotechnical Commission	IEC
The Leadership in Energy and Environmental Design	LEED-NC 2.2 USGBC
International Standards Organization	ISO
Insulated Cable Engineers Association	ICEA
European Committee for Electrotechnical	CENELEC
National Electrical Code	NEC
National Fire Protection Association	NFPA
American National Standard Institute	ANSI
National Electric manufacturers Association	NEMA
Good Automated Manufacturing Practices v5	GAMP5
Institute of Electrical and Electronic Engineers	IEEE
Factory Mutual	FM
Underwriters Laboratories Inc.	UL
Electronic Industries Alliance	EIA
Telecommunications Industry Association	TIA
International Society of Automation	ISA
American Society of Heating, Refrigerating and Air Conditioning Engineers	ASHRAE
Agência Nacional de Vigilância Sanitária (Regulatory Agency, Brazil) - RDC 301	ANVISA

6. PROJECT DELIVERABLES.

6.1 Drawings and documents for conceptual design, that follow Hemobrás's requirements and standards.

6.2 Drawings will be issued in AutoCAD and Documents will be issued in Microsoft Office.

6.3 Drawings:

7A-I-1-3-15	Ground floor	Drug Product	Automation EMS
7B-I-1-3-15	Ground floor	Drug Substance	Automation EMS
7A-I-2-3-25	First floor	Drug Product	Automation EMS
7B-I-2-3-25	First floor	Drug Substance	Automation EMS
7A-I-0-7-03	EMS Architecture	Drug Product	
7B-I-0-7-03	EMS Architecture	Drug Substance	

6.4 Documents:

PRD-AIC-TSP-026 - Automation EMS Design Basis

PRD-AIC-LIS-044 - Bill of materials - EMS

7. ENGINEERING INFORMATION.

7.1 Actual conditions.

7.1.1 Takeda/Hemobrás prefers to implement a Distributed Control System (DCS) solution for Project Buriti.

7.1.2 Various system integrators can be considered to ensure a competitive procurement landscape, but compatibility with already existing systems at Goiana site (Wonderware software platform) is preferred.

7.2 Environment Monitoring System (EMS)

7.2.1 The EMS System is responsible for monitoring the environmental conditions of the production areas (basically rooms, air locks and corridors, and will consist of one by a PLC Controller, remote I/O distributed in the building and a supervision system with operating stations and operator panels.

7.2.2 The location of the controllers must be strategic, and the controller must communicate with the Remote I/O by Ethernet network.

7.2.3 For entire building that includes the environmental monitoring system, I/O distribution panels (Remote) must be installed. The remote I/O must be connected to the measuring instruments with digital and analog I/O and must allow the monitoring of the environments in relation to the temperature and humidity of the rooms, differential pressure between rooms and quantity of suspended particles.

7.2.4 The DCS Server will oversee hosting all the data of the EMS system.

7.2.5 The DCS Server will be virtualized and installed in the Automation Room of new building B07B.

7.2.6 The physical medium for the communication of the EMS system between the Hemobrás Operational Center Building and the new building B07 to be monitored must be by optical fiber.

7.2.7 The EMS system must have an operation station (Thin-Client) running the EMS client application and must be installed in the control room located in the new building B07A and allow the monitoring of the system.

7.2.8 The EMS system should provide only the GMP data related to the particle counter, ambient temperature, humidity, and differential pressure according to HVAC system definitions.

7.2.9 The EMS system must contain Tower Lights and Sirens installed at strategic locals in the production areas so that operators are immediately notified of the occurrence of critical alarms.

7.2.10 The system must be qualified/validated and the applications of the DCS system must be under CQV management. The system must be able to meet the requirements and requirements of ANVISA and CFR 21 part 11 standards, related to the issue of electronic security.

7.2.11 The system shall monitor and provide the data related to the loops according to the process definitions and CQV definitions.

7.2.12 EMS system devices should be segregated from any other system and should not be shared.

8. DESIGN REQUIREMENTS

8.1 Power supply

8.1.1 DCS Controllers power supply must be powered by UPS.

8.1.2 DCS Remote I/O power supply must be powered by UPS.

8.1.3 DCS Server power supply must be powered by UPS.

8.1.4 The electrical supply of the ethernet network devices (switches, converters to fiber optics, etc.) must be powered by UPS.

8.1.5 Operator Workstations (Thin-client) and Operator panels must be powered by UPS.

8.2 Cable Pathways

8.2.1 Hot dip Galvanized Steel wire basket and conduit is considered in administrative areas. They will be installed on walking ceiling floor, preferably.

8.2.2 Hot dip Galvanized Steel conduit and fittings is considered in production areas.

8.2.3 Stainless Steel conduit and fittings is considered in clean rooms.

8.2.4 Cable will not exceed 40 % of occupancy in conduits and 50% in cable trays.

8.2.5 Cable tray and conduit pathways will be supported to the ceiling or to the wall every 1.8 to 2.5 meters according to the area.

8.2.6 No more than two 90° curves are allowed between pull boxes or device boxes.

8.2.7 A pull box must be considered in pathways with distances larger than 30 meters.