DOC NUMBER: **569-DB07-AIC-110-005**	CLIENT NUMBER: **PRD-AIC-TSP-009**
CLIENT: **TAKEDA/BAXALTA**	
PROJECT **BURITI EPCMV PROJECT**	

AUTOMATION BMS

DESIGN BASIS

REV	DATE	DESCRIPTION	EXEC	CHECK	APPROV.
0	22OCT2021	ISSUE FOR CONSTRUCTION	MAV	MAF	RSP
E	16JUN2021	90% DD ISSUE	MAV	MAF	RSP
D	17DEC2020	FINAL BD ISSUE	MAV	MAF	MSS
C	16OCT2020	FINAL BD ISSUE	MAV	MAF	MSS
B	28AUG2020	90% BD ISSUE	MAV	MAF	MSS
A	09JUL2020	50% BD ISSUE	MAV	MAF	MSS

INDEX

1. REVISION HISTORY

Rev.	Reason for change
A	50% BD ISSUE
B	90% BD ISSUE
C	FINAL BD ISSUE
D	FINAL BD ISSUE
E	• Included DOC NUMBER and rename CLIENT NUMBER (Former PRD-AIC-TS-009). • General review in index numbering because of the new table 1 (revision history) • As requested by Takeda/Baxalta, has been segregated the BMS Design Basis from EMS Design Basis. • Inclusion of the Emergency Generator building and Wastewater Treatment plant in item 3 (Scope). • Updated item 3.1.a. • Updated item 7.2
0	• Updated item 2. • Item 3.2 revised. • Updated item 4. • Updated item 6.3. • Updated 7.2.4, 7.2.5, 7.2.6, 7.3.1, 7.3.2, 7.3.3 and 7.3.4. • Added items 7.4, 7.5, 7.6, 7.7 and 7.8. • Updated item 8.

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 – B07C, Emergency Generators – B07F and Wastewater Treatment plant - WWT) 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 and sanitary 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 BMS Automation system considered for the Hemobrás Project - Building B07A, B07B, B07C, B07F and WWT:

a) BMS System (HVAC control and monitoring system, Black Utilities control and monitoring system, Electrical subsystem, ACS system, CCTV system, Fire Alarm system and Wastewater Treatment)

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 Wonderware existing system at Goiana site is required.

4. ABBREVIATIONS.

AHU	Air Handler Unit
API	Active Pharmaceutical Ingredients
APS	Advanced Planning Schedule
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
VM	Virtual Machine
W&D	Weighing and Dispenser
WFI	Water for Injection
WMS	Warehouse Management System
WWT	Wastewater Treatment Plant

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 Reference Drawings:

7A-I-1-3-11	Ground floor	Drug Product	Automation BMS
7B-I-1-3-11	Ground floor	Drug Substance	Automation BMS
7A-I-2-3-21	First floor	Drug Product	Automation BMS
7B-I-2-3-21	First floor	Drug Substance	Automation BMS
7A-I-0-3-01	Walkable ceiling	Drug Product	Automation BMS
7A-I-0-3-01	Walkable ceiling	Drug Substance	Automation BMS
7A-I-3-3-31	Second floor	Drug Product	Automation BMS
7A-I-3-3-31	Second floor	Drug Substance	Automation BMS
7C-I-1-3-11	Ground floor	Boiler	Automation BMS
7A-I-0-7-04	BMS Architecture	Drug Product (sheets 01/07 to 07/07)	
7B-I-0-7-04	BMS Architecture	Drug Substance (sheets 01/07 to 08/08)	
7A-I-0-7-02	Fire Alarm Riser Diagram - Building B07A		

7B-I-0-7-02	Fire Alarm Riser Diagram - Building B07B
7A-I-0-7-05	CCTV Riser Diagram - Building B07A
7B-I-0-7-05	CCTV Riser Diagram - Building B07B
7A-I-0-7-06	ACS Riser Diagram - Building B07A
7B-I-0-7-06	ACS Riser Diagram - Building B07B

6.4 Documents:

PRD-AIC-TSP-009 - Automation BMS Design Basis
PRD-AIC-TSP-008 – Data & Voice Design Basis
PRD-AIC-TSP-014 - BMS Technical Specification
PRD-AIC-LIS-043 - Bill of materials BMS

7. ENGINEERING INFORMATION.

7.1 Actual conditions.

7.1.1 Takeda/Hemobrás prefers to implement a Distributed Control System (PLC+SCADA) 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 required.

7.2 Building Management System (BMS)

7.2.1 The BMS system is responsible for controlling the entire HVAC system and will consist of a BMS server, PLC Controller, remote I/O distributed in the buildings and a monitoring system with operating stations and operator panels.

7.2.2 The controller must communicate with the Remote I/O by Ethernet network. Remote I/O should be placed on panels that will be installed next to the HVAC equipment, Air Handling Unit - (AHU). The I/O points must be connected to the AHU with digital or analog signals and must allow control/operation of the HVAC system.

7.2.3 The Automation server host, installed in the Automation Room of new building B07B, where will be implemented a virtual machine (VM) to run the applications belonging to the BMS system.

7.2.4 1:1 redundancy should be provided for the Automation Host and the BMS´s VM.

7.2.5 The BMS PLC controller must communicate with the BMS´s VM by Ethernet network. The physical medium for the communication of the BMS system between the new building B07 and the Hemobrás Operational Center Building must be via optical fiber.

7.2.6 The BMS system must have an operation station (Thin-Client) running the BMS Client application located in the control room, ground floor B07B and allow the control and operation of the BMS system. It should also be possible to operate the BMS system through operation station (Thin-Client) located in the Automation room of building B07A.

7.2.7 The BMS system includes the Black Utilities industrial utility generation system and should control equipment such as cooling towers, and should start/stop chillers, boilers, and compressors.

7.2.8 BMS system devices, such as pressure, temperature, and humidity sensors, should be segregated from the EMS system and should not be shared. The BMS system will be tested and commissioned and will not be validated (definition).

7.3 Black Utilities (BU) – Integrated into the BMS System

7.3.1 The Black Utilities generation systems will be systems with embedded automation (PLC and HMI) supplied in a Chilled Water, Hot Water, Compressed Air packages. These systems must have Ethernet TCP/IP interface for communication with the BMS PLC that includes the Black Utilities system. If no network communication is possible, Takeda should be consulted if discrete signals can be used to exchange information between the BMS PLC and the embedded systems of the Black Utilities system.

7.3.2 The Black Utilities distribution system is responsible for controlling the utilities described above to ensure distribution to all points of consumption, as required by the process. The system will be added to the PLC BMS Controller, remote I/O distributed in the buildings, and a supervision system BMS SCADA (Wonderware) with operation stations and operator panels.

7.3.3 The location of the PLC controllers should be strategic, and the PLC controller should communicate with the I/O Remotes via Ethernet network.

7.3.4 In the technical or underground floors of the production buildings, I/O remotes shall be installed to interface the PLC controller with the field instruments. Communication between the PLC controller and the remote I/O will be over Ethernet network / optical fiber.

7.3.5 The Black Utilities system shall have a Thin-Client operating station running the Black Utilities client application and shall be installed in a supervisory room located in the in the new building B07 and allow for system monitoring and operation.

7.3.6 The system shall control and provide the data related to the loops according to the process definitions.

7.4 Electrical Subsystem – Integrated into the BMS System

7.4.1 The BMS system shall monitor the electrical subsystem from electrical rooms and emergency generators building and the BMS will also carry out specific controls.

7.5 Fire Alarm System – Integrated into the BMS System

7.5.1 The BMS system shall provide an overview screen with the status of smoke detectors individually for the Fire Alarm system of buildings B07A, B07B, B07C and emergency generators building - B07F.

7.6 CCTV System – Integrated into the BMS System

7.6.1 The BMS system shall provide an overview screen with the working/failure information of the CCTV devices of buildings B07A, B07B, B07C and B07F. Further information shall be accessed through the operator interfaces of the CCTV system itself.

7.7 Access Control System – Integrated into the BMS System

7.7.1 The BMS system shall provide an overview screen with the working/failure information of the Access control devices of buildings B07A, B07B, B07C and B07F. Further information shall be accessed through the operator interfaces of the Access Control system itself.

7.8 Wastewater Treatment Plant – Integrated into the BMS System

7.8.1 The BMS system shall monitor the Wastewater Treatment Plant.

8. DESIGN REQUIREMENTS

8.1 Power supply

8.1.1 PLC Controllers power supply must be powered by UPS - 220 VAC.

8.1.2 PLC Remote I/O power supply must be powered by UPS - 220 VAC.

8.1.3 BMS Server power supply must be powered by UPS - 220 VAC.

8.1.4 The electrical supply of the ethernet network devices (switches, converters to fiber optics, etc.) must be powered by UPS - 220 VAC.

8.1.5 Operator Workstations (Thin-client) and Operator panels must be powered by UPS - 220 VAC.

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.