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CLIENT: **TAKEDA/BAXALTA**	
PROJECT **BURITI EPCMV PROJECT**	

ACCESS CONTROL SECURITY SYSTEM

DESIGN BASIS

REV	DATE	DESCRIPTION	EXEC	CHECK	APPROV.
0	01OCT2021	ISSUE FOR CONSTRUCTION	MAV	MAF	RSP
B	10SEP2021	90% DD ISSUE	MAV	MAF	MAJ
A	15JAN2021	ORIGINAL ISSUE – FOR APPROVAL	MAV	MAF	MAJ

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1. REVISION HISTORY

Rev.	Reason for change
A	ORIGINAL ISSUE – FOR APPROVAL
B	• General review in index numbering because of the new table 1 (revision history) • Updated item 2.3 • Inclusion of the Emergency Generator building and Wastewater Treatment plant in item 3 (Scope). • Updated item 7.1, 7.1.1, 7.1.2
0	• Cancelled Item 7.2.4. Wristbands have been cancelled. • Updated Item 7.2.10.

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 (Warehouse, QC Lab, Administration, Cafeteria and Utilities) 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, systems such as Security Access Control, Security CCTV, Voice&Data and so on.

3. SCOPE

3.1 This document is a technical guideline to design the Access Control system considered for the Hemobrás Project (Phase 2, 3 & 4) – Building B07A, B07B, B07C and B07F.

3.2 This document has the minimum engineering requirements to be considered to integrate a complete and functional Access Control system to the existing facility.

4. ABBREVIATIONS

LAN	Local Area Network
VLAN	Virtual Local Area Network
Ethernet	It defines a number of wiring and signaling standards for the physical layer of the OSI networking model as well as a common addressing format and Media Access Control (MAC) at the data link layer.
IEEE 802.3	Institute of Electrical and Electronics Engineers. Standards defining the physical layer and data link layer's media Access control (MAC) sublayer of wired.
Server	Computer that links other computers or electronic devices together. They often provide essential services across a network, either to private users inside a large organization or to public users via the internet (not part of Telecom Scope).
TCP/IP	Transmission Control Protocol (TCP) is one of the core protocols of the Internet Protocol (IP) Suite. TCP provides the service of exchanging data reliably directly between two network hosts, whereas IP handles addressing and routing message across one or more networks.
OSI	The Open Systems Interconnection.- It is a way of sub-dividing a communications system into smaller parts called layers.
UPS	Uninterruptible Power Supply
CCTV	Closed Circuit Television
FPS	Frames Per Second
NPT	National pipe threaded-tapered threaded hubs
SFP	Small Form-Factor Pluggable
NVR	Network Video Recorder
UL	Underwriters Laboratories
UPS	Uninterruptible Power Supply
RU	Rack Unit
VA	Volt ampere
VoIP	Voice over IP
PAL	Phase Alternating Line
PoE	Power over Ethernet
FTP	Foiled Twisted Pair
PTZ	Pan/Tilt/Zoom
LSZH	Low smoke Zero Halogen
AFFL	Above Finished Floor Level
BU	Black Utilities
CU	Clean Utilities

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	GAMP
Institute of Electrical and Electronic Engineers	IEEE
Factory Mutual	FM
Underwriters Laboratories Inc.	UL
Electronic Industries Alliance	EIA
Telecommunications Industry Association	TIA

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-0-7-06	Riser Diagram	Drug Product	Access Control
7B-I-0-7-06	Riser Diagram	Drug Substance	Access Control
7A-I-1-3-12	Ground floor	Drug Product	Access Control
7B-I-1-3-12	Ground floor	Drug Substance	Access Control
7A-I-2-3-22	First floor	Drug Product	Access Control
7B-I-2-3-22	First floor	Drug Substance	Access Control
7A-I-0-3-02	Walkable ceiling	Drug Product	Access Control
7B-I-0-3-02	Walkable ceiling	Drug Substance	Access Control
7A-I-3-3-32	Second floor	Drug Product	Access Control
7B-I-3-3-32	Second floor	Drug Substance	Access Control
7C-I-1-3-12	Ground floor	Boiler	Access Control
7F-I-1-3-12	Ground floor	Generator Building	Access Control

6.4 Reference documents:

PRD-AIC-TSP-015 – Access Control Security System Design Basis

PRD-AIC-TSP-003 – Security Access Control Equipment & Devices Technical Specification

PRD-AIC-LIS-022 – Security Access Control Equipment & Devices Schedule

PRD-AIC-LIS-040 - Bill of materials - ACS

7. ENGINEERING INFORMATION

7.1 New Buildings Layout

a) Filling Drug Product (formulation/filling/lyophilization)
b) Bulk Drug Substance (up- and downstream)
c) Boilers room
d) Generator building

7.2 Access Control System

7.2.1 The purpose of access control system is to monitor and detect all attempts at access (unauthorized and also authorized) to all possible access areas to the new HEMOBRÁS building (B07).

7.2.2 The areas considered for access control system are:

a) FDP Building
b) BDS Building
c) Automation Room
d) Electrical room
e) Emergency generators room

7.2.3 Access Control System performs a continuous record of people entering and leaving restricted areas. The system records event information such as date, time and user identity and store them in a database and is capable to issue reports for management and security.

7.2.4 Access Control system design considers the following devices:

a) Access Control box
b) Smart Card Readers. Wiegand 26 bits interface
c) Electronic maglocks
d) Strikes
e) Automatic door openers
f) Emergency buttons
g) Interlock between doors

*** Note**: equipment and wiring will be defined on detailed engineering process, as well as the location of each device, identification, communication network and all physical and logical infrastructure.

7.2.5 The Access Control system of the new building must be integrated with the BMS system for monitoring. The configuration will be carried out on the ACS system itself, which controls your connected devices. The existing management system, if it belongs to Hemobrás, must be confirmed.

7.2.6 User's access levels will be established according to their profile.

7.2.7 Access Control software will be installed in the access control server in the BMS control room. This server is LAN integrated by security access switch and distribution switch for integrating with the Hemobrás backbone. Access Control software is able to issue and export reports.

7.2.8 Access Control box monitors the status of the door and grant or deny access to the personnel according to their ID card. Exceeded time Open door audible alarm is included.

7.2.9 Proximity card readers are connected via a two conductor cable to the Access Control box and are connected to the LAN through FTP Cat 6A cable.

7.2.10 Power supply for Access Control boxes will be 220 VCA come from uninterrupted electric power lines (UPS). Proximity card readers will be powered via access control box with voltage 24 VDC.

8. DESIGN REQUIREMENTS

8.1 Power supply

8.1.1 Access control systems equipment will be powered via an UPS input voltage of 220 VAC @ 60 Hz, considering a 15 minutes power backup at full load in case of main power system failure. In case of the UPS is powered by generator voltage the back-up time would be that of the generator.

8.1.2 Access control systems power supply is Electrical design scope.

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.