DATA&VOICE

DESIGN BASIS

2	27JAN2022	ISSUE FOR CONSTRUCTION CONSIDERING COMMENTS	MAV	MAF	RSP
1	29OCT2021	ISSUE FOR CONSTRUCTION CONSIDERING COMMENTS	MAV	MAF	RSP
0	29SEP2021	ISSUE FOR CONSTRUCTION	MAV	MAF	RSP
E	17SEP2021	90% DD ISSUE	MAV	MAF	RSP
D	31MAR2021	30% DD ISSUE	MAV	MAF	RSP
C	16OCT2020	FINAL BD ISSUE	MAV	MAF	MSS
B	28AUG2020	90% BD ISSUE	MAV	MAF	MSS
A	09JUL2020	50% BD ISSUE	MAV	MAF	MSS
REV	DATE	DESCRIPTION	EXEC	CHECK	APPROV.

INDEX

TESSLER engenharia	**ips**	**Takeda**	**Hemobrás** Empresa brasileira de hemoderivados e biotecnologia

DOC NR:	**569-DB07-AIC-110-001**	CLIENT NR:	**PRD-AIC-TSP-008**	
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1. REVISION HISTORY

Rev.	Reason for change
A	50% BD ISSUE
B	90% BD ISSUE
C	FINAL BD ISSUE
D	• Included DOC NUMBER and rename CLIENT NUMBER (Former PRD-AIC-TS-008). • General review in index numbering because has been segregated the Data&Voice system from Security systems ACS & CCTV. • Deleted reference drawings of Security system ACS & CCTV in item 6.4 and new numbers of documents in items 6.5 • As requested by Takeda/Baxalta, has been segregated the Data&Voice system from Security systems ACS & CCTV. • Updated item 7.2.8, quantity of devices.
E	• Updated items 3.1 and 3.2. • Updated items 7.2.2 and 7.2.8. • Updated items 8.1.1 and 8.1.2. • Added item 9.
0	• Updated to Issue for Construction
1	• Revised item 3.2
2	• Updated item 3.1

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.

3. SCOPE

3.1 This document is a technical guideline to design telecommunications systems considered for the Buriti Project – Buildings: B07A - Drug Product, B07B - Drug Substance and Boilers, B07C:

    3.1.1   Voice and Data
    3.1.2   Wi-Fi

3.2 This document has the minimum engineering requirements to be considered to integrate a complete and functional telecommunications systems to the existing facility. The hardware and software of the Voice&Data and Wi-Fi system devices and equipment to be designed shall be compatible with Hemobrás' devices and equipment.

4. ABBREVIATIONS

AP	Access Point (Wi-Fi)
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
MDC	Modular Data Center (Container)
BDF	Building Distribution Facilities
FPS	Frames Per Second
NPT	National pipe threaded-tapered threaded hubs
PBX	Private Branch Exchange
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 Systems design, equipment, materials, and procedures, considered in this project, have to fulfill the next regulations and standards:

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

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

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6.4   Reference drawings:

7A-I-0-7-01	Riser Diagram	Drug Product	Telecom (VoIP&Data)
7B-I-0-7-01	Riser Diagram	Drug Substance	Telecom (VoIP&Data)
7A-I-1-3-10	Ground floor	Drug Product	Telecom (VoIP&Data)
7B-I-1-3-10	Ground floor	Drug Substance	Telecom (VoIP&Data)
7A-I-2-3-20	First floor	Drug Product	Telecom (VoIP&Data)
7B-I-2-3-20	First floor	Drug Substance	Telecom (VoIP&Data)
7A-I-3-3-30	Second floor	Drug Product	Telecom (VoIP&Data)
7B-I-3-3-30	Second floor	Drug Substance	Telecom (VoIP&Data)
7C-I-0-7-01	Ground floor	Boiler	Telecom (VoIP&Data)

6.5   Reference documents:

PRD-AIC-TSP-008 – Data&Voice Design Basis

PRD-AIC-TSP-013 - Data&Voice System Technical Specification

PRD-AIC-LIS-019 - Data&Voice Equipment & Devices Schedule

PRD-AIC-LIS-039 - Bill of materials - VoIP&Data

7.   ENGINEERING INFORMATION

7.1   Actual conditions.

7.1.1   HEMOBRÁS has a MDC based LAN, this LAN has to include and manage the new data switches considered for this project. A star physical topology is considered for data switches connection to the LAN. HEMOBRÁS IT team must locate free data ports in MDC for the new data switches.

7.1.2   Existing IPBX expansion and a remote gateway are considered for new VoIP services.

7.1.3   New Buildings Layout:

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

7.2   Voice and Data System

7.2.1   This system considers a structured cabling based LAN. Ethernet configuration for Network, Email, Internet, and Intranet. TCP/IP protocol. Network speed: 10/100/1000 Mbps.

7.2.2   Voice and Data services horizontal cabling is in star topology. All Telecommunications Outlets cable will be consolidated in the new Buildings B07A, B07B and B07C. Distance between patch panel and Telecommunications Outlets will be no further than 90 meters according to TIA-568 standard.

7.2.3   Equipment, cabinets, cabling and cable pathways will be tagged according to Telecommunications drawings.

7.2.4   Voice and Data system design considers the following devices:

a)   Data Switch, 48 PoE+ ports and 1000 BASE-SX ports.
b)   Data Switch, 24 PoE+ ports and 1000 BASE-SX ports.
c)   PoE IP Telephones.
d)   Cable FTP Cat 6A, 4 pairs 23 AWG. LSZH jacket.
e)   Multimode Optical Fiber Category: OM3. 50/125 µm. 6 strands. Wavelength 850 nm.
f)   Fiber Distribution Unit (FDU). 24 ports. LC duplex connectors.
g)   Cooper Patch Panels. 48 RJ-45 ports. Cat. 6A. FTP ready.
h)   Horizontal and Vertical Cabling handlers.
i)   Cabinet with 19" Rack (42 RU).
j)   Cabinet with 19" Rack (24 RU).

7.2.5   Data switch's specifications have to meet existing equipment technology to guarantee integration. PoE and PoE+ ports included. Up to 1000 VLANs. UPLINK SFP optical fiber ports. Ethernet ports: 10/100/1000 Mbps.

7.2.6   Takeda/Baxalta cabinet's equipment:

a)   Rack 482.6 mm (19")
b)   Vertical and Horizontal cable handlers
c)   Power distribution Units
d)   Grounding system
e)   Ventilation

  * **Note:** equipment and wiring will be defined on detailed engineering process.

7.2.7   Telecommunications outlets are wall mounted at 30 cm above the finished floor level, including VoIP and data ports.

7.2.8 Voice and data services will be distributed in the following areas:

Area	Services	
	Voice&Data	Wi-Fi (AP)
Ground floor		
FDP	74	7
BDS	101	3
BOILERS	2	-
First Floor		
FDP	22	8
BDS	16	6
Second Floor		
Corridor FDP	2	1
Automation room FDP	4	
Electrical room FDP	2	
Corridor BDS	2	1
Automation room BDS	2	
Electrical room BDS	2	

7.2.9 New data switches will be connected to the existing Hemobrás backbone using 6 strands Monomode Optical Fiber and horizontal cabling will be FTP, see item 9.1. All cabling follows TIA-568-1-D.

7.2.10 FTP, 4 pairs 23 AWG, Cat. 6A cables will be used to connect Telecommunications Outlets to the BDF's copper patch panels. Telecommunications Outlets will have two RJ-45 CAT 6A jacks at least and a maximum of four. Connecting FTP cables in the RJ-45 jacks follows T568-B standard.

7.3 Wi-Fi system

7.3.1 The Wi-Fi system will have a controller capable of providing three networks with different properties:

a) A process network to provide connectivity to equipment in the manufacturing area, such as pockets, tablets and others that require wireless network connectivity.

b) An Enterprise network to provide connectivity to employees' wireless devices in areas as necessary, such as meeting rooms, auditoriums, training rooms, et others. This network must be protected by authentication with secure protocol and strong encryption, this authentication must be done with integration of the Wi-Fi system and a domain controller.

c) A Guest network to provide connectivity to visitors who need an internet connection. This Guest network must be on a network separate from the Enterprise network and with access only to the internet. Access to this network must be via temporary tickets and access must be monitored and information must be recorded for future checking.

7.3.2   APs (access points) devices must be installed in offices and manufacturing areas in enough numbers to guarantee the best and greatest signal coverage, avoiding dead zones, interference, and connection problems.

8.   DESIGN REQUIREMENTS

8.1   Power supply

8.1.1   Voice & Data 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 Point (Wi-Fi) field devices will be Power over Ethernet (PoE) through UTP cable from the switch.

8.1.3   UPS for Telecommunications 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 walkable 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.

9.   APPENDIX

9.1   Hemobrás topology

Adobe Acrobat Document

Bloco 07 Switch Acesso ADM
3 Arubas 2930F 48G 4SFP+ PoE
Switch Stack
RU-B1012-A

Rack
Bloco 12

Bloco 01

Bloco 02

Bloco 05

Bloco 07 Switch Acesso ADM
2 Arubas 2930F 48G 4SFP+ PoE
Switch Stack
RU-A1031-A
RU-A3002-A
RU-B3010-A

Bloco 07 SW Distribuição ADM
Módulo Stacking Traseiro
Aruba 3810M 16SFP+ 2-slot Switch
RU-B3010-A

RU-B3010-B

Bloco 03

TRK

Bloco 07 SW Distribuição Automação
Módulo Stacking Traseiro
Aruba 3810M 16SFP+ 2-slot Switch

Bloco 06

Bloco 04

Portaria

Bloco 07 SW Acesso Security (CFTV/ACS)
Aruba 2930F 48G 4SFP+ PoE
RU-A1031-A
RU-A3002-A
RU-B3010-A
RU-B1012-A

Bloco 07 SW Acesso Automação (PCS/EMS/BMS)
Aruba 2930F 48G 4SFP+ PoE
RU-B3010-B

Bloco 07 Switch Automação
Siemens 6GK52062BB002AC2

Legenda

— Fibra 10G
— SPF+ DAC 1m 10G
— Stack