SAUTER
Creating Sustainable Environments.

Reference:
Roche Diagnostics Suzhou IVD Greenfield Project

Sauter Beijing Co., Ltd.

Sep., 2017

PharmaTEC 制药业

SAUTER
Creating Sustainable Environments.

- Full range of building automation products
- 全系列高端楼宇自控系统服务

- Control of Pharma, Bio Lab, BSL-3 and BSL-4
- BSL3以及BSL4， 制药和生物实验室控制

- Life science and healthcare
- 医疗设施及生命科学设施自控系统

- System integration service
- 系统集成服务

High quality

高品质

SAUTER
Creating Sustainable Environments.

‘Made in Switzerland’ quality
“瑞士制造” 保持最高质量品质

- The product manufacturing is headquartered in Switzerland (Basle).
- 产品总部集中在瑞士巴塞尔

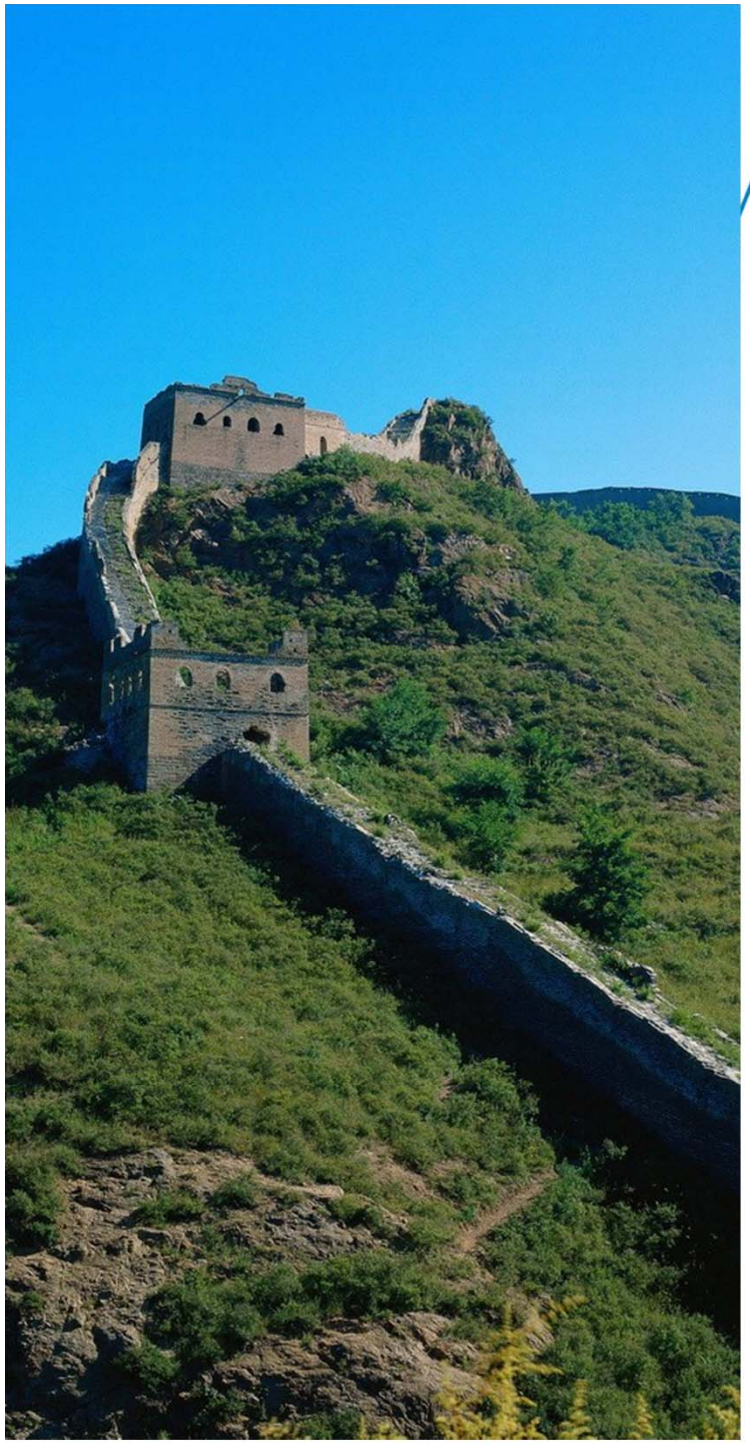
- Loyalty to our location, and Swiss virtues.
- 忠诚于所在地瑞士的专注和品质保证的美德

- Directly adjacent to research and development.
- 高度关注研发

- Reference to standards ISO 9001, ISO 14001 and OHSAS 18001 is controlled.
- 产品的生产严格遵照ISO9001 ISO14001 和 OHSAS 18001 标准

- eu.bac-certified products.
- 全部产品符合欧盟eu.bac 协会的标准要求

Pharma·TEC 制药业



SAUTER
Creating Sustainable Environments.

SAUTER China
SAUTER 中国

- Sauter China was established in 2004
- 索特中国成立于2004年

- Sales, Engineering and Service.
- 索特中国可以为中国的客户提供销售、工程实施和服务等全方位的支持

- Remarkable Business Growing.
- 中国业务的高速增长

- The leading company in Pharmaceutical and Laboratory Automation.
- 目前已成为制药和实验室环境控制的领先公司

Pharmaceutical Reference

Pharmaceutical Factory

Roche Shanghai
RoSE I project

Owner: Shanghai Roche Pharmaceuticals Ltd.

- ■10,000 control points
- ■HVAC, Lab, Fumehood, FCU, Ground Heating pump, Steam System.
- ■Monitoring System
- ■Validation and Qualification
- ■Working with Lendlease

罗氏 **RoSE I** 厂房, 上海

Pharmaceutical Reference

制药厂

诺华制药生产厂房
北京

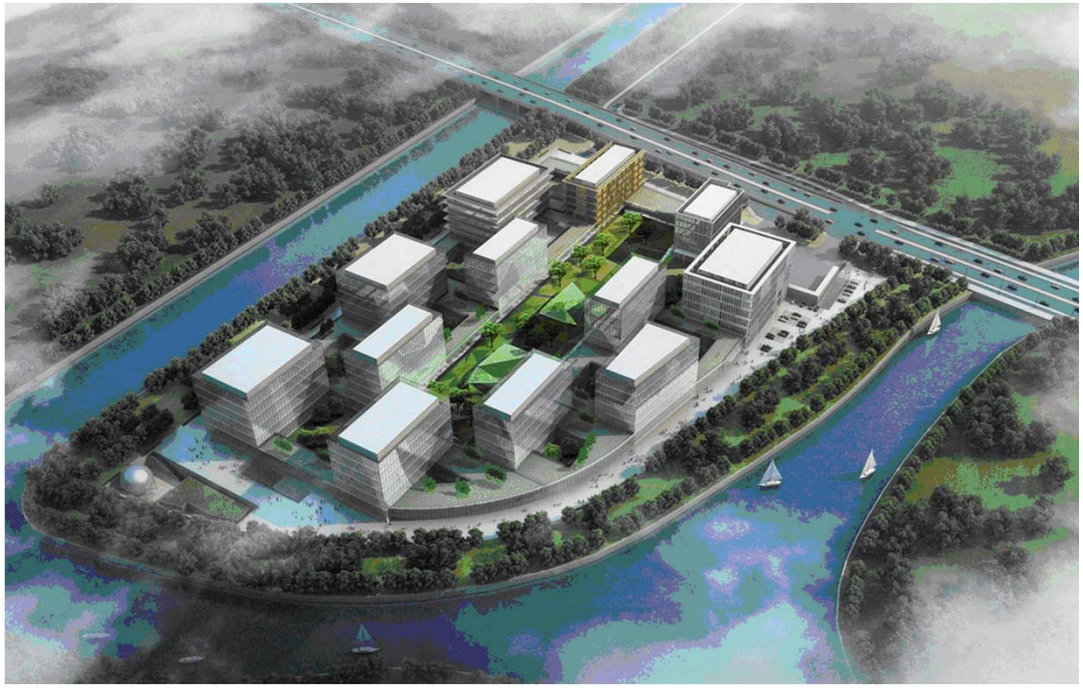
Pharmaceutical Factory

Novartis Pharma Plant In Beijing
EPCP1,EPCP2

Owner: Beijing Novartis Pharmaceuticals Ltd

- 10,000 sqm
- HVAC (22 sets of AHUs)
- Pneumatic SA/EA VAV control
- Room Monitoring System is fully validated, complied with FDA CFR 21 Part 11
- Building Automation System is fully qualified

Pharmaceutical Reference



诺华中国研究中心—全球最大的制药研发中心
上海

R&D Center

Novartis Institute of Bio-medical Research

Owner: Novartis Pharmaceuticals Ltd

- 45,000 Control Points
- HVAC
- System Integration (Fire alarm, Lighting, Chiller, Boiler)
- Lab control (C5, C11-2)
- 2000+ VAV Box
- Fumehood (172 sets)
- Animal facility
- Data center
- Energy center
- Office Buildings

Pharmaceutical Reference

制药厂

勃林格殷格翰上海**Panda, Biolab, NewLocker**项目
上海张江

Pharmaceutical Factory

Boehringer Ingelheim Pharmaceuticals Panda, Biolab Project

Owner: Boehringer Ingelheim Pharmaceuticals Ltd.

- 1,800 control points
- HVAC
- System Integration
- Energy Management System
- Environmental Monitoring System
- C&Q Support

Pharmaceutical Reference

研发中心

R&D Center

Novo Nordisk China R&D Center

诺和诺德中国研发中心

- 6,100 Control Points
- HVAC
- 1000 VAV Box
- 80 labs for dogs and rodent
- Fumehood control
- Chiller
- Boiler
- System integration

诺和诺德中国研发中心
北京昌平

BMS System

General description

- **Area受控区域:**
  - ✓ 生产楼 Production Building
  - ✓ 行政楼 Admin Building
  - ✓ 质检楼 Quality Inspection Building
  - ✓ 公用设施楼 Central Utility Building
  - ✓ 危险化学品库 Hazardous Chemical Storage
  - ✓ 维修车间 Maintenance Building
  - ✓ 仓库 Warehouse
  - ✓ 门卫 Guardhouse

General description

➢ **Work Scope 工作范围:**

- BMS
- Intelligent Lighting Control System（Included in BMS）
- EnMS
- Fluid Leakage System（Included in BMS）
- Gas Detection System（Included in BMS）
- EMS

BMS System

BMS系统包括以下控制内容：
BMS system includes the following sub-systems:

- ✓ 空气处理机组 Air Handling Unit
- ✓ 新风机组 Make-up Air Unit
- ✓ 送排风机 Supply/Exhaust Air Fan
- ✓ 变风量系统 VAV System
- ✓ 通风柜控制 Fume Hood Control
- ✓ 房间压力控制 Room Pressure Control
- ✓ 空调冷热水 Chilled and Hot Water for HVAC
- ✓ 蒸汽系统 Steam System
- ✓ 压缩空气系统 Compressed Air System
- ✓ 智能灯光控制 Intelligent Lighting Control System
- ✓ 液体泄漏监测系统 Fluid Leakage Detection System
- ✓ 危险气体探测系统 Dangerous Gas Detection System
- ✓ 能源管理系统 Energy Management System

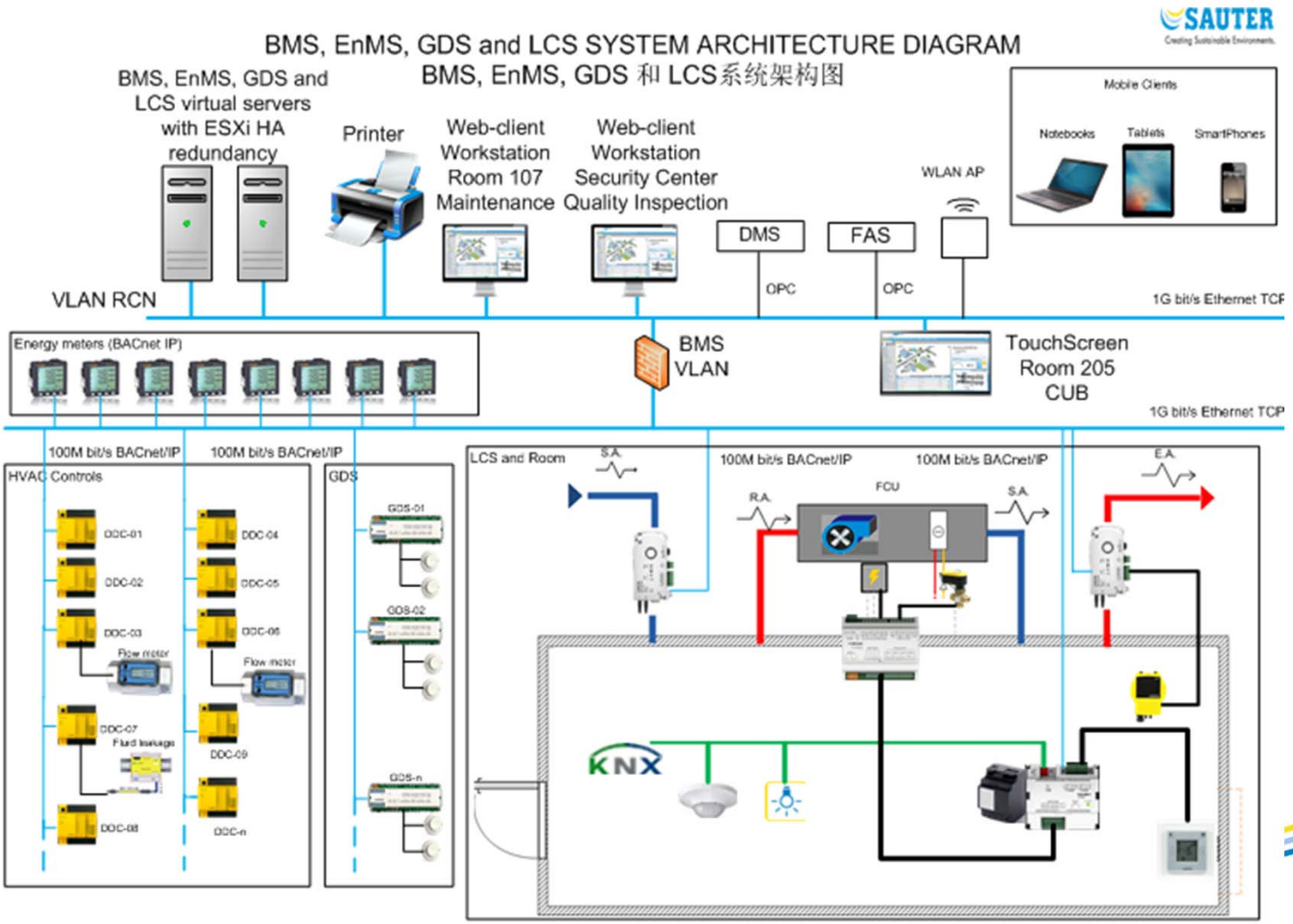
BMS System

BMS系统包括以下集成内容：
BMS system integrates with the following sub-systems:

- ✓ 危险管理系统 Danger Management System--OPC
- ✓ 火灾报警系统 Fire Alarm System--OPC
- ✓ 冷水机组系统 Chiller package--BACnet/IP
- ✓ 冷水系统稳压系统Chilled Water Pressure maintaining package--BACnet/IP
- ✓ 乙二醇水混合系统Glycol water compounding package--BACnet/IP
- ✓ 质检大楼热水生产包Hot Water Generation Package for Quality inspection building--BACnet/IP
- ✓ 生产大楼1（北区）热水生产包Hot Water Generation Package for PB 1 (North part) --BACnet/IP
- ✓ 生产大楼1（南区）热水生产包Hot Water Generation Package for PB 1 (South part) --BACnet/IP
- ✓ 行政楼热水生产包Hot Water Generation Package for Adimin building--BACnet/IP
- ✓ 维修车间热水生产包Hot Water Generation Package for Maintenance building--BACnet/IP
- ✓ 仓库热水生产包Hot Water Generation Package for Warehouse--BACnet/IP
- ✓ 压缩空气制备包Compressed Air Generation Package--BACnet/IP
- ✓ 天然气计量站NG metering station--BACnet/IP
- ✓ 氨气洗涤塔Ammonia scrubber--BACnet/IP
- ✓ 太阳能热水Solar Water System--BACnet/IP
- ✓ 给水泵组Water supply system--BACnet/IP
- ✓ 中水变频泵组Reclaim water system--BACnet/IP
- ✓ 冷却塔Cooling Tower--BACnet/IP
- ✓ 沙滤系统Sand Filter Package--BACnet/IP
- ✓ 化学投药系统Chemical Dosing Package--BACnet/IP
- ✓ 光伏系统Photovoltaic System--BACnet/IP
- ✓ 电源管理系统Power Management System--BACnet/IP
- ✓ 柴油发电机Emergency Diesel Generator--BACnet/IP
- ✓ 不间断电源系统UPS--BACnet/IP
- ✓ 废水处理系统Waste Water Treatment System Package Unit--BACnet/IP
- ✓ 液氮存储与减压系统Liquid nitrogen Storage and evaporating System--BACnet/IP
- ✓ 2~8℃冷库2-8 degC 'Cold room 1--BACnet/IP
- ✓ 高甲仓库high bay 2-3 and precooling room--BACnet/IP
- ✓ -25℃存储间-25 degC storage--BACnet/IP
- ✓ 热回收系统Heat Recovery Unit--BACnet/IP
- ✓ 精密空调High accuracy HVAC--BACnet/IP
- ✓ 气体检测系统Gas detection System--BACnet/IP

BMS System

BMS System Structure:



SAUTER advantages to comply

SAUTER
Für Lebensräume mit Zukunft.

- Only service based
- Remote SQL
- No local application as the servers are in the server room
- All actions from the web
- Full HTML5 (no plugin needed)
- The VMs can move in the server farm
- VMware vmotion, HA, DRS and FT compliant
- No physical connection
- Fully FDA compliant and already installed in FDA plants in Asia

BMS System

Total I/O point:

Building	DI	DO	AI	AO	Total IO
Production1	391	421	299	140	1251
Quality Inspection	203	397	270	167	1037
Warehouse	123	181	129	68	501
CUB	193	91	113	6	403
Admin	157	488	463	319	1427
Maintenance	76	132	78	51	337
Hazardous Chemical Storage	51	22	15	7	95
Guardhouse	18	29	17	5	69
Total	1212	1761	1384	763	5120

BMS System

Control Logic：

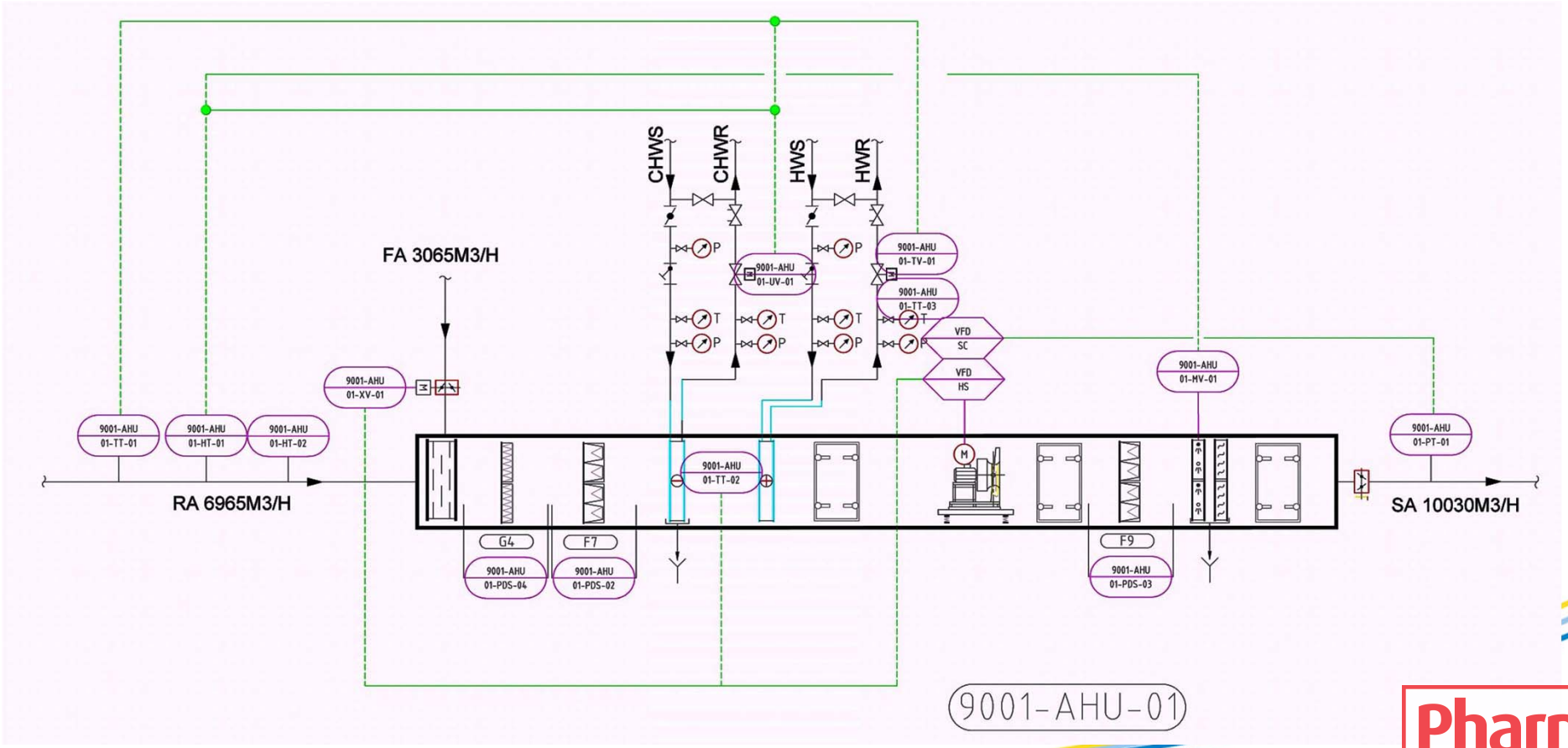
- ✓ 空气处理机组控制逻辑 AHU control logic
- ✓ 新风机组控制逻辑 MAU control logic
- ✓ 风机盘管控制逻辑 FCU/FFU control logic
- ✓ 冷梁控制逻辑 CB control
- ✓ 房间压力控制逻辑 Room pressure control logic
- ✓ 通风柜控制逻辑 Fume hood control logic
- ✓ 房间压力与通风柜联合控制逻辑 Room pressure and fume hood combine control logic
- ✓ 冷冻水系统控制逻辑 Chilled water control logic
- ✓ 热水系统控制逻辑 Hot water control logic
- ✓ 集成系统介绍 Third party system integration description
- ✓ 智能灯光控制逻辑 Intelligent lighting control system
- ✓ 液体泄漏监测系统控制逻辑 Fluid leakage detection system
- ✓ 危险气体探测系统控制逻辑 Dangerous gas detection system control logic
- ✓ 能源管理系统 Energy management system

BMS System

9001-AHU-01 P&ID Control Schematic：

AF&ID:00493-8343-25-121-9001-0001 For 9001-01 AHU System_S1

Production 1 Building

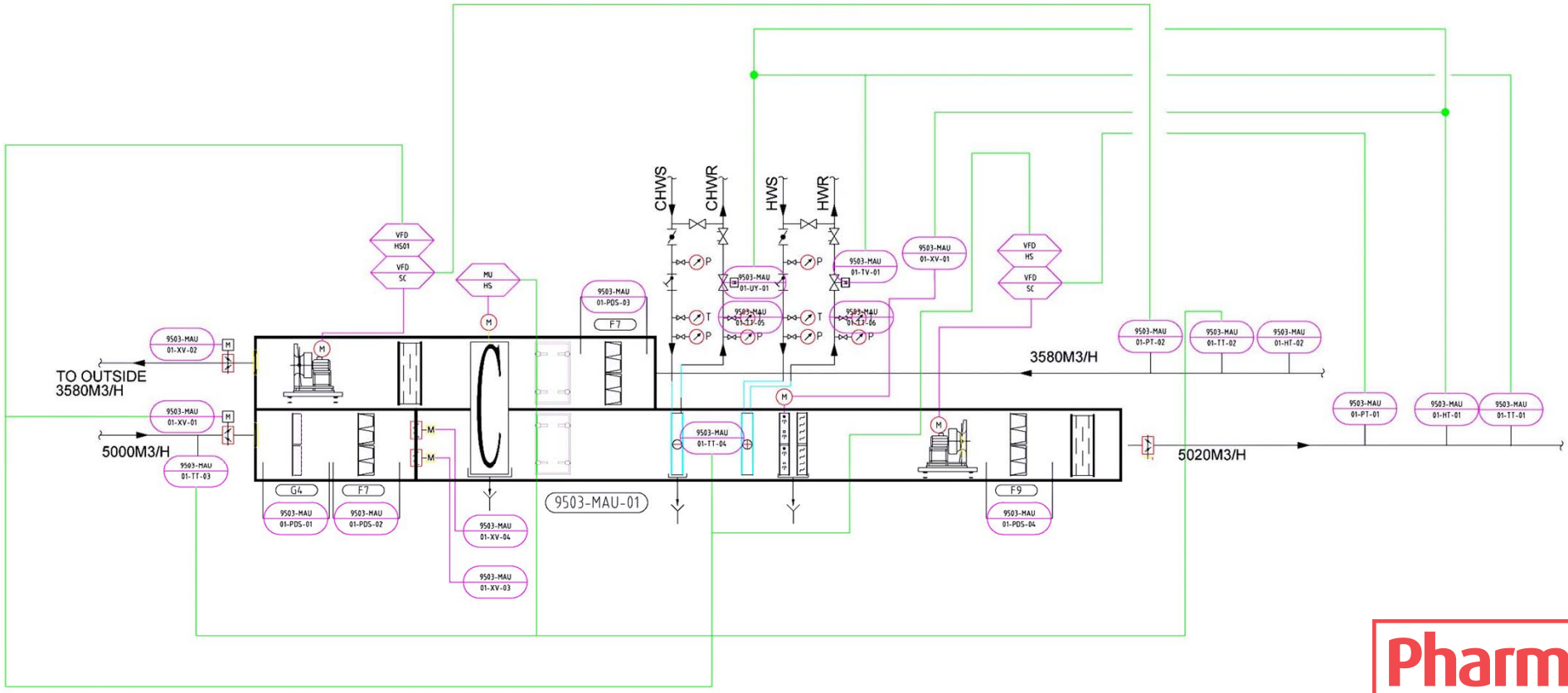


BMS System

9503-MAU-01 P&ID Control Schematic

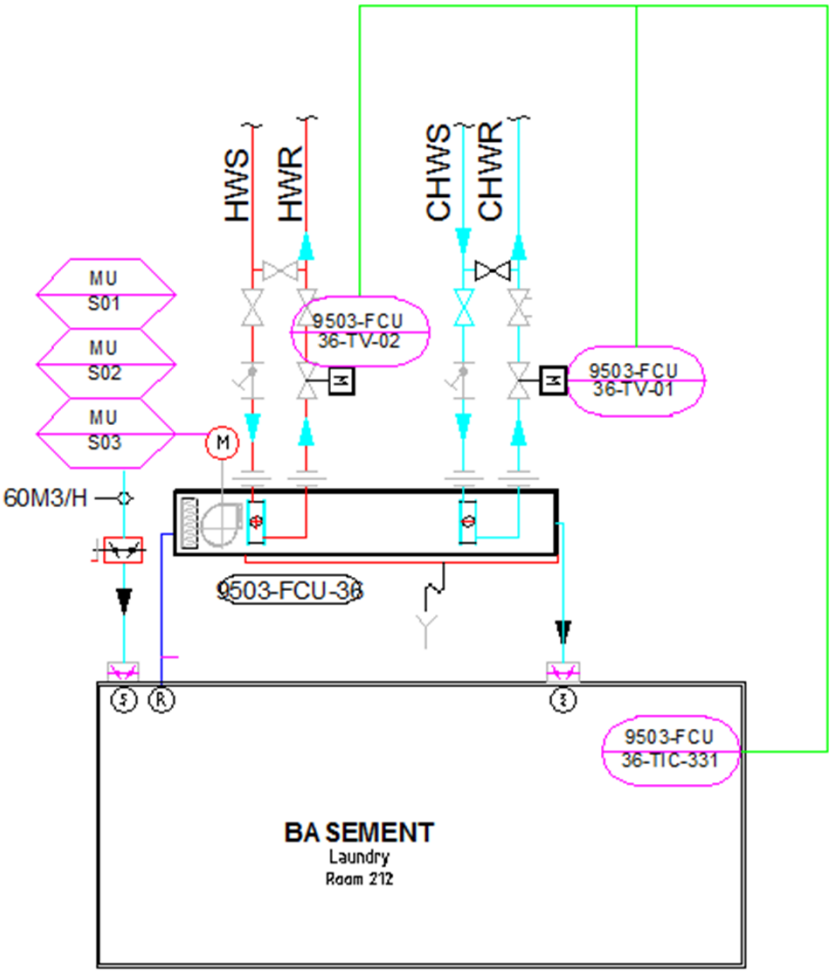
AF&ID:00493-8343-25-113-9503-0001_AF&ID for 9503 MAU System01_R2

Quality Inspection Building

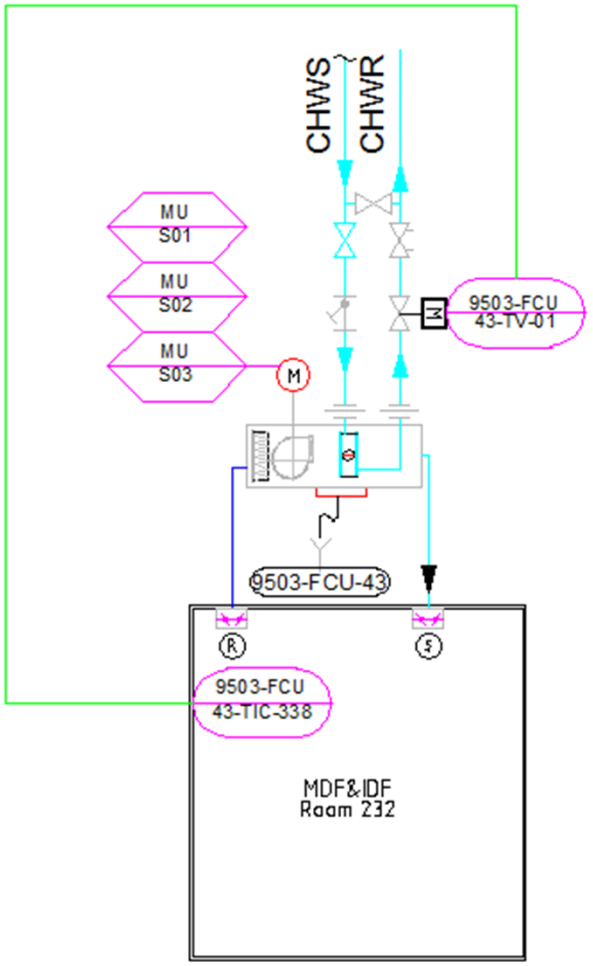


BMS System

FCU/FFU Control Logic：



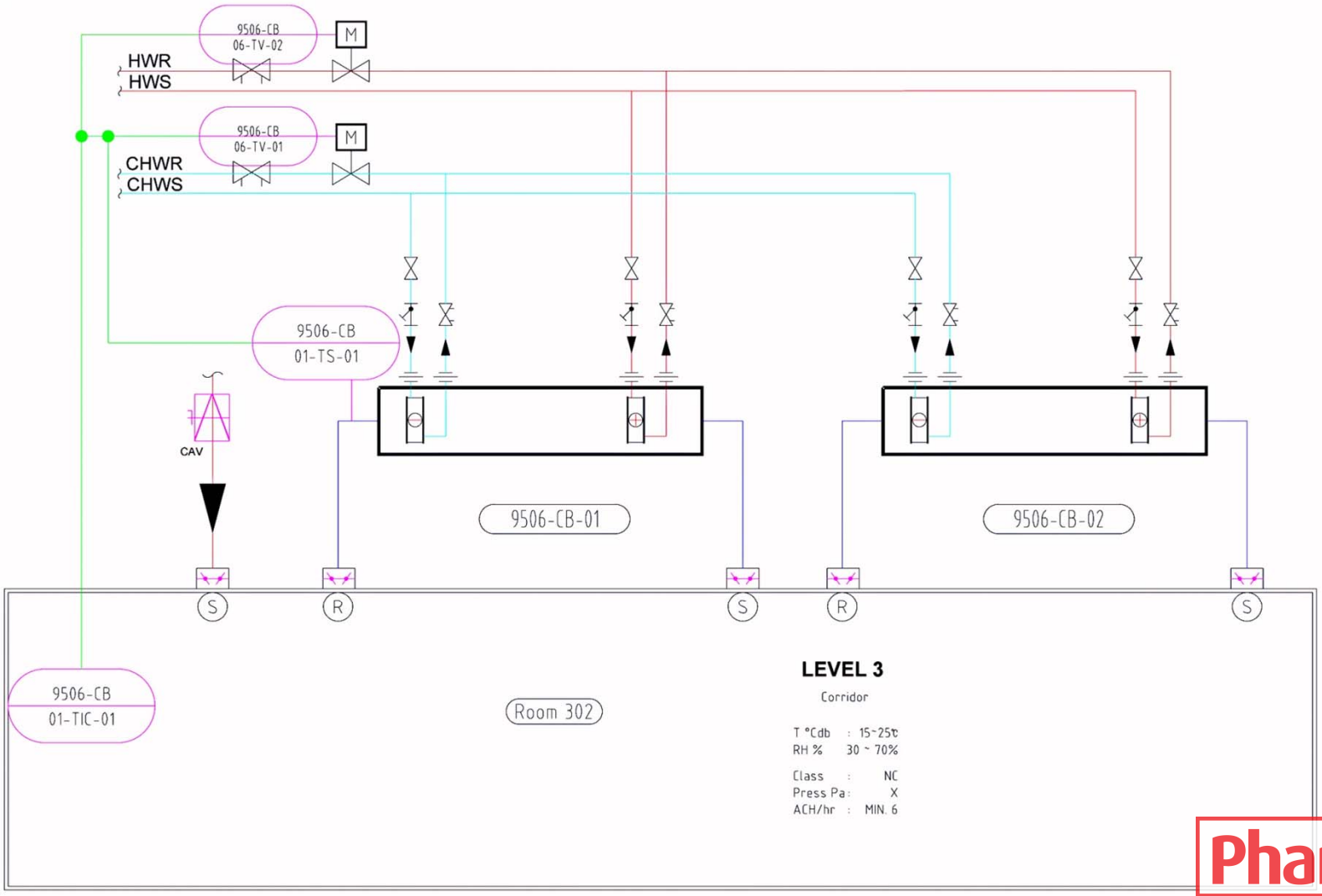
FCU Control Type 1



FCU Control Type 2

BMS System

CHB Control Logic：



BMS System

Chilled water system Control Logic:

✓冷水机组控制 Chiller sequence control

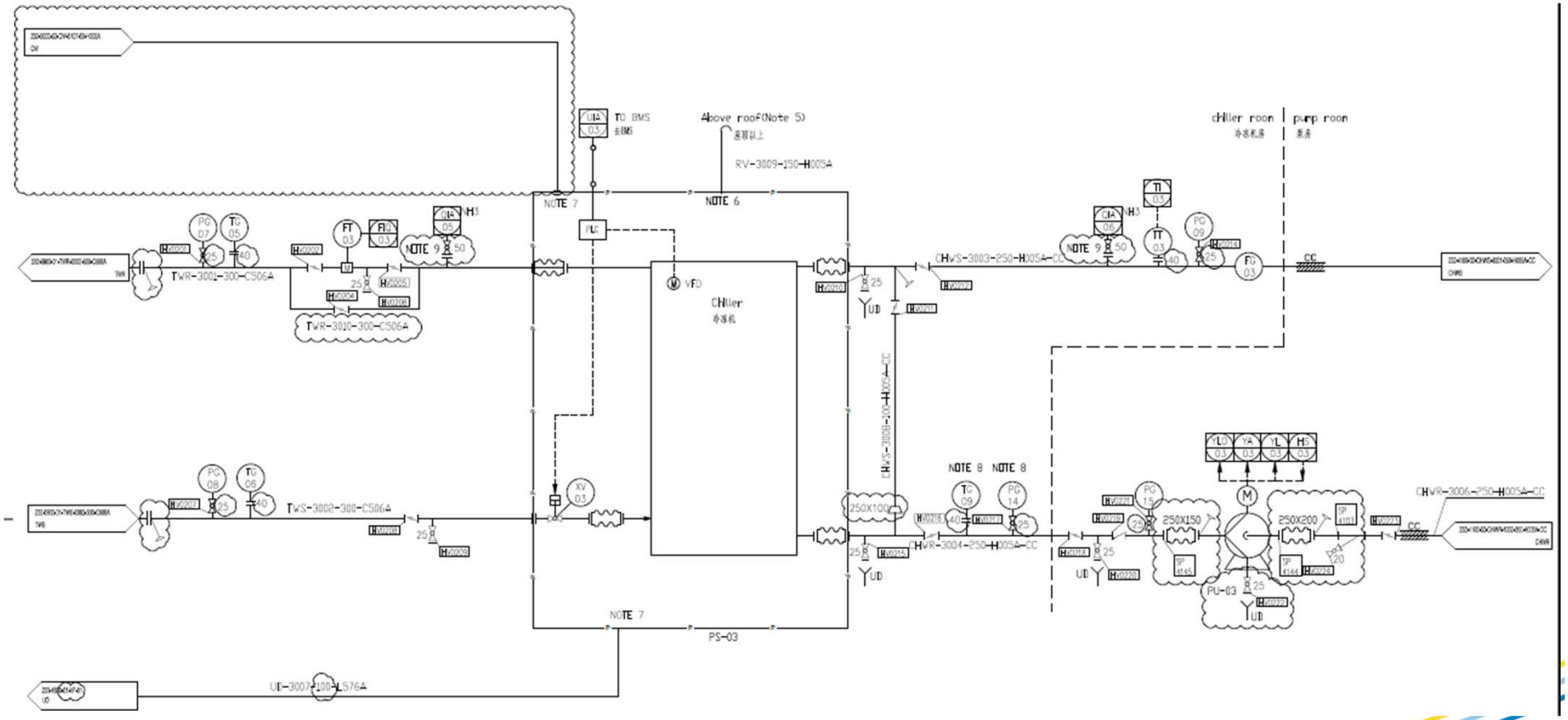
✓冷冻水回路控制 Chilled water loop control

✓冷却塔控制 Cooling tower control

✓冷却水回路控制 Cooling water loop control

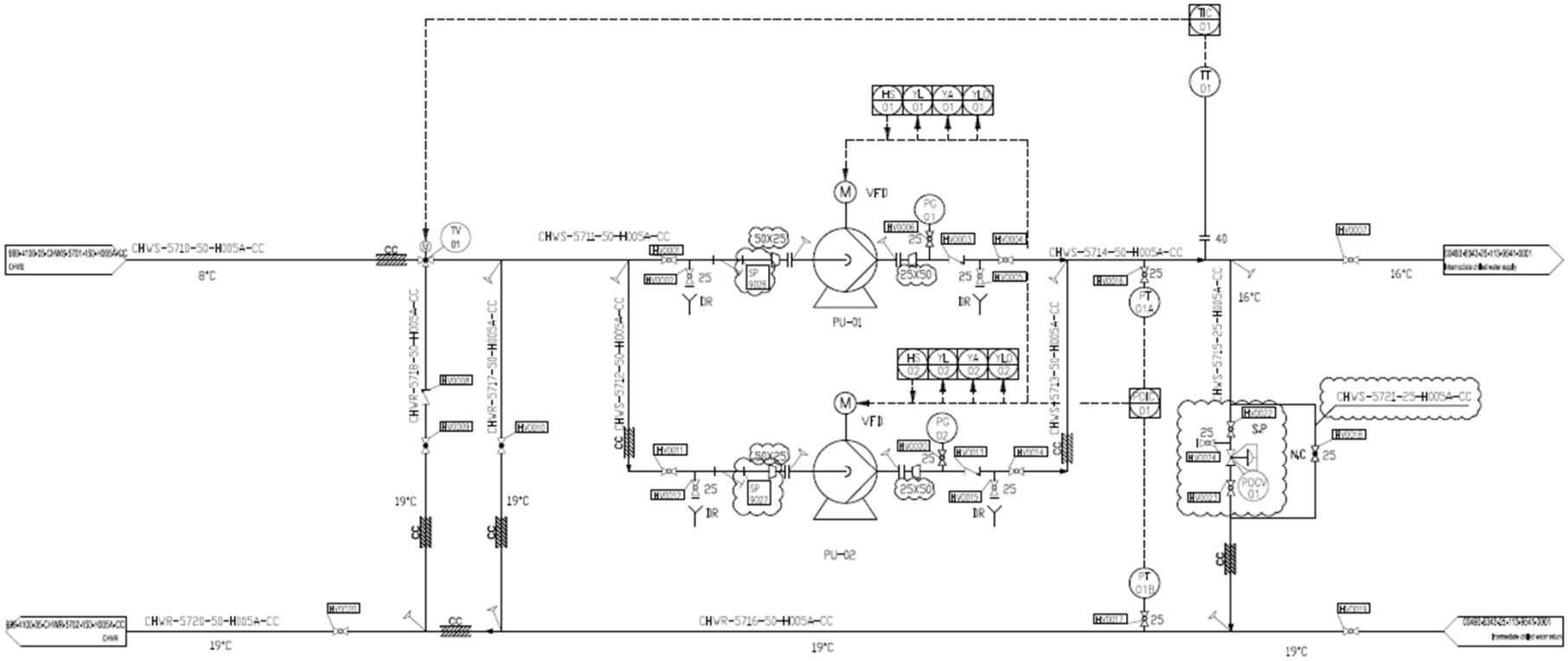
BMS System

Chilled water system Control Logic:



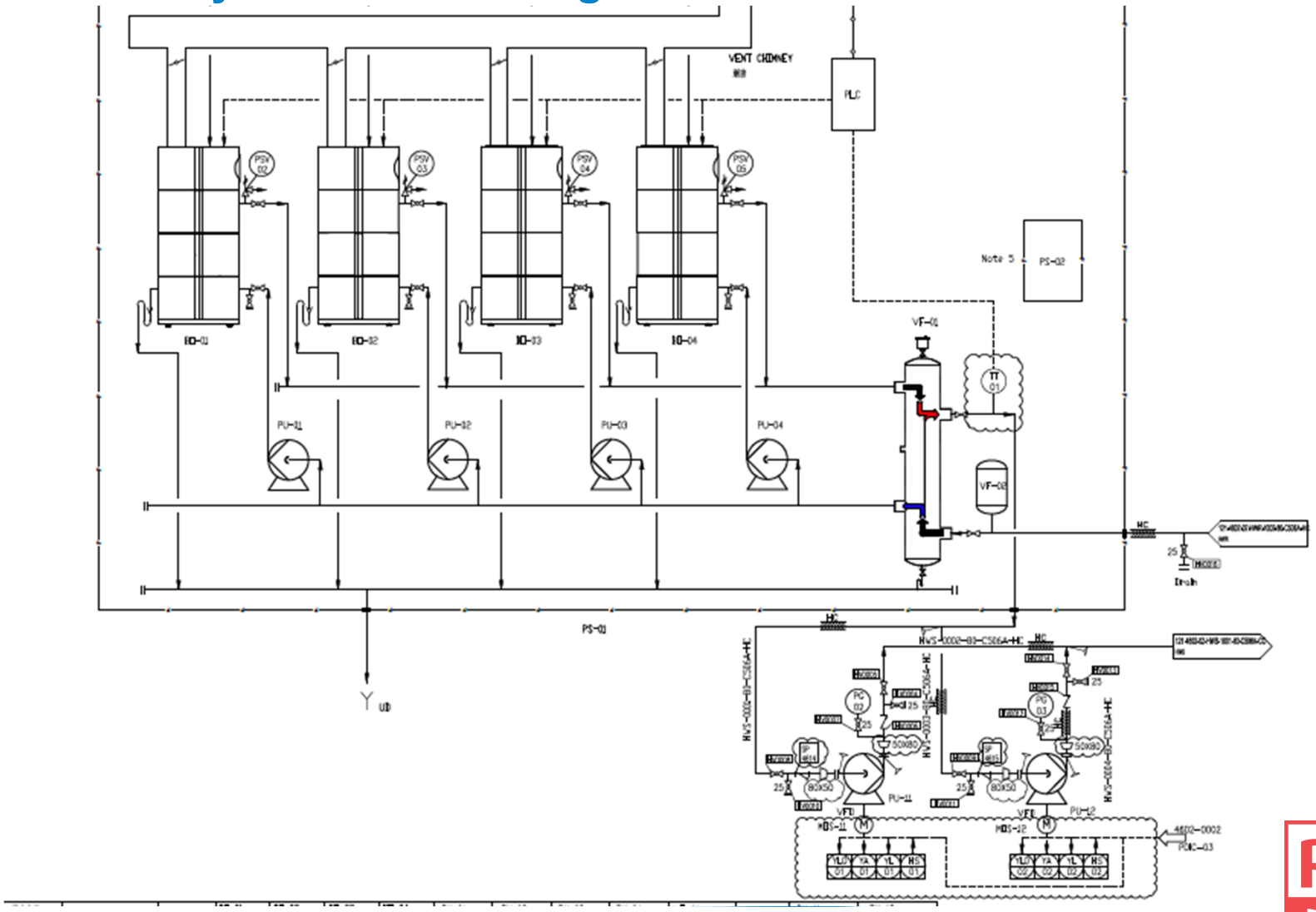
BMS System

Chilled water system Control Logic:



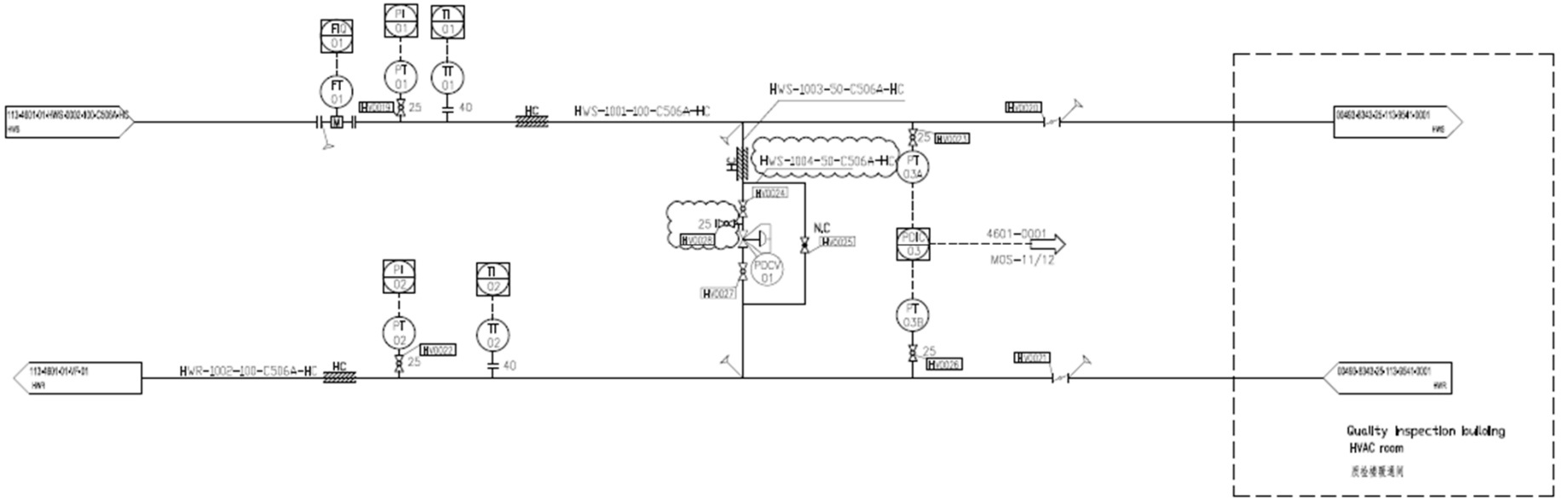
BMS System

Hot water system Control Logic:



BMS System

Hot water system distribution Control Logic:



BMS System

Third party system integration :

- ✓ 危险管理系统 Danger Management System--OPC
- ✓ 火灾报警系统 Fire Alarm System--OPC
- ✓ 冷水机组系统 Chiller package--BACnet/IP
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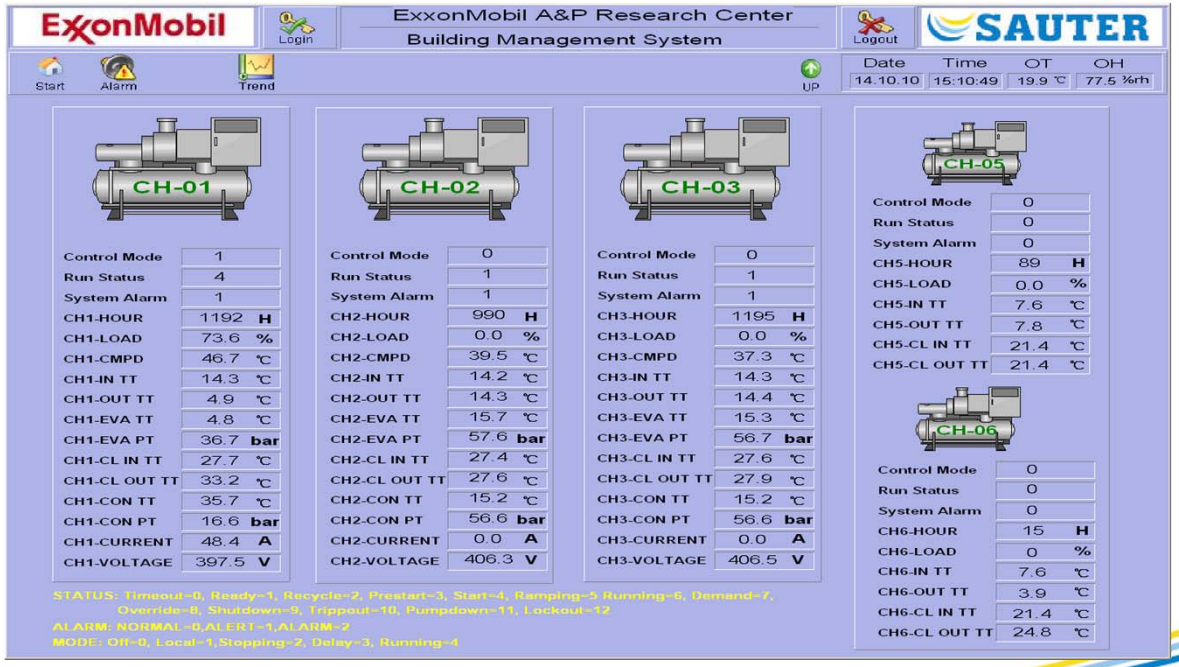
- ✓ -25℃存储间-25 degC storage--BACnet/IP
- ✓ 热回收系统Heat Recovery Unit--BACnet/IP
- ✓ 精密空调High accuracy HVAC--BACnet/IP
- ✓ 气体检测系统Gas detection System--BACnet/IP

BMS System

Chiller System Integration:

冷水机组系统需要采集以下参数：机组运行状态、故障报警、压缩机总负荷%、冷冻水温度设定值、机组累积运行时间、冷冻水进水温度、冷冻水出水温度、远程启停、冷热反馈、冷热切换控制。

以下参数可能也需要采集：A回路排气压力、A回路吸气压力、A回路排气温度、A回路吸气温度、B回路排气压力、B回路吸气压力、B回路排气温度、B回路吸气温度。



BMS System

Room Pressure control

Sauter solution:

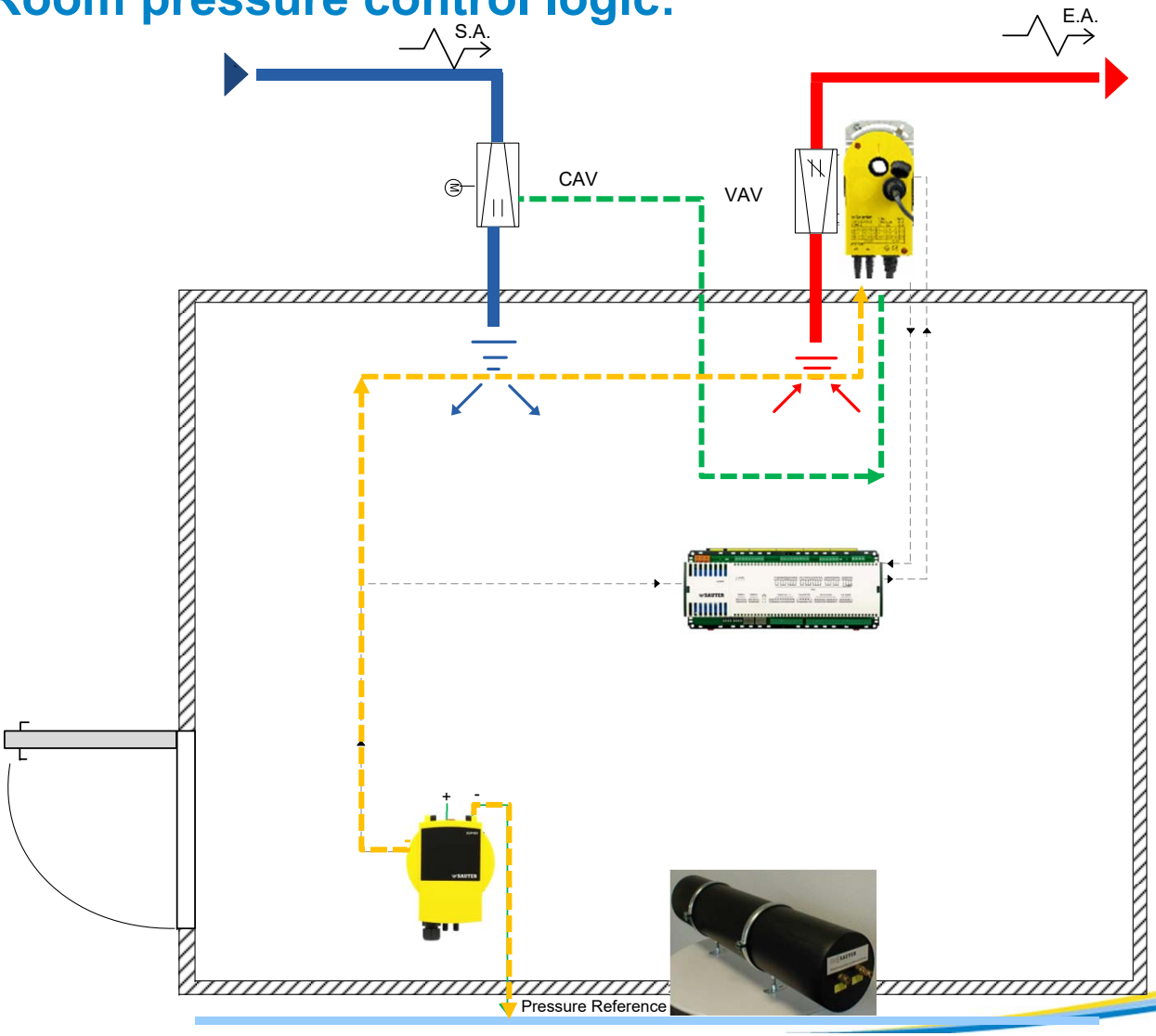
Cascade control

Airflow tracking + Differential pressure

- Airflow tracking is the basic control loop;
- Differential pressure is the offset loop.

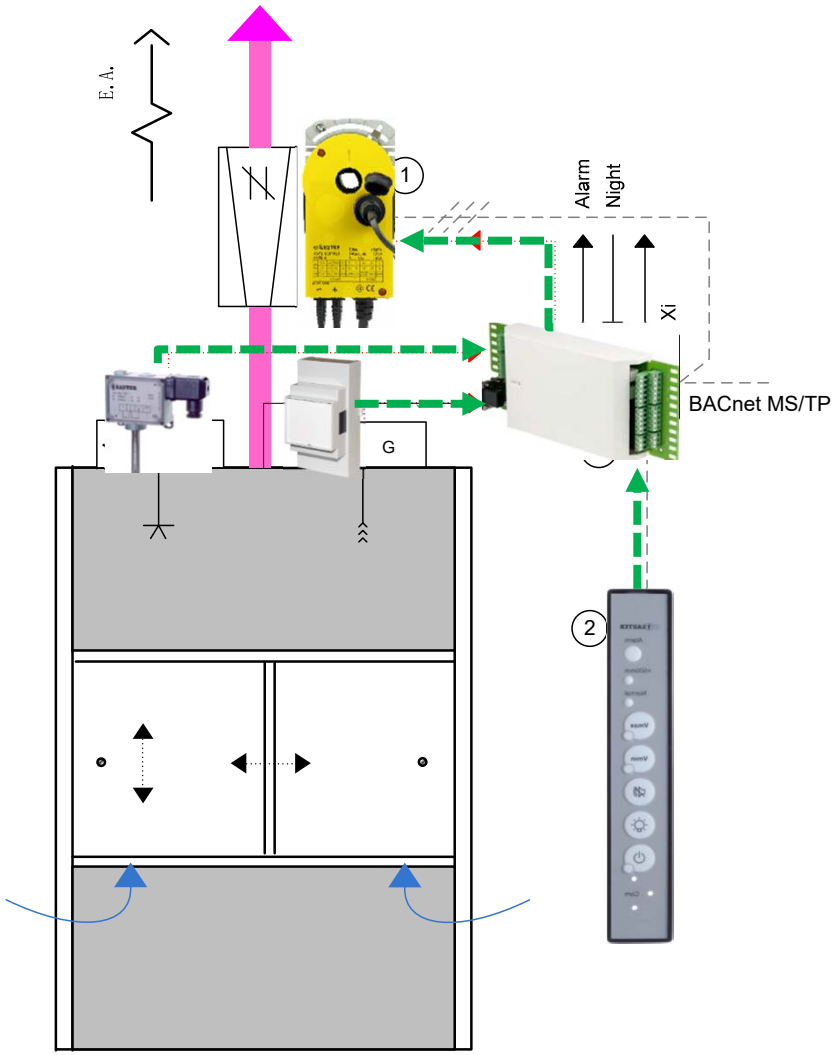
BMS System

Room pressure control logic:



BMS System

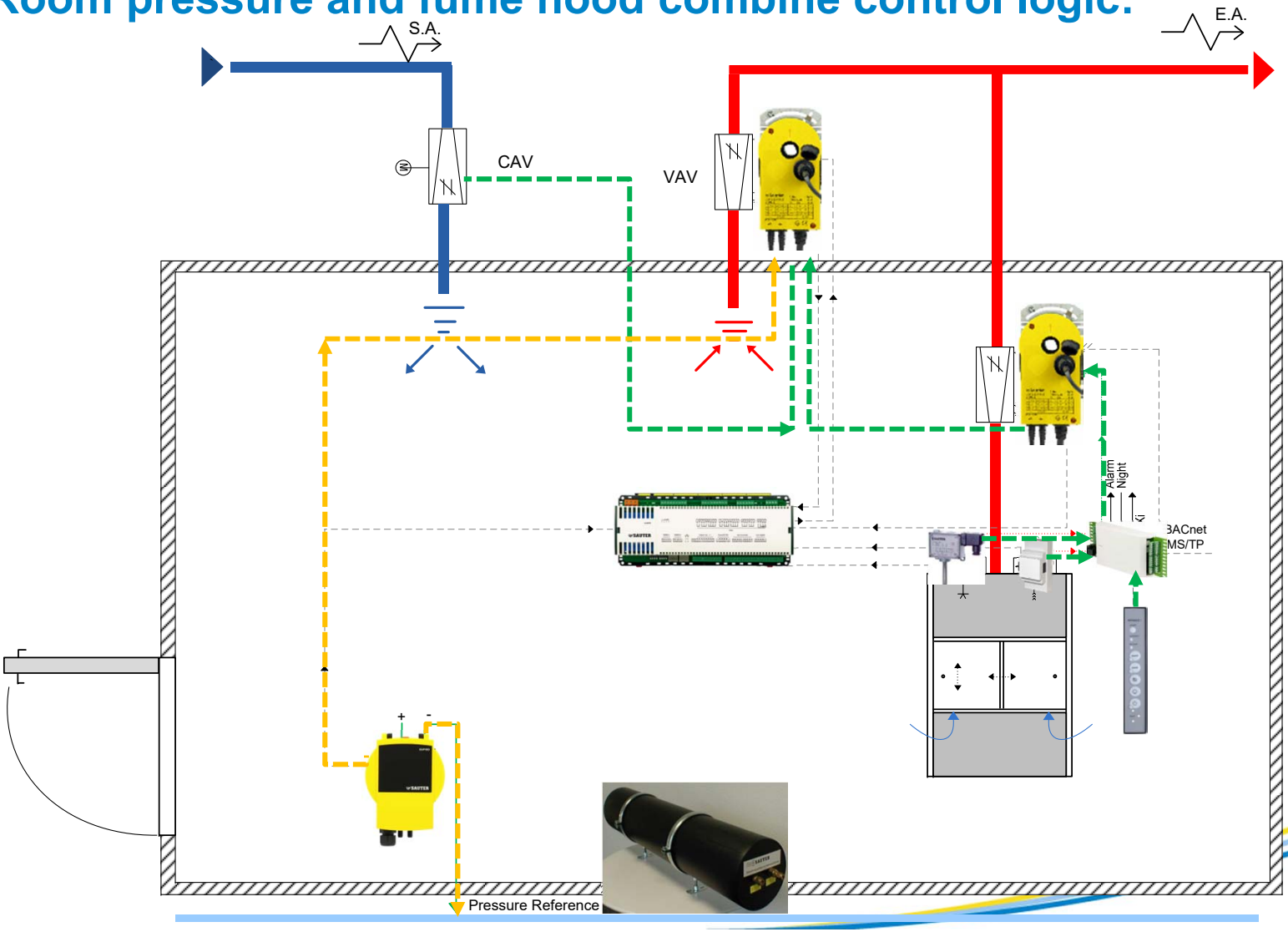
Fume hood control logic:



- Measure the opening height (4) and the air flow speed (5) at the front sash.
- Calculate the exhaust air flow volume by the VAV controller and adjust VAV box opening by fast running actuator(1).
- Continuous protect against harmful emissions by increasing the volume of the air flow when the front sash is open; maintain a face velocity in 0.5 m/s (EN 14175)

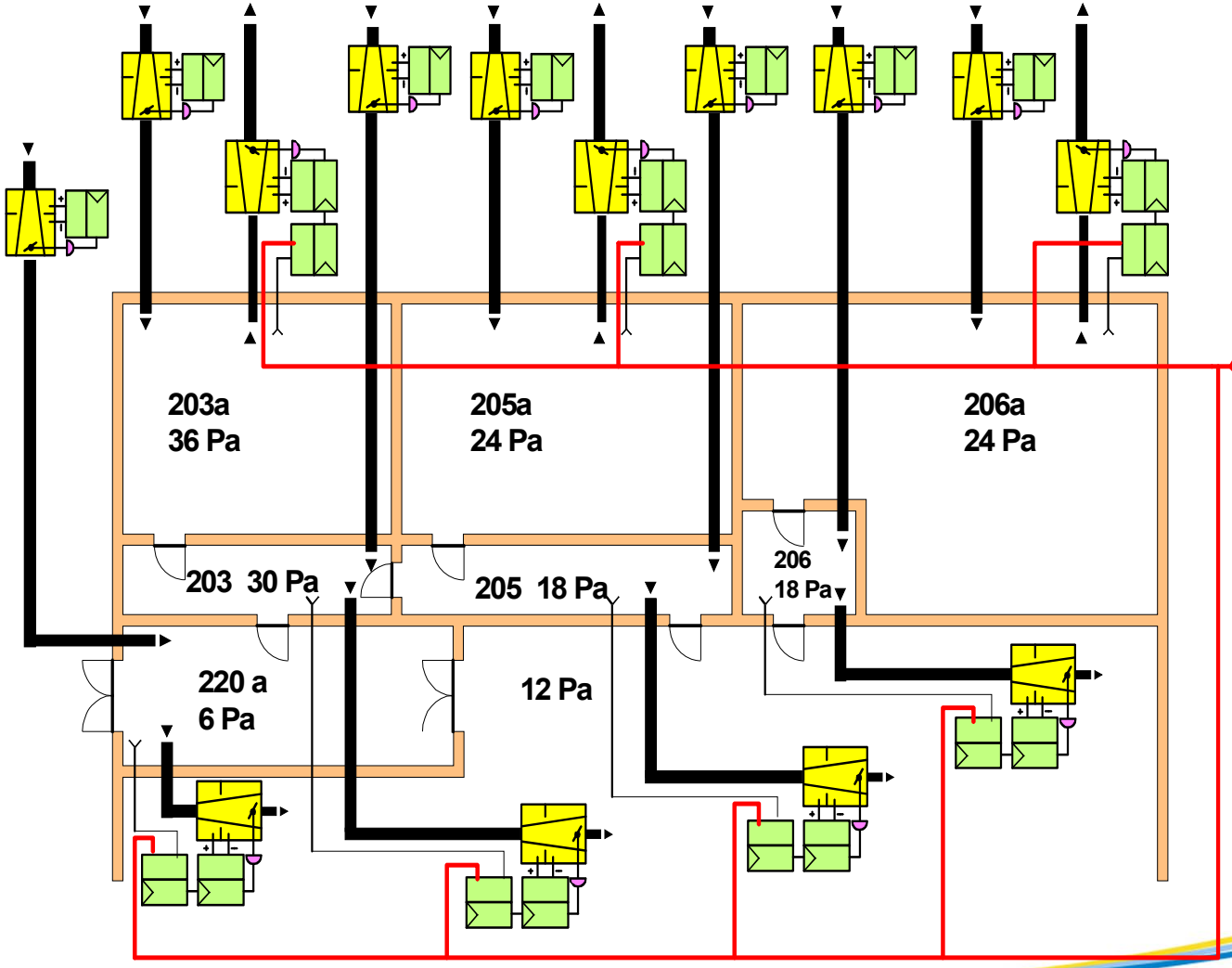
BMS System

Room pressure and fume hood combine control logic:



BMS System

Differential Pressure Reference Unit :



RC Unit

BMS System

SAUTER
Creating Sustainable Environments.

Controller

BACnet®

eu.bac Cert

- 32 Bit CPU
- Embedded Linux
- Operating system
- Network
- BACnet/IP
- Ethernet
- 10/100MHz

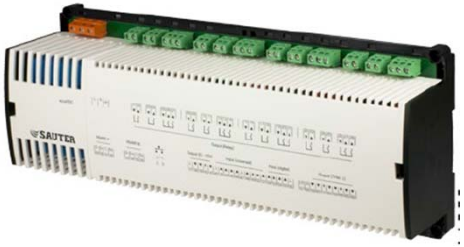
525

- Memory :48M
- Max IO:156
- Control for Chiller and utility system

521

- Memory :400M
- Max IO:94
- Control for AHU/MAU and HVAC system

500/504



- Memory :48M
- Max IO:96
- Control for FCU/CB/FFU and GDS system
- Extension up to 8 room operating unit

EY-RU344

- Room operating unit
- Speed control
- Temperature measure and setting

BMS System

Fast VAV Controller ASV115:

Fast actuator，torque:10Nm
Full running time:3s

PC connection interface
5 I/O points

Air flow measure range
Accuracy:1%, 1…150 Pa

Features:
VAVcontroller，with 3s fast running actuator , high accuracy air flow sensor and RS 485 interface

Application:
Pressure control for fume hood and laboratory.

BMS System

Differential Pressure Sensor EGP100:

Pressure setting

Sensor zero point cottection
PI control Tn ,Xp parameter setting

(Adjusting range: 100 …50%)
Measuring range
-75 … 75 Pa

Features:

Pressure transmitter

Application:

Combine with supply/exhaust VAV controller to realize room pressure cascade control

BMS System

Pneumatic Damper Actuator AK31: Explosive-proof

Apply in areas of zone 1 II 2 G T6

Apply for damper and VAV

CDA supply:1.3Bar
CDA output: 0.2…1.0Bar

Torque:1.8Nm

Features:
Pneumatic damper actuator, combine use with pneumatic air flow sensor RLP100

Application:
Control for damper and VAV system

Gas Detection System

当O_2,CO_2,O_3,SF_6或者可燃气体浓度超出要求范围时，报警灯发出信号提醒工作人员注意，同时开启相应的排风机。

When O_2,CO_2,O_3,SF_6 or flammable gas concentration is out of range, the lamp will flicker to remind the operators, and at the same time, the relative exhaust fans will be started.

Intelligent Lighting Control System

Control mode：

场景控制（Lighting Scene）

在不同的时间段执行相应的场景模式（上班模式，下班模式，深夜模式），通过系统时钟自动切换。也可通过智能面板进行人为操作，使办公生活更便捷。

Different Lighting Scenes will be executed automatically by computer according to different time setting. Also can be controlled directly by touch panel on site.

Intelligent Lighting Control System

Control mode：

调光控制(Dimming control)

根据模式的选择，灯光会呈现出不一样的照度。例如，就餐时，灯光可以自动调整成80%的照度。这样，既可以保证照度，也可以合理的节约用电。

Lighting brightness will be different in lighting scenes.

Intelligent Lighting Control System

Control mode：

人体感应控制（Sensor control）

人体感应探测器可以自动感应人体的移动。实现人来灯开，人走灯灭。
Lights can be automatically turned on/off when sensors are activated by human movement.

Intelligent Lighting Control System

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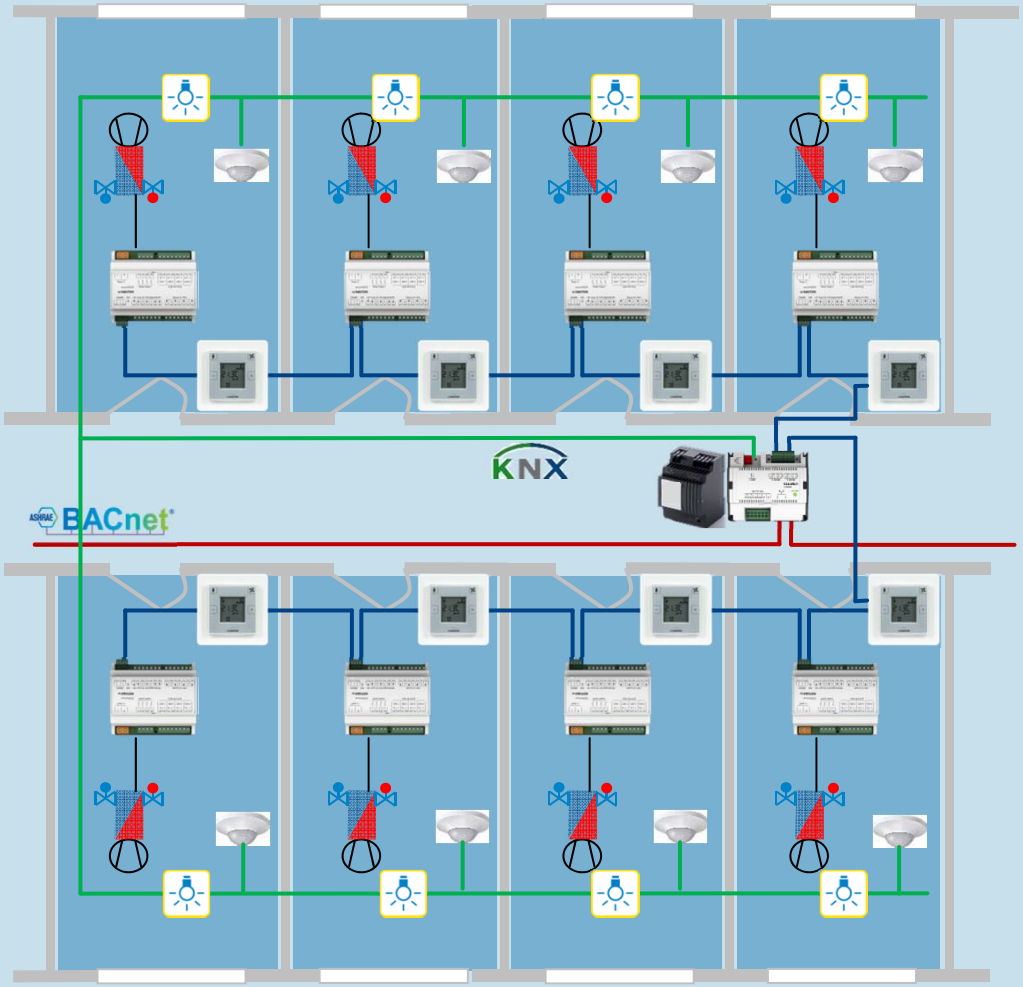

Function

- 8 fixed rooms
- Room climate with fan coil
- Occupancy control
- Optional: Window contacts, dew point sensor

Devices

- 1x EY-RC504F001
- 8x EY-EM510F001
- 8x EY-RU344F001
- Power supply module (24V AC due to AXT)

PharmaTEC 制药业

ecoUnit 1 Room Control Units
2nd Generation

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Conditions of use in a weekly cycle

BEST IN CLASS

•Minimum illuminance:

EY-RU14*: 250 lx, 5 h (1250 lx * h daily)

EY-RU14* + EY-SU106: **125 lx, 5 h (625 lx * h daily)**
5 days illumination, 2 days dark phase

•Backup period in darkness:

Full function: **60 h (2.5 days)**

Low power mode: **Additional 60 h (2.5 days)**
Pushbutton Light/blinds
Temperature measurement with reduced cycle
No setpoint adjustment

SAUTER Wireless Room Automation

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No wires:

- No wiring costs
- Reduced fire load
- Very simple installation

No batteries:

- Maintenance-free
- Environmentally friendly

No limits:

- International standard ISO/IEC 14543-10
- Large amount of interoperable third-party products available
- **ecoUnit 1 sales via components channel**

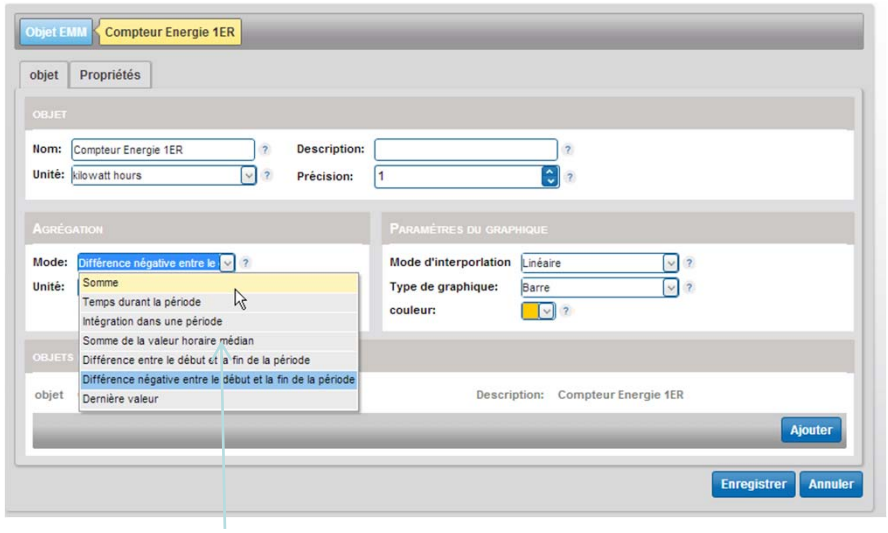
Maximum Flexibility – Minimum life cycle costs:

- Easy to add/move control units and sensors
- Inexpensive, no dirt, no noise
  with conversion or change of room layout

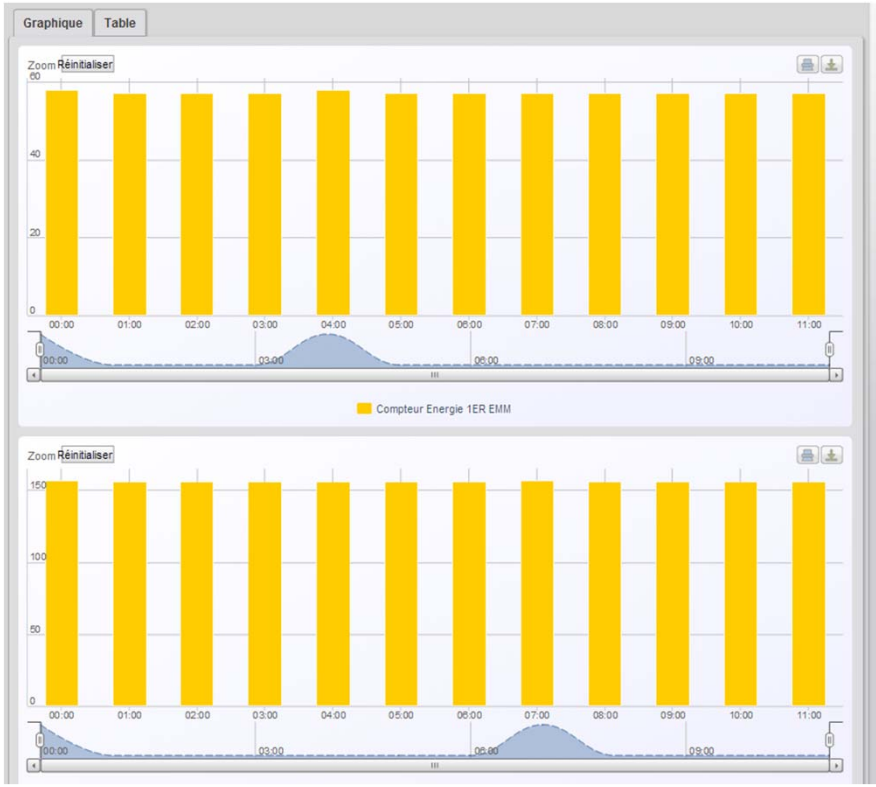
Energy Management System

What is the Energy Monitoring

An Energy Module displays the energy consumption of the building.



List of possible aggregations



Using EMM data in two graphs of an SVC report

Understand your building to save energy!

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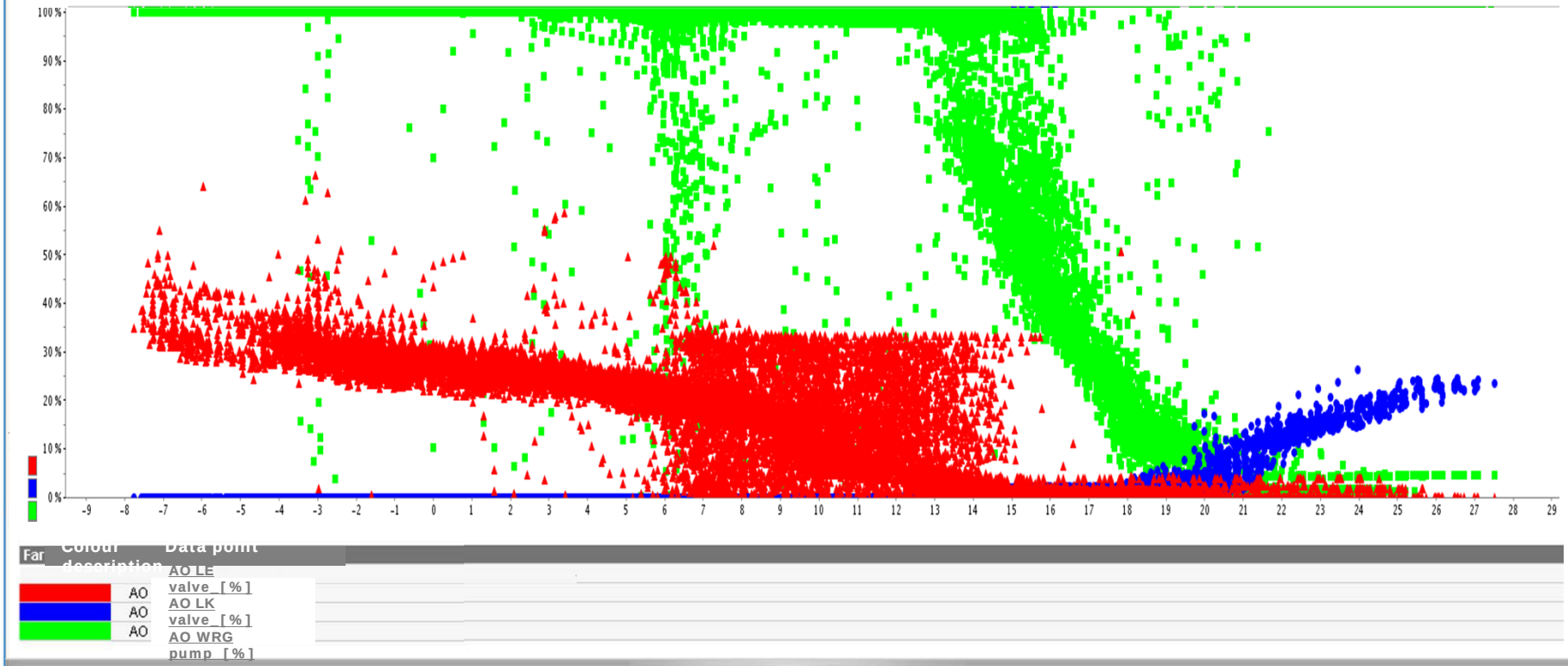
Statistical evaluation of positioning signals depending on the outside air temperature



Understand your building to save energy!

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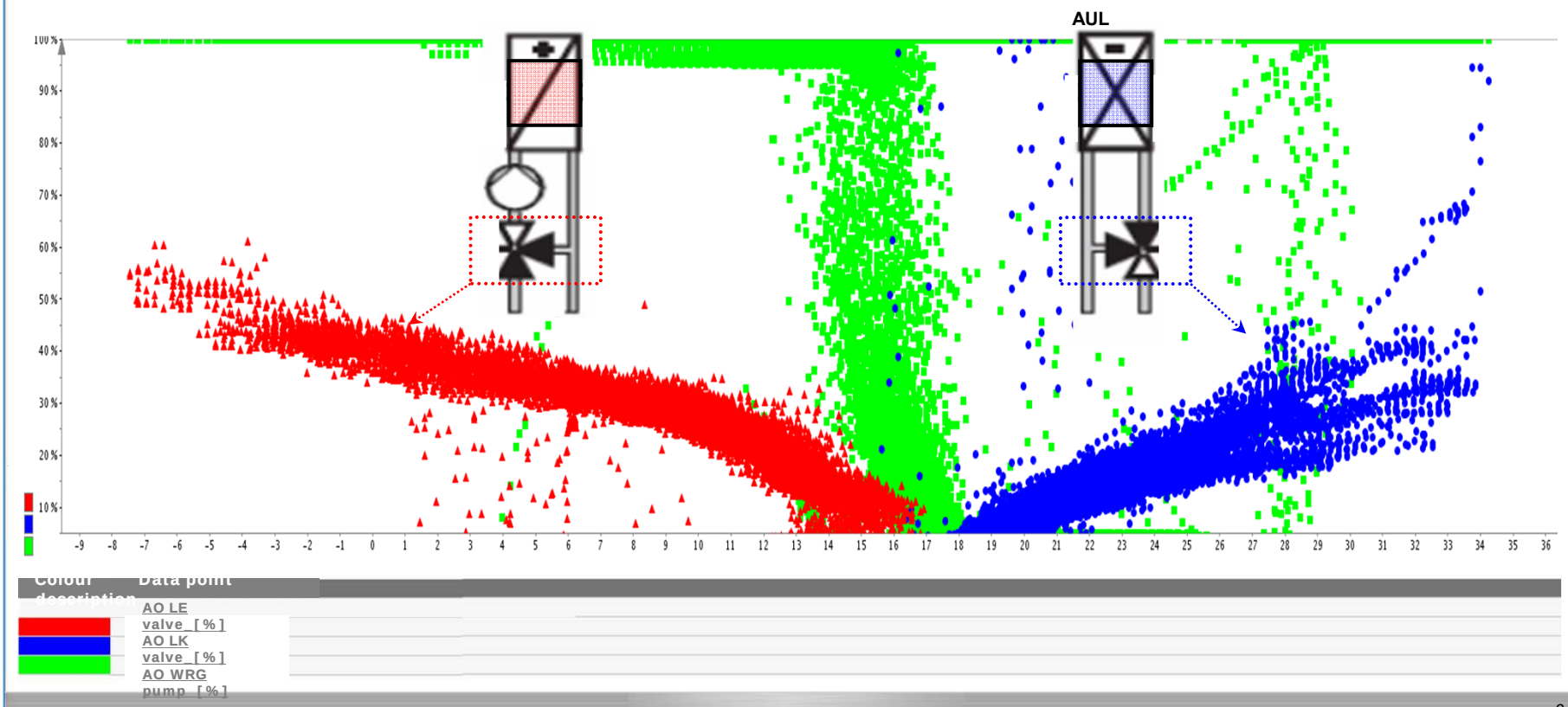
Statistical evaluation of positioning signals depending on the outside air tempe



Understand your building to save energy!

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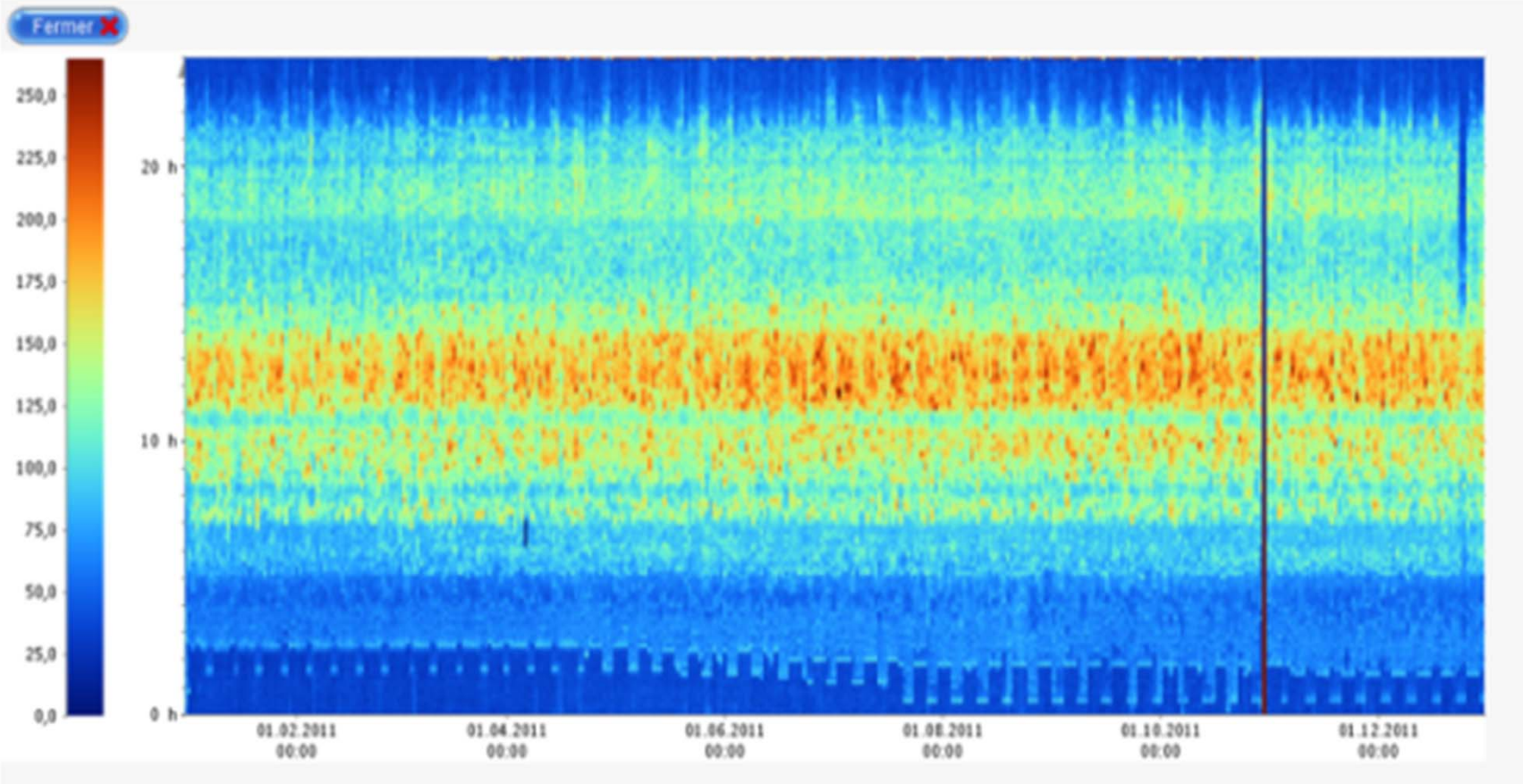
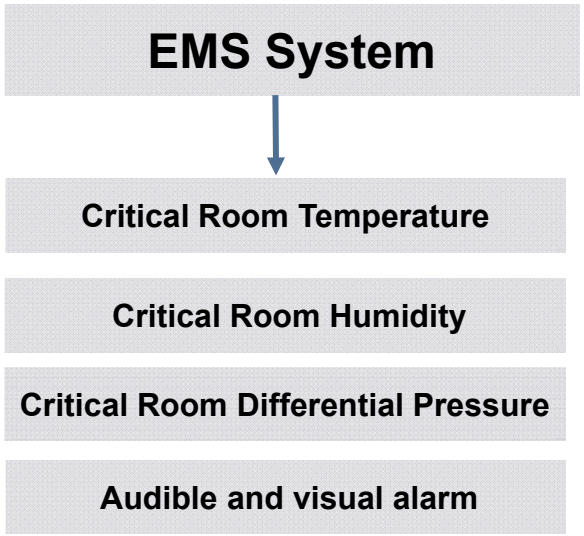


EMS System

EMS System

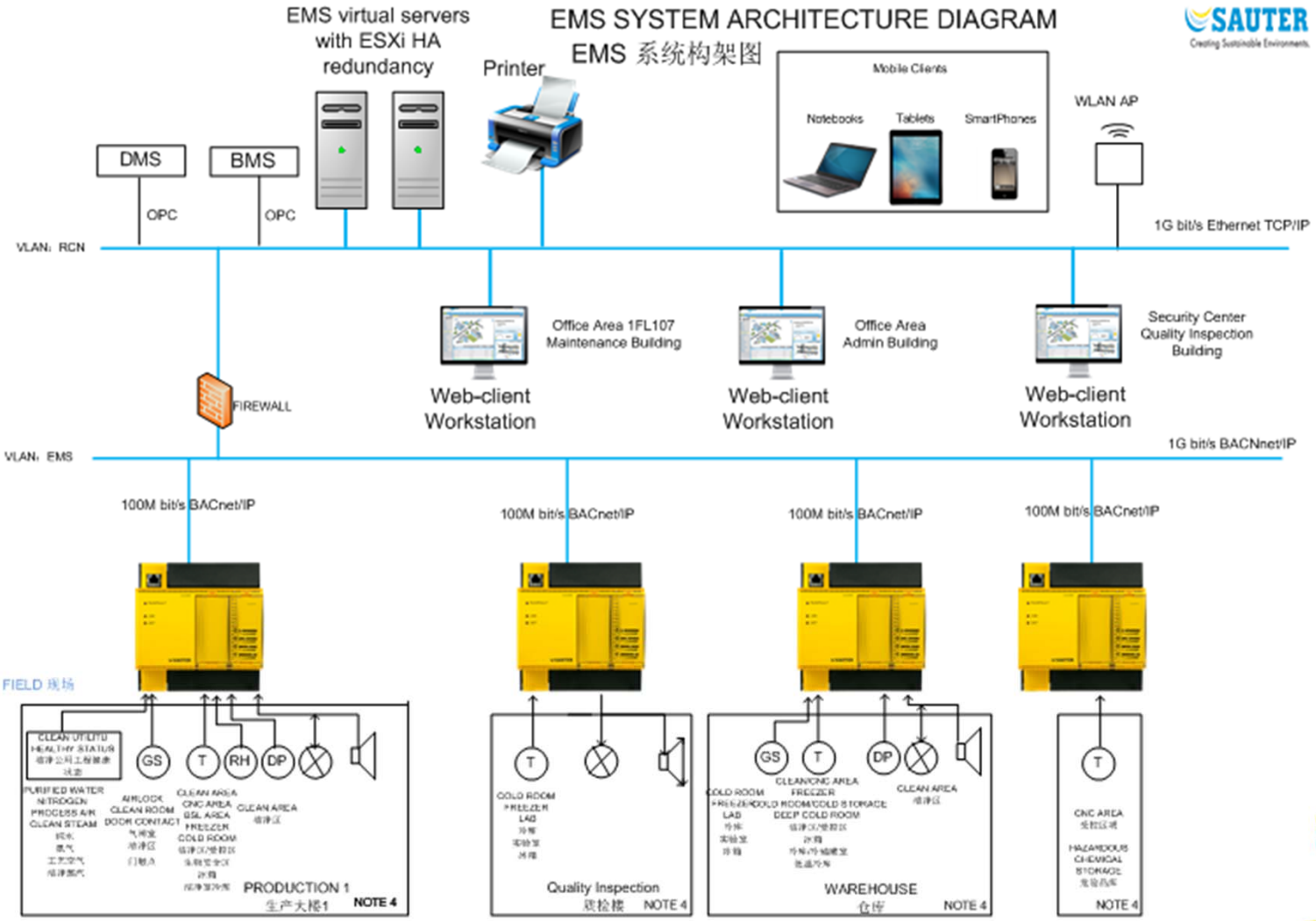
生产楼（PB），质检楼，危险化学品库，仓库设有独立的EMS验证系统。洁净区域安装有温湿度以及压力进行在线监视及参数超限报警。

For Production Building, Quality Inspection Building, Hazardous Chemical Storage and warehouse, there will be an independent validated EMS. For clean area, there are on-line temperature and humidity sensors and differential pressure sensors to constantly monitor the room parameters and make alarms when parameters are out of range.



EMS System

EMS System Structure:



EMS System

Total I/O point:

Building NO.	DDC	DI	DO	AI	AO	Total IO
Quality Inspection	DDC-01	0	5	33	0	38
Production	DDC-02	23	19	64	0	106
Hazardous Chemical Storage	DDC-03	0	0	6	0	6
Warehouse	DDC-04	4	1	62	0	67
	Total	**27**	**25**	**165**	**0**	**217**

QV & Documentation

Sauter qualification & validation service covers

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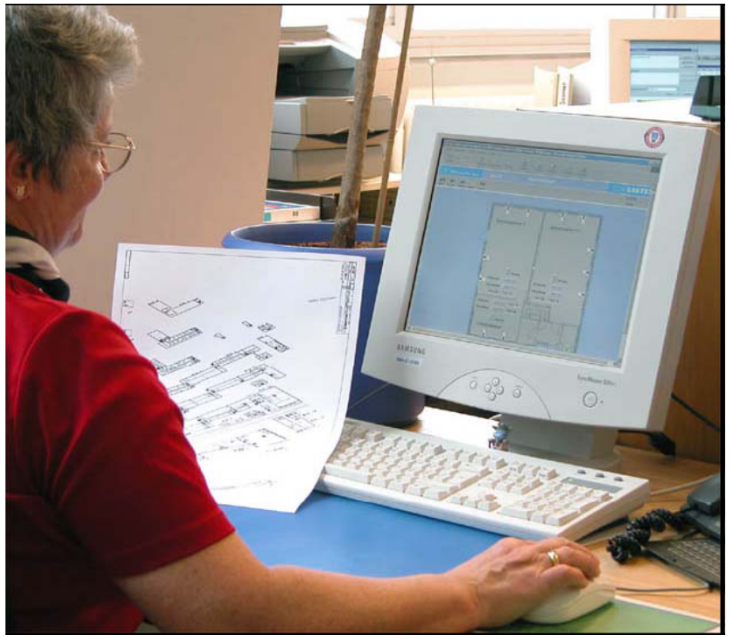
Building Automation/Management System

- Served for GMP areas

Environment/Room Monitoring System

- An independent system
- Recording and monitoring of GMP relevant data



Qualification Service Process

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Quality & Project Plan

SAT – Installation

SAT – Function

Design Qualification Protocol
Functional Specification
Hardware Design Specification
Software Design Specification
Software Configuration Specification
Wiring Diagram
DQ Deficiency/Deviation List
Design Qualification Report

Installation Qualification Protocol
Hardware Installation Testing Protocol
Software Installation Testing Protocol
Loop Testing Protocol
Calibration List
IQ Deficiency/Deviation List
Installation Qualification Report

Operational Qualification Protocol
Functional Test Protocol
Software Function Test Protocol
OQ Deficiency/Deviation List
Operational Qualification Report

FAT

Turn over package
As built documents and drawings
Technical manuals
Training documents

Planning phase | Design Phase | Engineering phase | Installation phase | Commissioning Phase | Operational phase | Project close out

DQ | IQ | OQ

Server Installation Test
Computer Installation Test
Printer Installation Test
Loop Test
DDC Hardware Installation Test
Field Equipment Physical Check

System Function Test
Software Function Test

Project scope of work

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- **Building Management System**
  - FAT protocol, test plan and report
  - Installation completion check list and report
  - SAT protocol, test plan and report
  - Commissioning protocol, test plan and report

- **Environmental Monitoring System**
  - FAT protocol, test plan and report
  - Installation completion check list and report
  - SAT protocol, test plan and report
  - Commissioning protocol, test plan and report
  - IQ protocol, test plan and report
  - OQ protocol, test plan and report

Sauter strengths

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- Complete qualification documentation template package
- Full experience in qualification & validation service with international and domestic pharmaceutical clients
- Local resource for better understanding and communication

Guidelines

Strictly follow GAMP5, GDP and GTP guidelines.

- All the qualification activities are well executed.
- All the qualification activities are well documented and can be traceable.
- All execution engineers will be trained.
- All execution engineers will have rights tools, documents or drawings.

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THANKS