

## CGT Process Equipment

- Varies based on therapies/origins (academia, clinics, hospitals)
- OEM-centric embedded solutions
- Systems not traditionally networked, often requiring removable media to manually transfer data

## Why Digitalize

- Process Control System (PCS) provides visibility and in-process checks to support continuous improvement and demonstrate manufacturing readiness
- Timely availability of data, reducing the vein-to-vein time of the therapy to the patient

## DATA SOURCES & DEFINITION

### Continuous Data (PCS based alarms)

- Fridges
- Freezers
- Incubators
- Environmental Sensors

### Result Data (Report data w/ alarm history)

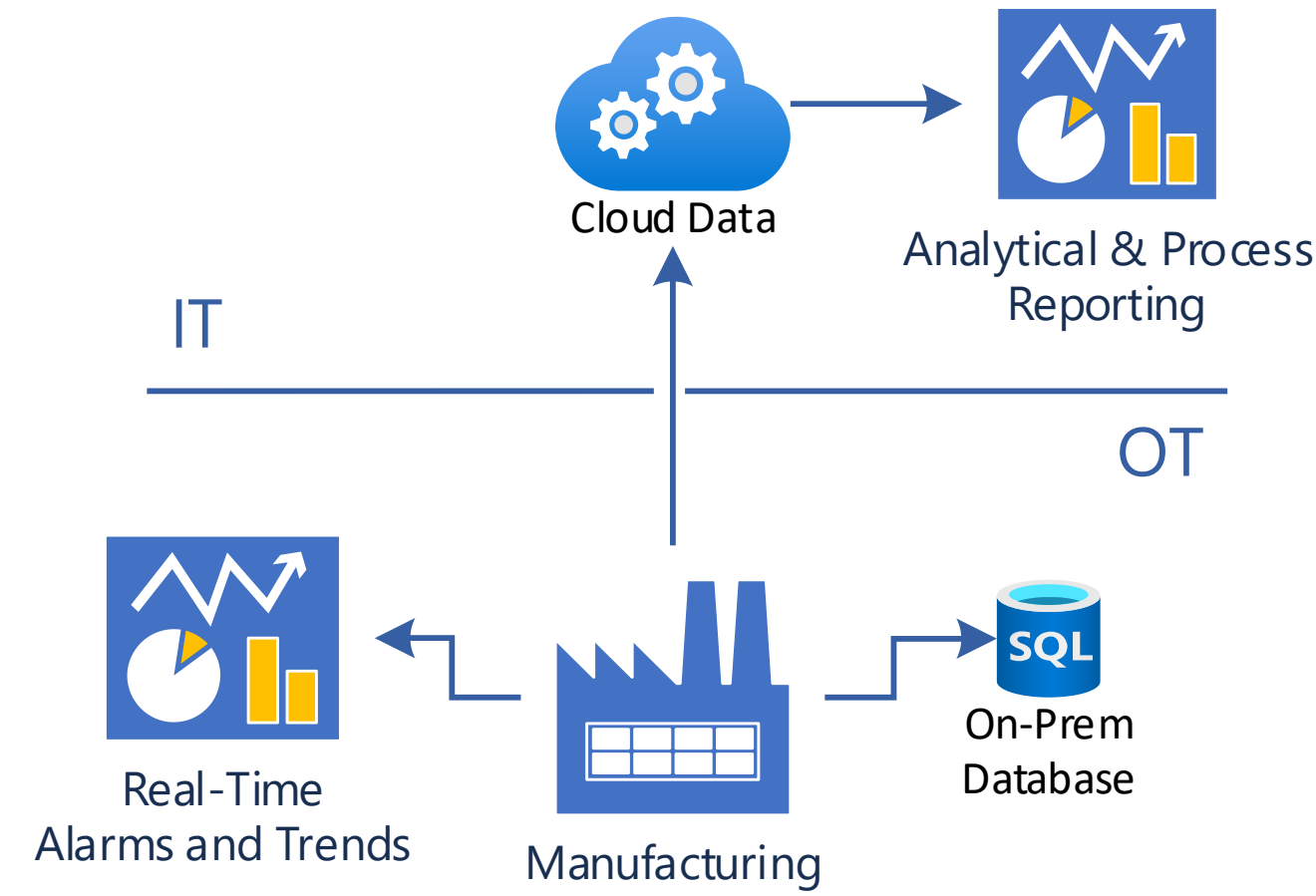
- Cell Counters
- Controlled Rate Freezers and Thawers
- Sepax Cell Processor

### OEM Integration of Real-Time Data

- Miltenyi Prodigy Hardware Data & Audit Trail



## BRIDGING THE IT/OT GAP: “CONVERGENCE”



### OT/IT Convergence

- Leverage on-premise data for dashboards and reporting in real-time
- Provide secure access to OT data sources for querying and analysis
- Support Autolus' current and future data architecture as it grows and changes
- Reduce in-house data storage and maintenance costs

## DATA INTEGRITY COMPLIANCE: 21CFR PART 11, ALCOA+

### Rendering Records

- All electronic records that an auditor might want to see and/or copy can be provided in a language/format that humans (not just computers) can understand

### Document Storage & Record Retention

- The PCS protects records and keeps them readily available for as long as required using scalable redundant storage and automatic backups

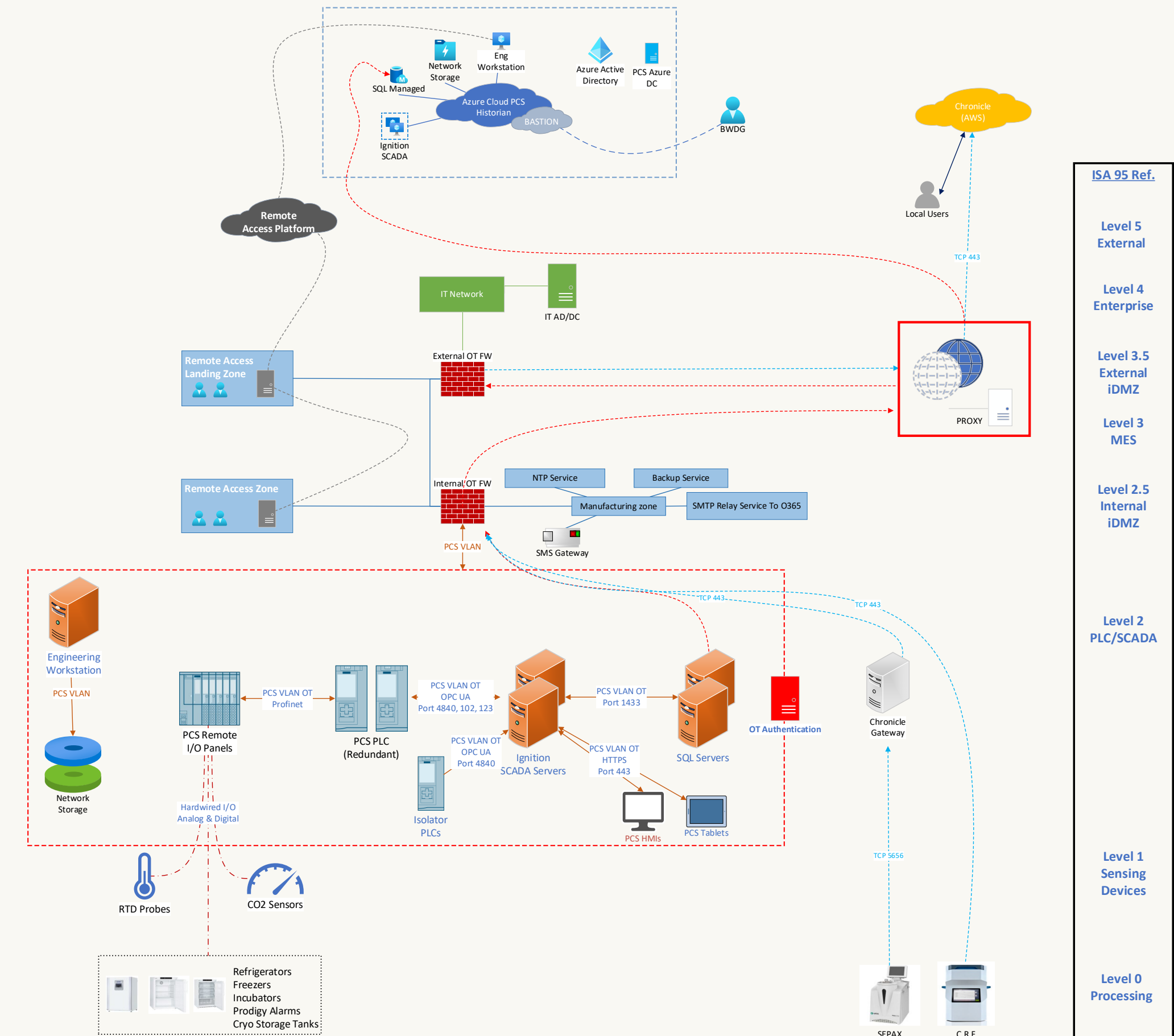
### System Access/Authority Checks

- The PCS and its data sources authenticate all users, authorize only necessary activities for each user level, attribute and timestamp data at the source, and protect data within their individual scopes
- Data transfers are automated with store-and-forward and record verification at each transfer point to maintain data integrity as it passes from one system to another

### Audit Trails

- The PCS keeps a record of user interactions and captures “who” made the changes “when” and “what” records, new and previous values, ensuring a complete history of the record is captured, retained, and viewable by humans

## DIGITAL HYBRID ARCHITECTURE



## SUMMARY & CONCLUSIONS

### Production & QC

- Use PCS monitoring, instrument result data, and reported exceptions for control and batch release
- Batch review efficiencies; visibility, in-process checks, and exception reporting
- Timely availability of qualified data accelerates product release by facilitating these processes
- Further efficiencies expected from integration with planned MES/EBR system

### PD & MSAT

- Data Lake “ready” to correlate and analyze data from multiple systems to develop process understanding, controls, and improvements
- Demonstrate manufacturing readiness for regulatory application filings and drive manufacturing improvements
- Utilize data for Continuous Process Verification throughout product lifecycle

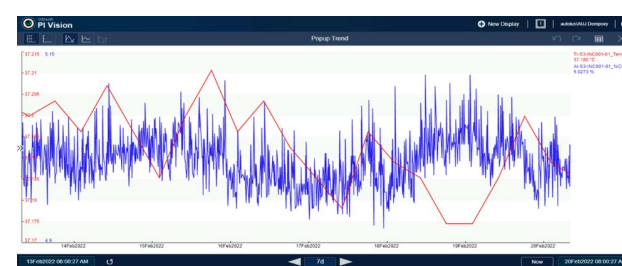
### Supporting PCS Functionality

- PCS overcame barriers to integrating traditionally research-oriented equipment to enable recording critical process and material storage data that is validated, enduring & accessible
- PCS and associated integrations will facilitate MES batch and exception reporting and data analysis
- PCS contributes to overall analytic and reporting capabilities that support timely manufacturing authorizations and product release for critically needed autologous therapies

## END-USER DATA REQUIREMENTS

### Production

- Real-time alarm monitoring
- Dashboards in Cleanrooms
- Trending data to support deviations
- Audit trail data from systems that generate electronic records or signatures



Item	Unit	Value	Status
Temperature	°C	4.5	OK
Pressure	PSI	120	OK
Flow Rate	L/min	10	OK
Humidity	%	45	OK

### MSAT & PD

- Process result data for continuous process improvement
- Reporting Capabilities (BLA filings)
- PCS data to be a Data Lake tributary

Batch ID	Start Date	End Date	Status	Operator	Location
BLA-2022-001	2022-01-15	2022-01-20	Completed	J. Doe	Lab A
BLA-2022-002	2022-01-25	2022-02-01	In Progress	A. Smith	Lab B
BLA-2022-003	2022-02-10	2022-02-15	On Hold	M. Jones	Lab A