BPSA Single-use Summit
July 2023/Nick Troise

Single-use Sensors and Industry 4.0

Fundamental Role

July 13th, 2023

METTLER TOLEDO

Industry 4.0 and Industrial Internet of Things (IIoT)

Industry 4.0 is transforming modern manufacturing

- Integration of Manufacturing execution systems (MES), Enterprise Resource Planning (ERP), and Supervisory Control and Data Acquisition (SCADA) Systems together on digital platform
- Optimize processes with the help of intelligent platforms, machine learning, and artificial intelligence
- Simplify otherwise long, meticulous, and complex biopharmaceutical manufacturing processes.

Benefits include:

- More proficient process
- Increased productivity
- Better facility use
- Lower COGS
- Harmonization across multiple manufacturing locations
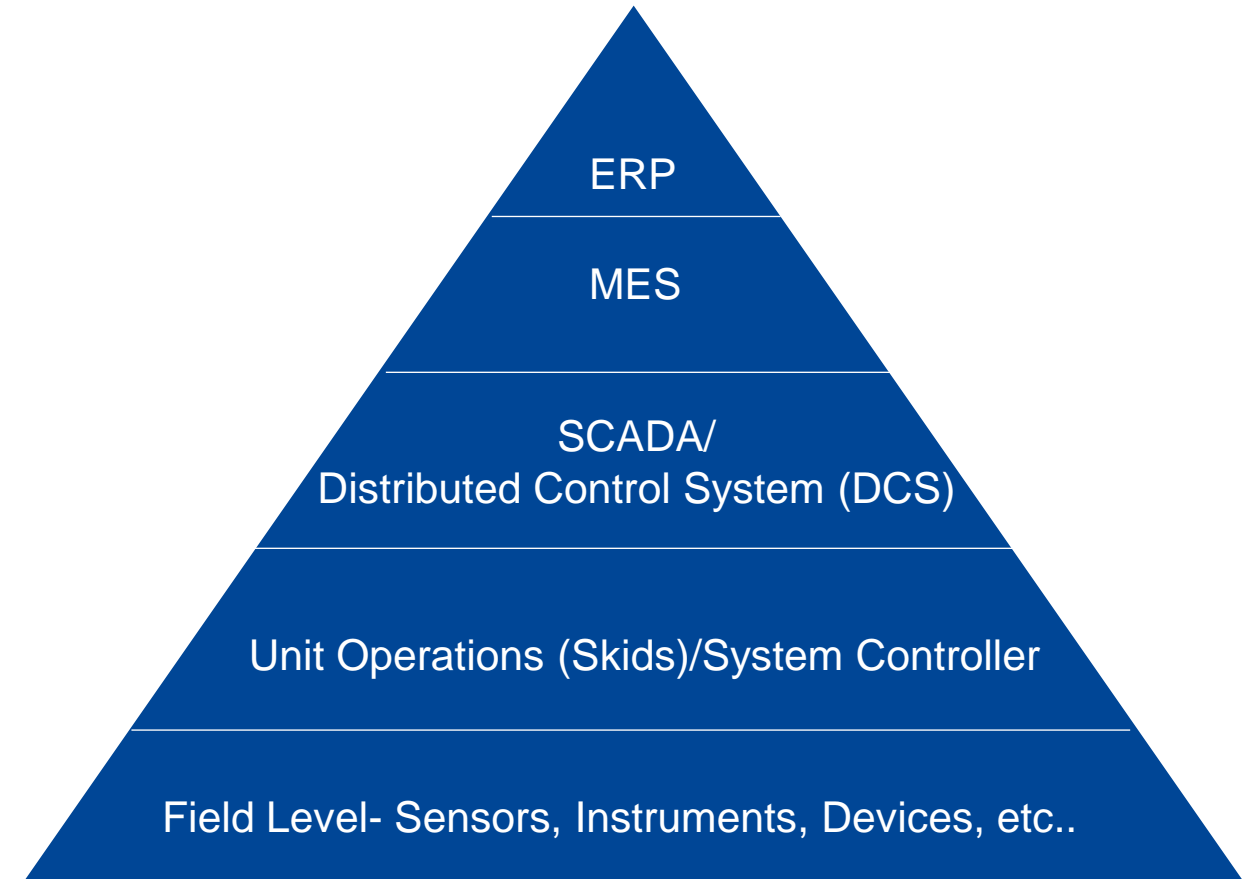
Agenda

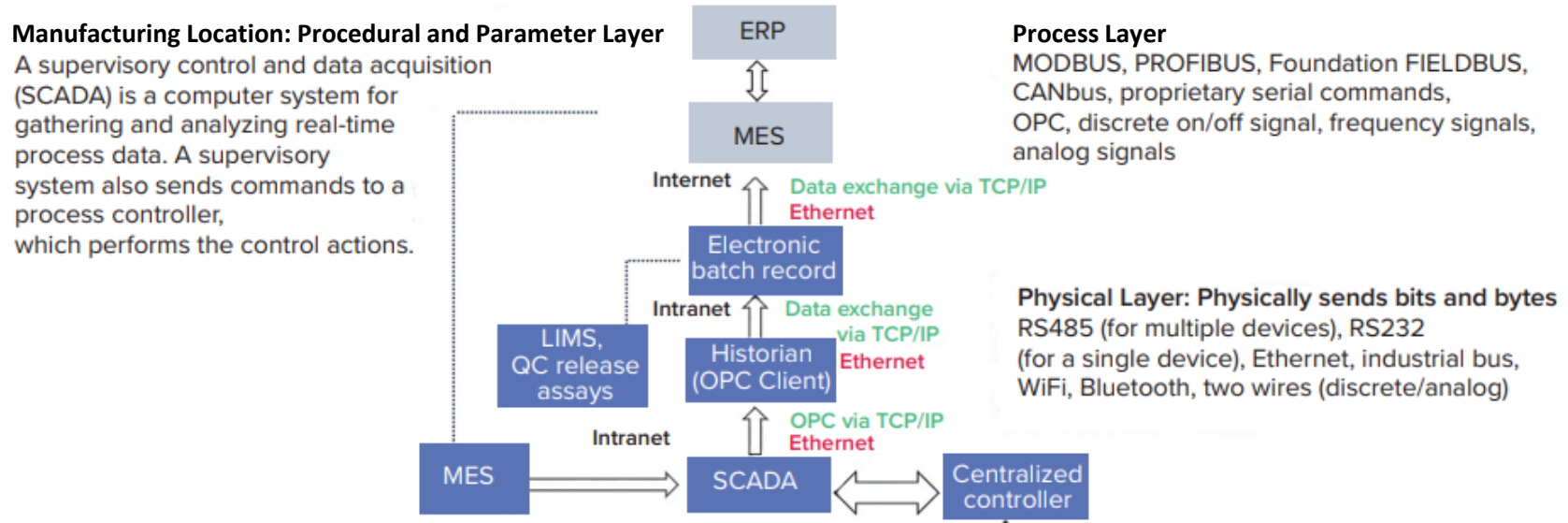| 1	Introduction
2	Background
3	Single Use Sensors and Industry 4.0
4	Current Integration Status
5	A look towards the Future
6	Implementation Challenges
7	Conclusion

Procedural and Parameter Layer
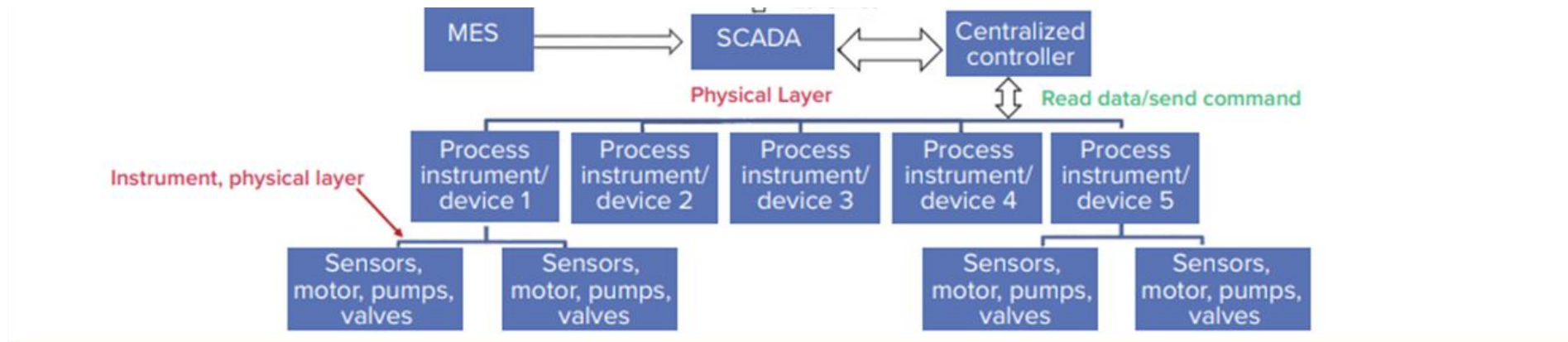
Sample System map depicting data flow from physical layer to SCADA

Unit Operation devices/sensors communicate with common Automation framework or centralized controller

- Individually, or grouped together (e.g. packaged unit)

- Typically via 4-20mA or other analog/digital signals

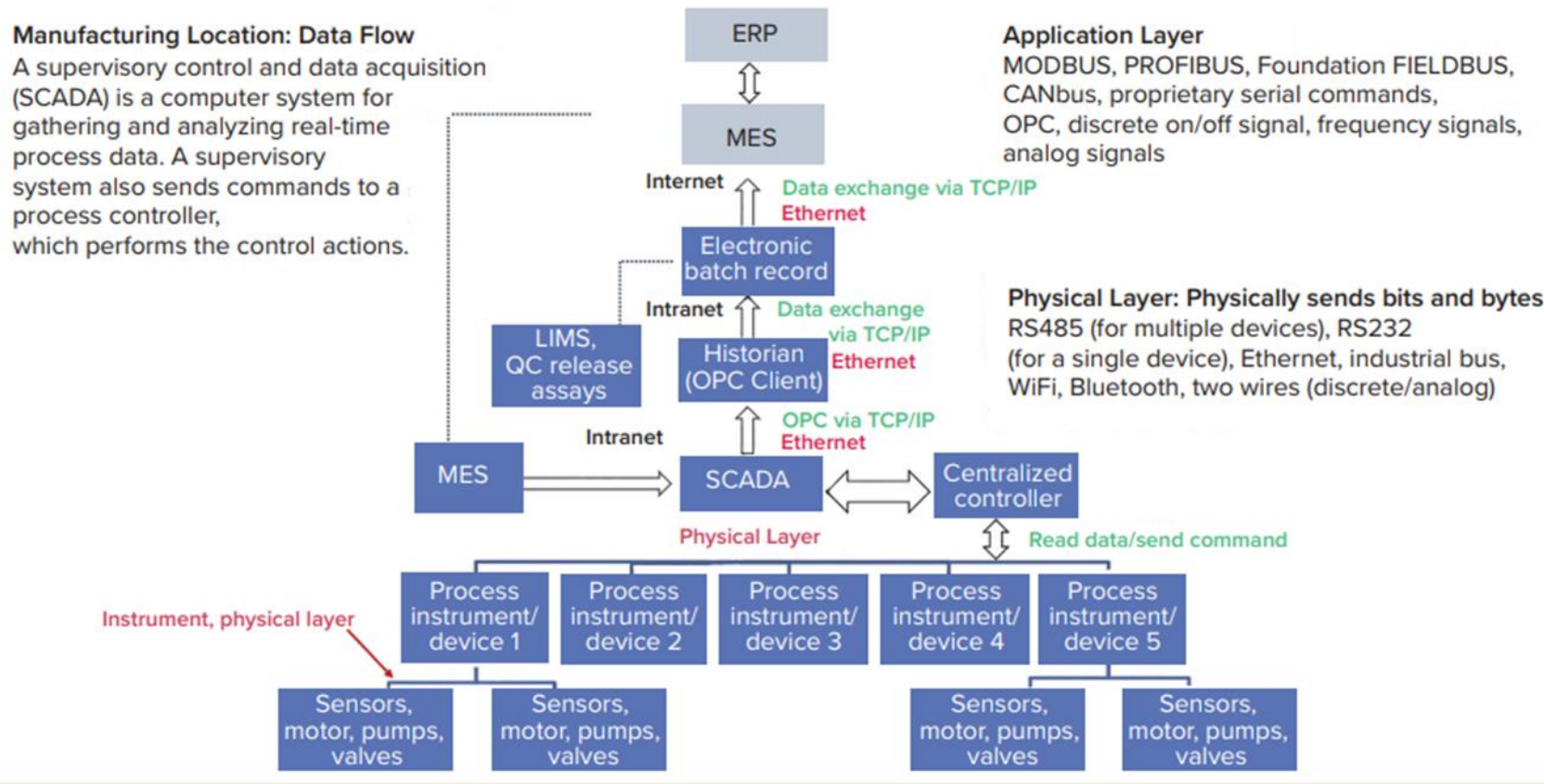**Centralized Controller communicates by-directionally with SCADA system**

- Physical Layer (RS485, **Ethernet**, WiFi, etc..)

- Process layer (Modbus, Ethernet I/P, Profibus, OPC UA, etc..)

- Send data from instruments to SCADA and commands from SCADA back to instruments

Manufacturing Location: Procedural and Parameter Layer

A supervisory control and data acquisition (SCADA) is a computer system for gathering and analyzing real-time process data. A supervisory system also sends commands to a process controller, which performs the control actions.

Process Layer

MODBUS, PROFIBUS, Foundation FIELDBUS, CANbus, proprietary serial commands, OPC, discrete on/off signal, frequency signals, analog signals

Physical Layer: Physically sends bits and bytes

RS485 (for multiple devices), RS232 (for a single device), Ethernet, industrial bus, WiFi, Bluetooth, two wires (discrete/analog)

Sample System map depicting data flow in an industrial manufacturing process from SCADA to MES/ERP

Manufacturing Location Procedural and Parameter Layer

SCADA

SCADA gather and analyzes process data in real time

Relays information to MES/ERP
- Resource management
- Batch information

- Feeds batch data back into SCADA for analysis/control

- Communicates back to packaged units and individual devices for optimization

Manufacturing Location: Data Flow
A supervisory control and data acquisition (SCADA) is a computer system for gathering and analyzing real-time process data. A supervisory system also sends commands to a process controller, which performs the control actions.

Application Layer
MODBUS, PROFIBUS, Foundation FIELDBUS, CANbus, proprietary serial commands, OPC, discrete on/off signal, frequency signals, analog signals

Physical Layer: Physically sends bits and bytes
RS485 (for multiple devices), RS232 (for a single device), Ethernet, industrial bus, WiFi, Bluetooth, two wires (discrete/analog)

Goals for SU sensors

Capture	**Publish**	**Improve**	**Resources**
Critical process information	To network for analysis	Batch control.	Better manage and optimize

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Automation Framework/Architecture

- **Monitors/Transmitters read SU Sensors and then communicate with centralized controller (4-20mA, 0-5V, etc..)**
Realtime sensor reading

- **Controller can send signals back individual devices** Perform a Tare, Start/stop a pump, Clear alarm, etc..

- **Trending towards more digital communication**
Via other signals (RS232, RS485, etc..
Can capture more data and more quickly
Monitor information, alarm limits, device status, etc..
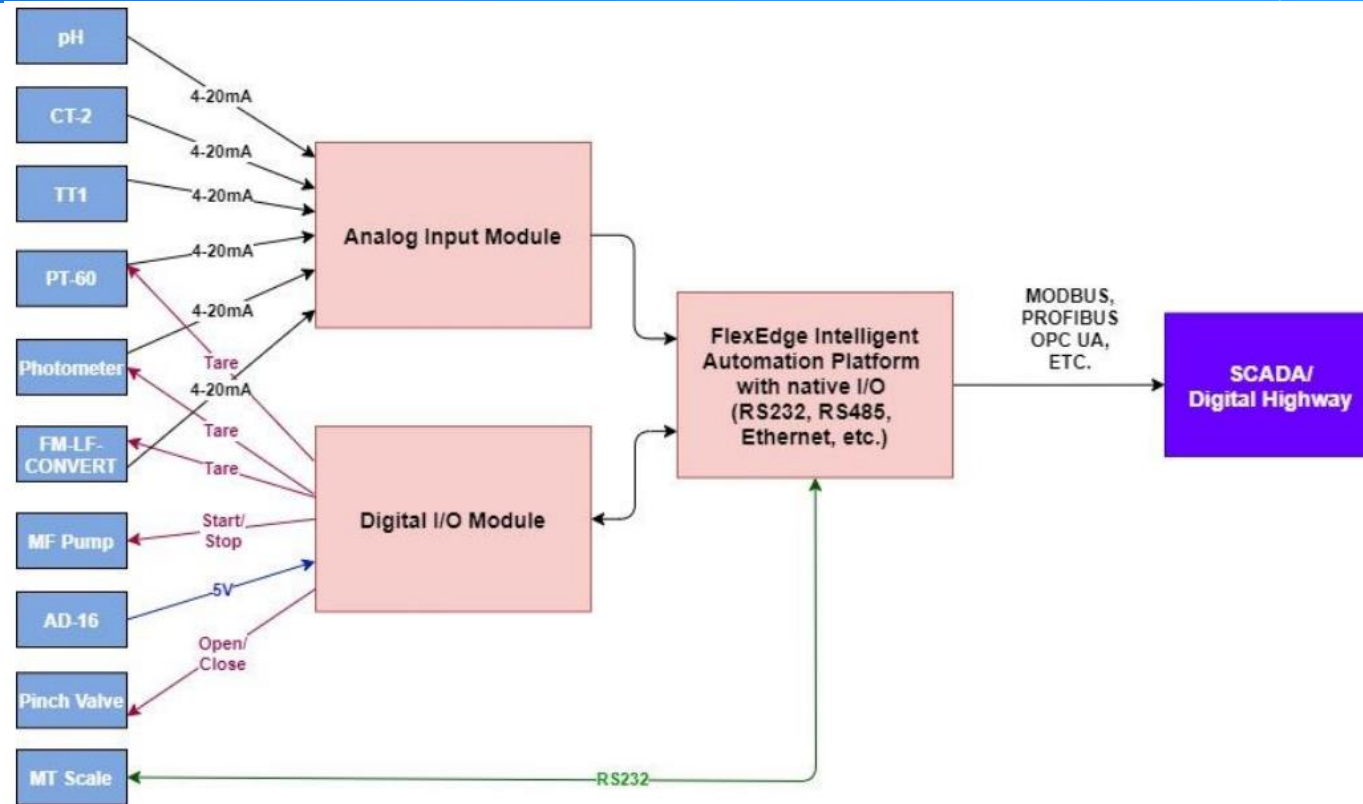
Block diagram of signals from transmitters to controller/modules

Annotated picture of an example setup of devices connected to an IAP

Automation Framework/Architecture

- Automation Architecture can be connected anywhere in facility and uses industrial communication capabilities to convert to digital data/parameter values making it easily accessible

  - Map values to an internal Tag, which can then be mapped to other devices, such as an HMI/PLC, or sent to other clients via EtherNet I/P, Modbus TCP, OPC, or other protocols
  - Provide flexibility for a manufacturing facility to enable correct information to be used when and where it is needed
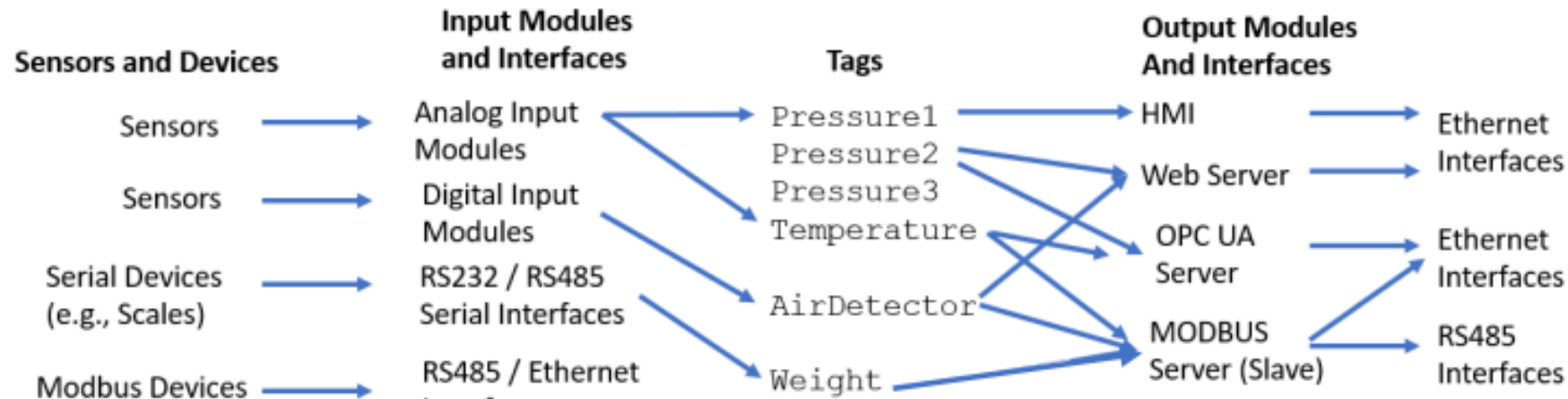
Conceptual diagram of dataflow in and out of an intelligent automation platform

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Intelligent Sensor Technology with a Single Use Footprint

Currently "intelligence" resides in the monitors/transmitter

- With the re-usable portion, not the single-use/consumable component
  - Difficult to communicate individual sensor specific information, can only share the information that is received from the sensor
- Existing Smart Sensor technology exists, but primarily in re-usable sensors, e.g. Mettler Toledo ISM® or Hamilton Arc sensors
- Some adaptation for true Single Use sensors through Smart Sensor "heads" or adapters, but still in the early stage.

Building true "intelligent" single use sensors could allow for

- Communication of key sensor information- serial number, lot number, calibration information
- Self-Diagnosing Sensors- shelf life management, performance monitoring, need for re-calibration/new sensor
- Better inventory management
- Bypass monitors/transmitters completely, simplifying the dataflow
- Improved sustainability- maximize duration of use of consumable

Use of Ethernet, WiFi, and more advanced digital communication instead of analog, RS232, RS485, etc.

- Industry quickly trending in this direction:
  - Allows for much faster and more reliable communication
  - Able to transfer a lot more data beyond just sensor reading
    - Specific monitor/sensor information, diagnostics info, current status, alarm values, etc..

More robust communication back to monitor/transmitter

- Tare sensor, actuate a valve, set pump flow rate, change device settings, clear alarm, etc..
- Ability to communicate with device from many locations in a facility

Non-Invasive Intelligent Sensors
- E.g. Optical, clamp-on, or other sensors that are not fluid contact and thus do not need to be irradiated
- Opportunity to build-in memory and advanced communication capabilities directly into sensor

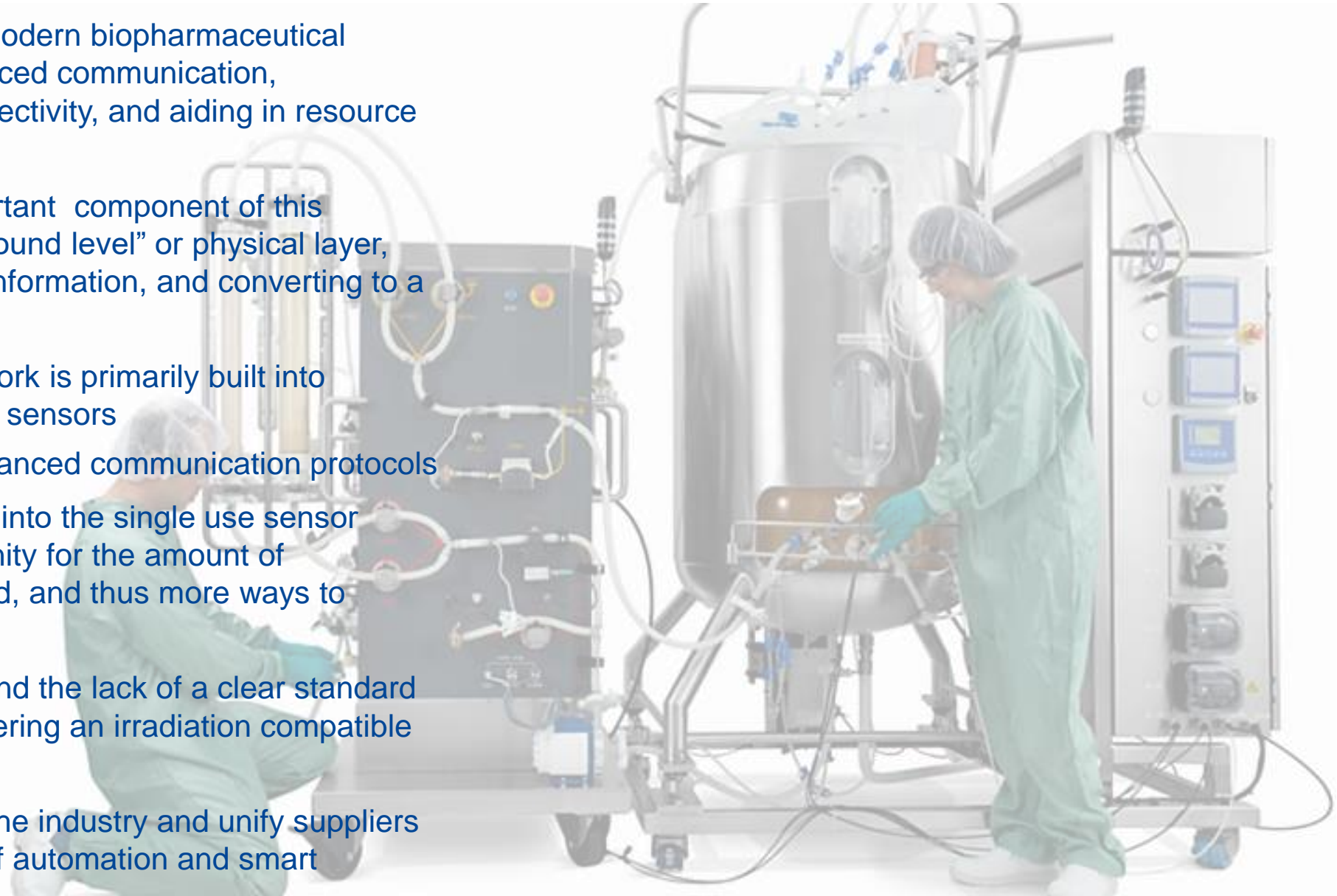| 1	Introduction
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Challenges

Standardizing Across the Industry

1 End user's all use different Hardware/PLCs, and have unique communication requirements
- Challenge for suppliers- what platforms to support and communication protocols to build in
- Expensive to support all in a single device and complex to offer different versions

2 Goal- Standardize on primary communication protocol
- Ethernet I/P, ProfiNet, Modbus TCP, OPC-UA, etc.

Sterilization and Irradiation Compatibility

3 Need to keep bioburden levels low via Ionizing Irradiation or other sterilization technology without compromising performance, functionality, shelf life, usage duration, etc..

4 Locally storing specific sensor information to transmit to monitor/transmitter in an irradiation stable manner is challenging
- Gamma Stable memory chips exist, but some applications are IP restricted
- Unique external sensor adapter/head is not sustainable and has logistical issues

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- Industry 4.0 is transforming modern biopharmaceutical manufacturing through enhanced communication, optimization, facility interconnectivity, and aiding in resource management

- Single Use Sensors are important component of this ecosystem, starting at the "ground level" or physical layer, capturing important process information, and converting to a digital highway

- Currently, automation framework is primarily built into monitors/transmitter that read sensors
  - Trending towards more advanced communication protocols

- Building "intelligence" directly into the single use sensor portion offers a lot of opportunity for the amount of information that can be shared, and thus more ways to optimize processes

- Main challenges revolve around the lack of a clear standard for the industry, as well as offering an irradiation compatible "smart" consumable

- Important for BPSA to guide the industry and unify suppliers to allow for easy integration of automation and smart technologies

Thank You