

# Future-Proof GxP Monitoring

Ensuring Your System Can  
Adapt  
to the Future of GxP

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## Vaisala in Brief

- We serve customers in weather and controlled environment markets
- 80 years of experience in providing a comprehensive range of innovative observation and measurement products and services



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## Vaisala - Life Science

### Our Offering

Provides measurement instrumentation, continuous monitoring systems and validation systems for regulated or highly controlled life science environments.

### Our Goal is to help customers

- Reduce their risk of lost or adulterated product
- Reduce their risk of failing to meet GxP regulations and/or guidelines



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## Vaisala Team



### Speaker:

Paul Daniel  
Sr. GxP Regulatory Expert  
Vaisala, Inc.



### Chat operator:

Janice Bennett-Livingston  
Marketing Manager, Life Science  
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## Future-Proofing



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## Goals

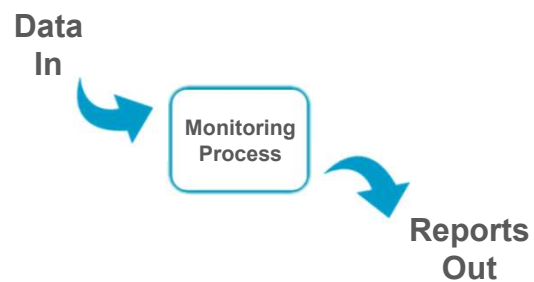
- Explore History of Computerized Systems
  - Monitoring Systems
  - GxP Manufacturing Systems
- Explore Modern GxP Manufacturing
- Identify Trends from History
- Use Trends
  - To design Future-Proof Monitoring System



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## Basic GxP Monitoring



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## GxP Monitoring History

- Logbooks and Thermometers
- Chart Recorders
- Thermocouples
- Digital Readouts
- Databases
- Networked Systems
- Data Loggers
- Automated Systems
- Enterprise Systems



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## Modern GxP Monitoring System

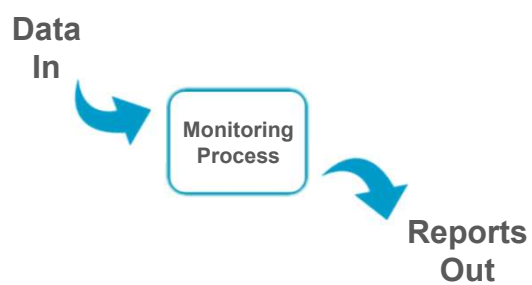
- Full transition to Computerized
  - Alarming
  - Email/SMS Notifications
  - Enterprise System
- New Concerns
  - Part 11 / Annex 11
  - Electronic Records
  - Data Integrity
  - Security
  - Validation



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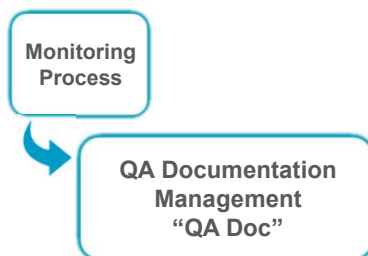
## Basic Monitoring



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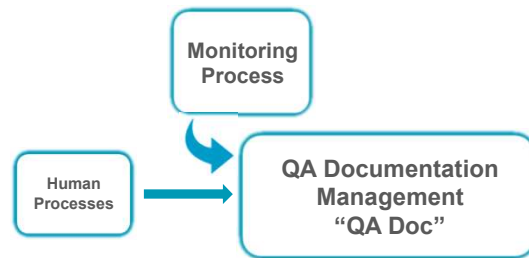
## Building a GxP Manufacturing System



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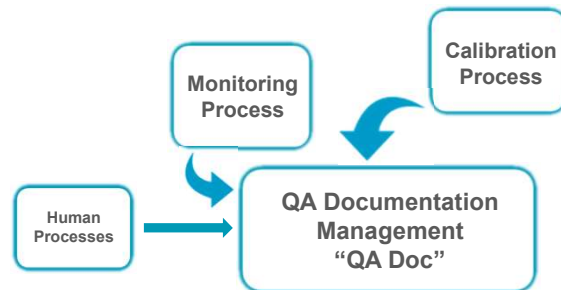
## Building a GxP Manufacturing System



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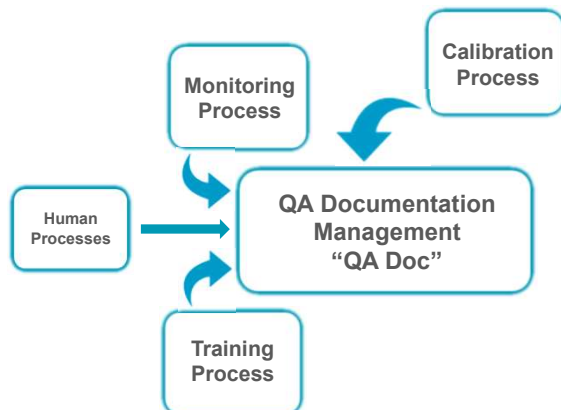
## Building a GxP Manufacturing System



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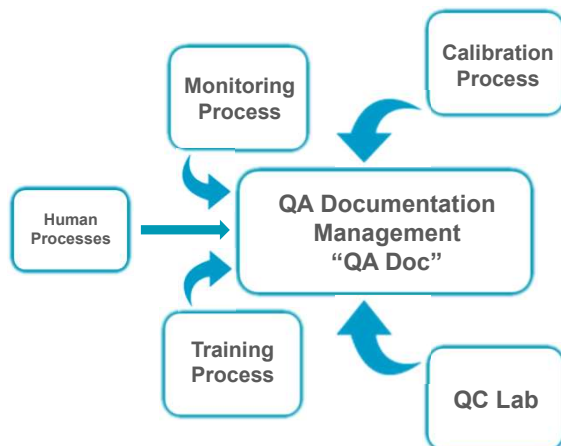
## Building a GxP Manufacturing System



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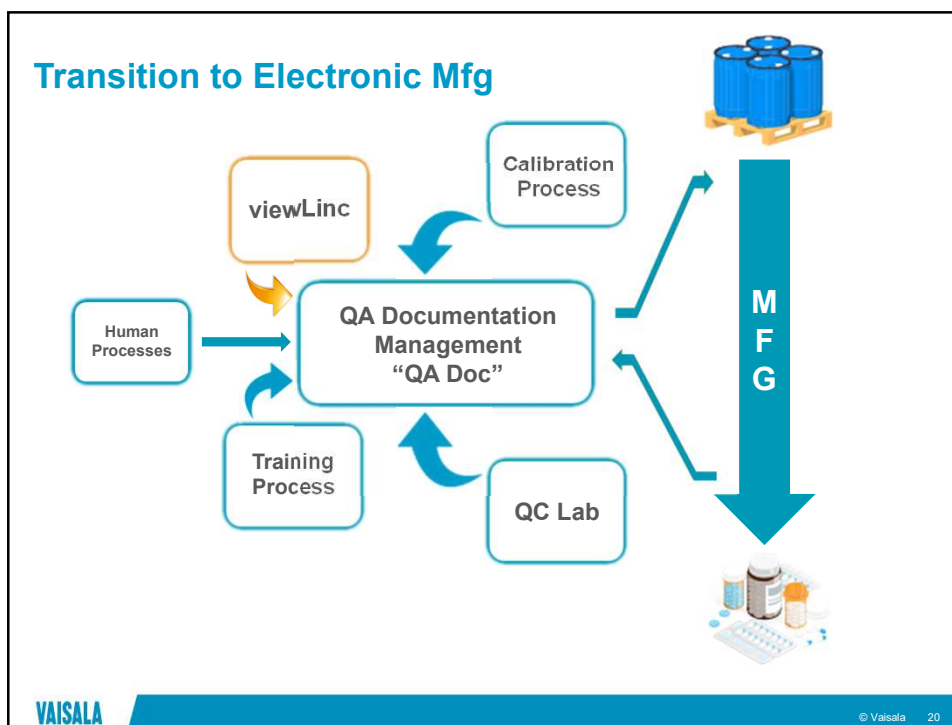
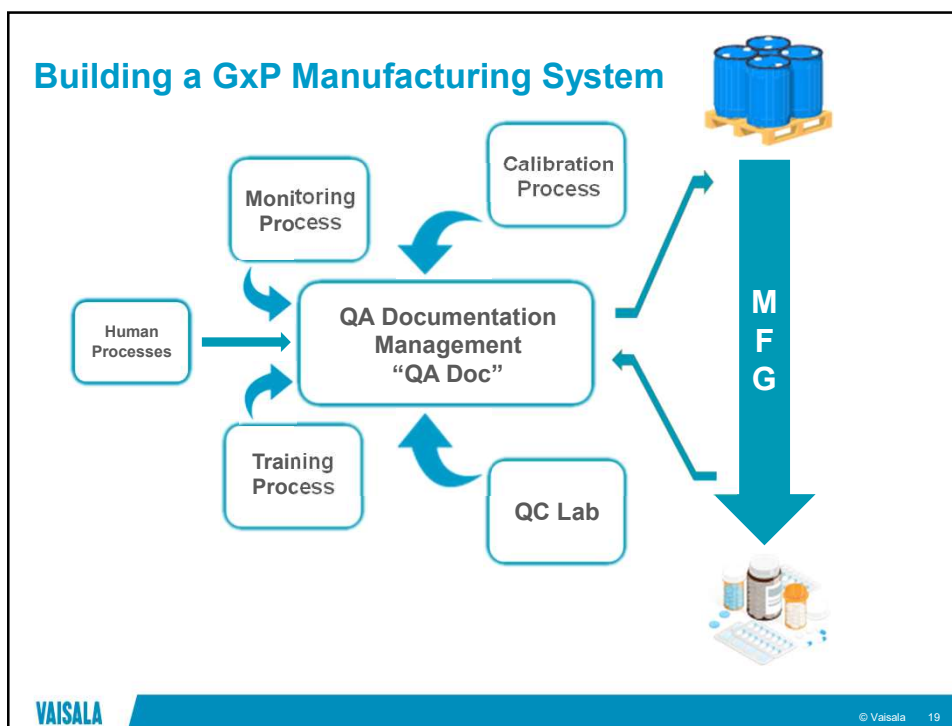
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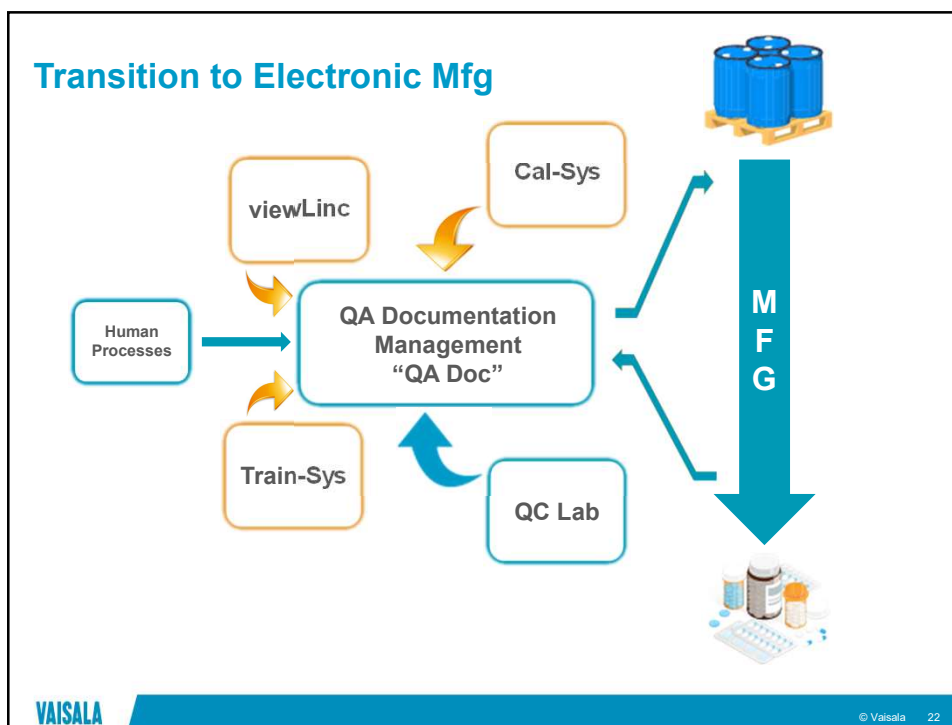
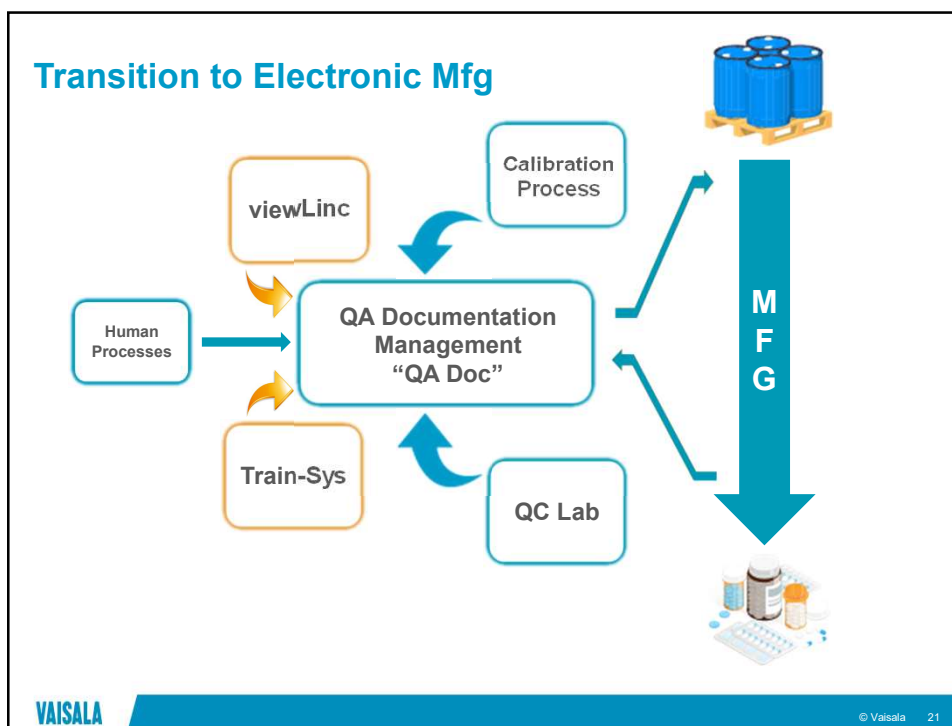
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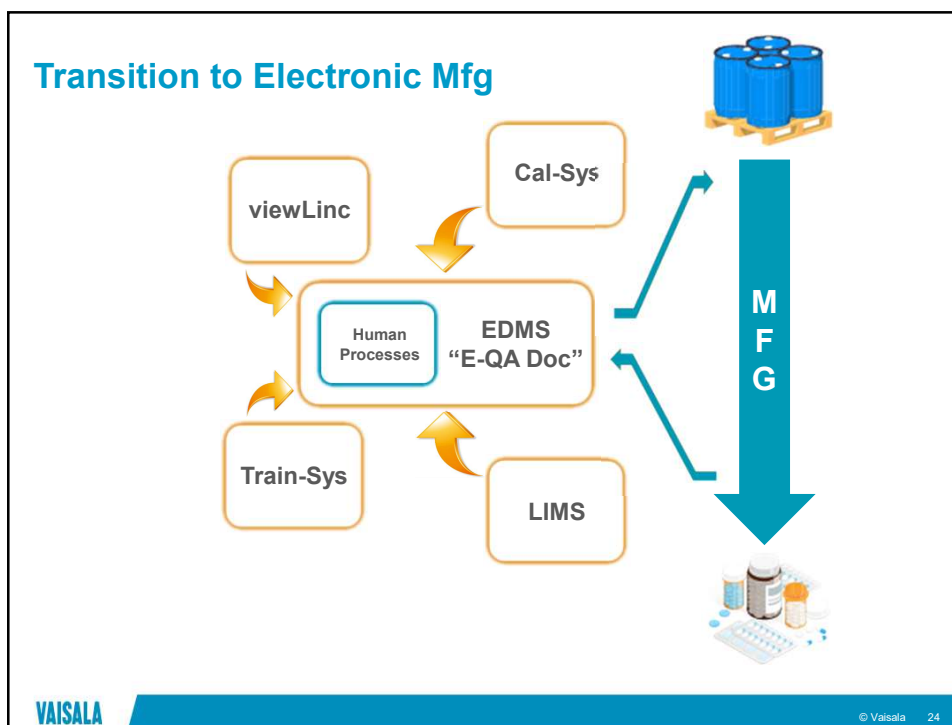
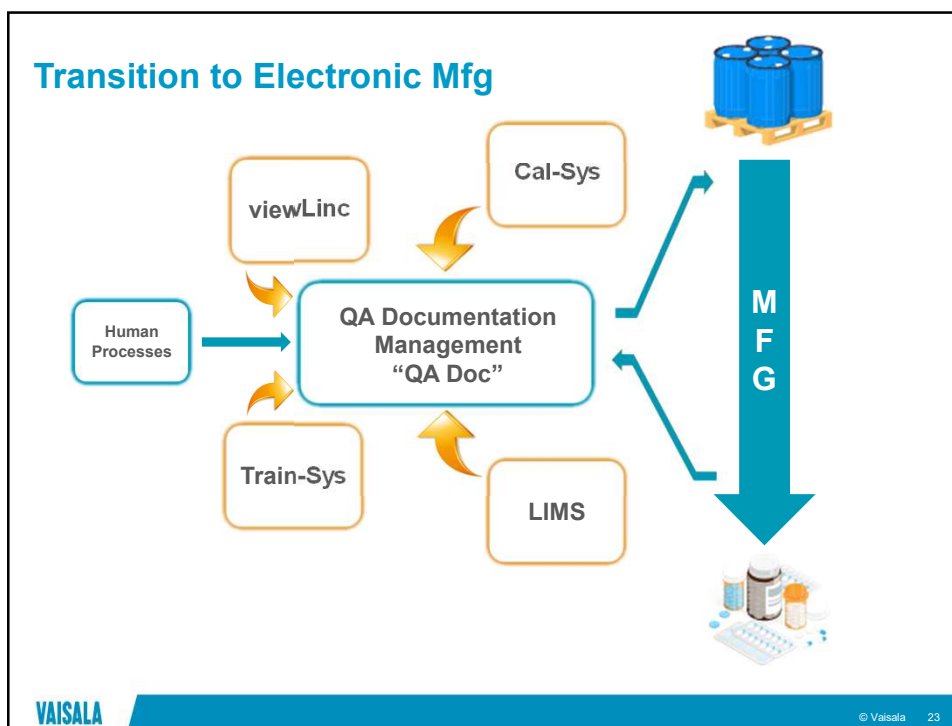


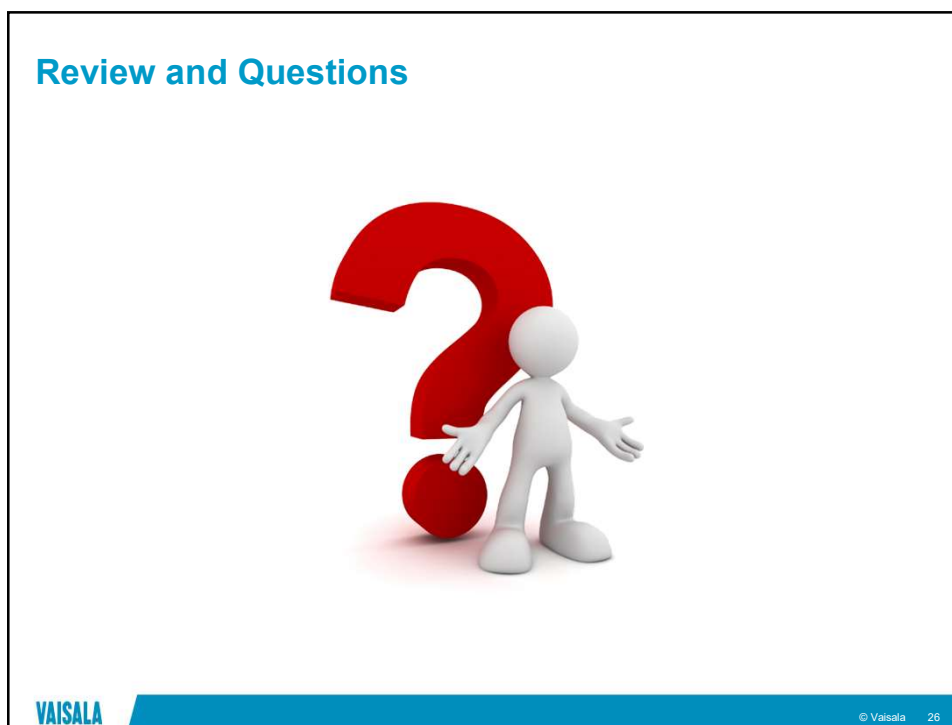
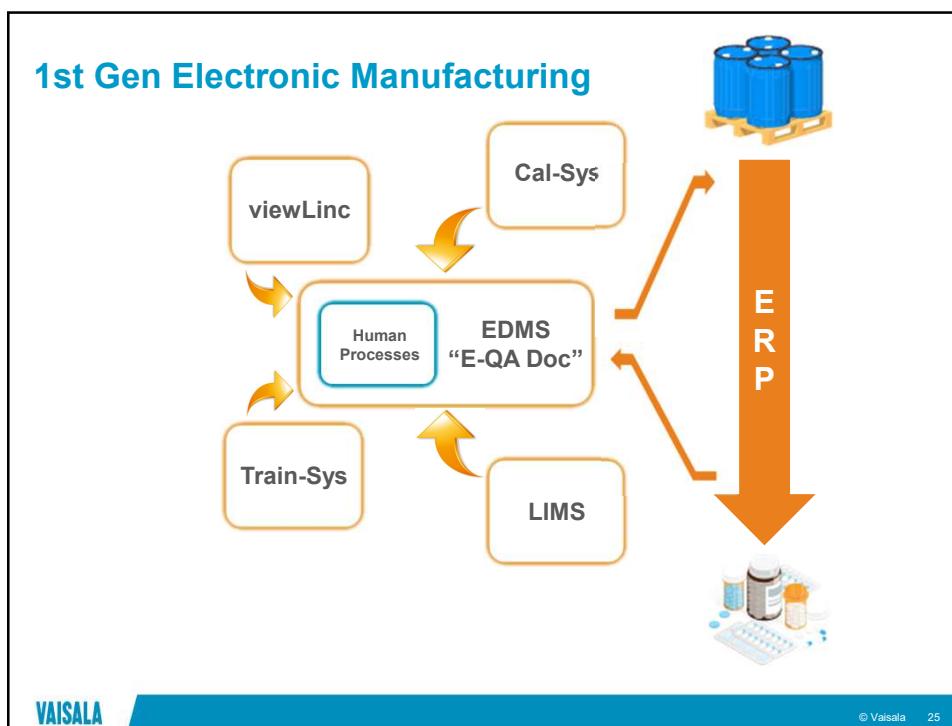
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## Trends

### ■ Trend 1: Paper to Electronic

- Paper Records are low-risk low-efficiency
- Electronic Records are high-risk high-efficiency.



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## Trends

### ■ Trend 2: Validation and Data Integrity

- Decrease Validation Effort
- Increase Data Integrity
- How?
  - Standardized Systems
  - Simple and Transparent Workflows



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## Trends

### ■ Trend 3: Networking / Outsourcing / Virtualization

- First systems were “stand-alone” systems.
  - Just a single room or site.
- Networking happens organically
  - When we add more rooms and sites
- Enterprise Level is achieved
  - When multiple sites are served
  - By one instance of the software.
- Networking is Outsourcing
  - All sites have internally “outsourced” their monitoring to the Enterprise system.
- Virtualization is Outsourcing of the Physical Hardware
  - This path leads to a private cloud, then to...?



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## Trends

### ■ Trend 4: Electronic & Digital Signature

- Like Electronic Records
  - Electronic signatures are very efficient, but high risk.
- Like a Paper Signature
  - An Electronic signature is only valid if it can be authenticated.
- Authentication is currently only possible
  - Inside the system where the record was signed.

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## Trends in GxP Computerized Systems

- Trend 1: Paper to Electronic Records
- Trend 2: Decrease Validation and Increase Data Integrity
- Trend 3: Networking / Outsourcing / Virtualization
- Trend 4: Electronic & Digital Signatures



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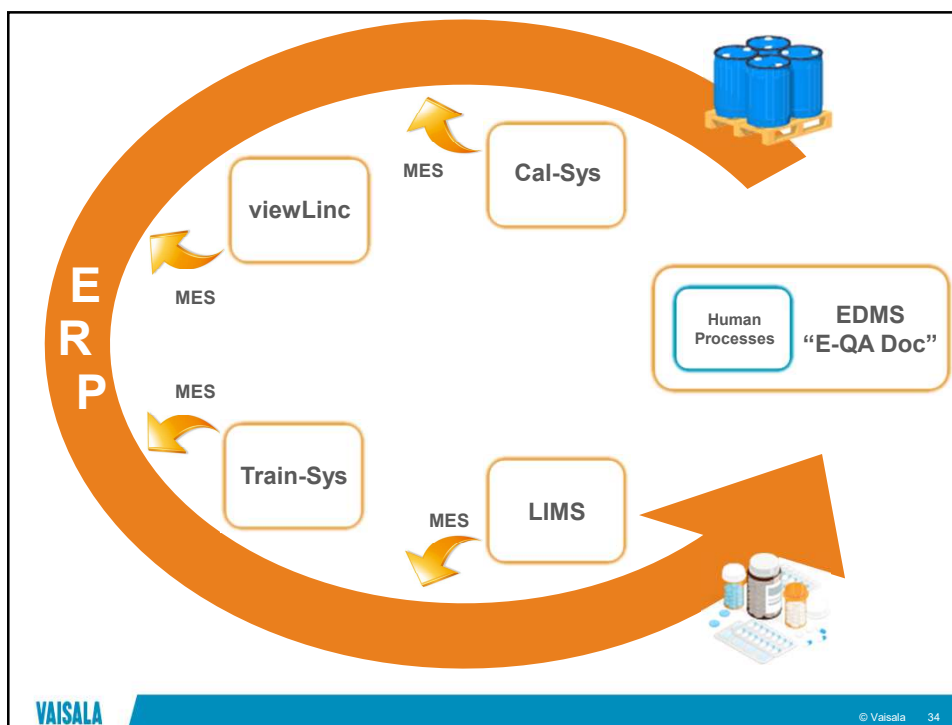
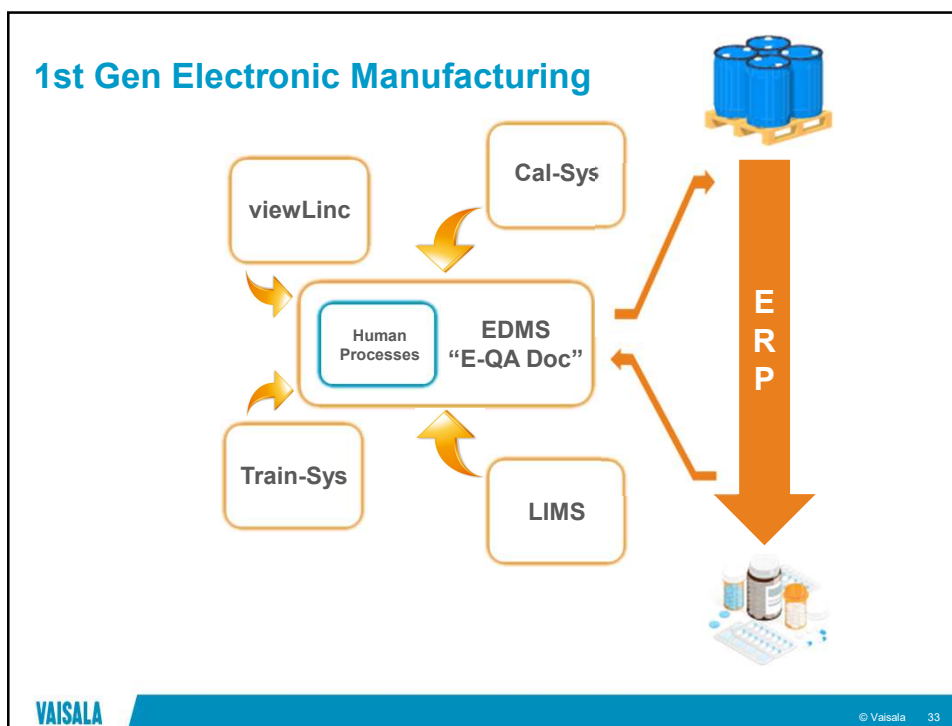
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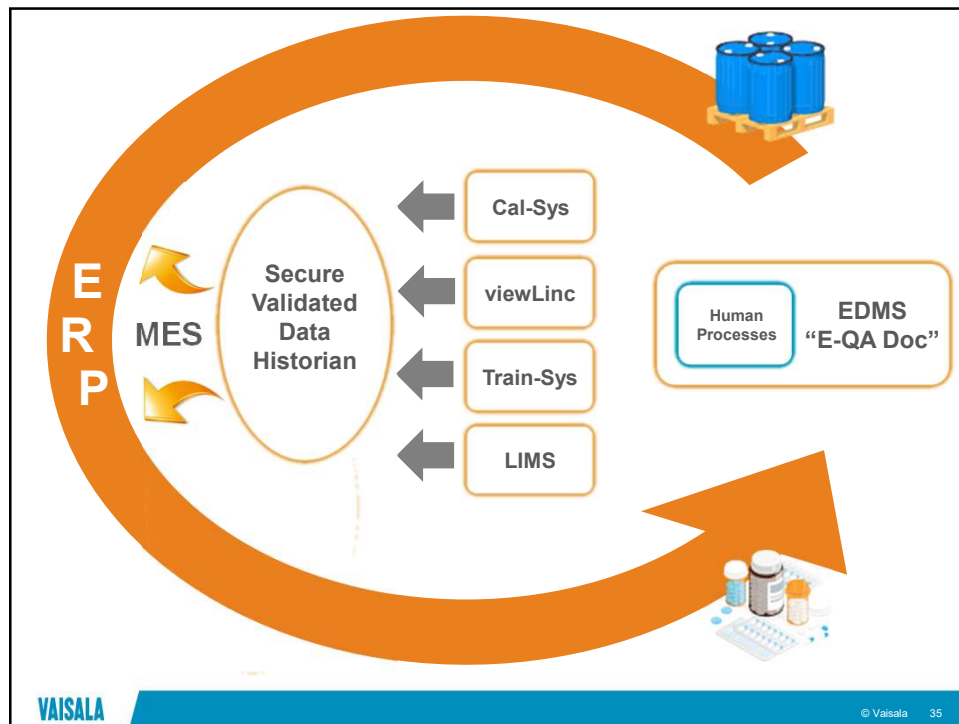
## Question Break?



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### Poll : Multiple Products / Multiple Sites

- Question:
  - Does your company have multiple sites or GxP products.
- Answers:
  - Yes, Multiple sites and/or Products
  - No, Single Site and Product

## Multiple Sites & Multiple Products

- If each product and site are at a different tech level...
  - Each site will need a different monitoring solution!
- Example
  - 3 sites with 3 products... Will have 3 different monitoring needs!



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## Three Solutions?

- 1) Get a different monitoring system for each site.
  - NO: Individual systems is against the trends.
- 2) Get all sites to standardize.
  - NO: High cost of standardization is against the trends.
- 3) Get a single system that is adaptable enough to work with all (or most) sites.
  - YES: This is a workable solution.



Basic Hypothesis – Adaptability is key to Future-Proof Monitoring.

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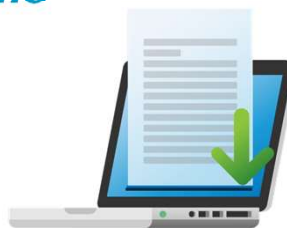
## Trends in GxP Computerized Systems

- Trend 1: Paper to Electronic Records
- Trend 2: Decrease Validation and Increase Data Integrity
- Trend 3: Networking / Outsourcing / Virtualization
- Trend 4: Electronic & Digital Signatures



## Trend 1: Paper to Electronic

- Include the following requirements:
  - Option for Paper Records
    - Example: The system must allow reports to be physically printed for ink signature approval.
  - PDF Outputs as Standard
    - Example: The system must generate reports in PDF format to allow for electronic export to other systems.
  - MMI : Machine to Machine Interface
    - Example: The system must provide a standardized pathway for data transfer through an MMI interface, such as a Web API or OPC.



## Trend 2: Validation and Data Integrity

- Include the following requirements:

- Simple and Standardized Solutions

- Examples:
  - The system must be GAMP Category 4 or simpler - custom systems are not acceptable.
  - The application must be standardized such that configuration of the software package by the vendor is not required.



- Data Integrity Protection

- Examples:
  - The system must store all data in an encrypted and tamper-proof database.
  - The system must not allow any user to make changes to raw data.
  - The system must track all changes to system parameters in an audit trail.
  - The system must have simple and transparent workflows for data movement from collection to storage.

## Trend 3: Electronic & Digital Signatures

- Include the following requirements:

- Do not sign documents in the system.

- Example: The system must allow for electronic signature only for approval of parameter changes and critical actions. There should be no capability for electronic review of data.

- PDF Outputs as Standard

- Example: The system must generate reports in PDF format to allow for electronic export to other systems **for approval and electronic signature**.

- MMI : Machine to Machine Interface

- Example: The system must provide a standardized MMI pathway for data transfer to an ERP or Data Historian **for approval and electronic signature**.

## Trend 4: Networking / Outsourcing / Virtualization

- Split this into two trends:
  - Trend 4: Networking to Enterprise
  - Trend 5: Outsourcing to Virtual

Both Trends are different faces of an economic drive to use fewer IT resources.

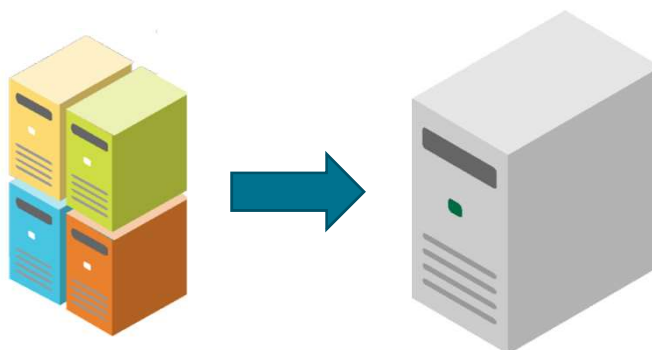


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## Trend 4: Networking to Enterprise

- Include the following requirements:
  - Enterprise Level System.
    - Example: The system must be an Enterprise Level solution, allowing multiple sites to be monitored over the corporate LAN using a single instance of the monitoring application on a single server.



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## Trend 5: Outsourcing to Virtual

- Include the following requirements:
  - Virtual Server.
    - Example: The system must be installed on a virtual server, and operate successfully in a virtual environment.
- Increasing Outsourcing
  - No Outsourcing (Physical Local Server)
  - Low Internal Outsourcing (Physical Enterprise Server)
  - High Internal Outsourcing (Virtual Enterprise Server)
  - <sup>1</sup>Low External Outsourcing (Virtual Cloud Server)
  - <sup>1</sup>High External Outsourcing (Software as a Service)

Footnote 1: Questionable GxP compatibility.



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## Conclusions from 5 Trends

- Adaptability is REQUIRED.
- Adaptability Requirements Summary
  1. Enterprise Multi-Site System
  2. Compatible with Virtualization
  3. Standardized at Category 4 or simpler
    - User Configurable only
  4. PDF Reports for Print or Transmit
  5. MMI for High-Tech Manufacturing
- This is ONLY tech variability...
  - Actual Sites will Vary in many important ways.
    - Other kinds of adaptability are needed...



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## Adaptability to Match Site Differences

- Measurement Parameters
- Infrastructure Density
- Alarming Formats
- Interface Diversity
- International Locations



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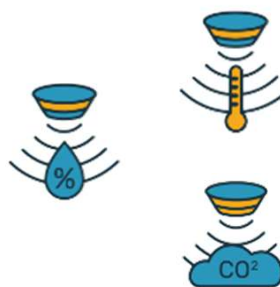
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## Site Variability: Measurements

- Include the following requirements:

- **Measurement Parameters**

- Example: The system must measure:
  - Ambient “Room” Temperature
  - Relative Humidity
  - Differential Pressure
  - Carbon Dioxide
  - Vaporized Hydrogen Peroxide
  - Airborne Particles
  - Door Contacts
  - Ultralow Temperatures



- **Standardized Sensors**

- Example: The system must provide the required parameters through standardized sensors and repeatable data collection pathways. Custom sensors and data collection methods shall not be tolerated.

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## Site Variability: Infrastructure Density

- Include the following requirements:

- **Communication Modes**

- Example: The system sensors must send data by:
  - Wired LAN (Ethernet)
  - Short-Range Wireless (WiFi)
  - Long Range Wireless (RF)



- **Power Sources**

- Example: The system sensors must be powered by:
  - AC Main (Wall Plug)
  - PoE (Power Over Ethernet)
  - Long Life Battery



## Site Variability: Alarm Formats

- Include the following requirements:

- **Alarm Formats**

- Example: The system must notify users of alarms via:
  - Email
  - SMS (Short Message Service)
  - Telephone Voice Call
  - Signal Tower
  - On-Screen Notification
  - Third Party Alarm Service



## Site Variability: Interface Diversity

- Include the following requirements:

- Interface Diversity**

- Example: The system must allow users access via:
      - Desktop Internet Browser
      - Mobile Device
      - Public Display
      - Touch Display
      - Data Historian



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## Site Variability: International Sites

- Include the following requirements:

- Time Zones**

- Example: The system must allow data time-stamps to be adjusted to match local and corporate time-zones.



- Interface Language**

- Example: The system must provide a user interface in the following languages:
      - English
      - Spanish
      - Swedish
      - German
      - French
      - Portuguese
      - Chinese
      - Japanese



- Technical Support**

- Example: The vendor must provide first level technical support during the business day in time zone UTC -X.

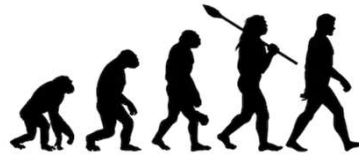


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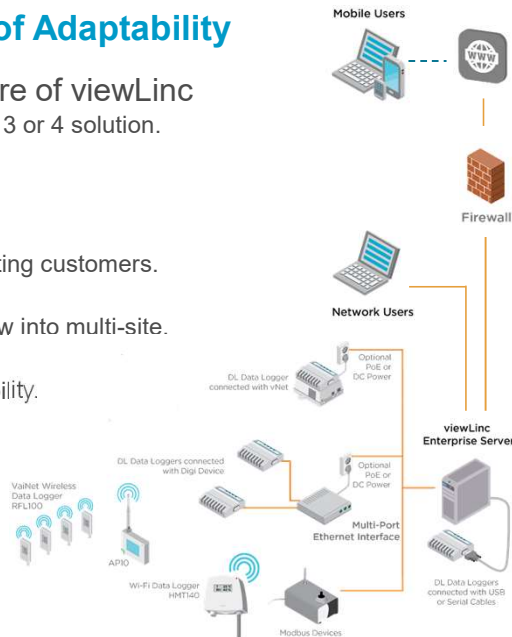
## Future-Proofing through Adaptability

- Basic Hypothesis
  - Future-Proofing is best achieved through adaptability
    - If we can meet a variety of current needs...
    - Good chance it will meet **most** future needs.
  - Put requirements for maximum adaptability in URS!
    - Technological Trends
    - Site Variability
- We believe this at Vaisala.
  - So what did we do with viewLinc?



## viewLinc - an Example of Adaptability

- Adaptability is a key feature of viewLinc
  - The most adaptable Category 3 or 4 solution.
- History
  - Key Detail
    - Best customers were our existing customers.
  - Strategy
    - Match their needs as they grow into multi-site.
  - Result
    - Organically produced adaptability.
- Lessons Learned
  - Scalability
  - Backwards Compatibility
  - Leveraged Administration



## Scalability

- Scalability is a key feature of viewLinc
- Why?
  - Commitment to customers that want to grow.
- Solution
  - Same application can support:
    - 5 Loggers
    - 50 Loggers
    - 500 Loggers
    - 5000 Loggers

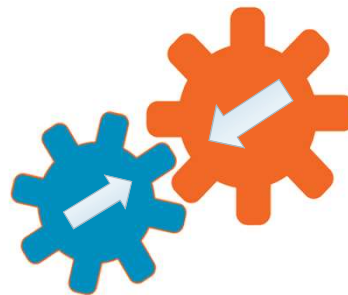


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## Backwards Compatibility

- Backwards Compatibility is a key feature of viewLinc
- Why?
  - Commitment to older low-tech customers to provide a growth path.
- Solution
  - Devices
    - Legacy devices work with new software versions.
  - Data
    - Legacy data migrates to new software versions.



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## Simplify Administration



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## Future-Proof Monitoring Systems

- **One Truth:**
  - Unfeasible to Future-Proof an EXISTING monitoring system.
- **One Solution:**
  - Make sure your next monitoring system is Future-Proof.
- **One Path Forward:**
  - Include "Adaptability Requirements" in URS.



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## Review

- Imagined Future
  - By understanding the past
    - Identified Trends in Transition
- Created a model of GxP Manufacturing
  - This moved from Paper to Computerized
  - Look at new high tech iterations responding to the trends...
- Explored Trends
  - Identified Adaptability as a key component to future-proofing.
- Identified Requirements
  - Put "Adaptability" in URS to ensure of a future-proof monitoring system



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## Requirements for Adaptability

- Network
  - Enterprise-level solution compatible with virtualization.
- Data Outputs
  - Paper, PDF and Machine-to-Machine Interface
- Multiple Parameters
  - Maximize measurement parameters with standardized sensors.
- Flexible Infrastructure
  - Communication Modes and Power Sources
- Interface Diversity
  - Interface Types and Alarm Notification Pathways
- International and Regional Capability
  - User Languages and Time Zone Normalization



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## POLL:

**Would you like a Vaisala Applications Engineer to contact you?**

- Yes, I'm interested in... Loggers
- Yes, I'm interested in... Continuous Monitoring System
- Yes, I'm interested in... Process Instrumentation
- Yes, I'm interested in... Hand-held devices
- Yes, I'm interested in... Other
- Not at this time, thanks.

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**Questions?**



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**Thank you for your time!**



For more information....  
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