

THE FACILITY OF THE FUTURE

Critical considerations for deploying smart, fast
and flexible Life Sciences facilities

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BEGIN ▶



The next industrial transformation is here

Biotech and pharma companies are looking to intelligent, connected operations as a way to remain competitive and better serve those who rely on their products.

While the opportunities are endless, the challenges are many. Innovation remains critical as patents expire, lifecycles shorten and counterfeits flood the market. Cellular biology advancements have driven complex process changes, creating greater challenges for Life Sciences companies, including:

- **A growing demand for more targeted, smaller volume orphan drugs and personalized medicines.** This demand is driving operations away from large-scale bulk production to multiproduct facilities that require complicated batching, frequent changeovers and meticulous tracking.
- **A shift from large, centralized facilities serving the world, to smaller, locally focused facilities.** This shift can bring active pharmaceutical ingredient (API) production to lower-cost locations, and personalized drugs closer to patients.
- **Pressures to get drugs to market faster, while maintaining compliance and data integrity.** These pressures require greater process management, the convergence of IT and OT and more efficient R&D operations to get approval from regulators.

START MAKING WHAT'S POSSIBLE A REALITY TODAY

You can meet these challenges with a new kind of facility – a facility of the future. One that is smart, secure, connected, flexible, compliant and is possible today.

The approach you take to create your facility of the future will greatly influence your success.

When done right, you can maximize ROI, optimize asset utilization, achieve greater speed to market and maintain quality and compliance throughout.



With 7,000 classified rare diseases affecting 300 million people, pharmaceutical companies are challenged to advance their technology.

Source: rarediseases.org

A game-changing facility for today, optimized for the future

Imagine a facility that leverages digital technologies to connect systems both horizontally and vertically. One that provides data to improve decision-making, performance and compliance. Where modular and mobile equipment creates more opportunity for “plug and play” operations and less dependency on manual intervention than ever before. Where automatic equipment recognition and verification systems can track and confirm your equipment placements. And where modern visual solutions can guide operators seamlessly through process steps.

These benefits are just the beginning of your competitive advantage. You can gain even more efficiencies and cost benefits by leveraging:

- **A flexible operations environment** that takes advantage of single-use technologies and mobile equipment to optimize capital utilization.
- **A communications infrastructure** that leverages Pharma 4.0 concepts and Industrial IoT technologies to swap out and repurpose assets easily.
- **Intuitive operator interfaces** that serve up real-time data and go where operators go.

PHARMA 4.0

the power of seamless connectivity



actionable analytics



digitized records and processes

An essential part of a connected enterprise that helps optimize quality management, data integrity and productivity.

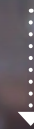
The right up-front design and proven technologies can help you quickly deploy this new facility and realize significant outcomes, including:

- **A smaller building footprint** by removing hard piping for utilities and capitalizing on easily repurposed, modular equipment.
- **Startups as fast as 6 to 12 months** using pretested and validated equipment, and standardized process skids and packages.
- Up to **25 percent greater yield** by reducing costly cleaning downtime.
- **Better labor utilization** through productivity enabling technologies.
- **Reduced inventory** through data-driven process control and predictive quality metrics.
- **Maintained quality and compliance** when making process changes.
- **A scalable and agile facility** with flexible and adaptive equipment and infrastructure design.



THE FACILITY OF THE FUTURE

Built using digital automation solutions, Industrial IoT connectivity, single-use equipment, prevalidated skids and other flexible manufacturing approaches.



OPTIMIZE

COMPLIANCE | COST | QUALITY | ASSET UTILIZATION

Drug discovery takes years – getting to market doesn't have to

Agility, connectivity and speed are central to a successful facility of the future. But, where do you start?

Creating flexible operations

Flexibility can mean executing smaller batches, optimizing asset utilization and being first to a new market. This agility is achieved using single-use technology, actionable data and prevalidated, modular equipment. It employs a mobile design concept to accommodate changing market demands and competing priorities. And, it requires rethinking how you make and move product.

COORDINATING THE DANCE

Your future facility's layout may resemble a ballroom: an open area with no fixed equipment and minimal segregation, allowing mobile equipment, materials and HMI's to enter and exit based on demand.

Reactors are wheeled into position and connected using disposable tubing. The intermediate can be transferred back into a tote and sent into a centrifuge or depth filtration. Downstream, media is hard-piped through ultrafiltration, defiltration and chromatography columns.

With carefully architected plug and play connectivity, free movement and interchangeable processes, utilities and rooms are possible.

A traditional stainless steel reactor can take **up to 2 days to clean and sterilize**. A single-use reactor bag can be changed in **2-4 hours**.

BRINGING SMART TOTES ONLINE

Smart totes are integral to the movement of materials through the facility of the future. But adding instruments like temperature probes and level switches requires adding I/O and wiring it back to the distributed control system (DCS). This connection can pose DCS integration challenges that require engineering intervention and can result in data integrity risks.

One proven solution is a hardened I/O module connected to docking stations via Ethernet cables. This approach minimizes the need for additional wiring and each I/O module then has its own IP address.

A modern DCS uses that address and critical setpoints unique to each unit to auto-recognize a tote and alert an operator if the wrong one has been connected. Workers can then better identify and track each of the dozens of totes moving throughout their facility.

MOBILIZING PROCESS EQUIPMENT

In a facility of the future, even traditionally fixed bioreactors and mixing tanks are mobile.

For instance, a smart mixing tank can be moved, docked and identified via its IP address. It can also be cleaned in different locations, allowing other equipment to move into the clean room, optimizing production.

As the tank progresses through production, workers can track when it has been used and cleaned, and confirm its hygienic status.

Achieving this flexible reality means that your workers are responsible for hundreds of possible configurations and connections, introducing the potential for human error.

And that's where the right DCS can make the difference.

On a typical single-use bioreactor, an operator can be required to perform **up to 900 manual connections.**



Choosing the right DCS

There are two choices when it comes to selecting a DCS: traditional or modern. This decision matters! The DCS you deploy directly impacts the level of connectivity, productivity, flexibility and quality achievable in your facility.

TRADITIONAL DCS – FACILITY OF THE PAST

When first introduced, DCS solutions were a reliable way to connect multiple controllers and points of access throughout a plant. But, the traditional DCS is showing its age.

For starters, they are built on proprietary technology, disparate from other control systems. This divergence results in fragmentation between process, packaging, utilities and other critical areas. Separate systems are costly, difficult to integrate and can restrict your agility and responsiveness to future needs.

Additionally, a traditional DCS often uses outdated fieldbus protocols not suitable for plug and play operations. The result is a flood of alarms and errors when equipment is disconnected.

To avoid these disruptions, some traditional systems use closed proprietary protocols that allow disconnections. But this comes with complex physical design criteria.

For example: you must identify every point where any node could be connected, greatly constraining your “ballroom” options.

MODERN DCS – FACILITY OF THE FUTURE

A modern DCS offers the same core capabilities of a traditional system, with additional, information-enabled functionality designed for a scalable facility of the future.

Specifically, a modern DCS built on open, unmodified Ethernet can deliver smart docking stations, and seamless, plug and play connectivity of your mobile equipment.

This approach minimizes alarms and errors when reconfiguring mobile equipment. And multiple portable totes can be used while the data transfer to the DCS remains consistent. Think of it like undocking a laptop and plugging back into the network in a different location. All with minimal system disruption.

In addition, a modern DCS won't enable controls for mobile equipment that is docked in the wrong location. It can support the scanning of materials, pipes and other components to confirm they're used with the right equipment at the right time.

This system all helps to mitigate human error and save valuable validation time. And production areas realize improved changeovers with a high degree of confidence while requiring minimal intervention from operators or engineering staff.

Why use a modern DCS with Ethernet?

- 1** Simplify connections and reduce network-based problems
- 2** Know that equipment and materials are in the right place, every time
- 3** Create a more repeatable process
- 4** Reduce equipment change times
- 5** Support equipment, material and hygienic tracking to maintain quality and regulation compliance

MODERN DCS – ULTIMATE CONNECTIVITY

Perhaps even more important are the benefits derived from a common data structure. This interoperability connects your ERP system down to individual equipment, raw materials and end products, and back up again. It also gives workers real-time data in a single, consistent format, providing valuable production insights.

This two-way communication for both your vertical and horizontal processes is critical for data integrity, batch quality by exception and evolving regulatory needs.

FROM LAB TO FACTORY FLOOR: A SEAMLESS TRANSITION

Many research laboratories are employing modern DCS solutions on small bioreactors in their labs, and are gaining regulatory approval under this process.

There has been a 206 percent increase of patents issued from the Technology Transfer Office in the past decade¹. This trend means the ability to seamlessly transfer new technologies into your operation will only become more critical over time. And DCS compatibility, from one modern system to another, can greatly increase speed to market and accelerate new revenue streams.

¹ *Concept to Commercialization: The Best Universities for Technology Transfer, Milken Institute, April 20, 2017*

Customer success

One biopharmaceuticals giant faced skid control obsolescence, poor data visibility and downtime causing alarms.

With the transition from a traditional to modern DCS, the company went from 5 to 6 communication-related alarms per week, to zero in the first 2 months of operation. Added operational improvements have come from a “family” code approach that cut skid validation time in half. Greater visibility has reduced troubleshooting to as little as 2 minutes.

[Read more](#) about how this company is now more agile and positioned for future market demands with a scalable, modern DCS.

Empowering your workforce

Visualization is critical to maximizing the accuracy and efficiency of your facility of the future. Fixed operator screens or terminals are no longer practical. Instead, workers are more effective when they have tablets or mobile screens that can follow them, and production, through the facility.

MOBILE ENABLED

Thin client technology makes mobile visualization possible and helps reduce the risk of error that can accompany mobile equipment.

Location-based mobility solutions can recognize an operator's location and enable relevant screens and applications, while disabling others. It can also use location resolvers like QR codes, Wi-Fi, GPS and Bluetooth beacons, to help make sure that mobile users and devices only receive content in authorized areas.

For example: an authorized operator standing in front of Reactor No. 1 will receive control of that machine. If they move, they can retain visualization of Reactor No. 1 but will lose control of it. This feature keeps the worker informed while minimizing the risk of erroneous operation.

GUIDED BY AR

Training resources are tightening while your workforce is asked to do more. So imagine the ability for any technician to walk up to any connected device and receive hands-free, visual instruction on how to operate equipment or fix a problem.

Visualization technologies like augmented reality (AR) provide standard operating procedures directly to the operator. They can also help mitigate downtime events and quickly resolve incidents by doing just this. Appearing right before your eyes will be the information needed to assess a machine's condition or perform a task.

A manageable gateway to virtualization

Take advantage of a fully managed virtual infrastructure, supported by a **data center** engineered specifically for production environments.

Compliance-driven design does more than check a box

Auditing is no longer a static process. Global laws and regulations surrounding patient care require extensive, digitally integrated documentation of pharmaceutical production. This directive in itself is a significant challenge. At the same time, you need to scale up production, run smaller batch sizes and increase changeovers.

With all this complexity, compromised quality and compliance can feel inevitable at times. But implementing a modern, integrated manufacturing execution system (MES) can change that story and help you stay compliant, and drive profitability.

In-process quality data collection and analytics can turn weeks of review into **real-time-release**, with no quarantine required.

Asking more of your MES

Lengthy compliance activities drive up the cost of your production operations while your product sits waiting to be shipped. This time and expense is unacceptable in an industry pressured to lower overall drug costs. The right MES can bring unified integration from ERP to the shop floor, real-time quality dashboards, order-completion data and greatly reduced time to qualify.

When looking to adopt or upgrade an MES, look for attributes that fully support flexible manufacturing practices and an enterprise-wide approach. A few key capabilities include:

- A comprehensive electronic batch record (EBR) that captures complete product genealogy, facilitates review by exception and connects with your anti-counterfeiting serialization system.
- Role-based recipe management, optimized for each stage of a recipe lifecycle and that drives time to results for every user.
- A robust solution for data integrity, helping ensure that documentation or production human errors do not result in wasted product, contamination or potential recalls.

Customer success

Pharmaceutical producer, Zhejiang Medicine Company (ZMC), needed to quickly increase production to meet global demand.

The answer was in an MES that eliminated time consuming, error-prone paper-based documentation. This helped increase efficiencies, reduce costs and enforce compliance in real time.

Now, 100 percent paperless, ZMC has:

- Reduced the risk of errors
- Calculated up to 10 percent labor savings
- Reduced product and management review times by 50 percent or more

[Read more about how ZMC improved compliance with MES software.](#)

Using information to drive improvements

With a future-focused information infrastructure in place that brings together IT and OT, key process data is no longer siloed. You can collect and analyze real-time data to help workers make better decisions while achieving compliance.

Scalable analytics tools convert your raw data into customized, actionable information. They can be deployed in phases at any level of your organization, adding value and helping you solve simple to complex challenges.

With contextualized insights around your quality and batch deviations, you can achieve:

- Quality compliance and conformity at a lower cost
- Increased output and decreased inventory
- Lean and continuous improvement goals
- Improved processes and asset utilization
- Faster time-to-market to maximize revenue

MINING THE TERABYTES

Although many have streamlined with modern MES and EBR, data analytics hold the key to process optimization on many levels.

One processing line or inspection system can produce multiple terabytes of data each day. Successfully mining this data for temperature deviations, refrigeration exposure time or other abnormal events can minimize the time batches are held before release. With easily accessible quality insights, you can use analytics to realize proactive process improvements and productivity.

45% of manufacturing executives report the inability to access data as a key barrier to solving their challenges.

SCM World/Cisco "Smart Manufacturing & The Internet of Things 2015" survey

Securing a connected facility

More connection points bring a huge competitive advantage, along with a greater attack surface to protect. Prepare for not only bad-actor hackers, but also well-intentioned mistakes.

Your facility of the future requires comprehensive cybersecurity that goes beyond traditional IT systems, an industrial DMZ and even a defense-in-depth strategy. The next step in maintaining business continuity is to adopt capabilities, addressing risk across an attack continuum.

The NIST cybersecurity framework outlines the following functions as a good place to start in implementing strong cyber hygiene practices. These steps will also prepare you for IEC 62443 global standard requirements:

- Understand your current attack surface and asset vulnerabilities, including your higher risk, obsolete hardware or software.
- Implement protective measures to safeguard your industrial control systems.
- Work with a partner to vigilantly monitor risks and detect when threats bypass your protection mechanisms.
- Develop an action plan for immediate response to security incidents and to minimize damage.
- Quickly recover and return to production, with root-cause incident investigation to follow.

By practicing good cyber hygiene, you can minimize disruptions to your operations. This program can be built in-house with the support of industry consultants. Look for experience that spans both IT and OT [network security design](#).



“The average cost of **a single data breach incident rose to \$3.86 million** in 2018... If this trend continues, total cyber crime damages around the world are poised to hit \$6 trillion per year by as soon as 2021.”

IBM Security and Ponemon Institute “2018 Cost of a Data Breach Study”

Optimize, innovate, deliver and protect – starting today

The facility of the future leverages single-use technology, information and connectivity, and modular and mobile design concepts to reimagine production. It can help you realize lower capital costs, faster facility startups, streamlined changeovers and more efficient production.

But the facility of the future isn't a concept for tomorrow. It is being proven around the world today, using enabling technologies designed with mobility and flexibility in mind. To learn more about making your facility of the future possible, visit [our website](#) or contact your local sales representative.

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