FOUR STEPS TO IMPROVED OPERATIONAL EFFICIENCY

In pharmaceutical manufacturing facilities

Honeywell

Technology is the cornerstone of operational efficiency. As pharmaceutical manufacturing campuses become more complex with more assets, devices and control systems, operators need better technology to help effectively run them and have the proper level of visibility into their assets.

To be truly operationally efficient, operators must be able to connect to their assets, devices and control systems and see how they're performing so that they can tune them accordingly. Operational efficiency is required at all facets of a building automation project. In pharmaceutical manufacturing, it's important to consider four key stages where operational efficiency can be impacted: project planning, implementing solutions, regulatory reporting and validating compliance. Let's look at each of these areas.

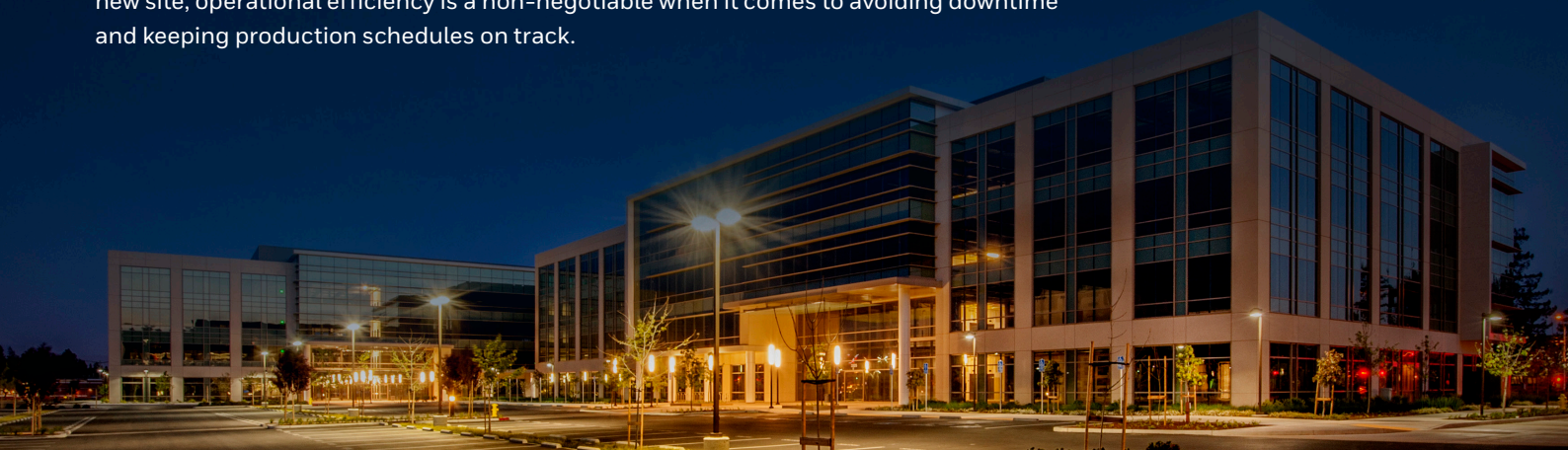
1

PLANNING FOR SUCCESS

Whether you're updating a brownfield site or building a greenfield pharmaceutical facility, planning a building environment that fosters operational efficiency is key. It's important to engage project partners – specifiers, contractors and building automation experts – that understand the nuances of pharmaceutical manufacturing, assets and operations to design spaces built for efficiency. This includes understanding GMP requirements and identifying the needs of direct and indirect impact systems.

Taking a holistic view, even where the project scope is limited, can take account of interdependencies between systems. Integrating building systems – from fire and life safety systems, security systems and building management systems – can help enhance situational awareness, optimize workflows and improve asset utilization. Beyond system integration, it's important to plan for comprehensive views of building performance to help proactively identify potential asset failures or factors that may disrupt operations or compromise compliance. This includes safety and security, both in terms of physical access control and life safety and cybersecurity.

Greater insight into asset and building performance can also help you better manage energy use and help improve occupant experience. In facilities where operating conditions must be managed closely and carefully – and often differently depending on the work being performed – planning for operational efficiency of systems like heating, air condition and ventilation can help facilities protect GMP and maintain indoor air quality requirements. No matter if you operate an aging facility or new site, operational efficiency is a non-negotiable when it comes to avoiding downtime and keeping production schedules on track.



2 IMPLEMENTING SOLUTIONS

A proper understanding of the business and GMP requirements can guide a tailored, outcome-focused solution to meet them. Two operational efficiency-focused concepts can be central to success:

- Deploying high-end control solutions with high levels of redundancy for a high availability design. This means redundant power and control modules to help protect operations in the event of failures. Taking this a step further, deploying hot-swappable design mean that if a device fails, it can be replaced without interrupting the process.
- Leveraging automated responses and notifications based on the GMP requirements and creating well-defined and documented process definition and standards. This can enable rapid responses (either on-site or remotely) when things are starting to go wrong to minimize potential impact and avoid downtime.

Predictive maintenance is a critical technology that can help enable this by leveraging artificial intelligence (AI) and machine learning (ML) analytics to detect early signs of potential issues. It can also avoid unnecessary routine, scheduled maintenance and parts replacements to help reduce workloads on stretched technical staff helping to ease the skills shortage.

3

REPORTING TO REGULATORS

GMP and regulatory compliance is about more than just following the correct procedures and maintaining the production environment. It is essential to be able to prove compliance and accurately identify deviations when things go wrong. The pharmaceutical industry requires historical monitoring data to be easily retrievable for audit purposes to prove compliance with regulatory bodies and for traceability purposes. This means capturing and recording data across building systems to enable proper auditing required by regulatory bodies. Integrating building systems can help fulfil requirements while containing compliance costs and minimizing workloads.

Facility operators must be able to bring critical building domains together to capture real-time data relevant to GMP requirements, record this for easy retrieval, and automate extraction and reporting for simpler, more straightforward compliance. In the event of failures or incidents, using building platforms with this capability can allow operators to quickly identify any production impact and meet regulatory reporting requirements. The underlying data can also enable root cause analysis of failures to help prevent reoccurrence.

4

VALIDATING COMPLIANCE

While part of compliance efforts more broadly, it is worth considering validation specifically, due to how time-consuming it can be to workloads. Regulations, such as 21 CFR Part 11 of the FDA's Code of Federal Regulations (CFR) or the European Union's Annex 11, cannot be ignored. Pharmaceutical facility operators must provide current and robust documentation for direct impact systems (and potentially documentation to support classification of indirect and non-impact systems). Again, this may encompass not just environmental controls but security controls and fire safety. Validation, like all compliance efforts, is an ongoing process. Measurement and verification associated with validations must be robust and continually maintained. It is also one that building solution partners should be well placed to support given that they understand the capabilities and features of their own systems. That may be through support, advice and in-built validation tools in solutions, or even, in the case of partners such as Honeywell, through field service teams, remote or onsite, that provide ongoing provide ongoing maintenance support.

CONCLUSION

Honeywell understands the pressures of the pharmaceutical industry, from changing government regulation and sustainability goals to diverse ecosystems and supply chain issues. To make strides in each of these areas, it's important to take an outcome-based approach. With decades of experience catering to the unique needs of the pharmaceutical industry, Honeywell can help improve your operational efficiency through integrating hardware, software and services across your pharmaceutical campus or mix-use facilities.

Contact us today to learn more about how we can reimagine your buildings for a better future.

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