Honeywell | THE FUTURE IS WHAT WE MAKE IT

Fast Track Automation for Life Sciences

Solution Note

Honeywell believes the solution to most efficiently ramp up production of potential therapies is to facilitate development of full commercial scale manufacturing earlier, while treatments and prevention therapies are still in clinical trials. Our pre-structured process automation solution can be available for use in development applications in half the time depending on process requirements, and enable life sciences companies to immediately scale up to full production once FDA approval is granted.

Life sciences manufacturers leading development of new therapies realize that new technologies are the strategic drivers of innovation, safety, and speed. As clinical trials are finalized, the ability to rapidly pivot to produce new products and ramp up to meet production demand severely test technology infrastructures. The ability to simulate, visualize and qualify manufacturing strategies – even in advance of the typical commercial readiness timelines – are the levers needed to speed execution. The availability of real-time manufacturing data, with enhanced visibility and the power of predictive insights, will enable agile response to demand fluctuations.

Patients are Waiting

Honeywell believes the solution to most efficiently ramp up production of potential therapies is to facilitate development of full commercial scale manufacturing earlier, while treatments and prevention therapies are still in clinical trials. Our pre-structured process automation solution can be available for use in development applications in as little as a few months depending on process requirements, and enable life sciences companies to immediately scale-up to full production once FDA approval is granted. Parallel path development of an engineered solution can start now with minimum formulation details for the final therapy.

The manufacturer can even start to apply digital transformation to the manual steps during clinical trials to better consolidate and analyze data, and prepare

Bring products to market faster while ensuring compliance, quality, and efficiency.

- *Fast-track approval with electronic data submission*
- *Scale up to full production in half the time*

FEATURES & BENEFITS

- Ready to go
- No waiting on design and engineering
- Parallel work starts immediately
- Fast-track approval with electronic data submission
- Scale up to full production in half the time
- Configuration flexibility
- Bring new formulations to market faster
- Agile response to demand fluctuations
- Safeguard compliance
- Ensure quality
- Improve efficiency
- A360 outcome-based Service contracts available
- Real-time, enterprise-wide manufacturing data
- Enhanced batch visibility
- Predictive insights

electronic submittals for FDA review and approval. Then, the data can be used to prepare for the final production automation design. Our Fast Track Automation includes the process automation elements that can be rapidly configured virtually and then implemented once a therapy is approved and ready to be produced for public distribution. Once process parameters are finalized, a treatment or vaccine can go from approval to production in as little as 4 weeks.

Our project delivery ecosystem – the integrated way we leverage our global Batch Centers of Excellence, engineering teams, internal project execution, and authorized solution providers – delivers greater value for all aspects of 21 CFR part 11 compliant applications; project design, execution, startup and commissioning. Our delivery ecosystem is positioned to serve the needs of the life sciences industry at an expedited pace.

Deliverables and Implementation

The delivered fast track automation solution includes an automation system, SCADA or DCS depending on process requirements, detailed engineering of the system design and applications, project execution with validation, and process equipment skids specified and procured by a channel partner.

The complete system is scalable to meet the needs of varying process requirements, and integration is already pre-planned and ready to go. Automation can be planned for processing several potential therapies until final trial results and approvals are complete. That way, a pre-prepared manufacturing system is ready to go for whichever formulation is approved. Implementation starts with development of the automation system on a virtual engineering platform (VEP) in a private cloud. The design and engineering includes application configuration and qualification services provided by Honeywell's selected authorized solution provider, Wunderlich-Malec Engineering. If a manufacturer wants to repurpose existing process equipment, Honeywell will work to integrate the identified equipment into the final solution.

Hardware is then assembled and shipped to the data center, where the facility's servers, virtual hosts, and switches are set up; and to the site, where the process equipment, skids, and controllers are installed. Finally, the engineering design is transferred from the virtual host to the production system.

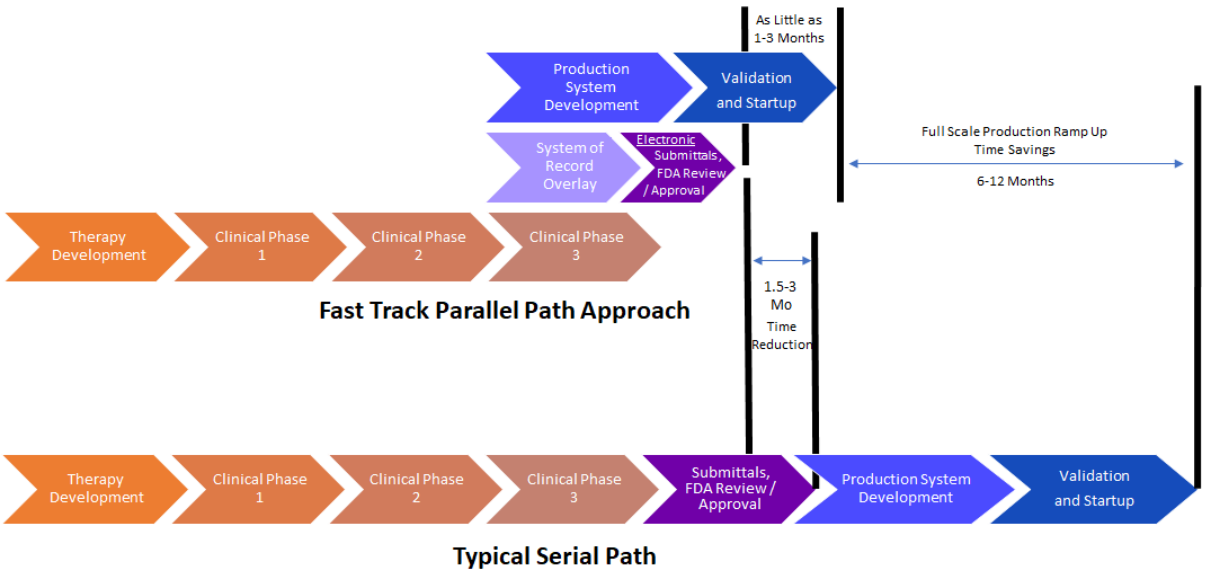
Differentiators

Honeywell has been providing automation hardware and software to the life sciences industry for over 30 years, and has continued to evolve and innovate, generating significant advances in automation technology. We have recently strengthened our focus in the life sciences industry by enhancing our level of expertise, our team, and our offerings to the industry. Honeywell has developed the most integrated, yet "open" technology in the automation industry, able to integrate seamlessly with the most modern equipment from any manufacturer, and by leveraging a breadth of complete virtual and cloud solutions not matched by any other technology company.

Use data collected during Phase 3 clinical trials to prepare for the full production automation system.

An Experion SCADA system overlaying clinical trial data collection can be scaled up into a DCS system when needed.

Experion is flexible and nimble enough to be scaled up or down in response to demand fluctuations.



Example comparison timeline showing time saved using a parallel path approach

Examples include Industry 4.0-ready virtual engineering sandboxes, virtual factory acceptance tests (FATs), virtualized control as a service, data center configuration to remotely manage installed assets, and remote collaboration and control monitoring. Our end to end cyber security is embedded in each of our solutions from the start.

In addition, Honeywell has entered into a collaboration with Bigfinite for an integrated interface for consolidation of business-wide data for real-time visibility and predictive insights. Combining Honeywell's expertise in process automation and controls with Bigfinite's data analytics, artificial intelligence and machine learning platform, the new solution will minimize regulatory risk, increase operational efficiencies and deliver products to market faster while reducing rejections and waste.

Our unique ability to combine these differentiated, proprietary technology innovations makes this fast-track production solution flexible and scalable. Using the power of the cloud, virtualization, flexible assignment of computing power, remote asset management from a data center, and efficient fast-track project implementation, Honeywell can immediately start to prepare manufacturing automation design in parallel with clinical trials to have production ready to go once a medical therapy is approved.

Summary

Honeywell's technology components and project execution come together to provide the flexibility necessary for faster advancement from clinical trials to full scale production of new treatments and prevention products. Working together with modular facility construction, the manufacturer can go from fast-track trial and approval to production in as little as months. There is no waiting on design and engineering. The pre-designed automation process enables parallel work to start immediately, so manufacturers are ready to go once a therapy is approved.

Why Honeywell?

Some of Honeywell's greatest innovations are the result of our commitment to helping customers continuously evolve while maintaining their current systems. We provide lifecycle investment protection by providing smooth migration paths to the latest control system technology when the time is right. All our solutions are supported with global training, engineering, and support as well as over 45 years of experience in control automation, with the largest installed base of integrated systems and the greatest longevity in the industry. Manufacturers rely on our experience and expertise to reduce risk and expedite proven performance.

For More Information

Learn more about Honeywell's Life Sciences suite of offerings by visiting our website at www.HoneywellProcess.com/LifeSciences or contact your Honeywell Account Manager, Distributor or System Integrator.

Honeywell Process Solutions

1250 West Sam Houston Parkway South
Houston, TX 77042

Honeywell House, Skimped Hill Lane
Bracknell, Berkshire, England RG12 1EB UK

Building #1, 555 Huanke Road,
Zhangjiang Hi-Tech Industrial Park,
Pudong New Area, Shanghai 201203

www.honeywellprocess.com

SO-04-20-ENG
April 2020

THE FUTURE IS WHAT WE MAKE IT

Honeywell