ThermoFisher SCIENTIFIC

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CHEMISTRY & CONVICTION

Decision point:

Build vs. buy continuous manufacturing

Seven approved oral solid dose products have launched into the US market using continuous manufacturing. As a result, this innovative solution is quickly gaining momentum and adoption within the industry. Continuous manufacturing provides a variety of benefits throughout the manufacturing of oral solid dose, which includes savings up to 1.65X on scale-up costs, reduction in total cost of ownership and a decrease in API usage. Read more about nine considerations to help evaluate if you should build or buy a continuous manufacturing suite.

Time to launch

BUY

It takes approximately three years to build and fully qualify a line for continuous manufacturing. If you are looking to launch quickly, outsourcing is going to be the best option.

New skills & staff required for product development

BUY

Finding expertise and staff to develop and execute your continuous manufacturing strategy can be challenging; typically, five senior and experienced team members are needed to launch a successful program (recommend: three development, one process engineer, one operator). The pool of talent that has this unique skillset within pharma is relatively small and competitive. CDMOs already have the talent in place, making them a more strategic and practical choice for outsourcing continuous manufacturing.

Process training for current employees

BUY

It might seem like a good strategy to train existing employees to be able to own a continuous manufacturing process. However, this niche skillset within the industry is more complex than you think. If you take this approach, you must keep up with training employees on two processes. This puts you at risk for errors and costly training procedures. It can also cause burnout with your team.

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Best return on investment

DEPENDS

This selection factor is going to depend on frequency of use and volume. If you plan on using this as a core manufacturing solution and your volume output is high, then building in-house might make more sense. However, if you are creating a single part where volume is low, outsourcing might be the best option. For this key decision point, we recommend that you create utilization models to help support your case, while also factoring in the cost, risk, and ROI. Conversations with a strong CDMO partner can help you select the path that's right for you and your molecule, while providing additional models, guidance, and perspectives.

Demand planning

DEPENDS

In some cases, pharma and biotech companies have demand planning perfected. If this is not your company's strong suit, leveraging a CDMO might be the better option for you. A partner can provide you with additional value add services like ensuring that you have enough API for demand planning and forecasting.

Flexibility with manufacturing runs

BUILD

You will have a different level of control and flexibility within your manufacturing runs when building out a continuous manufacturing suite. If you leverage a CDMO, you are often locked into their schedules and availability; of course they sometimes can offer flexibility when things arise, but you will get more control and prioritization in-house.

Adoption for quality systems and regulatory

BUY

If you build in-house, it can be a challenge to get the right regulatory experts in place who have continuous manufacturing knowledge. Partnering with the right CDMO that has a strong and vast knowledge of regulatory regarding continuous manufacturing can help you optimally and strategically file your IND with the appropriate information and data with speed and agility.

Maintenance

DEPENDS

Usually in the short term, your maintenance will probably have a relatively low impact since things will be new. However, in the long run, routine maintenance can be cumbersome and expensive. This component should be a part of the upfront modeling to see which avenue makes sense in the short term and long term.

Exact feature set

DEPENDS

If you are looking for exact feature sets with installation and process, building is a more attractive choice. Outsourcing means that you are leveraging what is existing. However, if a CDMO offers condo spaces, they could potentially build a dedicated continuous manufacturing suite that not only has your exact feature sets, but also allows you to have additional control, while still leveraging all the resources and expertise of the CDMO.

Workflow efficiencies

DEPENDS

If you are working with one outsourcing partner, there is a significant amount of value that can be added vs. working with multiple vendors. Working with one vendor that has drug substance, drug product and clinical trial solutions can ensure efficiency, cost, and time gains that will help you get to market with speed and agility.

Overall, building a continuous manufacturing suite in-house has more risks and challenges than outsourcing it. When leveraging the right partner, you can build a long-term, sustainable manufacturing strategy that reduces total cost of ownership, while helping you get to market quicker.

Want to find out if continuous manufacturing is right for your oral solid dose?
Contact us today.

About us

Thermo Fisher Scientific provides industry-leading pharma services solutions for drug development, clinical trial logistics and commercial manufacturing to customers through our Patheon brand. With more than 65 locations around the world, we provide integrated, end-to-end capabilities across all phases of development, including API, biologics, viral vectors, cGMP plasmids, formulation, clinical trials solutions, logistics services and commercial manufacturing and packaging. Built on a reputation for scientific and technical excellence, we provide pharma and biotech companies of all sizes instant access to a global network of facilities and experts across the Americas, Europe, Asia and Australia. We offer integrated drug development and clinical services tailored to fit your drug development journey through our Quick to Care™ program. Our Quick to Clinic™ programs for large and small molecules help you balance speed and risk during early development so you can file your IND quickly and successfully. Digital innovations such as our mysupply Platform and Pharma 4.0 enablement offer real-time data and a streamlined experience. Together with our customers, we're rapidly turning pharmaceutical possibilities into realities.

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