

Build **or** Buy?

Top challenges to consider when building an AMS system for your pharma company



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Managing Change

The pressure to change, adapt, and keep pace at an individual, team and corporate level is ever-present in the Life Sciences Industry.

How much has your workday changed over the last year? How many new tools have you had to use or new guidelines have you had to start following?

Maybe you've taken a course to study the latest regulations, or attended a webinar to catch up on emerging trends. Whatever your approach, keeping up-to-date with an evolving industry takes real commitment, both in terms of time and financial investment.

Best practice is not an absolute – it changes rapidly. In the artwork and labelling space, technology, legislation, and compliance can all shift on a monthly, even weekly basis. An organisation that fails to stay on top of its obligations runs the risk of product recalls and fines.

Challenges in the Life Science Industry that will impact your business include:

- ✓ Quality standards
- ✓ Regulatory changes
- ✓ Product proliferation
- ✓ Managing change control
- ✓ Process changes
- ✓ Changing legislation
- ✓ Serialisation
- ✓ Approval bottlenecks
- ✓ New product introduction
- ✓ Rebranding
- ✓ Competitors

Table 1: Challenges in the Life Sciences Industry

What Can An AMS Do For My Team?

Robust, effective online platforms are the key to managing the constantly shifting demands of the Life Sciences Industry. While precision and auditability are baseline requirements, these systems need to be more than just fit for the process they're managing today.

A system's real value comes from how it helps you prepare for tomorrow. It needs to be able to respond to changing market requirements as quickly and efficiently as possible.

One of the key tools for keeping up with Life Science artwork standards is an artwork management system (AMS).

Employing an AMS to handle your artwork process allows concise, compliant, consistent workflows to be applied across an entire organisation.

Installing an AMS gives focus to your processes, positions you to streamline and optimise, improving overall time-to-market.

Defining and then centrally managing workflows means compliance is easier to enforce, potentially reducing the risks your organisation is exposed to.

On top of getting to market faster and with less risk, an AMS can harvest actionable data on a monthly, weekly and even daily basis.

Specific pain points can be exposed – like where errors are occurring and what they actually are – as well as generating KPI reports at the touch of a button.

Using an AMS with a fully validated code base also gives an organisation complete ownership over its end-to-end process. The advantages of an AMS include:

- ✓ Standardised, best practice processes for all projects
- ✓ Eliminate task duplication
- ✓ Incorporates all stakeholders into process
- ✓ Gives visibility to possible improvements
- ✓ KPI Dashboards

Table 2: The Advantages of an AMS

Build or Buy?

An AMS fundamentally brings together several separate processes into one central system. What these processes actually entail varies greatly from company to company. A more established company may already be employing elements of an AMS, either in a physical form (written SOPs, signoff sheets) or digitally (text/graphic verification tools) while a start-up on the cusp of bringing its first products to trial might still be managing this part of its process in an ad hoc way.

Whatever stage of development a company is at, the same core question applies when it comes to embracing the potential benefits of an AMS. Do we take our own processes and try to mould them into a system of our own? Or do we look to external vendors?

Do we build or do we buy?

Building – The Customisation Trap

Within the Life Science Industry, the processes for managing artwork are vastly different from company to company. An internally built AMS is going to be completely customised. Of course that sounds very appealing – a system exactly specified to how you handle artwork.

What sounds great in theory can very quickly become a crippling liability. Without deep industry knowledge *and* experience in developing a properly validated AMS, the potential for being blindsided either during, or worse, after the project is high.

The budgets of a custom-built system can quickly get out of control and the project can stall long before completion simply because it became too expensive.

“One of the primary pain points on a custom build is the need to be validated.”

Building internally would require an organisation to commit **to complex, long term validation**, dedicating resources to creating a large, comprehensive set of documentation to cover every touch point of the AMS. Correct validation is integral to having an effective, compliant system.

Without proper validation the system falls at the first regulatory hurdle it encounters.

Throw into this mix the many different stakeholders to be included in the AMS – regulatory, quality assurance, project

managers, engineers, CMOs, suppliers and external labelling vendors. Their input needs to be considered before, during and after the development process and anticipating their changing needs, and thus changes in the system, is an onerous task.

All this can lead to situations where your full validation pack has just been signed off, only to almost immediately require a change due to entering a new market or legislative shift.

Buying – Immediacy of Improvement

So what about the other side of the argument?

A configurable system is one which has had all its code base already validated. This means that everything that *can* happen in the system has been tested. Changes don't have the same domino effect that they would on a system being custom built.

So when you get your hands on it, all you have to do is either adjust the settings yourself or get a business analyst or other SME to configure the system until it does what suits your organisation and process.

Buying an AMS can immediately realise several improvements over a built system in three distinct areas:

01 Immediate best practice

Having mapped your process, identified bottlenecks and anticipated any potential challenges, an AMS implementation team will ensure that how you approach artwork tasks is in line with current **industry best practice**.

It doesn't end with implementation either – the correct partner will constantly benchmark the system giving you peace of mind that you're starting and staying on the cutting edge of the industry.

02 Immediate regulatory alignment

Tying in with constant process benchmarking, a bought and configured AMS will also be aligned and updated with the regulations relevant to the territories you do business in. Not only that, if you are planning on expanding into a new market, you can rely on your AMS partner to handle any changes necessary to accommodate the regulatory environment in that new market.

03 Immediate adaptability

By now, you might have pinpointed the primary pain point that the buy versus build argument seeks to resolve: how does an AMS deal with change.

Being able to add on new technology, adapt to new standards and ensuring your artwork isn't getting in the way of growth is huge advantage of a bought AMS.

Outside of regulatory and process changes there are many other scenarios that an AMS accounts for:

- Integration with ERP technologies like SAP.
- Scaling up to add more users.
- Migrating data from other sources.
- Maintaining security protocols and keeping data integrity.
- Adding features like Single Sign On.

Whether your system is configured from the start with any or all of these features in mind, or sudden successes require you to quickly upgrade, a purchased AMS will be much more adaptable and your organisation will be spared the expense and inconvenience of hiring developers, buying licenses or managing the validation issues.

Conclusion – Staying Agile and Being Ready for the Future

You cannot find yourself in a situation where keeping up with industry best practice becomes too much of a technical or financial headache to consider. Being agile and lean, **having the ability to react to new business challenges and opportunities** needs to be the cornerstone of any growth focused strategy.

“This can lead to a situation where changing your system simply becomes too expensive.”

Buying an AMS from a reliable, industry expert partner is the best action you can make to contribute to that strategy and futureproof your process.

