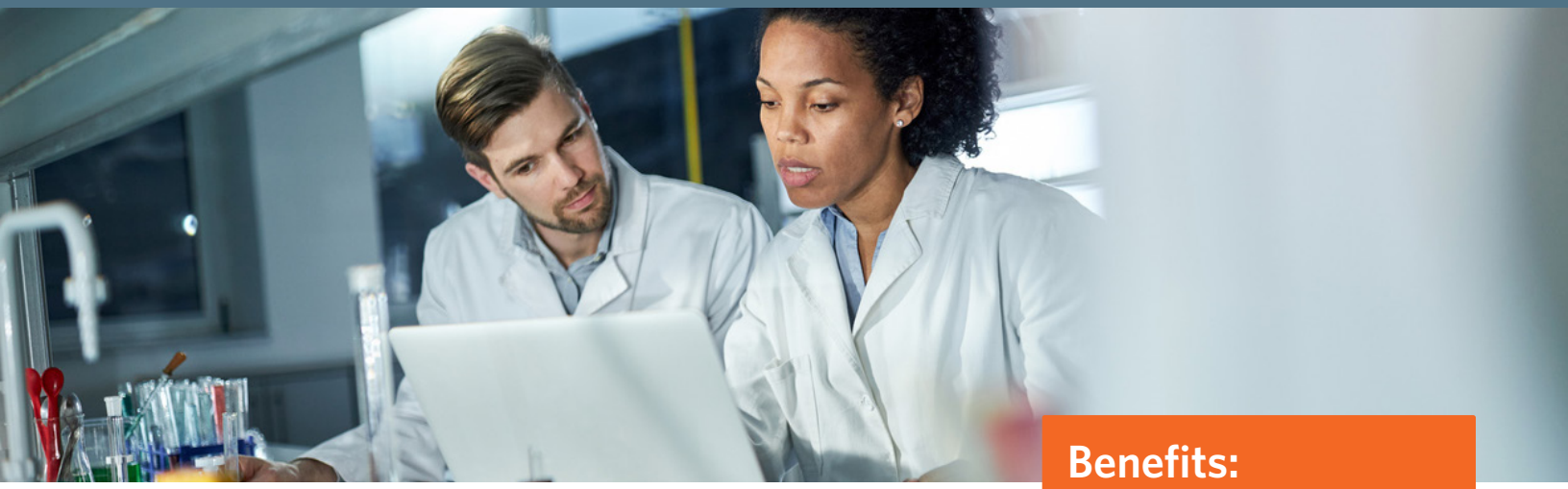
argano



FDA Validation Solutions & Services

Easily clearing the life science industry's highest hurdle

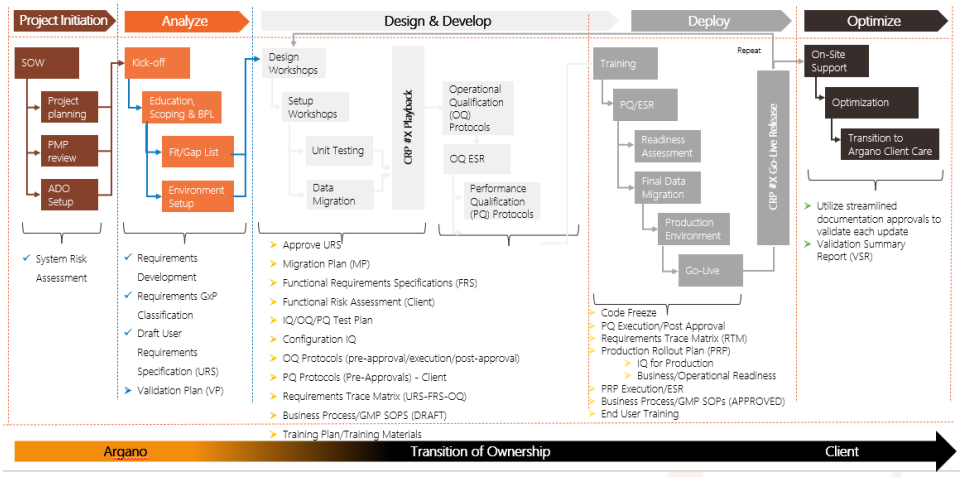
For life science companies, staying FDA compliant in an evergreen solution such as Microsoft Dynamics 365, is the elephant in the room. No matter how deep your research was, how tested your product is, how solid your science may be, a "no" from the FDA makes it all irrelevant (and can put an end to a company entirely).

Which is why life science companies lean on the FDA validation tools and expertise of Argano 4 Microsoft.

Our solutions experts come from the life science industry and know exactly what the FDA is looking for to ensure compliance with a wide array of regulations and standards in computerized system validation (CSV), such as 21 CFR Part 11, which regulates electronic documentation, or GMP, which regulates your manufacturing and/or distribution process.

Leveraging Dynamics 365 automations and Argano's industry expertise, life science clients enjoy a solution that:

- Delivers total governing policies, practices, and processes enabled with a complete computerized validation framework.
- Puts the expertise in the "tools" rather than personnel, minimizing resource requirements and constraints.
- Empowers an organization with repeatable, high-quality processes that can be used during the life of a validated system, reducing overall costs and timelines to maintain validation.



Benefits:

- A digitally transformed validation framework, improving governance and workflows
- Repeatable validation processes, reducing costs and speeding software development
- Decreased paperwork and manual effort; increased data insights and auditability
- Focus on your next innovation — let Argano deal with the latest regulation

A proven methodology

The Argano approach follows the International Society for Pharmaceutical Engineering's Good Automated Manufacturing Practice guidelines. It includes extensive deliverables, beginning with a System Risk Assessment that defines potential compliance risks associated with a system and the recommended validation to mitigate the risks.

Following the assessment, a statement of work kicks off the courses of action outlined in Figure 1.

Tangible deliverables

In addition to the features and functionality installed, activated, and tailored to fit your business needs, Argano offers a wide swath of

materials and supporting services to equip you and your team for success in FDA validation.

A **Production Rollout Plan** provides an executable checklist for system, operational, and validation readiness.

Training plans and materials help identify the who, what, where of training, define your training environment and approach, and assess overall training efficacy.

Standard Operating Procedures documentation helps ensure system maintenance and administration, and alignment with business processes.

Additional deliverables include functional risk assessments, system design specifications and unit testing summary reports, and overall system testing plans.

With Argano as your validation solutions and services provider, we follow the latest GAMP5 guidance for GxP processes, so you can focus on your next innovation rather than the latest regulation.

Contact us at microsoft@argano.com to learn more about FDA Validation Solutions & Services.

About Argano

Argano, a next-generation business and technology services provider, builds Digital Foundations that make businesses run better. We are committed to helping clients think differently about how they deploy and manage people, processes, and technology. Combining strategic consulting and services, we deliver interconnected solutions that enable innovation and drive operational excellence.