

EMC PERSPECTIVE



**Services for Agile Software
Development in Life Sciences**



Services for Agile Software Development in Life Sciences

Business challenge

Large or complex software development projects in any industry frequently exceed their budgets, are delivered late, and often fail to deliver the system behavior desired by the business. Often, the key drivers of project failure can be traced to poorly defined or misunderstood business requirements. The traditional Waterfall software development lifecycle—with monolithic phases for requirements, design, build, test, and deploy—magnifies the errors and misunderstanding by divorcing the requirements and design activities from construction and testing. For years, a number of iterative development methodologies (e.g., Rational Unified Process, Spiral, Xtreme Programming), which can mitigate these effects and produce better results, have been available to IT professionals. One of the best known is the Agile software engineering methodology that uses the Scrum techniques for project delivery.

As depicted in Figure 1, rather than trying to lock down requirements in a single upfront phase, teams need to embrace the fact that requirements will change during the project. Under the old way of working, large or complex IT projects generally produced systems in which more than 60 percent of features developed were not used by the business. By confronting requirements change head-on, the probability of developing a system that actually meets the highest value requirements is greatly improved. Furthermore, by fixing the time and effort to be expended in developing the first release of a complex solution, the risk of delays and cost overruns is significantly reduced.

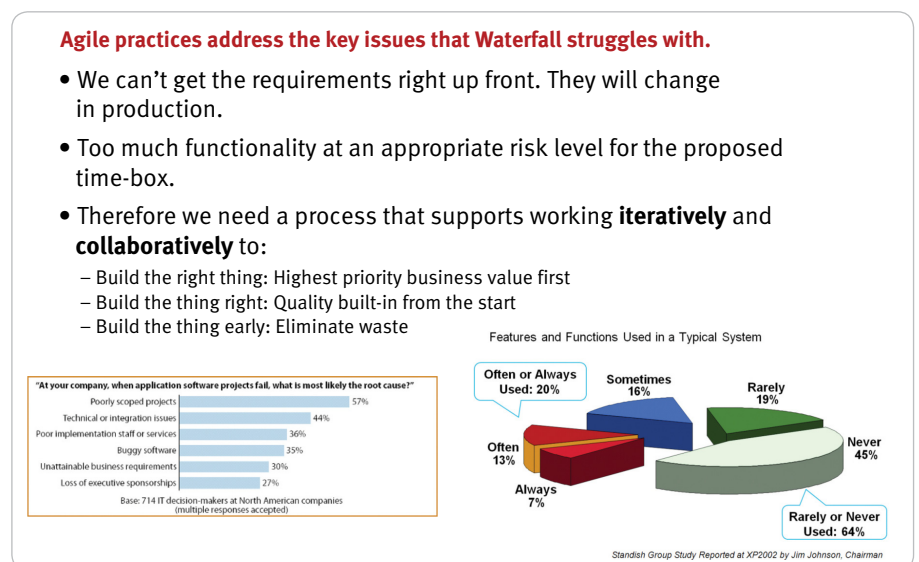


Figure 1: Why Agile?

While the benefits of taking an Agile approach are clear, it is often difficult for those responsible for application development in the heavily regulated life sciences industry to take advantage of it. For most IT quality assurance organizations in life sciences firms, the specific documentation deliverables and test evidence requirements of Computer Systems Validation (CSV) 21 CFR Part 11 make it difficult to consider using any systems development lifecycle other than Waterfall. To capture the benefits of Agile outside of non-validated solutions, life sciences firms need a way to reconcile this seeming contradiction between continuously evolving requirements and the need to sign off and freeze requirements during the lifecycle.

EMC® Consulting has developed a modified version of the Agile methodology that addresses these concerns. Our A11 Methodology reconciles the iterative nature of requirements development inherent to Agile with the need to maintain requirements traceability for testing, test evidence, and full user acceptance testing. The key is to use automated testing tools and test documentation approaches that can be executed in each iteration and then again for regression testing purposes—without significant additional manual effort.

Figure 2 shows the high-level cycle to be completed in each iterative design, build, and test cycle. Highlights of our approach and special considerations for the needs of validated projects are listed below:

- **Incremental requirements.** Agile methods use “stories” to capture requirements. As long as these stories are detailed, fully specified, and highly testable, they are not inconsistent with the need to maintain “full requirements” for validation purposes.
- **Unified requirement and test creation.** By writing the requirements using the Requirements-by-Example (RBE) technique, testability is enforced, traceability is maintained, and, depending on the automated testing approach used, documentation is captured.
- **Validation activities performed outside the iterations.** A validation plan is still prepared before the iterations begin, and there are validation activities to perform after the last iteration, including:
 - Finalization and Approval of Requirements
 - Finalization and Approval of Design Documentation
 - Formal Unit and System Testing
 - IQ/OQ into the Staging/Test Environment
 - User Acceptance Testing
 - IQ/OQ onto Production Environment
 - Validation Report

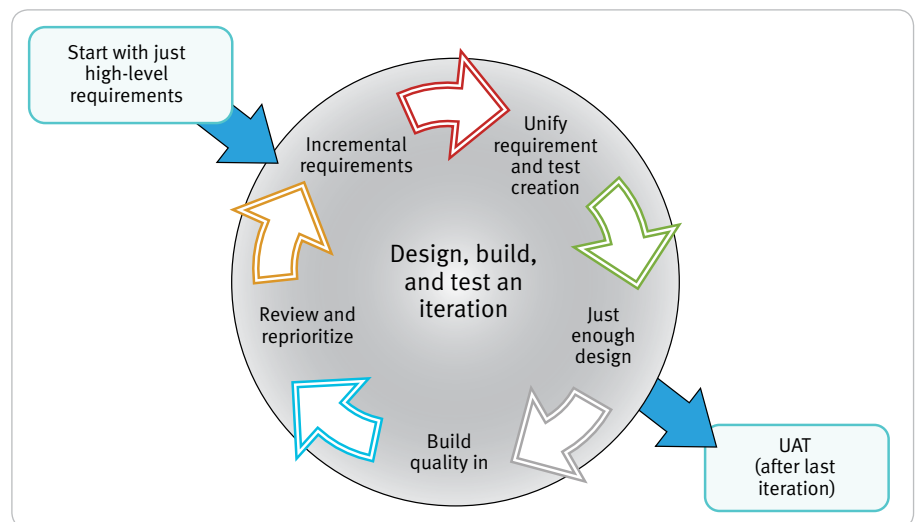


Figure 2: Key Components of the Agile Approach

EMC Consulting has applied the A11 approach in a variety of technical solution areas to prove out the methodology in a variety of conditions. A11 has been used in validated solutions as diverse as a clinical data warehouse and reporting solution and a workflow and electronic data capture solution for execution of CNS clinical research studies. EMC Consulting has also used Agile development practices to develop Enterprise Portal solutions for Employee Portals, R&D Collaboration Portals, and Patient/HCP Community sites.

As illustrated in Figure 3, there are many ways EMC Consulting can help your organization realize the benefits of Agile software development.

EMC Consulting Life Sciences Practice

EMC Consulting combines life sciences industry expertise and delivery capability to develop and realize information-driven strategies that assist companies in meeting industry challenges and improving operational performance. Our expertise spans the value chain—from discovery and pre-clinical development through marketing, sales, and manufacturing. We leverage capabilities in business process improvement, industry solutions engineering, and compliance and risk management to optimize business processes and the use of information technology in the enterprise and to minimize compliance risk.

By leveraging leading industry practices, we assist biopharmaceutical, medical device, and diagnostics companies in developing strategies, processes, and solutions to improve:

- Discovery and clinical development
- Management of scientific information and interactions
- Product commercialization
- Supply chain management
- Sales and marketing effectiveness, including use of multiple channels
- Compliance and regulatory processes

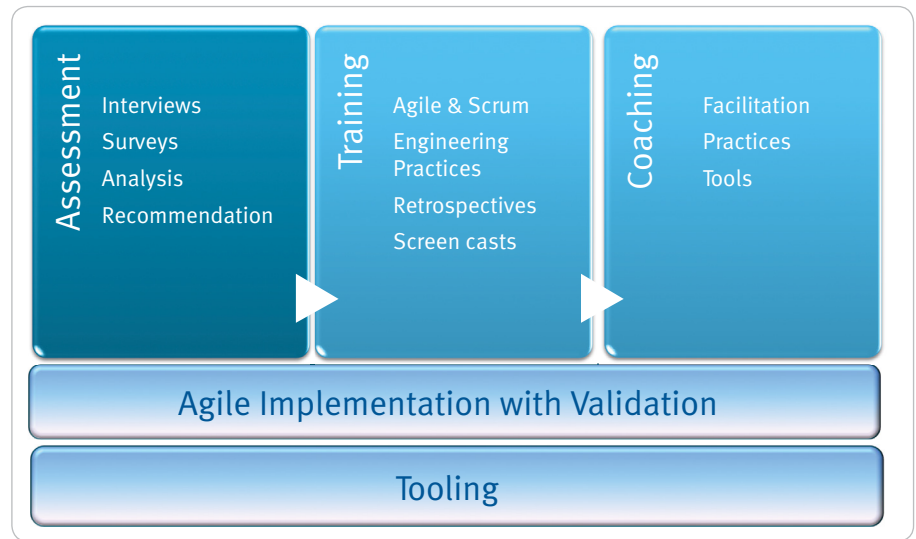


Figure 3: EMC Consulting Agile Services Offerings

Service description

EMC Consulting engages with clients in many ways to meet their needs for Agile services. Our main offerings are:

- **Assessment.** For clients seeking to use Agile for the first time or extend their existing capabilities, our Agile experts can evaluate staff capabilities and processes against our maturity model. The results of the assessment are used to prepare a roadmap with recommendations for how to improve proficiency with Agile techniques and drive better outcomes.
- **Training and coaching.** EMC Consulting has certified Scrum trainers who can run certification classes for Scrum practitioners, product owners, Scrum masters, and new trainers. These same staff can coach and advise client project teams on how to apply Agile and A11 validation approaches successfully on their projects.
- **Agile implementation with validation.** At the client's discretion, EMC Consulting can take full responsibility of a project to deliver a validated solution using A11 and a blended team of client and EMC resources.
- **Tooling.** EMC Consulting can also provide tool evaluation, selection, and deployment to aid in Agile project delivery and test automation/execution.

About EMC Consulting

As part of EMC Corporation, the world's leading developer and provider of information infrastructure technology and solutions, EMC Consulting provides strategic guidance and technology expertise to help organizations exploit information to its maximum potential. With worldwide expertise across organizations' businesses, applications, and infrastructures, as well as deep industry understanding, EMC Consulting guides and delivers revolutionary thinking to help clients realize their ambitions in an information economy. EMC Consulting drives execution for its clients, including more than half of the Global Fortune 500 companies, to transform information into actionable strategies and tangible business results. Read more about EMC Consulting at www.EMC.com/consulting.

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