Topic	Paper	Digital
Validation Planning **Change requests** **Validation planning**	On a small scale, it is straightforward to use paper-based processes for validation planning and associated traceability, change requests, etc. On a larger scale where you have multiple releases and periodic changes, paper-based processes develop into cumbersome, complex, and time-consuming activities. For validation planning, digital is the better approach. **Not recommended.**	In contrast to paper, it is possible on both a small and large scale to produce the overall validation plan and underlying change requests in a digital validation tool. Such tools make it possible to digitally identify the various test phases, tracing them to in-scope requirements for validation planning. **Recommended.** **Benefits** A 50% increase in validation efficiency A 10% decrease in project duration

Topic	Paper	Digital
Handling of Risk • **Creation** • **Classification** • **Impact Assessment** • **Traceability to requirements** • **Review & approvals**	Much like validation planning, risk management activities can certainly be paper-based. Again, there is a caveat – the higher the complexity and number of, for example, review and approval iterations, the greater the documentation effort. **Not recommended.**	Digital risk management processes offer time and cost benefits. The processes are also significantly simpler as risk assessments are incorporated into the system and linked to appropriate in-scope objects, entities, and/or requirements. This gives you real-time visibility of the status of each risk record. With a digital tool, risk and impact details are easily reviewed. It is all very well to have these details on paper, but it is only with a digital tool that you can keep track of risk profile changes in real-time to determine any additional mitigation measures that might be needed. Risk approval is performed in compliant digital tools according to the FDA's 21 CFR Part 11 and the EU's Annex 11 requirements. **50% less time in completing risk management.** **Recommended.**

Topic	Paper	Digital
Requirement Handling • **Creation** • **Link to risks** • **Link to test cases** • **link to test phases**	Requirements may be managed manually using a traditional controlled paper-based approach. Traceability to risks and risk mitigation activities, including testing and test phases, may also be paper-based. However, too much paperwork can become confusing, making it harder to maintain and inspect the life-cycle deliverables for relevant systems.[1] **Not recommended.** *[1] GAMP5 2nd ed. (on digital thinking)*	Asset sharing (i.e., the sharing of multiple requirements between multiple items) is one of the key advantages of using a digital tool as digital tools make it easy to manage one-to-many requirement relationships. This reduces the number of overall requirements. Therefore, in requirement management, digital is the best option. Digital tools support critical thinking and enhance confidence and efficiency while simplifying requirements handling, from traceability to mitigation to testing activities. 50% less time in requirement management. **Strongly recommended.**

Topic	Paper	Digital
Supplier • **Assessments** • **Statements of works (SoWs)** • **Link to risks** • **Link to requirements**	Supplier-related activities include planning, conducting, and reporting supplier assessments. This can include contracts, SoWs, and traceability to identified requirements and risks. These deliverables can be paper based but there are downsides. For example, controlling accuracy, ensuring correctness, and maintaining completeness quickly becomes cumbersome and inefficient. **Not recommended.**	We recommend a digital approach to capturing data and controlling supplier activities. A digital tool will deliver efficiency savings while ensuring compliance and optimizing supplier assessments. Suppliers include contract development and manufacturing organizations (CDMOs) that perform drug development and manufacturing for a pharma company – which underlines the width and breadth of the digital approach. **Recommended.**

Topic	Paper	Digital
Design Activities • **Creation** • **Link to risks** • **Link to requirements** • **Link to test cases** • **Link to test phases**	Design activities typically end with a Design Review Report that references the requirements specifications and risk assessments. These design activities, including traceability processes, can be paper-based. However, establishing and maintaining even simple traceability between these activities is a challenging task. **Not recommended.**	Using a digital tool for design activities is more efficient compared to a paper-based approach. For example, linking design activities and requirements in a digital tool provides real-time visibility and ensures the appropriate control of design artifacts. **Recommended.**

Topic	Paper	Digital
Implementation Activities • **Code reviews** • **Software unit tests** • **Link to test phases** • **Link to design** • **Incoming inspection** • **Mechanical completion**	Various complex and comprehensive activities can be performed during implementation processes. Simpler implementation deliverables can be paper-based but the benefits of manual approaches are few and are easily outweighed by digital. **Not recommended.**	Compared with a paper-based approach, a digital tool enables greater control, higher quality, and lower risks when completing implementation phase activities. **Recommended.**

Topic	Paper	Digital
Test Activities • **Test case authoring** • **Test case approval** • **Test case execution**	The testing of critical items and processes is a fundamental verification activity to ensure compliance and fitness for the intended use. It is possible to record on paper the various activities involved in tests, including author, approval, and execution data. However, these processes are unnecessarily cumbersome and prone to human error. **Not recommended.**	Testing is an obvious candidate for digitalization. The nature of testing, and the need for ensuring compliance (for example, with controlled and dynamic changes), mean digital tools bring a range of benefits including analytics, scalability, and efficiency. With a digital tool, test records are captured with electronic signatures and can include relevant digital evidence such as photos, files, hyperlinks, videos, and audio. This capability ensures a complete FDA 21 CFR Part 11 or EU Annex 11 compliant audit trail. **Recommended.**

Topic	Paper	Digital
Defect Handling • **Create and link defects** • **Assign defects** • **Analyze defects** • **Resolve defects** • **Close defects**	The handling of defects, including their creation, analysis, and resolution, is another fundamental compliance activity. While a paper-based approach may be compliant, it is not optimized or best suited to the efficient tracking and managing of defects during their life cycle. **Not recommended.**	Digital tools provide integrated defect management that reduces the risk of human error. As defects can be signed electronically and digitally linked to other items (such as potential impacts), they allow for instant analytics and the real-time overview of everything from the status of defects to the actioned resolutions. **Strongly Recommended.**

Topic	Paper	Digital
General Status / Progress Reports	A paper-based approach to status and progress reporting is possible but it involves significant disadvantages. This includes the fact that manually gathering and compiling the required data is a cumbersome process that is prone to human error. **Not recommended.**	Digitally supported status and progress reporting is the recommended approach. With the use of real-time data and dashboards, digital tools enable reliable, efficient, and continuous decision-making for mission-critical implementations. **Strongly Recommended.**

Topic	Paper	Digital
Audit Readiness	Inspections and audits typically involve presenting evidence and information that is requested on a validated system. Paper-based evidence and records may require significant time and effort to locate and be made ready, making the process overly cumbersome. Furthermore, a paper-based approach can increase the risk of non-compliance as records can be misplaced, incorrect, or incomplete. **Not recommended.**	The level of audit readiness in a life sciences sector company makes or breaks its state of compliance. With a digital solution, there is no need to prepare for audits or inspections as the digital tool ensures you remain in continuous audit readiness mode. This makes you better prepared to respond to audit and inspection requests as controlled evidence and records are readily available in digital form. As always, a digital solution can be limited by the humans controlling it. That said, the efficiency gains of simply going paperless (even without all the other benefits) significantly outweigh that risk. **Strongly Recommended.**

Conclusions

Compared with paper, digital tools provide compelling benefits. In a nutshell, going digital ensures the creation and maintenance of legible, accurate, contemporaneous, and original high-quality records. This results in audit readiness at any time.