Digital Tools enabling Regulatory & Quality Compliance

The Digital Future is Now!

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The Industry Perspective

In a dispensation warranting pharmaceutical and healthcare companies to maintain the highest levels of quality and regulatory compliance, these industries play very critical role in the people's progress, happiness and the growth of a nation.

Global regulatory agencies are tirelessly working hard to strengthen the security and safety of the patients. Pharma and Life science companies across the globe are continuously under pressure to execute and comply to the regulatory requirements time to time.

In order to meet the expectations of global regulatory agencies, there is a compelling need of adopting new technology trends, enhanced communication, understanding and proper execution of regulatory recommendations. The quality and regulatory professionals must lead the situation in confidential manner to support the growth and to sustainability of an organization.

The Problem

On the face of COVID-19 pandemic, Pharma & Lifesciences went through a variety of issues questioning quality of operations, shortage of manpower, less access to data, shortage of supplies and many other challenges w.r.t business continuity.

These challenges include . . .

- Lack of efficiency to streamline processes.
- Lack of transparency in paper-based systems.
- Lack of resources to identify bottlenecks in production lines.
- Higher cost of manpower with lesser outcomes.
- Inconsistency in operations which leads to poor quality.
- Higher chances of human errors due to lack of knowledge / stress.
- A big question mark on reliability of data.
- Missed promises to customers and breach of trust.

"Quality is not an act. It is a habit"

Solution ? . . .

The Solution

Solution is **Digitalization**. The pandemic also surfaced out many opportunities to transform companies towards digitalization.

Difference between **Digitization** and **Digitalization**.

Digitization – A true conversion of data from analog to digital.

Digitalization – Is a complete transformation from Paper based system to digital platform. In other words, Digitalization holds the ability of capturing data, processing, analysing and reporting to establish data trends and helps to take better business decisions.

What are the advantages?

Organizations may run more effectively, save time and unnecessary expenses, Improve quality and efficacy, and boost production are some of the advantages of digitalization in business.

Streamlined Processes

Increased Productivity

Reduced Operational Costs

Improved Transparency

High Degree of Quality and Consistency

Better Compliance

Encouraged Employee Participation

Accuracy and Perfection for better decision making

Superior Customer Satisfaction

What are the barriers to Digital Transformation?

it's not about companies "choosing" to transform, instead it is about "how" to progress with the future demands.

Successful Digital Transformation requires not only the right set of tools but the right expertise & guidance as well.

	Small	Medium	Large
1	No IT roadmap	Limited Involvement	Disconnected Systems
2	Lack of expertise	Limited IT budgets	Employee Pushback
3	No IT budgets	Employee attrition	Limited expertise
4	Skilled resources	Employee Pushback	Difference in expectations

Without clear strategic direction and strong involvement, digital initiatives often struggle to succeed.

What are the options?

	Area of Operation	Digital Application
1	Materials & Purchase	ERP (Enterprise Resource Planning), Materials Management and Inventory control system, QR Code System or Track and Trace Systems etc.
2	Production	ERP, Production Planning and Control Systems, EBMR etc.
3	Analytical / Quality Control / Testing Labs	LIMS (Laboratory Information Management Systems), ELNB (Electronic Lab Note Book), SDMS (Scientific Data Management System), Sample Management System etc.
4	Quality Assurance	QMS (Quality Management System)
5	Regulatory	eCTD (electronic Common Technical Document)
6	Engineering & Maintenance	CMMS (Computerized Maintenance Management System), EMMS (Engineering and Maintenance Management System)
7	Documentation	DMS (Document Management System)
8	Training & Learning	TMS / LMS (Training or Learning Management System)
9	Audits	AMS (Audit Management System)
10	Control Monitoring	Electronic Format Recording System, Digital Recording and Monitoring Systems.
11	Data and Analytics	Power BI Tools, Data Analytics and other systems
12	Sales & Marketing	CRM (Customer relationship management) etc.

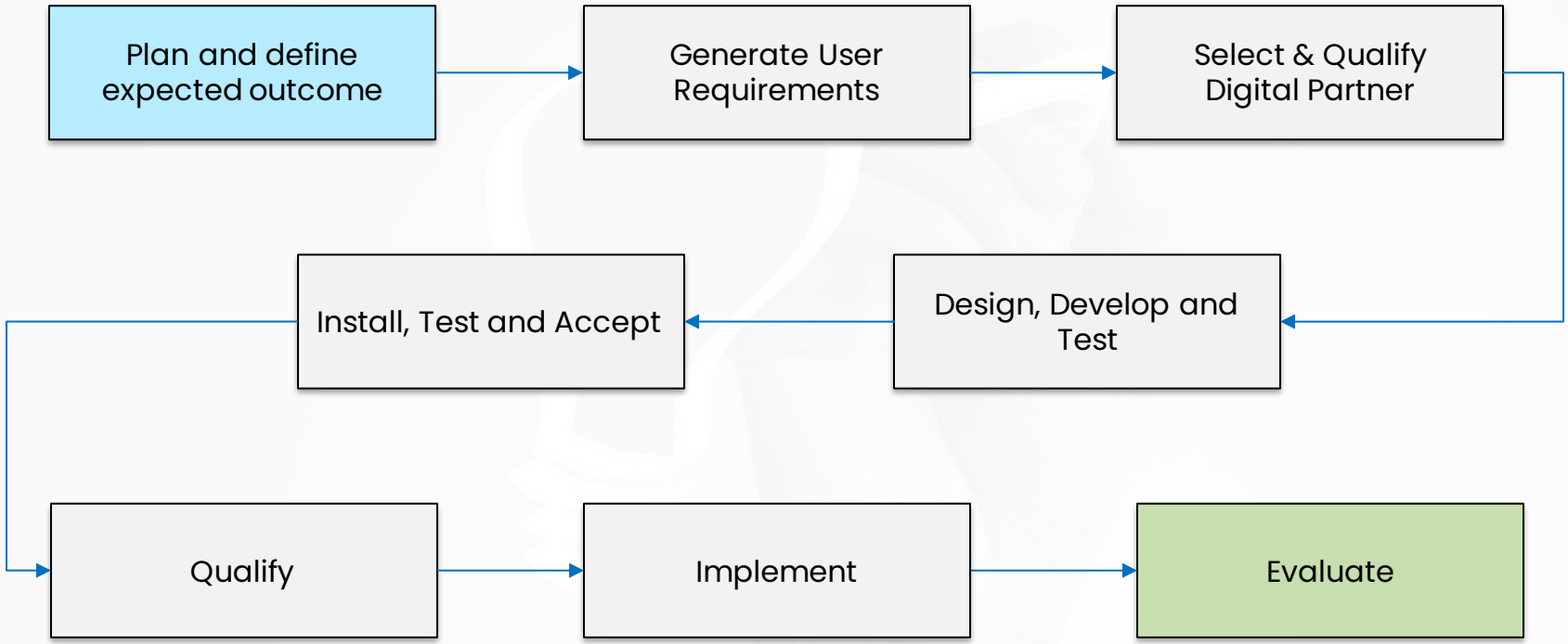
How Digitalization Helps to achieve Quality and Regulatory Compliance?

- ✓ Automated Practices – Helps to achieve consistency in operations.
- ✓ Realtime data – Help to attain greater transparency.
- ✓ Electronic data capture – Saves time in drafting and error free data.
- ✓ Process Automation – Less involvement of human intervention. Enables to make better use of time on quality aspects.
- ✓ Digital Monitoring – Realtime visibility on operations and better review mechanism.
- ✓ Digital Assurance – Accurate, precise, high-quality and dependable reporting.
- ✓ Automated Alerts – Less chances of human errors, reminders and no missing tasks.
- ✓ Ease of Data Access – Quick and reliable data during audits.

Other Benefits

- ✓ Electronic Signatures – Secured and time stamped.
- ✓ Data Retrieval – Fast and accurate data.
- ✓ Integrated Systems – Eliminate repetitive and redundant activities.
- ✓ Data Analytics – Trending, summary and key indicative performances.
- ✓ Electronic Records – No chances of manipulation or misuse, reduced paper.
- ✓ Systemic Communication – Realtime updates, alerts and reminders.
- ✓ Data Accessibility – Secured remote access from anywhere in the world.

Steps to follow for making digital



Few interfaces of digital applications

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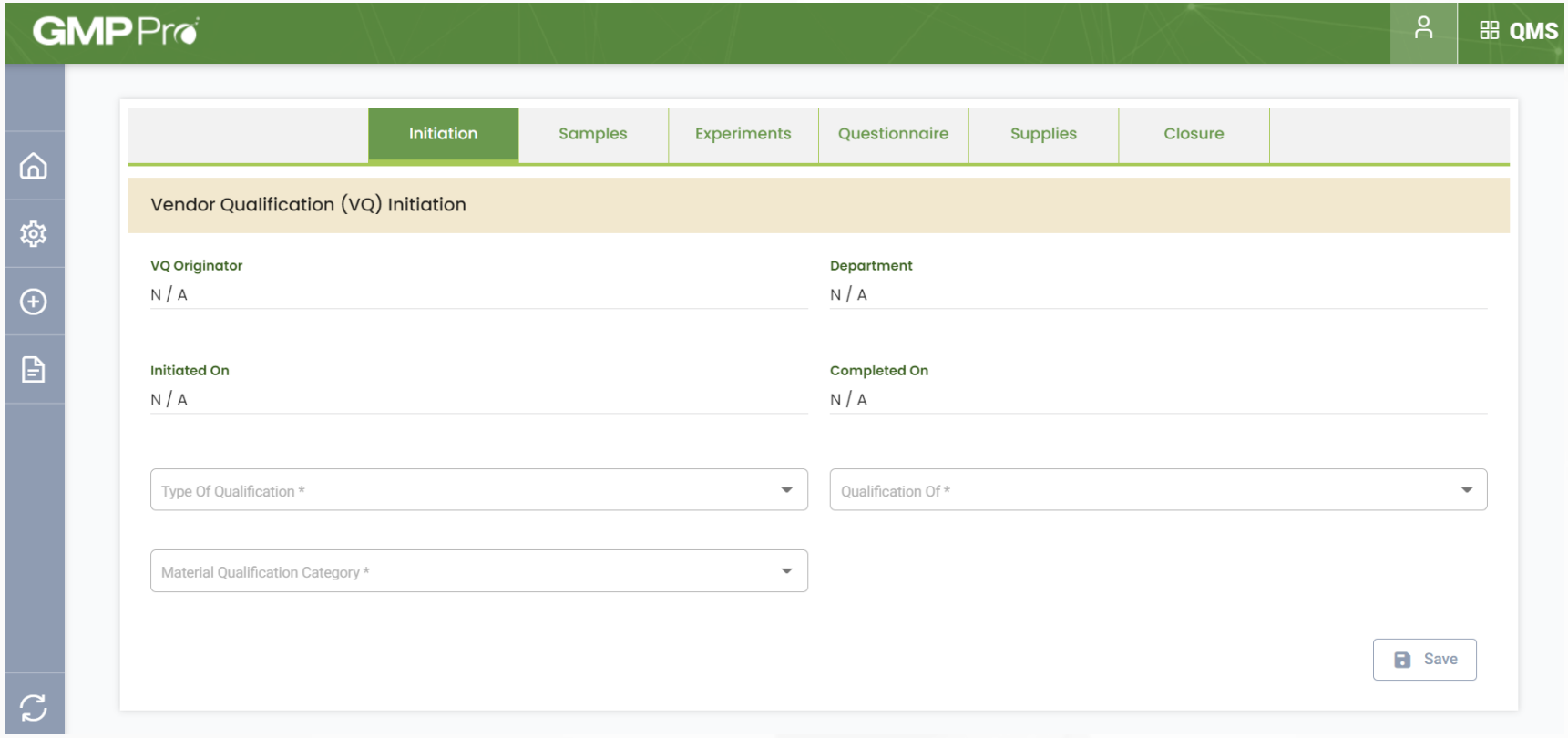


About CSV

Computer System Validation (CSV) is to achieve and maintain compliance with the applicable GxP regulations and fitness for intended use by. . .

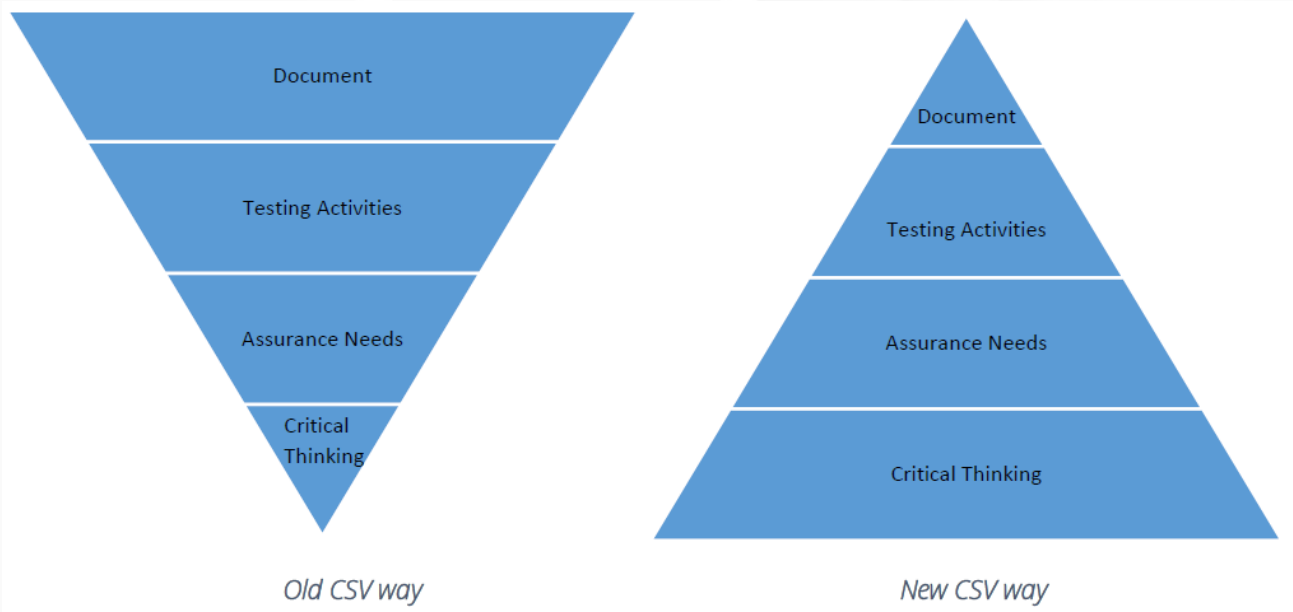
- The Adoption of principles, approaches and life cycle activities within the framework of validation plans and reports
- The application of appropriate operational controls through the life of the system

The traditional computerized system validation process was conceptualized prior to the current technology evolution and being updated to some extent but is not able to cope up with industry expectations.

Lack of expertise, understanding of the technology and over thinking makes the traditional computerized system validation process as prolonged activity.

About CSA

Current industry practice of CSV program is documentation heavy. Documentation is done at the cost of critical thinking and testing. CSA (Computer System Assurance) brings new approach by encouraging critical thinking over documentation. By using CSA concepts, companies can execute more testing with less documentation based on risk associated with requirement.



GAMP Categories

The GAMP categories were originally introduced to provide an initial assessment as to the validation requirements / deliverables, In GAMP 4 there were five software categories. These have been revised in GAMP5 to four categories as detailed below:

Category 1 - Infrastructure software including operating systems, Database Managers, etc.

Category 3 – Non configurable software including, commercial off the shelf software (COTS), Laboratory Instruments / Software.

Category 4 – Configured software including, LIMS, SCADA etc.

Category 5 – Bespoke / Tailor-made software

Validation Deliverables

1. Initial Risk Assessment (IRA) or GxP Document
2. User Requirement Specification (URS)
3. Vendor Assessment / Supplier Assessment (VA / SA)
4. Functional Requirement Specification (FRS/FS)
5. Configuration / Design Specification (CS / DS) / Design Qualification (DQ)
6. Validation Plan (VP)
7. Factory Acceptance Test (FAT)
8. Site Acceptance Test (SAT)
9. Functional Risk Assessment (FRA)
10. Installation Qualification (IQ)
11. Operational Qualification (OQ)
12. Performance Qualification (PQ)
13. Traceability Matrix (TM)
14. Validation Summary Report (VSR)
15. System Release Certificate or Software Release Note

“Keep It Simple & Short !

Questions . . .

Thank You...

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