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Review Article

Computer System Validation and Quality Engineering Alignment for Manufacturing Equipment

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Abstract: *Computer system validation (CSV) and quality engineering have often evolved along partially separate institutional paths, although both aim to ensure that manufacturing equipment consistently meets predefined requirements and supports product quality. This review examines how lifecycle validation, process analytical technology, multivariate monitoring, digital manufacturing, and predictive maintenance can be aligned in equipment-intensive manufacturing settings. The literature indicates a clear transition from document-centred qualification to risk-based lifecycle assurance, together with increased adoption of in-line and at-line analytics, multivariate statistical methods, cyber-physical architectures, and digital twins. Across the reviewed studies, alignment is strongest when user requirements, critical quality attributes, equipment functions, and data architectures are connected through traceable risk controls rather than treated as isolated validation records. Important gaps remain in model governance, software change assessment, cross-platform calibration, data integrity, and validation strategies for adaptive analytics. These issues are especially relevant to pharmaceutical, biopharmaceutical, and other regulated manufacturing sectors, where equipment is increasingly automated, software-driven, sensor-rich, and data-intensive. Sustained alignment between CSV and quality engineering is therefore essential for maintaining the validated state, operational reliability, and scientifically defensible release assurance.*

Keywords: *Computer System Validation, Continuous Manufacturing, Digital Quality Assurance, Manufacturing Equipment, Quality Engineering.*

I. INTRODUCTION

Over the past two decades, manufacturing equipment has undergone a fundamental technological transformation. Granulators, tablet presses, lyophilizers, filling lines, bioreactor skids, and packaging systems can no longer be regarded as purely mechanical assets; they now operate as software-mediated platforms incorporating sensors, embedded controllers, alarm systems, recipe management, historian functions, and interfaces with enterprise data systems. In regulated industries, this transition has expanded the role of computer system validation from a narrow compliance activity to a core means of demonstrating that automated operations remain controlled, reliable, and verifiable. Over the same period, quality engineering has shifted emphasis away from end-product inspection toward systematic control of process variation through design knowledge, process capability analysis, measurement discipline, and data-intensive monitoring. These two disciplines therefore overlap substantially, even though the literature often discusses them through different terminologies and problem frames. Early quality-by-design work in biopharmaceutical manufacturing already showed that product quality is strengthened by systematic process understanding and control rather than reliance on end-product testing alone [1].

This change was reinforced by a second stream of literature which viewed quality as a product of active design, understanding of parameters and controlled production instead of post hoc quality testing. According to the pharmaceutical quality-by-design literature, critical material attributes, critical process parameters and design space relationships had to be defined at an early stage in the development process and therefore formed an analytical basis for subsequent qualification and monitoring operations of the equipment [2]. This shift directly affects how manufacturing equipment should be viewed; one cannot just test anymore that either a controller is turning on, a recipe is downloading or a report is printing correctly. The presence of automated capabilities to strongly control the process conditions that affect critical quality attributes should also be taken into consideration in the important validation package. There is therefore an in-depth relationship between equipment automation and process science as well as operational decision rules as indicated in the literature.

The above broader view was well-founded in the work of quality by design concepts of abbreviated new drug applications that connected the knowledge in the development, process control strategy, and lifecycle management into a more coherent regulatory and technical framework [3]. This type of work can be applied to the design of equipment since the design choices of equipment cannot be disaggregated with the design choices of control strategies. The process capability may be impaired by the feeder with poor refill dynamic, or the refill is operated by a historian that cannot be fully audited, or the HMI is used to treat ambiguous setpoints when formal qualification documentation indicates otherwise. It is the quality

engineering that offers the method of dealing with these flaws by concentrating on the validity of measurements, reduction of variability, detection of faults and demonstration of control statistically. CSV has been leaning towards traceability on the other hand, documented testing and change control. The management of these two views as two streams of deliverables rather than two complementary parts of one model of lifecycle assurance is one such concern of long-term practice.

This importance of alignment was also underpinned by the fact that the question of continuous and semi-continuous manufacturing systems gained popularity. The closer coordination of equipment design, automation logic, real-time sensing, and quality decision making that many legacy qualification models were designed to support in order to modernize pharmaceutical manufacturing to batch to continuous production compared to most legacy qualification models were built to support [5]. In batch manufacturing, the separation between processing, testing, review, and release can obscure weak equipment–process interactions. Continuous systems separation results in a narrow separation and exposes flaws in data architecture, alarm management, soft sensor governance, and exception management. It is on this basis that CSV must extend beyond a pass/fail check of the implemented software functionality to a lifecycle practice that demonstrates a steady data flow, a stable algorithm, readability of operator interface, and a long-term suitability of analytical models in daily usage.

The literature on the process analytical technology also assisted in further interpretation that the multivariate analysis and real-time measurements might be more efficient in providing operational assurance in comparison to static verification [4]. However, peer-reviewed literature which explicitly addresses the notion of computer system validation in the context of manufacturing equipment is rather thin as opposed to the literature on guidelines and in-house industrial handbooks. To a very great degree, the best journal evidence is found in other closely linked disciplines such as PAT, multivariate statistical process control, cyber-physical manufacturing and predictive analytics. This review therefore brings these streams to a common plane of analysis. This is to explore the application of the literature to justify the fit of CSV and quality engineering to manufacturing equipment, to understand prevalent trends and limitations of methodology, and to understand how the reported studies can guide a more comprehensive lifecycle view. The parts that follow are concerned with the development of the literature, key methodological strategies, findings and conclusions that are presented in the literature, future research requirements and an organized conclusion.

II. LITERATURE REVIEW

The early literature relevant to alignment between validation and quality engineering came out of research on analytical monitoring and continuous processing, not out of a discussion of CSV as a field in and of itself. The reviews of the near-infrared spectroscopy and chemometrics in the pharmaceutical technology proved that the equipment could no longer be considered a neutral delivery mechanism of a process developed elsewhere; the sensors, the positions of the probe, the signal preprocessing, the calibration structure and the control-room data handling are the additional parts of the product assurance [6]. Parallel work on continuous processing argued that the industrial mindset needed to change to a more sustained operational control that the material flow, residence time distribution and equipment state transition require different assurance logic than in traditional qualification packages which were based on batch quantification. A similar point has been earlier discussed in more process-oriented terms in terms of the shift in the timing and location of quality-relevant information due to continuous equipment and has been used to redefine the evidentiary basis of validation and release [8].

A second set of research was on real-time trace of critical process behaviour. In continuous powder mixing, in-line NIR measurements have been used to show that drug concentration can be measured in real time as opposed to being determined by rare offline measurements, and to have direct implications on the specifications of how mixing equipment performance needs to be qualified and monitored [9]. Continuous manufacturing of solid dosage forms work on PAT to extend that observation by demonstrating that feeders, blenders, granulators, and tablet presses are integrated units the quality of which relies on the coordinated measurement and control structure, instead of the independent qualification of mechanical modules [10]. This literature shifted the field out of its too-narrow question, did the equipment do the scripted test to a more challenging question, did the equipment help to detect and control variability promptly in the face of representative operating conditions? This is a change that quality engineering revolves around and the validation design is greatly affected by it.

There was a third stream that expanded the scope of discussion on process-level analytics, to digital manufacturing architectures. Survey industry 4.0 characterized a situation where machines, devices, networks, analytics, and enterprise information systems create interconnected production ecosystems, as opposed to single assets [11]. An architecture of cyber-physical systems of Industry 4.0-based manufacturing systems at the time offered a more detailed technical model between the state of physical equipment, digital models and decision logic [12]. Smart manufacturing research based on data also highlighted that the value structural data collection, contextualization, and algorithmic interpretation throughout the life cycle of production assets are the basis of high-value quality assurance [13]. This literature can be applied to CSV in a variety of ways since the scope of validation grows with every equipment function being resourced to PLC code, edge devices,

historians, manufacturing execution systems, data lakes, analytics dashboard. The validated state comes to be not so much a property of a single software application but rather a property of a managed sociotechnical system.

A fourth theme is the digital twins, predictive maintenance and lifecycle intelligence. The literature on digital twins presented the connection between a virtual model and equipment behaviour and the ability to conduct deviation analysis and enhance scenario testing, but also posed unanswered questions concerning model credibility, frequency of updates, and update governance [14]. Reviews of predictive maintenance revealed the increasing adoption of machine learning in predicting machine failures, machine health ratings, and prioritization of maintenance in industrial systems [15]. Developments are two-sided, to be validated. On the one hand, fault prediction will be able to enhance the preventative aspect of quality engineering, decreasing unexpected drift and mechanical degradation. Conversely, adaptive models and high-dimensional pipelines of data make it more challenging to apply traditional validation reasoning since static test scripts do not work well with algorithms based on retraining, data quality policies, and time-based performance measurement. The literature thus indicates a turning point: quality assurance is turning more informative, but assurance mechanisms themselves need more advanced validation approaches.

Table 1 presents some representative studies that are used to form the existing evidence base. The studies mentioned not all use the language of CSV, but each of them is a contribution to the technical logic that is necessary to harmonize the validation of equipment with quality engineering. One pattern that has resurfaced in these publications is the shift away from endpoint confirmation to lifecycle evidence that is constructed out of measurement, process knowledge and digitally mediated control.

Table 1: Summary of Key Findings

Ref	Focus	Key Findings
[6]	NIR spectroscopy and chemometrics in pharmaceutical operations	Established non-destructive, multivariate monitoring as a practical route for in-process quality assurance; highlighted calibration transfer, spectral preprocessing, and model maintenance as decisive technical issues.
[7]	Continuous processing in pharmaceutical manufacturing	Argued that continuous operations require a shift from batch-oriented verification toward control of flow dynamics, transient states, and integrated equipment behaviour.
[8]	Batch versus continuous granulation	Showed that continuous granulation alters the temporal location of process knowledge and requires equipment understanding beyond endpoint granule testing.
[9]	Real-time NIR monitoring of continuous powder mixing	Demonstrated dynamic tracking of blend potency during operation, supporting tighter coupling of mixer qualification, sensor placement, and control decisions.
[10]	PAT in continuous solid-dosage manufacturing	Identified feeders, blenders, granulators, and tablet presses as interdependent units whose assurance depends on linked sensing and control architectures.
[11]	Industry 4.0 technologies and applications	Described digitally connected production environments in which validation scope extends across sensors, connectivity, analytics, and system interoperability.
[12]	Cyber-physical systems architecture for manufacturing	Proposed a layered model connecting physical assets, digital models, and decision logic, clarifying how equipment state can be translated into actionable quality information.
[13]	Data-driven smart manufacturing	Positioned contextualized production data as a foundation for predictive quality management, lifecycle learning, and real-time decision support.
[14]	Digital twin technologies in manufacturing	Showed that virtual replicas can enhance scenario analysis and equipment understanding, while introducing governance challenges around synchronization and model credibility.
[15]	Machine learning for predictive maintenance	Reported strong potential for early fault detection and maintenance optimization, but identified persistent concerns involving data quality, interpretability, and deployment robustness.

Significant limitations are also shown in the literature. Numerous researches are technically good but small-scaled within single unit operation, single product family or a single platform. External validity is thus skewed particularly when there is a transfer of calibration models between sites, scales, operators or between equipment vendors. Methodological imbalance is the other limitation. The PAT and monitoring papers tend to examine the signal quality and prediction accuracy more thoroughly and pay less attention to the evidence of a software upgrade, the modification of the historian

configuration, the electronic records, access by role, or exception workflow validation. On the other hand, compliance-focused discussions in practice tend to report software testing in a rigorous manner, but overemphasize on the capability of the measurement system, model drift, and statistical evidence of continued control. This gap is why the alignment between CSV and quality engineering is a dynamic research and practice challenge, but not an established framework.

III. METHODOLOGY

The approaches to methodologies in the literature can be grouped into four general categories; process analytical measurement, multivariate statistical monitoring, data-driven inferential modelling and digital lifecycle architectures. The process analytical measurement techniques revolve around obtaining quality-related data on running equipment real time or close to real time. These techniques are based on spectroscopic platforms, sensor fusion, signal conditioning, calibration design and integration with control/supervisory systems. They have an indirect yet potent contribution to CSV. A validation strategy of an equipment platform becomes the more important when linked to a real measurement capability because now traceability has the opportunity to be performed to both user requirements and functional specifications, to the detection of quality-relevant disturbances. The best validation in this methodological tradition is in cases where test design is based on actual variability of processes and measurement uncertainty as opposed to the use of generic software functions only.

Multivariate statistical process control is a second level of methodology. Adjustments of statistical process control Multivariate processes were statistically regulated and shown that correlated process variables could not be efficiently observed with univariate limits which existed independently when processes were regulated by interaction structures and covariance patterns [16]. Generalization to batch processes Multivariate SPC charts worked generalized this argument to time-dependent curves where it was observed that process deviations would be more easily observed when a complete curve was plotted against a model of normal operation [17]. Its implication is enormous as regards to equipment production. A proven equipment control system can be designed to satisfy all the nominal software specifications and still fail to act on subtle yet significant deviations in case alarm logic is constructed based on a single tag and fixed limits. Quality engineering methods thereby increase the authentication of a binary documentation exercise to a performance based evaluation of capability of the system to identify, locate and maintain response to the important process variation.

Monitoring methodology process with data as the basis turned out to be a particularly relevant stream of methodology that was presented as especially relevant to the modern equipment platforms. A general family of methods in this area was described as survey work, which included principal component analysis, partial least squares, subspace identification and fault classification, and hybrid model-driven methods, all designed to do diagnosis and early warning in complicated industrial systems [18]. The methods are attractive in the generation of equipment as automated assets generate large number of multivariate data sets that reveal patterns of operation unattainable in scripted acceptance tests. But there is a complex of government which accompanies methodological power. The concept drift, sensor aging, maintenance, raw material or altered operating regimes may cause the data-driven models to degrade. The CSV-quality engineering model would also be required to align to the initial model development but also retraining rules, periodic review, model retirement, access control, and documented requalification criteria of data or software changes.

The fourth methodological category has to do with lifecycle architectures of interconnected manufacturing systems. The literature in this changes to more system level design. Equipment is considered a component of a digital thread interconnecting requirements, design intent, automation logic, process data, maintenance history, deviations and improvement actions. This architectural point of view comes in especially handy during the alignment as it reveals the fact that not only during the protocol execution can we find the validation evidence. Other evidence are design rationale, risk prioritization, parameter rationale, model performance review, event trending and controlled configuration knowledge. The methodological weakness comes in when the following streams of evidence are not continued between the engineering, quality, automation, and operations functions and interoperability is poor. In this situation, requalification initiatives become heavy but shallow in documents, and quality engineering insights would not impact validation priorities.

The conceptual framework in figure 1 is based on the literature reviewed. Equipment lifecycle phases, validation activities and quality engineering controls are in one interconnected structure to make sure that traceability flows through the requirements to continuous performance assurance. This structure reinforces the main idea of the review: alignment is facilitated when the validation evidence and process knowledge is handled as a single lifecycle system instead of compliance streams operating concurrently.

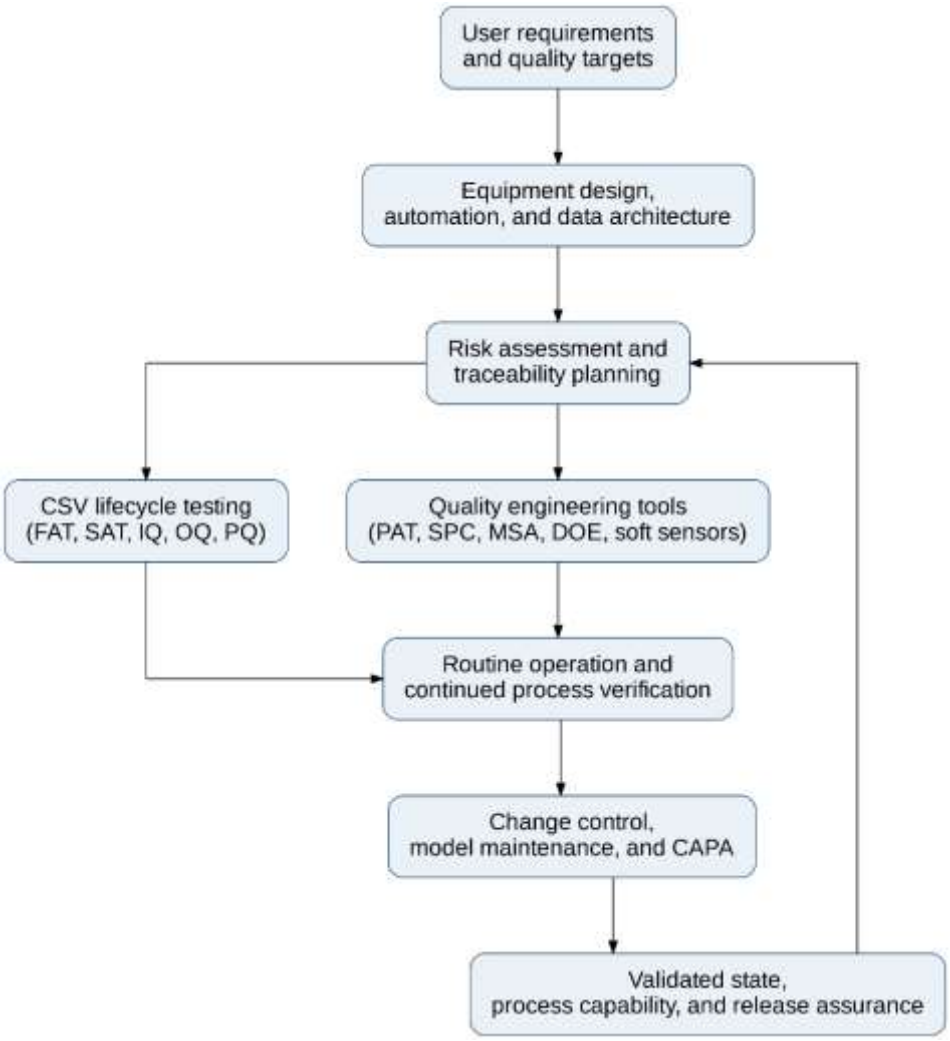

Figure 1: Conceptual Framework Linking Equipment Lifecycle, Computer System Validation, and Quality Engineering

The examined methodological approaches demonstrate that the most appropriate fit is a situation where the strategy of measurement, statistical oversight, software assurance and lifecycle governance are created collectively. A less strong tendency is observed when the qualification of automated equipment is performed with the help of static scripts and process understanding and data analytics are developed in other areas without any formal traceability. The literature thereby implies a broader methodological repercussion than compliance: a robust guarantee involves linking equipment functioning and information content and rationale into a solitary shown operating model.

IV. RESULTS AND DISCUSSION

The reported studies point to the definite shift to endpoint verification to real-time and lifecycle-oriented assurance. Preliminary process and PAT experiments concluded that in-line sensing can be used to indicate that dynamic behaviour hidden by off-line testing and in particular in mixing, granulation and other continuous operations [9], [10]. This is important to CSV since in traditional qualification models, the privilege has been given to the static qualification tests which are operated at pre-determined conditions whereas quality engineering puts more emphasis on variability, capability and detectability during normal and disturbed operation. The equipment platform synthesized literature indicates that the equipment platform may be said to have been fitted to be utilized in case automated control, data capture and analytical interpretation may be coherent when considering routine variability. This has quality engineering implications in that validation should not be viewed as completed with the implementation of protocols but also must encompass evidence that the system can sustain a sound operating behaviour, trend inspection and immediate action to drift.

The second key discovery is that of an expanding technical boundary of what is considered to be the system under validation. The presence of industry 4.0, cyber-physical manufacturing and smart manufacturing researches prove that equipment state is more and more modelled in distributed architectures instead of a local controller or HMI [11]–[13]. The practical implication is that the scope of validation should go beyond the application-level testing to consider data context, signal integrity, time stamping, interoperability and algorithmic consumption of equipment data. The application of digital

twins opens up a new frontier by showing that virtual simulations can be used to amplify fault detection, scenario planning and operational intelligence, yet must be governed by assumptions and synchronization regulations and model modifications with discipline [14]. A thin, CSV model that only verifies one layer of supervisory software but has poor upstream and downstream data transformations that are not well controlled is thus not aligned with modern manufacturing reality. It is quality engineering that offers a bridge that can reconnect the validation with the actual avenues whereby the performance of equipment can influence the quality of the products.

Figure 2 summarizes the thematic distribution of the reviewed studies across publication intervals. The figure is intended as an illustrative overview rather than a formal bibliometric analysis. Even so, it helps show a clear shift in emphasis from process-format change and analytical monitoring toward broader data-driven and digitally integrated assurance models.

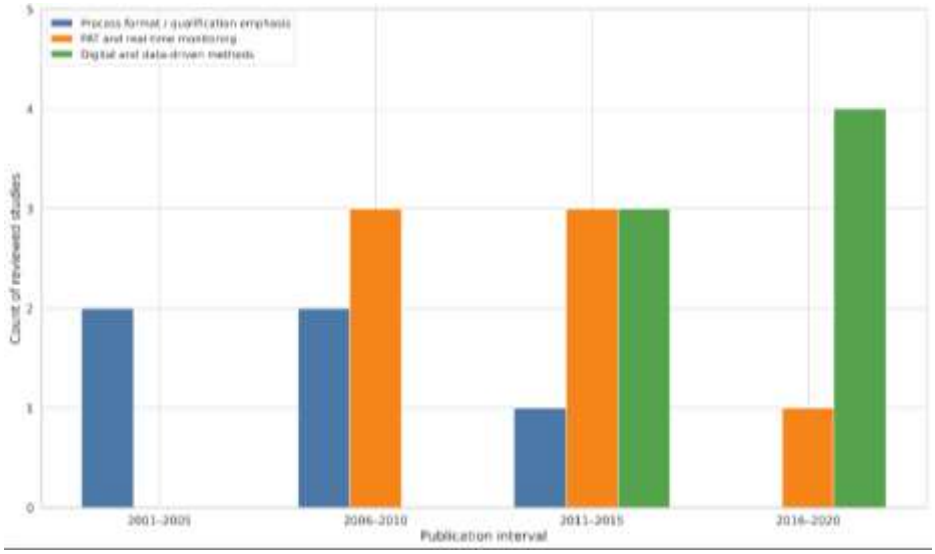

Figure 2: Thematic Shift in Reviewed Studies across Publication Intervals

The most empirical evidence in favour of alignment is the techniques that relate equipment behaviour directly to information that is important in quality. Soft sensor literature indicates that when the measurement of an inferential variable cannot be done practically the model may give useful operation visibility, but the model requires continuous verification of prediction error, stability of the input and maintenance status [19]. PAT work in biopharmaceutical applications goes further to demonstrate that the measurement architecture, sampling design and interpretation of data cannot be separated with the manufacturing system itself [20]. PAT reviews based on Raman also highlight the importance of chemically specific measurements and the need to address the strength of calibration and transferability of a process [21]. In these works, a similar lesson seems to be more telling validation evidence is more significant when it entails both software functional checking, as well as reported evidence that analytical and inferential layers can be used in decision support in the actual operating environment. Here is exactly where quality engineering reinforces CSV since model capability, repetition of measurements and management of variability are made explicit components of assurance case.

The strong and weak points of the significant methodological choices are also explained in the literature. Table 2 is a comparison of the representative methods in the reviewed studies. The comparison indicates that there is no specific method that can be used to make full assurance of complex manufacturing equipment. Spectroscopy offers direct process visibility, multivariate SPC offers better deviation detection and digital architectures will enhance lifecycle connectivity, but all ways come with governance tasks which need to be as rigorously tested.

Table 2: Method Comparison

Ref	Method	Strengths	Limitations
[6]	NIR spectroscopy with chemometric calibration	Non-destructive monitoring; rapid data acquisition; strong suitability for in-line deployment in powder and blend operations	Calibration transfer across instruments can be difficult; model maintenance burden can be high; performance depends on representative training sets
[9]	In-line NIR for continuous powder mixing	Directly links mixer state to potency trends; supports dynamic fault visibility and residence-time-aware	Sensitive to probe location, feed variability, and calibration scope; limited generalizability across

		monitoring	formulations
[10]	PAT architecture for continuous solid-dosage lines	Connects multiple unit operations within one control strategy; improves temporal proximity between disturbance and detection	Integration complexity rises sharply with line connectivity; substantial data management and model governance burden
[12]	Cyber-physical systems architecture	Clarifies data flow from physical asset to decision layer; supports equipment-state contextualization	Requires robust interoperability and time alignment; validation scope expands across multiple software boundaries
[13]	Data-driven smart manufacturing analytics	Enables predictive quality management and lifecycle learning from heterogeneous production data	Depends on strong data quality, metadata discipline, and explainability of analytical outputs
[14]	Digital twin modelling	Supports scenario analysis, virtual commissioning logic, and faster root-cause exploration	Model credibility, synchronization rules, and update governance remain challenging for formal validation
[16]	Multivariate statistical process control	Detects correlated variable shifts earlier than univariate alarms; supports richer fault signatures	Interpretation can be difficult for operators; false alarm management depends on model quality and maintenance
[17]	Batch trajectory monitoring with multivariate SPC charts	Captures time-dependent deviation patterns and supports early intervention in batch operations	Requires careful trajectory alignment and normal-operation modelling; performance can degrade after process changes
[19]	Soft sensors / inferential models	Extends monitoring to variables lacking direct sensors; useful for bioprocess and complex equipment environments	Model drift, input dependency, and retraining governance create continuing validation obligations
[21]	Raman PAT monitoring	High chemical specificity; useful for blend uniformity and bioprocess assessment	Optical sensitivity, fluorescence, and calibration robustness can limit deployment across sites or scales

The results released on multivariate surveillance studies show that the quality advantage with the aligned approaches is not the detectability, the context or the actionability but the combination of the three. Multivariate SPC experiments found out that correlated disturbances and varying batch paths could be identified earlier in comparison to the conventional, univariate, monitoring [16], [17]. The outcome is quite generalizable to the equipment validation manufacture process as the majority of failures do not manifest themselves as gross failures initially. Instead, the deviations come about as a result of the small-scale interactions between feeder instability, sensor noise, environmental variation, control loop drift and change with maintenance. A validation package that is merely concerned with deterministic test scripts may fail to detect such conditions and is specifically geared towards detecting such conditions with quality engineering tools. The literature therefore indicates that the validation confidence cannot be determined by a mere percentage of the protocol being completed but based on the capability that the equipment-data system can detect and manage realistic process variation.

The other related finding is that associated with maintenance and reliability of equipment. As per the predictive maintenance literature, the machine learning models that predict wear, degradation, or a looming failure can greatly benefit the industrial assets [15]. With the example of controlled manufacturing equipment, it creates a possibility to align the maintenance strategy and protection of product quality since unexpected deterioration in most cases is the antecedent to performance drift. Nevertheless, the literature warns that deployments depend on the data quality, labelling of failures, interpretability of failures and integration of operations. This can be translated into a CSV view that predictive models are supposed to be quality functions which are software controlled, and not an informal engineering add-on. The validation requirements are more when a prediction of maintenance is applied to influence scheduling, line clearance, alarm escalation, or in-service operations with an equipment train, to model provenance, threshold justification, exception management and periodic performance evaluation.

Figure 3 indicates how classical CSV deliverables and quality engineering controls are related. The figure means that the two domains do not compete but rather, complementary layers. Traceability can be enhanced as every validation artifact is supplemented with a quality-engineering control which deals with variability, detectability, or sustained capability.

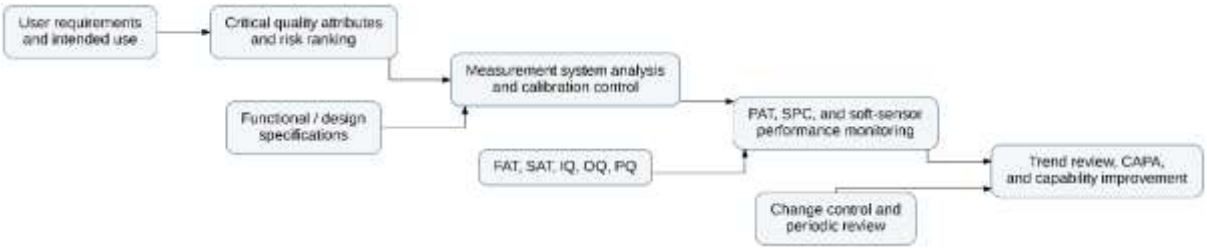

Figure 3: Relationship between CSV Deliverables and Quality Engineering Controls

This relationship chart supports the finding that static qualification remains necessary but is no longer sufficient with complex equipment platforms. Quality engineering provides evidentiary mechanisms that keep up with post-commissioning relevance, particularly when analytics, models, and interconnected layers of software are kept up to date. Without this kind of linkage, this will lead to validation being fully complete but operational assurance is undermined as time goes by.

The comparative findings observed in the studies are summarized in Table 3. There are three patterns that are supported by the table. To begin with, methods that create real-time (or near-real-time) insight enhance the detectability of quality drift caused by equipment. Second, data-rich techniques enhance the value of assurance only in the case of disciplined model governance. Third, lifecycle integration in design, monitoring, maintenance and change control is the least developed but could be the most consequential area for future development.

Table 3: Results Comparison

Ref	System	Metric	Outcome
[9]	Continuous powder mixer with in-line NIR	Real-time concentration prediction fidelity	Demonstrated dynamic visibility of blend potency, enabling earlier recognition of feed or mixing disturbances than offline testing alone
[10]	Continuous solid-dosage manufacturing line	Coverage of critical quality attributes during operation	Reported stronger process understanding and tighter coupling between unit operations, sensors, and control decisions
[12]	Cyber-physical manufacturing system	Integration of physical-state and digital-state information	Improved contextual interpretation of equipment events, supporting more informed operational and quality decisions
[13]	Data-driven smart manufacturing environment	Lifecycle data utilization for predictive decisions	Showed that contextualized production data can support proactive quality and equipment management rather than retrospective review
[14]	Digital twin-enabled equipment environment	Virtual-real synchronization and scenario analysis capability	Indicated faster root-cause exploration and change assessment, with unresolved concerns regarding model credibility and update governance
[15]	Predictive maintenance applications in industrial assets	Failure prediction capability and maintenance timing	Reported improved maintenance planning and reduced unplanned disruption, contingent on data quality and model interpretability
[16]	Multivariate industrial process monitoring	Fault detectability relative to univariate monitoring	Demonstrated stronger sensitivity to correlated disturbances and hidden covariance shifts
[17]	Batch trajectory monitoring	Early deviation recognition across batch time profiles	Enabled detection of abnormal trajectory development before endpoint failure became visible
[19]	Soft sensor applications in bioprocess and equipment	Inferential accuracy and response speed	Expanded monitoring coverage where direct sensors were absent, while increasing

	monitoring		lifecycle validation burden
[21]	Raman PAT deployments	Chemical specificity and calibration robustness	Supported high-information monitoring of composition-related changes, with transferability and maintenance constraints

The combination of the key findings of the review in one lifecycle is shown in Figure 4. The result of one qualification campaign and the result of a repeated process of risk review, design control, operational monitoring, model maintenance, and controlled change is maintenance of the validated state. The convergence of PAT, multivariate monitoring, cyber-physical systems and predictive maintenance literature are well aligned with this integrated perspective.

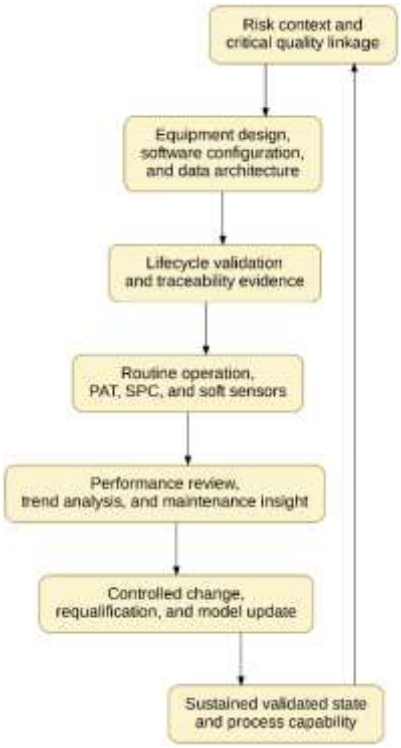

Figure 4: Integrated Lifecycle Model for CSV and Quality Engineering Alignment

When combined, the studies reported are indicative of a significant practical and academic finding. The future of CSV as a manufacturing equipment is not in the and-abandon-formal-qualification but repositioning qualification as part of a broader quality engineering architecture. There is greatest equipment assurance when there is risk-ranking of specifications, statistical credibility of measurements, data flows are controlled, reviewed through the lifecycle and change control is informed by real evidence on the operations of the equipment rather than through the assumption of constant values. There is not yet a single universal method of this alignment in the literature, but there is a definite indication of the direction of travel.

V. FUTURE DIRECTIONS

The gap between compliance based validation deliverables and performance based quality evidence is long-standing and needs to be bridged by research in the future. The general pattern of most of the existing implementations is still to treat requirement traceability, software testing, PAT model maintenance and statistical performance review as a separate work product. Future research could examine how these streams of evidence can be integrated into auditable knowledge structures of equipment platforms lifecycle. This is particularly required when systems are involved where PLC logic, supervisory software, historians, analytics services and electronic batch or maintenance records are interacting. The studies can help establish some universal parameters that can be used to define when software change or sensor replacement or model recalibration is required to trigger the issuance of a partial requalification and not a complete revalidation.

The second priority is around governance of advanced analytics. The use of digital twins, soft sensors, and predictive maintenance is gaining more and more popularity due to its ability to enhance detectability and decrease equipment-related drift [14], [15], [19]. Nevertheless, the peer-reviewed literature does not have well developed validation logic of these tools. Future studies should extend beyond the illustrations of the proof-of-concept accuracy measures and evaluate the longitudinal soundness, concept drift, retraining regulations, human understanding and the impacts of the selection in case

the production circumstances occur. It would also prove to be especially useful to do comparative research in a family of equipment, where the current evidence may be limited to a unit operation, or to a specific site-based architecture. Greater rigor in model-credibility testing might likewise enhance the trust in the utilization of the analytical outputs as part of formal quality decision-making.

The third direction is measurement and science and interoperability. The literature has always shown that monitoring of values depends on the placement of sensors, representativeness of the calibration, signal and metadata preprocessing [6], [21]. With increased interconnectedness in equipment ecosystems, even disaggregated components can have poor quality assurance, with failures in interoperability. Future studies should therefore investigate the standardized contextualization of data, sequence of events and time synchronization mechanisms that would ensure the traceability of validation of distributed systems. Studies that combine measurement system analysis, cybersecurity controls, and data integrity design would be particularly beneficial since new manufacturing platforms are based on interdependent data streams that have long-standing boundaries that are not limited to just one proven application.

The fourth and the final direction is connected with interdisciplinary integration. Coupling between CSV and quality engineering cannot be further developed by automation engineering, as well as by quality assurance scholarship. It takes integrated skills in control engineering, chemometrics, industrial statistics, software assurance, maintenance science, human factors, and controlled operations to make progress. Future research should therefore examine integrated lifecycle models in practice within real life production settings like brownfield sites with state of the art and old equipment. These works can contribute to a better understanding of how the formal validation discipline practice can be sustained in organizations with other adaptive, data-driven practices that contribute to the reliability of equipment and process handling capabilities. The way to go forward is most fruitful by transforming validation into a more of a scientifically based lifecycle practice that will not be destroyed by changes in technology.

VI. CONCLUSION

The literature reviewed in this paper indicates that alignment between computer system validation and quality engineering is becoming increasingly important for contemporary manufacturing equipment. As equipment platforms have become more software-driven, sensor-enabled, and analytically intensive, assurance can no longer rely on narrow qualification alone. Evidence from PAT, multivariate monitoring, smart manufacturing, digital twins, and predictive maintenance consistently points toward lifecycle-oriented assurance models grounded in measurement quality, detectability of variation, and controlled use of data-rich methods.

CSV and quality engineering address different but complementary dimensions of assurance. CSV provides documented traceability, formal testing, and controlled change management, whereas quality engineering contributes process understanding, measurement discipline, variability reduction, and sustained performance evaluation. Strong alignment is achieved when intended use, critical quality attributes, equipment functions, and data architecture are treated as interconnected elements of a single control framework. Weak alignment persists when documentation is extensive, but process capability, model governance, and operational detectability are not adequately considered.

The review also highlights persistent gaps. Literature explicitly focused on CSV for manufacturing equipment remains more limited than the broader literature on monitoring, analytics, and digital manufacturing. Validation approaches for adaptive analytics, digital twins, and predictive maintenance are still less mature than the technologies themselves. Greater attention is needed to cross-site transferability, data integrity across interconnected platforms, and criteria for partial requalification after software, model, or analytical changes.

Overall, the field is moving toward a lifecycle perspective in which qualification, monitoring, maintenance, and continuous improvement are treated as interrelated forms of evidence. As automation and digital complexity continue to increase, future equipment-assurance frameworks will need to be built at this intersection of validation discipline and quality engineering practice.

- **Interest Conflicts:** The author declares that there is no conflict of interest concerning the publishing of this paper.

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