WHITE PAPER

Leveraging Qualification with the Getinge Software Validation Process

GAMP 5 Compliance for Pharmaceutical Washers/Dryers

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Abstract

In the pharmaceutical industry, validation of automated equipment is essential, but can be costly and time-consuming. Regulatory frameworks like ISPE's GAMP 5 have raised expectations for data integrity and quality assurance in automated systems. This white paper explains how Getinge helps pharmaceutical manufacturers simplify compliance and accelerate validation through the Getinge Software Validation Process. By maximizing the use of GAMP 5 Category 4 (Configured Product) elements, Getinge minimizes onsite retesting and reduces validation risk, helping customers reach production faster with full regulatory confidence.

Glossary:

- **ALOCOA+ Principles:** Attributable, Legible, Contemporaneous, Original, Accurate, Plus Complete, Consistent, Enduring, and Available. This is the foundational standard for Data Integrity.
- **DDS:** Detailed Design Specification. DDS specifies how a system will be implemented to meet FDS requirements.
- **DI:** Data Integrity (Adheres to ALCOA+ Principles).
- **FDS:** Functional Design Specification defines what the system must do to meet the URS requirements.
- **GAMP 5:** Good Automated Manufacturing Practices, Version 5. ISPE framework that is widely used as a risk-based approach for validating computerized systems to ensure fitness for intended use and GxP compliance.
- **IQ/OQ/PQ:** Installation Qualification / Operational Qualification / Performance Qualification.
- **QbD:** Quality by Design. A systematic, risk-based approach to development.
- **QMS:** Quality Management System. The formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives.
- **Software Validation Process:** Getinge's validated GAMP 5-compliant software validation process used for Getinge cGMP pharmaceutical washer/dryers.
- **URS:** User Requirement Specification. A document that defines the high-level needs and expectations of the user for a new system or equipment.
- **V-Model:** A development and verification model linking design phases with testing activities

Introduction

Compliance is non-negotiable in pharmaceutical manufacturing. From detailed Standard Operating Procedures (SOPs) to formalized batch records and rigorous quality management systems (QMS), every process must meet strict regulatory standards. As operations become increasingly automated, the focus shifts to how the computerized systems that control essential equipment like washer/dryers meet expectations for integrity, efficacy, and repeatability. The industry therefore relies on the Good Automated Manufacturing Practices (GAMP 5) framework, established by the International Society for Pharmaceutical Engineering (ISPE), to govern this critical area.[1]

GAMP 5 mandates a disciplined, risk-based lifecycle approach for all automated systems, emphasizing that the effort required for validation must be proportional to the risk the system poses to product quality and patient safety.

Validation Challenges in the Pharmaceutical Industry

Despite the clear guidance offered by GAMP 5, validation teams face significant operational pain points when implementing new cGMP equipment:

- **High Cost of Duplication:** Every new piece of equipment requires extensive on-site testing (IQ, OQ, PQ), often duplicating testing already performed by the equipment vendor.
- **Extended Timelines:** Manual, comprehensive re-testing of vendor software, particularly when dealing with complex, custom-coded systems, significantly extends the project timeline, delaying production readiness.
- **Audit and Compliance Risk:** Non-standardized, custom software that is not pre-validated for the pharmaceutical industry can place a heavier burden on the customer's Quality Management System (QMS) to defend the validation approach during audits.

The core challenge for pharmaceutical validation teams is to find cGMP equipment that not only performs its function (washing/drying) but minimizes the residual validation effort of the software.

The Getinge Solution

A Pre-Validated, GAMP 5-Compliant Software Foundation

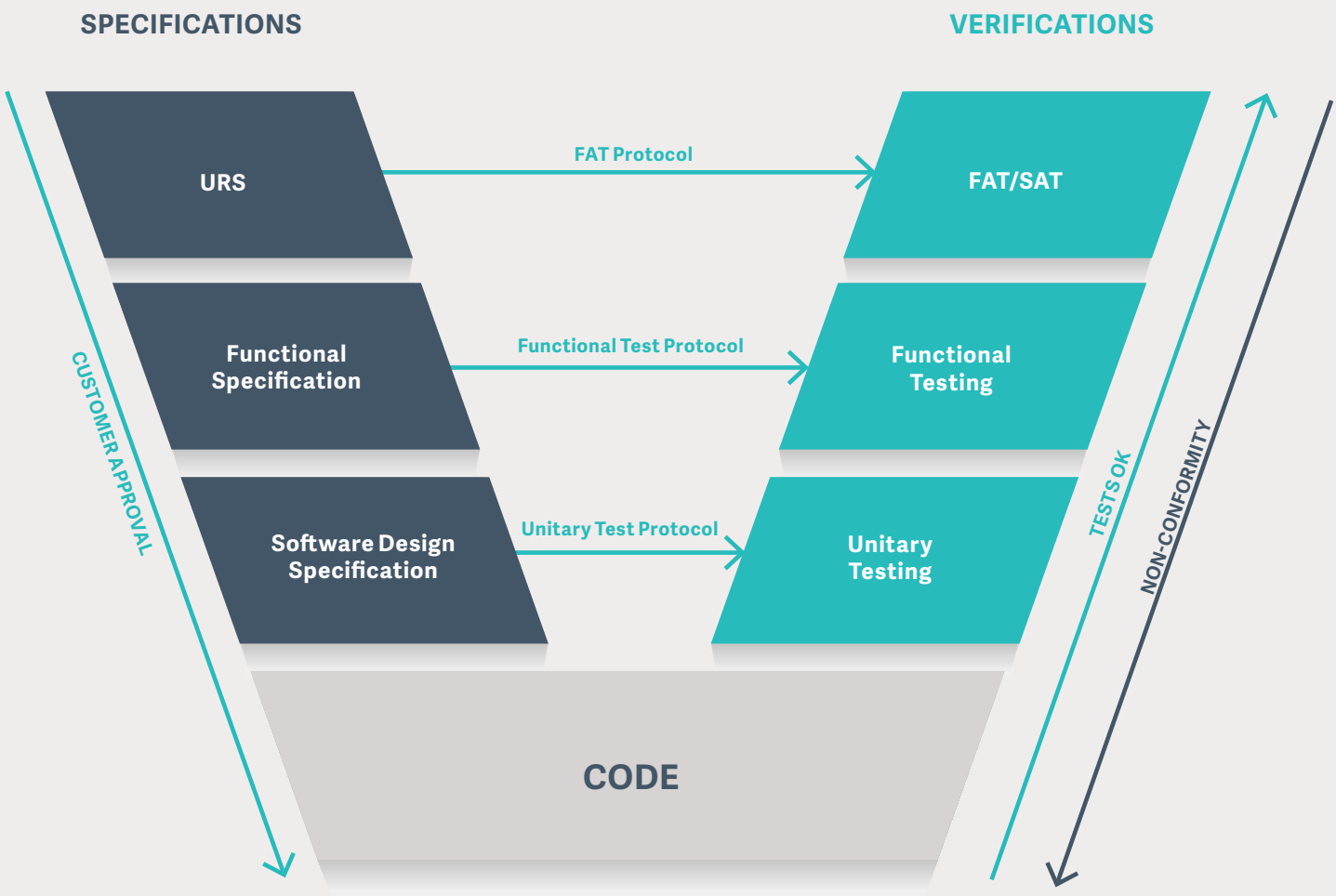
Getinge addresses this industry challenge by providing a rigorously pre-validated software foundation known as the Getinge Software Validation Process.

This Process is a master software baseline for all cGMP washers/dryers. It is developed and maintained under a formal V-Model lifecycle, ensuring that the vast majority of the core automation functionality is already verified and documented before the equipment reaches the customer's site.

This proactive approach ensures that the customer receives a system where compliance is built-in, resulting in:

1. **A demonstrable reduction in validation scope.**
2. **Faster site acceptance and time-to-production.**
3. **Lower overall validation cost.**

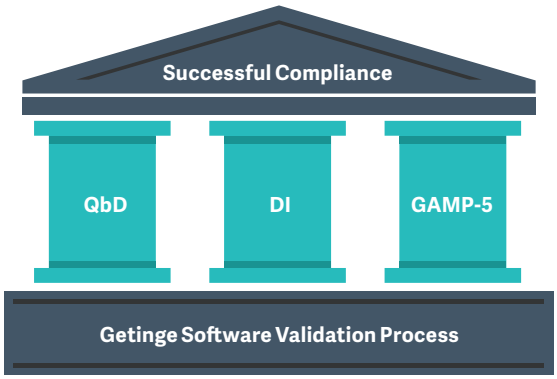
Building on this foundation, Getinge's approach to compliance integrates three core principles that ensure both quality and efficiency.



The Three Pillars of The GAMP 5 Validation Process

Successful compliance in the pharmaceutical industry is built upon three interconnected concepts:

- **Quality by Design (QbD):** QbD is a systematic approach to development that begins with predefined objectives and emphasizes process understanding and control based on sound science and quality risk management. QbD helps reconcile differing quality assurance and quality control focuses of global regulators, such as the European Medicines Agency (EMEA) and the US Food and Drug Administration (FDA).[2]
- **Data Integrity (DI):** DI ensures that all electronic records and data collected throughout the manufacturing lifecycle are complete, consistent, and accurate, adhering to ALCOA+ principles.
- **GAMP 5-Compliance:** Provides the essential risk-based framework for applying the principles of QbD and ensuring DI within the computerized control system of the equipment, leading to robust quality assurance. [3]



Reducing Site Validation Scope with GAMP 5 Categorization

A key differentiator of the Getinge approach is the strategic application of GAMP 5 software categorization, which directly reduces the customer's required testing.

By delivering systems based on the Getinge Software Validation Process, Getinge enables the customer's validation team to move from time-consuming software testing to efficient, targeted Operational Qualification (OQ) and Performance Qualification (PQ) activities. All Getinge team members working on customer projects are trained and certified according to the automation documentation present in the QMS as training is an important part of GAMP 5.

Often in customer projects, the final software is a combination of Category 4 (from the validated template) and Category 5 elements to fit the need of custom functionalities that are developed for a specific project. This ensures high compliance while accommodating unique operational customer needs.

True GAMP 5 compliance extends beyond validation. It requires continuous lifecycle management and complete traceability.

Any individual working on a customer project is trained and certified according to the automation documentation present in the QMS as training is an important part of GAMP 5.

GAMP Category	Description	Getinge Advantage
Category 4: Configured Product	Standard configurable software (e.g., PLC logic, SCADA) customized within defined limits.	Core functionality is Category 4 and fully validated by Getinge. Customers need only verify their site-specific configurations, not re-test base code.
Category 5: Customized Software	Bespoke code or non-standard configurations.	Reserved only for unique customer functions. Minimizing Category 5 reduces testing risk and validation time.
Category 1: Standard Hardware	Commercial, off-the-shelf components.	Standardized hardware simplifies IQ and ensures reliability.

Lifecycle Management and Traceability

Compliance with GAMP 5 mandates a disciplined lifecycle approach, formalized through the V-Model. Getinge's in-house software development strictly adheres to this model, ensuring complete traceability. Some recent GAMP 5-based methodologies focus on improving formal documentation in scientific software to ease integration into pharmaceutical collaborations, underscoring the importance of this traceable approach.[4]

- **Detailed Specifications:** The Validation Process includes rigorous specifications, the Functional Design Specification (FDS) and Detailed Design Specification (DDS), which are traceable to the User Requirement Specification (URS).
- **Risk-Based Verification:** A formal, documented software risk assessment is performed for the entire Process. This risk assessment determines the residual validation effort required at the customer's site, ensuring that site-based testing (FAT/SAT) is focused only on the high-impact or configurable elements, satisfying the GAMP 5 principle of risk proportionality.
- **Documentation Handover:** All artifacts supporting the Process validation, configuration records, and delivery risk assessments are retained by Getinge and provided to the customer as part of the full validation package, streamlining customer audits and regulatory inspections.
- **Software Change Control:** All template releases and customer-specific changes to the Software Validation Process follow Getinge's controlled change management process. Changes are risk assessed, documented, and subject to regression testing according to impact. Periodic review of the template and supported modules is conducted to ensure continued compliance with regulatory expectations to capture post-market observations.
- **Modular Architecture:** The software foundation is built using individual modules, the majority of which are classified as GAMP 5 Category 4 (Configured Product). This modular, pre-validated design is the primary justification for reducing the validation scope, as only new, unique functionalities developed specifically for a project require full validation effort.

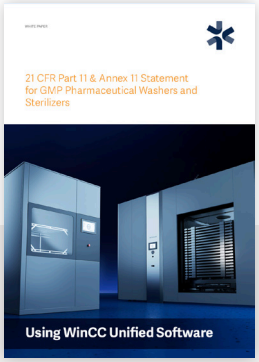
The Full Compliance Package

Data Integrity and FDA CFR 21 Part 11

Validation of the washer/dryer extends beyond GAMP 5 to encompass the entire regulatory landscape. The Getinge GAMP 5 Validation Process is designed as part of a complete compliance ecosystem. The system's control architecture is built to ensure the integrity of electronic records and signatures, a fundamental requirement of FDA 21 CFR Part 11.

The Getinge Validation Process incorporates controlled change management, formal risk assessment, and documented regression testing to maintain system integrity and compliance throughout its lifecycle. Periodic reviews ensure continued alignment with regulatory expectations and validated configurations.

- **Secure Records:** Generating secure, time-stamped audit trails for all critical actions, batch records, and configuration changes.
- **Electronic Signatures:** Robust, multi-level electronic signature functionality for batch release and recipe modifications.
- **Access Control:** Strict, role-based user authentication and access control, ensuring only authorized personnel can perform specific operations.



21 CFR Part 11 & Annex 11 Compliance

Our cGMP pharmaceutical washers and sterilizes are controlled by WinCC Unified software to meet 21 CFR Part 11 and Annex 11 standards.

Download the White Paper: getinge.com/dam/life-science/documents/english/getinge-washers-sterilizers-using-winccunified-whitepaper-112251-en.pdf

Conclusion

In pharmaceutical manufacturing, achieving speed, cost efficiency, and compliance simultaneously is a constant challenge. Legacy and highly customized software systems can increase risk and delay production when they are not validated. Getinge's GAMP 5-compliant software lifecycle and pre-validated process for cGMP pharmaceutical washer/dryers directly addresses these challenges. By embedding compliance into the system architecture and maximizing the use of Category 4 elements, Getinge shifts the validation effort upstream. This reduces your onsite testing burden and helps accelerate your time to production.

With Getinge, compliance isn't an added step. It is engineered into every system from the start.

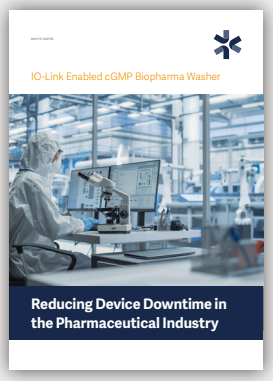
Accelerate Your Validation

Explore the complete portfolio of Getinge cGMP Pharmaceutical Washers/Dryers engineered for reliability and built to make your compliance process easier. The Getinge GAMP 5 Software Validation Process is the validated automation backbone for a full range of cGMP pharmaceutical washers and dryers.

Reducing Device Downtime in the Pharmaceutical Industry

Unplanned downtime can disrupt workflows, increase overhead costs, and, in some cases, contribute to delays in drug availability. To address these challenges, Getinge has introduced **IO-Link technology** into the **GEW 888 neo**, a compact cGMP washer/dryer developed for cleanrooms and clean spaces.

Download the White Paper: getinge.com/dam/life-science/documents/english/io-link-enabled-gmp-washer-whitepaper-102485-en.pdf



Complete Range of cGMP GEW Washer/Dryers

GEW 888 neo
480 L (17 cu.ft.)

GEW 9109
810 L (29 cu.ft.)

GEW 101210
1212 L (43 cu.ft.)

GEW 131313
2146 L (76 cu.ft.)

GEW 131820
4680 L (165 cu.ft.)

Pharmaceutical Production Solutions

Getinge is an industry leader in product solutions for pharmaceutical production sterility testing, API handling and aseptic transfer. Our isolation technology and isolator manipulation devices are trusted worldwide to provide a safe and controlled environment for your most critical steps.

Learn more: getinge.com/int/products-and-solutions/pharmaceutical-production/

References:

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3. Pedro, Francisca, Francisco Veiga, and Filipa Mascarenhas-Melo. "Impact of GAMP 5, data integrity and QbD on quality assurance in the pharmaceutical industry: How obvious is it?" Drug Discovery Today 28, no. 11 (November 2023). https://doi.org/10.1016/j.drudis.2023.103759

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With a firm belief that every person and community should have access to the best possible care, Getinge provides hospitals and life science institutions with products and solutions aiming to improve clinical results and optimize workflows. The offering includes products and solutions for intensive care, cardiovascular procedures, operating rooms, sterile reprocessing and life science. Getinge employs over 10,000 people worldwide and the products are sold in more than 135 countries.

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