

# BRIDGING R&D AND PRODUCTION WITH UNIFIED HIGH-PRECISION DISPENSING TECHNOLOGIES

GINGLIS

1	EXECUTIVE SUMMARY	3	
2	THE TECHNOLOGY GAP IN MEDTECH AND IVD MANUFACTURING	4	
3	UNIFIED DISPENSING: A NEW STANDARD FOR SPEED AND QUALITY	8	
4	THE ROLE OF IOT: REAL-TIME INSIGHTS FOR FASTER REPLICATION AND PROBLEM		
so	SOLVING 12		
5	THE CRITICAL VALUE OF LOW-MAINTENANCE PUMP TECHNOLOGIES	16	
6	GINOLIS SOLUTIONS: ENSURING A SEAMLESS TRANSITION FROM LAB TO		
PR	PRODUCTION		
7	CONCLUSION: PARTNERING FOR SUCCESS WITH GINOLIS	26	
8	ABOUT GINOLIS	30	

# 1 EXECUTIVE SUMMARY

In the highly competitive MedTech and In Vitro Diagnostics (IVD) industry, time-to-market and product reliability are paramount. Global regulatory frameworks, such as IVDR in Europe and FDA 21 CFR Part 820 in the United States, place strict demands on manufacturers for process consistency, traceability, and real-time quality assurance. Simultaneously, commercial pressures to launch innovative products faster than competitors have never been greater.

Yet, despite significant investments in R&D, many companies encounter critical barriers when scaling processes from the laboratory to full-scale production. Variations between research and manufacturing environments — including differences in dispensing technology, software versions, fluidic behavior, and operational parameters — often lead to unexpected delays, increased costs, higher scrap rates, and compliance risks. In many cases, production inconsistencies originate from using non-standardized equipment, leading to costly revalidation efforts and delayed market entry.

This white paper examines why the traditional separation between R&D and production technologies is no longer sustainable in today's MedTech and IVD manufacturing landscape. It proposes a unified approach: maintaining identical high-precision dispensing systems, software environments, process recipes, and pump technologies throughout the entire product development lifecycle.

By eliminating inconsistencies at the source, companies can dramatically accelerate production rampup, minimize risk, and preserve product quality as they scale. Additionally, the integration of IoT-based data platforms allows continuous monitoring, predictive analytics, and seamless replication of production anomalies in the R&D environment—enabling faster troubleshooting and preventive action.

Finally, this paper highlights how low-maintenance dispensing technology plays a vital role in achieving high Overall Equipment Effectiveness (OEE), ensuring maximum uptime and throughput in regulated manufacturing settings.

Organizations that align their laboratory development with manufacturing realities from the very beginning will be better positioned to lead the next wave of MedTech and IVD innovation — delivering quality products to market faster, more reliably, and at a lower total cost.

# 2 THE TECHNOLOGY GAP IN MEDTECH AND IVD MANUFACTURING

#### Chapter Summary

- Scale-up Challenges: Transitioning from R&D to production often fails due to mismatches in equipment, software versions, environmental conditions, and operator skill levels, leading to variability and re-engineering needs.
- Business Risks: Poor technology transfer can result in extended ramp-up timelines, higher scrap/rework rates, regulatory setbacks, delayed market entry, and loss of competitive advantage.
- **Key Avoidance Areas:** Ensure alignment in hardware/software, control environmental factors, standardize processes, provide adequate operator training, and maintain thorough documentation to mitigate transfer risks.

The transition from research and development (R&D) to full-scale production is a critical phase in the lifecycle of any MedTech or In Vitro Diagnostics (IVD) product. Despite successful laboratory prototyping, many organizations encounter unforeseen obstacles when attempting to replicate laboratory success at manufacturing scale. These challenges often originate from disparities between R&D processes and production environments, making the technology transfer phase a major source of project delays, cost overruns, and quality issues.

Several factors contribute to the risk of disruption during scale-up:

#### **Technical Mismatches**

Even minor differences in dispensing technology, hardware calibration, and fluid handling systems between laboratory setups and production machinery can introduce variability.

Laboratory equipment often prioritizes flexibility and precision at small batch volumes, while production equipment is optimized for speed and throughput. This divergence can alter fluid behavior, impact dispensing accuracy, and require re-engineering of validated laboratory processes.

#### Software Version Disparities

Control software inconsistencies between R&D and production lines can lead to significant performance deviations. Differences in software algorithms, firmware versions, or user interface designs can affect machine behavior, compromising reproducibility and triggering extensive revalidation efforts under regulatory scrutiny.

# **Environmental Condition Variability**

Environmental factors such as ambient temperature, humidity, and air pressure, which are often tightly controlled or manually adjusted during R&D, can fluctuate significantly in a full-scale production environment. These variations can impact reagent viscosity, evaporation rates, polymerization kinetics, and other fluid properties, directly affecting dispensing performance and product quality.

# Operator Skill and Training Gaps

R&D environments typically involve highly skilled technical personnel capable of managing and correcting small deviations manually. In contrast, production operators rely on standardized procedures and automated systems. If the dispensing technology or workflow differs significantly between R&D and manufacturing, substantial retraining, procedural rewriting, and human error risks arise.

# Consequences of Poor Technology Transfer

The cumulative effect of these inconsistencies often manifests in tangible business risks:

- Extended production ramp-up timelines
- Increased scrap and rework rates
- Regulatory compliance challenges
- Customer dissatisfaction and damaged brand reputation
- Erosion of competitive advantage through delayed market entry

#### Real-World Example

Consider the case of a microfluidic diagnostics startup that experienced a significant delay in commercializing its first product. After successfully validating their assay on a laboratory-grade dispensing system, the company transitioned to a different industrial dispensing platform for production, assuming minor adjustments would suffice. However, due to differences in pump behavior, fluid dynamics, and software control logic, the manufacturing process introduced unpredictable variability in critical reagent deposition steps. Despite intensive troubleshooting, the company faced a nine-month delay in market entry, missed strategic partnership opportunities, and incurred substantial unplanned validation costs.

Quick Checklist: Common Pitfalls to Avoid in Technology Transfer			
Technical Issues			
<ul> <li>Mismatched dispensing hardware between R&amp;D and production</li> <li>Inconsistent software versions or control logic</li> <li>Calibration gaps across equipment</li> </ul>	on		
Environmental Challenges			
<ul> <li>Uncompensated changes in temperature or humidity</li> <li>Fluid property shifts under different conditions</li> </ul>			
Organizational Gaps			
<ul> <li>Lack of standardized manufacturing recipes</li> <li>Insufficient operator training for new production equipment</li> <li>Missing or incomplete process documentation</li> </ul>			
Business Risks			
<ul> <li>Extended validation and requalification periods</li> <li>Increased scrap and failure rates</li> <li>Delayed regulatory submissions and audits</li> </ul>			

# 3 UNIFIED DISPENSING: A NEW STANDARD FOR SPEED AND QUALITY

#### Chapter Summary

- Unified Dispensing Strategy: Standardizing dispensing hardware, software, and process recipes across R&D and production ensures seamless scalability, reduces revalidation work, and accelerates time-to-market.
- Three Pillars of Success:
  - ♦ Recipe Integrity → preserves validated R&D processes without re-optimization.
  - ♦ Software Version Locking → eliminates variability by ensuring identical control logic across environments.
  - ♦ Hardware Calibration Stability → guarantees precision and repeatability from lab to production.
- Business Impact: Unified dispensing turns technology transfer into a controlled, low-risk process, enabling faster commercialization, higher product quality, and stronger regulatory compliance.

The technology transfer challenges faced by MedTech and IVD manufacturers often originate from inconsistencies between laboratory R&D and manufacturing equipment. To mitigate these risks and accelerate time-to-market, organizations must adopt a unified dispensing strategy—deploying identical dispensing systems, software, and process recipes throughout the product development lifecycle.

Unified dispensing creates a direct bridge between R&D and production, ensuring seamless scalability, minimizing revalidation work, and preserving product quality standards. By designing for manufacturability from the earliest stages of product development, companies can achieve a sustainable advantage in both operational efficiency and regulatory compliance.

Unified dispensing is founded on three critical pillars:

#### Recipe Integrity

Manufacturing recipes validated during R&D often represent hundreds or thousands of hours of scientific optimization. However, if these recipes must be adjusted during production transfer due to equipment or process differences, significant risks are introduced.

Using the same dispensing platform — including pumps, nozzles, and motion control systems — across both R&D and manufacturing environments ensures that:

- Dispensing volumes, speeds, and profiles remain identical
- Fluidic behaviors (such as shear sensitivity or droplet formation) are fully preserved
- Process validation and regulatory documentation from the R&D phase can be leveraged directly in production submissions

By maintaining recipe integrity, organizations eliminate the need for time-consuming reoptimization and re-validation steps that typically delay ramp-up and regulatory approval.

# Software Version Locking

Software discrepancies between laboratory and production systems are a frequent but often underestimated source of variability. Even minor differences in machine control algorithms, communication protocols, or interface logic can introduce operational deviations.

A unified dispensing approach mandates that:

- The same software platform is used across R&D prototypes and manufacturing lines
- Software updates, patches, and configurations are strictly controlled and version-locked
- User interfaces, recipe management tools, and system diagnostics behave identically across environments

This consistency ensures that operators, engineers, and quality assurance personnel can rely on standardized procedures and outcomes, further simplifying training, troubleshooting, and regulatory audits.

## Hardware Calibration Stability

Dispensing precision and repeatability are ultimately dependent on the mechanical and fluidic stability of the dispensing hardware — particularly pumps and nozzle assemblies.

Factory-calibrated dispensing pumps, with verified performance certifications, provide a stable baseline across the entire product lifecycle. In a unified system, this means:

- Laboratory dispensing results are predictive of production outcomes
- Minimal recalibration or fine-tuning is required during scale-up
- Long-term drift in dispensing accuracy is minimized, supporting high Overall Equipment Effectiveness (OEE)

By specifying high-precision, low-maintenance pump technologies from the outset, organizations ensure that dispensing performance remains within validated specifications over millions of cycles, thereby reducing maintenance interventions and avoiding unexpected downtime.

# Summary

Unified dispensing transforms the manufacturing readiness of MedTech and IVD companies. It turns technology transfer from a risky handover into a smooth, controlled scale-up — delivering faster market entry, better quality outcomes, and lower operational risk.



Figure 1 Ginolis' approach for ensuring ease of transfer from R&D to production is predicated on recipe integrity, software version locking, and hardware calibration stability. This is core to our approach of delivering products and services.

# 4 THE ROLE OF IOT: REAL-TIME INSIGHTS FOR FASTER REPLICATION AND PROBLEM SOLVING

#### Chapter Summary

- **IoT-Enabled Precision Dispensing**: Connecting lab and production systems to a centralized cloud enables continuous, real-time data capture, turning manufacturing from reactive to proactive.
- Core Capabilities:
  - $\Diamond$  Golden Batch Analysis  $\rightarrow$  ensures every run aligns with validated standards for consistency.
  - $\Diamond$  Anomaly Detection  $\rightarrow$  uses analytics and machine learning to spot early process deviations.
  - ♦ *Real-time KPI Monitoring* → provides live dashboards, alerts, and compliance-ready reporting.
- Business Impact: IoT integration reduces scrap and downtime, improves regulatory compliance, and accelerates innovation through predictive, data-driven manufacturing.

In today's highly regulated MedTech and IVD manufacturing environments, the ability to detect, diagnose, and resolve production issues rapidly is crucial to maintaining both quality and operational efficiency. Traditional approaches, which rely heavily on post-process inspection and manual troubleshooting, are increasingly insufficient.

The introduction of Internet of Things (IoT) technology into precision dispensing systems has transformed process monitoring and control. IoT-enabled systems continuously connect laboratory and production machines to a centralized cloud platform, allowing manufacturers to capture detailed, real-time process data across the entire lifecycle.

This connected infrastructure provides a foundation for proactive, data-driven manufacturing management, and delivers several critical advantages:

## Golden Batch Analysis

One of the most powerful applications of IoT-based data capture is the ability to perform Golden Batch Analysis.

Manufacturers can define a "golden" production run—an ideal batch with validated performance across all critical parameters— and use it as a benchmark against which future runs are automatically compared.

Key benefits:

- Immediate detection of deviations from optimal performance
- Standardized production quality across shifts, sites, and product versions
- Faster root-cause analysis during troubleshooting

By aligning every production run with a validated historical standard, manufacturers increase process consistency and reduce non-conformance rates.

# **Anomaly Detection**

IoT platforms employ real-time data analytics and machine learning algorithms to identify early warning signs of process anomalies — often before they escalate into full-scale production issues.

Examples of anomalies detected include:

- Minor dispensing volume drift
- Pressure spikes in fluidic systems
- Repeated micro-failures in mechanical actuation

• Slow deterioration in pump efficiency

Operators and engineers are alerted automatically through dashboards or mobile notifications, allowing immediate corrective action. Early anomaly detection reduces scrap, minimizes downtime, and prevents costly recalls.

## Real-time Process KPI Monitoring

Continuous visibility into key performance indicators (KPIs) such as flow rates, pressures, dispensing volumes, cycle times, and error rates empowers operators, production managers, and quality assurance teams to maintain tight control over manufacturing operations.

Modern IoT dashboards provide:

- Live trend graphs and alerts
- Historical data analytics
- Automated reporting for audits and compliance documentation
- Configurable thresholds for warnings and alarms

By visualizing process behavior in real-time, teams can respond faster, make better decisions, and ensure processes remain within validated control limits.

## Summary

The integration of IoT into precision dispensing systems enables the transition from passive to proactive manufacturing.

With IoT, manufacturers are no longer limited to reacting after defects occur — they can predict, prevent, and replicate production conditions scientifically, leading to higher yields, improved compliance, and faster innovation cycles.

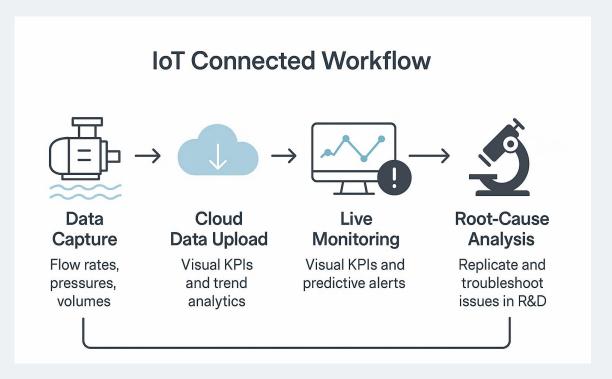


Figure 3 An IOT Connected Workflow enables live monitoring, facilitating immediate actions, and predictive maintenance for the future.

# 5 THE CRITICAL VALUE OF LOW-MAINTENANCE PUMP TECHNOLOGIES

#### Chapter Summary

- Pump Performance as a Strategic Factor: In MedTech and IVD manufacturing, low-maintenance, high-precision pumps reduce recalibration, servicing, and downtime, directly improving product quality, compliance, and operational efficiency.
- Key Advantages:
  - $\diamond$  5+ million cycles between service intervals  $\rightarrow$  fewer interruptions, lower spare part needs, and less reliance on maintenance staff.
  - $\diamond$  >98% OEE achievable  $\rightarrow$  higher uptime, throughput, and first-pass yield.
- Business Impact: Eliminating pump-related downtime boosts output, lowers unit costs, and enhances profitability — making pump selection a critical strategic decision, not just a technical one.

In precision dispensing applications for MedTech and In Vitro Diagnostics (IVD) manufacturing, pump performance is foundational to product quality and operational efficiency. The choice of dispensing technology directly influences dispensing accuracy, system reliability, and overall production economics.

Traditional pump systems often require frequent maintenance interventions, recalibrations, and parts replacements — all of which disrupt production schedules, reduce Overall Equipment Effectiveness (OEE), and introduce potential compliance risks. In contrast, low-maintenance, high-precision pumps represent a transformative advantage for manufacturers focused on scale, consistency, and profitability.

Advantages of Low-Maintenance Pump Systems

## 5+ Million Cycles Between Service Intervals

Ginolis' proprietary dispensing technologies are engineered to operate for more than five million dispensing cycles without requiring recalibration or part replacement.

This ultra-long maintenance interval means that production lines experience minimal interruptions, ensuring that validated processes remain stable over extended manufacturing campaigns.

Reduced service needs also translate into:

- Lower spare part inventory requirements;
- Fewer scheduled downtime periods;
- Less dependency on specialist maintenance personnel.

#### Over 98% OEE Achievable

High-quality low-maintenance pumps contribute directly to achieving and sustaining production OEE levels exceeding 98%.

OEE (Overall Equipment Effectiveness) is defined by the combination of:

- Availability (machine uptime);
- Performance (speed and efficiency);
- Quality (first-pass yield without rework).

By eliminating frequent pump-related downtime, Ginolis systems maximize production line availability and support continuous, high-throughput manufacturing with minimal quality deviations.

Figure 4

## Maintenance Cost Math: A Practical Example

Even seemingly minor downtime savings compound into substantial operational and financial benefits over time.

Consider the following illustrative example:

- Unplanned pump service requires 1 hour of downtime per week
- In a 48-week production year, this equates to 48 hours lost annually
- For a production line operating 24/7, this corresponds to ~2.5% annual
   OEE loss

Recovering this 2.5% OEE through low-maintenance pump technology translates into:

- Increased total unit output without additional capital investment
- Reduced cost per unit produced
- Higher profitability and improved asset utilization

In highly regulated markets where manufacturing margins are tight, such efficiency improvements are strategically significant.

## Summary

Selecting low-maintenance, high-precision dispensing pumps is not simply an engineering decision—it is a strategic business decision.

By securing pump stability and minimizing maintenance interventions, MedTech and IVD manufacturers can unlock higher production yields, faster scale-up, lower operational risks, and stronger returns on manufacturing investments.

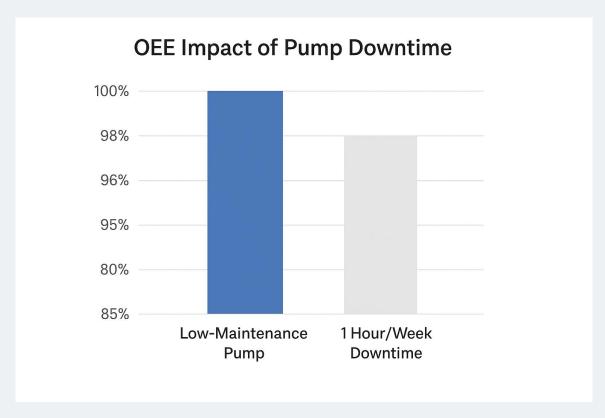


Figure 5 A short 1 hour downtime per week translates to a 2.5% OEE hit over a year. Typical production environments run for several years, and these cumulative costs can add up to significant OPEX.

# 6 GINOLIS SOLUTIONS: ENSURING A SEAMLESS TRANSITION FROM LAB TO PRODUCTION

#### Chapter Summary

- Seamless Technology Transfer: Ginolis eliminates R&D-to-production barriers with modular dispensing systems, unified software, and IoT connectivity—enabling faster timeto-market, regulatory-ready traceability, and consistent process control.
- Core Solution Pillars:
  - $\Diamond$  Modular High-Precision Systems  $\rightarrow$  scale from prototypes to full production without reengineering.
  - ♦ *Unified Software Environment* → version-locked validation, consistent machine behavior, simplified training.
  - ♦ Cloud-Connected IoT Platform → real-time KPI monitoring, anomaly detection, golden batch analysis, audit trails.
  - ♦ Low-Maintenance Proprietary Pumps → 5M+ cycles, high OEE, reduced downtime.
- Proven Business Impact: Case studies show 40% faster ramp-up, 35% OEE improvements, and six months saved in regulatory approval turning Ginolis into a driver of manufacturing excellence and competitive advantage.

At Ginolis, we recognize that successful MedTech and IVD manufacturing depends on seamless technology transfer — not as an afterthought, but as an embedded design principle.

Our platform is purpose-built to eliminate the traditional barriers between R&D and production, securing faster time-to-market, higher manufacturing efficiency, and superior product quality.

Ginolis offers a fully integrated dispensing solution that directly addresses the root causes of production ramp-up delays, variability, and compliance risks:

Key Elements of the Ginolis Solution:

# Modular High-Precision Dispensing Systems

Ginolis platforms are modular by design, enabling easy scaling from R&D prototypes to full-scale production lines without process reengineering.

Each system features:

- Factory-calibrated dispensing heads;
- Automated motion control optimized for microfluidics and diagnostic reagents;
- Compatibility with a wide range of substrates and device formats.

This modularity ensures that companies can move from lab-scale validation to high-volume manufacturing without changing core process parameters.

#### **Unified Software Environment**

Our standardized software architecture governs both R&D equipment and production machinery, maintaining:

- Consistent machine behavior and recipe execution;
- Identical data structures for process records;
- Version-locked validation documentation for regulatory submissions.

This approach reduces training burdens, simplifies process control, and strengthens traceability throughout the lifecycle.

#### Cloud-Connected IoT Data Platform

Ginolis' IoT-enabled systems continuously collect and upload critical dispensing process data—including flow rates, dispensing volumes, pressures, and environmental conditions—to a secure cloud platform.

#### Key features include:

- Real-time KPI monitoring;
- Automated anomaly detection and alerts;
- Golden batch comparisons for deviation analysis;
- Full audit trails for regulatory compliance.

By connecting laboratory and production data, Ginolis allows manufacturers to scientifically replicate and resolve production issues within controlled R&D environments.

# Proprietary Low-Maintenance Dispensing Technology

At the heart of Ginolis systems lies our proprietary precision dispensing technology, specifically engineered for low maintenance and high longevity.

#### Benefits include:

- 5+ million cycles between servicing;
- Consistent performance across complex reagent types;
- Reduced operational downtime and enhanced OEE.

Pump stability is critical for maintaining dispensing precision and securing predictable manufacturing yields.



Figure 6 Ginolis' integrated solution is built on unified software, module dispensing solutions that feed data to the cloud. Cloud-based analytics software helps predictability and reduces downtime, improving OEE.

# Micro-Case Examples: Real-World Results with Ginolis Solutions

Microfluidic Cartridge Production

A leading diagnostics company deployed Ginolis dispensing systems during both R&D and initial manufacturing phases.

By transferring validated lab recipes directly into production without modification, the company achieved a 40% faster ramp-up, reducing time-to-market by several months and gaining first-mover advantage in a competitive segment.

Lateral Flow Test Strip Manufacturing

In a high-throughput lateral flow device line, predictive maintenance enabled by Ginolis IoT monitoring helped maintain optimal pump performance.

As a result, the manufacturer realized a 35% improvement in Overall Equipment Effectiveness (OEE), minimizing unplanned downtime and maximizing output during a critical pandemic-response window.

High-Throughput Pipette Tip Coating

A precision consumables manufacturer used Ginolis technology to fully validate pipette tip coating processes during the R&D phase.

When transitioning to production, the identical equipment and recipe controls enabled direct regulatory approval without revalidation, saving approximately six months of review time and accelerating commercial readiness.

# Summary

Ginolis solutions are not simply manufacturing tools; we are enablers of strategic manufacturing excellence.

By designing for consistency, connectivity, and reliability from the start, Ginolis empowers MedTech and IVD companies to build future-proof manufacturing ecosystems — seamlessly bridging innovation and industrialization.

# 7 CONCLUSION: PARTNERING FOR SUCCESS WITH GINOLIS

#### Chapter Summary

- Unified R&D-to-Production Approach: MedTech and IVD manufacturers must integrate dispensing systems, software, and IoT data platforms early to eliminate inconsistencies, ensure compliance, and accelerate market entry.
- Action Plan: Audit current transfer processes, identify hardware/software/recipe mismatches, and pilot Ginolis modular dispensing technology in R&D to validate scalable, loT-enabled workflows.
- Why Ginolis: Provides precision from prototype to production, real-time IoT visibility, high efficiency with low-maintenance pumps, and scalable systems enabling faster, safer, and more profitable manufacturing excellence.

In an industry where precision, compliance, and speed define competitive advantage, MedTech and In Vitro Diagnostics (IVD) manufacturers must rethink the traditional divide between R&D and production environments.

The unified approach — integrating dispensing technologies, control software, and IoT data platforms from the earliest stages of product development through to full-scale manufacturing — is no longer optional; it is essential.

By eliminating inconsistencies, securing data continuity, and leveraging real-time operational intelligence, companies can significantly accelerate product launches, reduce technical and regulatory risks, and maintain the highest quality and manufacturing standards demanded by global markets.

Ginolis provides the tools, systems, and expertise to make this transformation possible.

Our integrated platform ensures that R&D efforts translate smoothly into industrialized manufacturing success, unlocking operational excellence and long-term profitability.

#### **Actionable Recommendations**

To prepare your organization for seamless R&D-to-Production scale-up, we recommend the following steps:

- 1. Audit Current R&D to Production Transfer Processes
  - Map current workflows, equipment platforms, software environments, and process recipes;
  - Identify potential mismatches and handover vulnerabilities early;
  - Prioritize critical-to-quality dispensing processes for review.
- 2. Identify Inconsistencies in Dispensing, Recipe Management, and Software
  - Evaluate whether your laboratory and production systems use identical or diverging dispensing hardware;
  - Review control software versions and compatibility across platforms;
  - Assess recipe portability and traceability between environments.
- 3. Pilot Ginolis Dispensing Technology in Your R&D Workflow

- Implement Ginolis modular dispensing systems during the R&D phase;
- Validate recipes and software in a production-replicable environment;
- Leverage IoT data collection to begin building golden batch benchmarks early.

This proactive approach future-proofs your technology transfer, reduces revalidation efforts, and shortens time-to-market while maximizing compliance readiness.

# Why Partner with Ginolis?

- Precision from Prototype to Production: Unified systems eliminate guesswork and protect quality;
- Real-Time Visibility: IoT data connectivity enables immediate insight and faster root-cause analysis;
- Maximum Efficiency: Low-maintenance pump technology and modular platforms ensure high OEE;
- Future-Ready Manufacturing: Flexible, scalable systems that evolve with your business needs.

Ginolis is committed to being your trusted partner in building a seamless, scalable, and smart manufacturing ecosystem — empowering you to deliver next-generation healthcare innovations to market faster, safer, and more profitably.

Let's build your future manufacturing excellence together.



Figure 7 Our seamless, scalable, smart manufacturing technology enables unification across the dispensing lifecycle.

# 8 ABOUT GINOLIS

#### Chapter Summary

- Who We Are: Ginolis is a global leader in high-precision dispensing, microfluidic automation, modular assembly, and in-line machine vision for MedTech and IVD, built to seamlessly scale from R&D to full production.
- Core Capabilities: Proprietary low-maintenance pumps, scalable modular platforms, IoTenabled data solutions, and advanced machine vision deliver precision, reproducibility, realtime quality assurance, and regulatory readiness.
- Customer Value: Tailored, future-proof solutions that accelerate time-to-market, reduce costs, ensure compliance, and empower healthcare innovators to reliably deliver nextgeneration medical technologies.

Ginolis is a global technology leader specializing in high-precision dispensing, microfluidic automation, customized assembly solutions, and in-line machine vision inspection for the MedTech and In Vitro Diagnostics (IVD) industries.

Founded on the principle of enabling seamless scale-up from research to full-scale production, Ginolis delivers innovative manufacturing platforms that combine engineering excellence, modular flexibility, and data-driven intelligence.

Our mission is to empower healthcare innovators to bring life-changing technologies to market faster, with greater reliability, and at a lower total cost of ownership.

Ginolis solutions are specifically designed for the unique challenges of regulated medical manufacturing environments, where precision, reproducibility, traceability, and real-time quality assurance are critical to success.

#### **Core Competencies**

#### Precision Dispensing Excellence

Ginolis offers industry-leading dispensing technologies capable of delivering ultra-precise microand nano-liter volumes across a wide range of reagents and substrates.

Our proprietary low-maintenance pump designs ensure long-term performance stability, supporting high Overall Equipment Effectiveness (OEE) and consistent product quality.

#### Microfluidic and IVD Automation

We specialize in automating complex manufacturing processes for microfluidic cartridges, diagnostic test strips, biosensor arrays, and other high-value medical consumables.

Our platforms are optimized for sensitive biomaterials and designed to maintain product integrity throughout the production cycle.

#### Modular, Scalable Manufacturing Systems

Ginolis modular systems allow customers to configure solutions that evolve with their needs — from laboratory pilot lines to full commercial production facilities — using the same core technologies.

This scalability protects investments and accelerates validation and regulatory approval processes.

#### IoT-Enabled Data Solutions

Our cloud-connected IoT platforms provide real-time process monitoring, predictive analytics, and full traceability from prototype to production.

Manufacturers gain unprecedented visibility and control over their operations, supporting faster root-cause analysis, predictive maintenance, and continuous improvement initiatives.

Advanced Machine Vision for Dispensing Quality Assurance

Ginolis brings extensive experience in deploying high-performance machine vision solutions specifically tailored for dispensing quality inspection.

Our integrated vision systems enable:

- In-line verification of droplet volume, position, and morphology;
- Detection of underfill, overfill, missing deposits, and defects in real-time;
- Closed-loop feedback control to adjust dispensing parameters dynamically;
- Automated statistical quality control (SQC) and compliance reporting.

By embedding machine vision into our dispensing platforms, Ginolis ensures that manufacturing defects are caught immediately, minimizing rework, reducing scrap, and strengthening regulatory audit readiness.

#### Customer-Centric Innovation

Every Ginolis solution is tailored to customer requirements, combining standardized modules with customized engineering to address specific product and process challenges.

Our teams work closely with clients across the entire lifecycle — from concept development through industrialization and ramp-up — ensuring strategic alignment and long-term success.



Figure 8 Ginolis provides integrated manufacturing excellence across the lifecycle: from R&D to Production

# Contact

Ginolis Oy

Website: www.ginolis.com

Email: sales@ginolis.com

Phone: +358 10 315 360