White Paper

The Era-Defining Impact of Unit-of-Use Medication on the North American Pharmacy Market

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Contents

Executive Summary

North American spending on unit-of-use (UoU) medications—from blistered oral solids to refrigerated GLP-1 pen injectors—has outpaced overall prescription growth by a factor of 13 over the past five years. Between 2019 and 2024, UoU packaging spend rose 40%, driven primarily by self-administered biologics and expanding cold-chain requirements. The most dramatic shift: GLP-1 medications alone grew from $13.7 billion to $71.7 billion—a 423% increase that epitomizes the rapid transformation of pharmaceutical dispensing [HealthcareReaders.com].

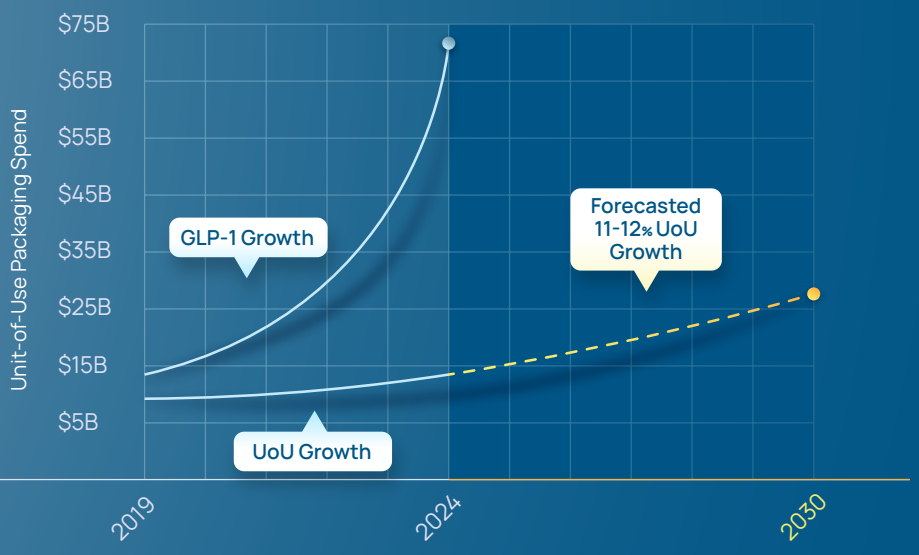
This evolution creates an unprecedented challenge for central-fill pharmacies. Infrastructure designed for high-speed pill counting now faces a growing volume of pre-packaged, serialized, often refrigerated medications that require entirely different handling capabilities. Cold-chain items represent just 0.2% of prescription volume yet account for nearly one-third of drug value—and their share continues climbing [IQVIA Pharma's Frozen Assets].

Market projections amplify the urgency. Analysts forecast the UoU packaging market will double again by 2030, growing at 11-12% annually compared to less than 3% for total outpatient volume [Grand View Research]. Temperature-controlled logistics already consume 18% of biopharma logistics spending [Biopharma Cold Chain Sourcebook 2020 via Mordor Intelligence]. Add looming DSCSA serialization requirements [FDA DSCSA Overview] and the case for infrastructure transformation becomes compelling.

Central-fill operations face a strategic inflection point. Organizations that modernize now with purpose-built automation for diverse packaging formats will capture significant advantages in efficiency, compliance, and scalability. Those that delay risk being overwhelmed by manual workarounds, compliance failures, and stranded assets as the market shifts beneath them.

The 40% Surge:

Unit-of-Use Transformation at a Glance



I. Introduction:

The Transformation of Pharmaceutical Dispensing

The pharmaceutical dispensing landscape is undergoing its most significant transformation in decades. Where pharmacies once primarily counted pills and filled bottles, they now navigate an increasingly complex ecosystem of pre-packaged, patient-ready medications. This shift from traditional oral solids to unit-of-use formats represents more than a packaging evolution—it fundamentally challenges the operational assumptions underlying central-fill pharmacy design.

Three converging forces make this transformation urgent for pharmacy leaders:

THE BIOLOGICS REVOLUTION.

The explosion of self-administered biologics has reshaped both the therapeutic landscape and the logistics required to deliver these medications safely. GLP-1 agonists for diabetes and obesity provide the most dramatic example: spending surged from $13.7 billion in 2019 to $71.7 billion in 2024, a 423% increase that shows no signs of slowing [HealthcareReaders.com]. These medications arrive not as bulk powders to be counted, but as pre-filled pen injectors requiring precise temperature control and serialized tracking.

REGULATORY IMPERATIVES.

The Drug Supply Chain Security Act (DSCSA) reached full enforcement in November 2024, mandating serialized tracking and interoperable data exchange for prescription drugs [FDA DSCSA Overview]. For central-fill operations handling thousands of pre-packaged items daily, this requirement transforms unit-of-use medications from a handling challenge into a compliance imperative. Manual verification processes that sufficed for lower volumes become untenable at scale.

ENVIRONMENTAL AND ECONOMIC PRESSURES

With healthcare contributing 4.2% of global carbon emissions [IQVIA Tip of the Iceberg], the environmental impact of pharmaceutical distribution faces increasing scrutiny. Temperature-controlled logistics consume disproportionate resources—transport refrigeration units alone produce 8 tonnes of CO_2 annually, equivalent to four average cars [Cenex via Pharmaceutical Technology]. As organizations commit to sustainability targets, the efficiency of cold-chain operations becomes both an environmental and economic priority.

Central-fill pharmacies play an increasingly critical role in pharmaceutical distribution as retail chains consolidate dispensing operations into centralized hubs to capture economies of scale and health systems expand mail-order capabilities to improve medication access and adherence.

In both cases, the ability to efficiently process unit-of-use medications determines operational success. Yet most central-fill infrastructure reflects an earlier era's priorities: maximum throughput for oral solids, minimal handling of specialty formats, and limited cold-chain capacity. This mismatch between infrastructure and demand creates mounting operational friction. Manual workarounds proliferate. Errors increase. Costs compound.

The question facing pharmacy leaders is not whether to adapt their infrastructure for the unit-of-use era, but how quickly they can transform operations to capture emerging opportunities while avoiding operational obsolescence. The window for strategic action remains open, but it won't stay open indefinitely.

II. Market Analysis:
Quantifying the Unit-of-Use Surge

THE FIVE-YEAR TRANSFORMATION (2019-2024)

Metric	2019	2024	5-Year Change
UoU/Unit-Dose Packaging Spend (North America)	$9-10B	$13.8B	+40%
Prefilled Syringe & Autoinjector Revenue (Global)	$5.2B	$8.0B	+54%
GLP-1 Cold-Chain Injectable Spend (U.S.)	$13.7B	$71.7B	+423%
Pharma Cold-Chain Logistics (North America)	$5.4B	$6.4B	+19%

The shift toward unit-of-use packaging represents one of the most dramatic transformations in pharmaceutical distribution history. Between 2019 and 2024, North American spending on UoU medications grew 40%, from approximately $9-10 billion to $13.8 billion [Grand View Research]. This growth rate—roughly 8% annually—dwarfs the 2-3% growth in overall prescription volume, signaling a fundamental change in how medications reach patients.

The most explosive growth occurred in cold-chain injectables, particularly GLP-1 agonists. What began as a diabetes treatment category has expanded into obesity management, driving a 423% increase in spending [HealthcareReaders.com]. Medications like semaglutide (Ozempic, Wegovy) and tirzepatide (Mounjaro, Zepbound) arrive at central-fill pharmacies not as vials to be counted, but as pre-filled pen injectors requiring 2-8°C storage throughout the supply chain.

GLP-1
5 Year Growth

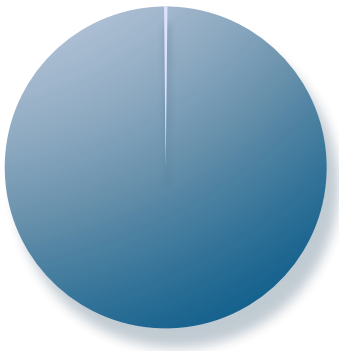
+423%

The Value Concentration Paradox

Perhaps no statistic better illustrates the challenge facing central-fill operations than this: **cold-chain medications represent approximately 0.2% of total prescription volume yet account for nearly one-third of pharmaceutical value** [IQVIA Pharma's Frozen Assets].

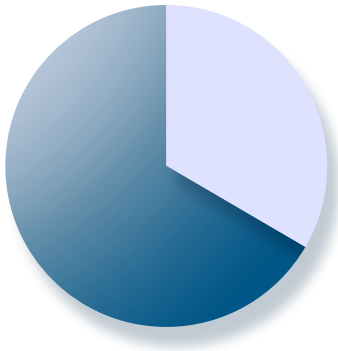
This extreme value concentration means that a tiny fraction of SKUs drives disproportionate revenue—and risk.

The financial implications of mishandling are severe. Industry estimates suggest biopharma loses approximately $35 billion annually to temperature excursions [IQVIA Institute via Sensire]. More troubling: 25% of vaccines reach their destination degraded due to cold-chain failures, while 30% of all pharmaceutical waste stems from logistics issues [Cargosense via Sensire].



COLD-CHAIN MEDICATIONS

0.2% of total prescription volume



COLD-CHAIN MEDICATIONS

~1/3 of pharmaceutical value

Common Cold-Chain Medications Driving Growth

The expansion of cold-chain requirements extends well beyond vaccines. Today's temperature-sensitive portfolio includes [TEC4MED]:

- Vaccines: Including routine immunizations (MMR, yellow fever) and COVID-19 vaccines
- Biologicals: Treatments for rheumatism, cancer, and autoimmune conditions
- Ophthalmics: Glaucoma medications requiring strict 2-8°C storage
- Respiratory: Select asthma inhalers with temperature sensitivity
- Diabetes: Temperature-sensitive insulin formulations

Each category presents unique handling challenges. Biologicals often arrive in odd-shaped packaging that defies traditional storage systems. Vaccines require batch tracking and temperature documentation. Insulin pens need consistent refrigeration but cannot freeze.

2030 Projections: The Doubling Ahead

Looking forward, the unit-of-use transformation shows no signs of slowing. Multiple analyst firms project 11-12% compound annual growth rates (CAGR) through 2030 [Grand View Research], [IMARC Group]. At these rates, the North American UoU market will double from its current $13.8 billion to exceed $27 billion by decade's end.

Key projections include:

$100B

Cold-chain injectable revenues expected to surpass $100 billion globally [Industry Analysis]

50%

Prefilled and autoinjector formats to exceed 50% of all parenteral prescriptions by 2029 [Grand View Research]

1/3

Temperature-sensitive biologics to account for over one-third of all new drug launches [Industry Reports]

$5.9B

Vaccine cold-chain logistics market growing from $3.5 billion to $5.9 billion by 2034 [InsightAce Analytic]

The Packaging Format Evolution

The shift from vials to prefilled formats represents another dimension of market transformation. Prefilled syringes offer multiple advantages: premeasured doses reduce errors, eliminate overfill waste, and minimize contamination risk [Fortune Business Insights]. This evolution from "vials to be filled" to "packages to be handled" fundamentally changes central-fill operational requirements.

Temperature-controlled logistics already consume 18% of total biopharma logistics spending [Biopharma Cold Chain Sourcebook 2020 via Mordor Intelligence], a figure expected to grow as biologics proliferate. The global vaccines market alone—valued at $90.28 billion in 2023—projects growth to $159.28 billion by 2032 [Fortune Business Insights].

Market Drivers Accelerating Change

Several forces converge to accelerate UoU adoption:

Self-Administration Trend: Patients increasingly manage chronic conditions at home, driving demand for user-friendly formats

Biosimilar Competition: As biologics lose patent protection, biosimilar entrants multiply packaging options

Personalized Medicine: Cell and gene therapies require patient-specific packaging and chain-of-custody documentation

Global Health Initiatives: Vaccine distribution programs demand stable, trackable packaging formats

Regulatory Evolution: Serialization requirements favor manufacturer-prepared packaging over pharmacy repackaging

The message from these market dynamics is clear: the fastest-growing, highest-value segments of the pharmaceutical market arrive in formats that traditional central-fill infrastructure struggles to handle efficiently.

Organizations that fail to adapt risk being overwhelmed by the very products driving industry growth.

III. The Infrastructure Gap: When Yesterday's Solutions Meet Tomorrow's Demands

THE MISMATCH BETWEEN DESIGN AND DEMAND

Most central-fill pharmacies operate with infrastructure designed for a fundamentally different product mix. These facilities excel at what they were built to do: count pills, fill bottles, and process high volumes of oral solid medications. Robotic dispensing cells, conveyor systems, and packaging lines optimize for uniform, predictable products that flow smoothly through automated systems.

Today's reality looks starkly different. A typical central-fill pharmacy now handles:

Pre-filled syringes in various sizes, requiring gentle handling to prevent breakage

Odd-shaped biologics packaging that won't fit standard storage cells

Temperature-sensitive products needing continuous cold-chain maintenance

Serialized items requiring individual scanning and verification

Combination products with multiple components to track and consolidate

The operational friction is immediately apparent. Products designed for patient convenience create pharmacy complexity. A pre-filled pen injector may be ideal for patient self-administration, but its irregular shape, temperature requirements, and serialization needs disrupt traditional workflows.

Quantifying Operational Inefficiencies

The costs of this infrastructure mismatch manifest in multiple ways:

MANUAL HANDLING PROLIFERATION.

Items that cannot fit automated systems default to manual processing. Pharmacy technicians hand-pick products from refrigerators, manually scan serialization codes, and individually package items. Labor costs for these products can be 3-5 times higher than automated alternatives.

TEMPERATURE EXCURSION RISKS.

Without integrated cold-chain automation, temperature-sensitive products face repeated handling. Each touch point—receiving, storage, picking, packing—creates excursion risk. Industry data shows 25% of vaccines arrive degraded due to temperature failures [Cargosense via Sensire], while biopharma loses $35 billion annually to cold-chain breaks [IQVIA Institute via Sensire].

SPACE UTILIZATION CHALLENGES.

Traditional racking and storage systems assume uniform packaging. Biologics and specialty medications often require 2-3 times the space per unit due to irregular shapes and temperature control equipment. Facilities designed for maximum density struggle to accommodate these lower-density, higher-value items efficiently.

SERIALIZATION BOTTLENECKS.

DSCSA requirements mandate tracking at the individual package level [FDA DSCSA Overview]. Manual serialization verification for thousands of daily items creates significant throughput limitations. What took seconds for lot-tracked bottles now requires individual scanning, verification, and documentation.

Technology Gaps in Current Systems

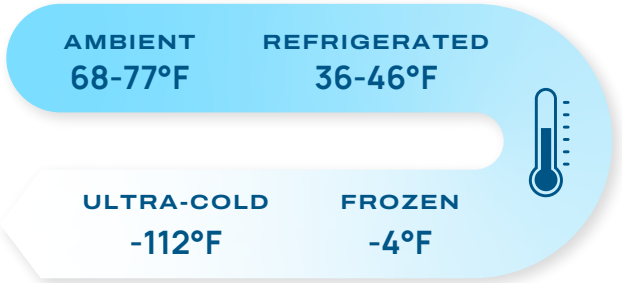
Traditional central-fill technology exhibits several critical gaps when handling UoU medications:

Fixed Storage Configurations: Robotic cells and carousels designed for uniform vial sizes cannot accommodate variable packaging

Limited Temperature Zones: Most facilities have binary options—ambient or refrigerated—missing the -20°C and -80°C requirements of newer biologics

Sequential Processing: Systems optimized for batch processing struggle with mixed product types requiring different handling protocols

THE COLD CHAIN CHALLENGE



Inadequate Data Integration: Serialization data often lives separately from inventory and order management systems

Inflexible Conveyance: Fixed conveyor widths and heights cannot accommodate the full range of package sizes

The Hidden Costs of Workarounds

Organizations respond to these gaps with manual workarounds that seem reasonable in isolation but compound into significant operational drag:

Dedicated staff assigned solely to specialty product handling

Multiple handling steps as products move between automated and manual zones

Excess inventory to buffer against temperature excursion losses

Redundant quality checks to catch errors from manual processes

Extended processing times that delay order fulfillment

One large health system reported that specialty medications requiring manual handling consumed 40% of pharmacy labor while representing only 8% of prescription volume. **The math is unsustainable as UoU volumes grow.**

Compliance Risks Multiply

Beyond operational inefficiencies, infrastructure gaps create compliance exposure. DSCSA requirements include [FDA DSCSA Overview]:

- Product verification at the package level
- Serialized data exchange with trading partners
- Suspect product quarantine and investigation
- Complete transaction documentation for every product movement

Manual processes struggle to maintain this documentation rigor at scale. A single missed scan or data entry error can trigger compliance failures. As enforcement intensifies, the risks of maintaining manual workarounds grow.

The infrastructure gap is not merely an operational inconvenience—it represents a fundamental mismatch between pharmacy capabilities and market requirements. As UoU volumes double over the next five years, this gap will widen unless addressed through purposeful infrastructure modernization.

IV. The Strategic Imperative: Why Incremental Solutions Fall Short

The True Cost of Delay

When faced with growing UoU volumes, many organizations default to incremental responses: hire more staff and implement partial automation for specific products.

While these measures provide temporary relief, they fail to address the fundamental mismatch between infrastructure and demand. Worse, they often increase complexity and cost without solving core issues.

Labor:	**3-5x**	Labor: 3-5x higher for manual processing
Product loss:	**$35B**	Product loss: $35 billion annually to temperature excursions
Vaccines degraded:	**25%**	25% of vaccines arrive degraded
Waste:	**30%**	30% of pharmaceutical waste from logistics issues
Extra FTEs:	**10**	10 additional FTEs needed for 3,000 UoU items daily = $725,000 annual cost

Consider the total cost implications of maintaining status quo operations:

LABOR COST ESCALATION.

Manual handling of UoU products typically requires 3-5 times the labor compared to automated processing. With pharmacy technician wages rising and persistent workforce shortages, the economics become untenable. A facility processing 3,000 UoU items daily typically requires 10 additional full-time equivalents (FTEs) compared to automated alternatives—an annual cost of about $725,000 in wages alone.

PRODUCT LOSS AND WASTE.

Temperature excursions cost the industry $35 billion annually [IQVIA Institute via Sensire]. For a mid-sized central-fill operation handling $500 million in cold-chain products annually, even a 2% loss rate represents $10 million in destroyed inventory. Add the cost of rush replacements, patient disruption, and reputation damage, and the true impact multiplies.

COMPLIANCE PENALTIES AND REMEDIATION.

DSCSA violations can trigger significant penalties, product recalls, and suspension of operations [FDA DSCSA Overview]. Manual serialization processes increase error rates exponentially. One mishandled serialization event affecting thousands of packages could result in millions in direct costs and immeasurable reputation damage.

Competitive Dynamics and Market Position

The window for competitive advantage through infrastructure modernization remains open—but not indefinitely. **Early movers capture multiple benefits:**

Preferred Partner Status:
Manufacturers seek distribution partners capable of handling their full product portfolio efficiently

Volume Aggregation:
Superior capabilities attract volume from competitors struggling with manual processes

Innovation Platform:
Modern infrastructure enables new services like patient-specific packaging and direct-to-patient delivery

Talent Attraction:
Automated facilities attract scarce pharmacy talent seeking technology-enabled environments

Margin Protection:
Efficient operations maintain profitability despite pricing pressures

Conversely, organizations that delay modernization face compounding disadvantages. As competitors automate, the relative cost disadvantage grows. Manual operations struggle to match the accuracy, speed, and reliability of automated alternatives. Market share erodes as manufacturers and patients gravitate toward more capable providers.

Risk Mitigation Through Transformation

Beyond opportunity capture, infrastructure modernization mitigates multiple risks:

1. FINANCIAL RISK.

Predictable automation costs replace variable labor expenses. Reduced product loss and improved inventory turns free working capital. Higher throughput from the same footprint improves return on facilities investment.

2. REGULATORY RISK.

Purpose-built serialization and verification systems ensure DSCSA compliance. Automated temperature monitoring and documentation exceed regulatory requirements. Digital workflows provide the traceability regulators demand.

3. OPERATIONAL RISK.

Automated systems reduce human error, ensure consistent handling protocols, and provide real-time monitoring. Digital documentation creates audit trails that manual processes cannot match.

4. STRATEGIC RISK.

Flexible, modular systems adapt to changing product mixes and volumes. Future-proofed infrastructure accommodates emerging therapies and packaging formats. Scalable platforms grow with business needs rather than constraining them.

The Innovation Imperative

Perhaps most critically, modern infrastructure creates a platform for innovation. Organizations with advanced automation capabilities can:

- Offer manufacturer-specific packaging and labeling services
- Provide real-time inventory visibility and demand sensing
- Enable patient-specific dosing and combination packaging
- Support clinical trial distribution with precise chain-of-custody tracking
- Integrate with digital health platforms for adherence monitoring

These value-added services differentiate beyond basic fulfillment, creating competitive moats that manual operations cannot replicate.

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Future-Proofing Considerations

While thermostable vaccine formulations may eventually reduce cold-chain dependence, experts project this transition will take 10+ years for widespread adoption [Stablepharma], [IQVIA]. In the interim, cold-chain requirements will intensify as biologics proliferate.

Similarly, continuous manufacturing may reduce some packaging complexity, but adoption remains limited to select facilities [Amgen, Sanofi via Pharmaceutical Technology]. The predominant model of manufacturer-prepared UoU packaging will persist through 2030 and beyond.

The strategic imperative is clear: incremental solutions cannot address the fundamental transformation in pharmaceutical distribution. Organizations must choose between comprehensive infrastructure modernization and accepting permanent competitive disadvantage. The cost of delay compounds daily, while the window for capturing first-mover advantages narrows. Strategic action is not just advisable—it's essential for long-term viability.

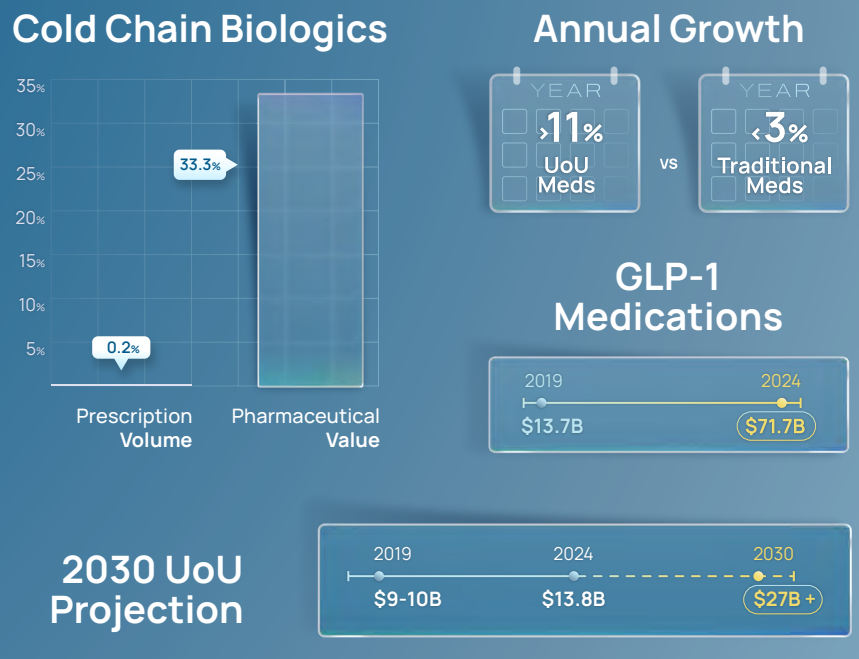
VII. Conclusion: Capturing First-Mover Advantage

THE TRANSFORMATION IMPERATIVE

The evidence is overwhelming: pharmaceutical distribution is undergoing its most significant transformation in decades.

Unit-of-use medications—growing at 11-12% annually versus less than 3% for traditional prescriptions—represent both the industry's future and its most pressing operational challenge. Central-fill pharmacies designed for counting pills now face an avalanche of pre-packaged, temperature-sensitive, serialized products that their infrastructure cannot efficiently handle.

STATISTICAL WRAP-UP



The numbers tell a stark story. Cold-chain biologics represent just 0.2% of prescription volume but command nearly one-third of pharmaceutical value. GLP-1 medications alone grew 423% in five years, from $13.7 billion to $71.7 billion. By 2030, analysts project the UoU market will double again, exceeding $27 billion in North America alone. Organizations clinging to traditional infrastructure face an existential choice: transform or become obsolete.

THE WINDOW OF OPPORTUNITY

Despite these pressures, a window of opportunity remains open for forward-thinking organizations. The complexity of transformation has delayed widespread adoption of next-generation automation, creating temporary competitive advantage for early movers. Organizations that act decisively can:

Capture Volume: As manufacturers seek capable distribution partners, those with proven UoU automation attract disproportionate volume

Command Premiums: Superior service levels for high-value products justify premium pricing

Reduce Costs: Automated operations achieve 50%+ labor savings while improving accuracy to 99.99%

Ensure Compliance: Purpose-built serialization and cold-chain systems exceed regulatory requirements

Build Moats: Advanced capabilities create switching costs that protect market position

THE COST OF INACTION

The infrastructure gap widens daily. Each month of delay means processing more UoU products through systems not designed for them, creating inefficiencies that compound over time. The operational drag becomes organizational quicksand—the more you struggle with workarounds, the deeper you sink.

The unit-of-use era has arrived, offering clear challenges and valuable opportunities for central fill pharmacy operators who respond strategically. The pharmacy leaders who will thrive in 2030 are making infrastructure decisions today. They recognize that engineering next-generation central fill is not about automation for its own sake, but about building future-proof capabilities that serve patients, support innovation, and create sustainable competitive advantage.

Next Steps

CONDUCT A UoU READINESS ASSESSMENT:
Evaluate current capabilities against future requirements

DEVELOP A STRATEGIC ROADMAP:
Create a phased plan balancing risk and opportunity

ENGAGE TECHNOLOGY PARTNERS:
Identify vendors aligned with your transformation vision

BUILD THE BUSINESS CASE:
Quantify both costs and strategic value

MOBILIZE LEADERSHIP:
Ensure organizational commitment to transformation

CAPSAHEALTHCARE

The Capsa team can help your organization with every step of the UoU transformation journey.

Reach out to schedule a consultation with our pharmacy automation experts.

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