The Digital Condition

How AEGIS by Mahalo Is Redefining Safe Access in the ACNU Era

From regulation to revolution — how intelligent software is redefining trust, access, and innovation in pharmaceutical compliance and consumer safety.

Mahalo Health | AEGIS Platform

Download the ACNU 2025 Playbook

Executive Foreword

> *"AEGIS embodies a new kind of regulatory intelligence — one that transforms compliance into confidence."*

The pharmaceutical industry stands at an unprecedented inflection point. For decades, the pathway from prescription to over-the-counter availability has been fraught with complexity, uncertainty, and significant barriers to innovation. The FDA's Alternative to Actual Use of an Rx-to-OTC Switch (ACNU) rule represents more than a regulatory update — it signals a fundamental reimagining of how we balance consumer access with safety imperatives.

At Mahalo Health, we recognised early that this transformation would require more than incremental improvements to existing systems. It would demand an entirely new approach to compliance infrastructure — one that treats regulatory requirements not as obstacles to overcome, but as opportunities to build trust, accelerate innovation, and deliver meaningful value to patients and pharmaceutical companies alike.

AEGIS was born from this vision: a platform that doesn't simply check boxes, but creates intelligent, adaptive systems that grow smarter with every interaction. As you explore this white paper, you'll discover how we've translated the promise of ACNU into practical, scalable solutions that serve as Software as a Medical Device (SaMD), meeting the highest standards of quality, safety, and regulatory compliance whilst opening new pathways to market.

The ACNU Inflection Point

The Rule That Changes Everything

The FDA's ACNU pathway represents a watershed moment in pharmaceutical regulation. For the first time, manufacturers can transition prescription medications to over-the-counter status by implementing robust "digital condition of use" programmes rather than relying solely on traditional label comprehension studies. This shift acknowledges what modern healthcare has long understood: technology can serve as an intelligent intermediary, ensuring safe self-selection and appropriate use through interactive, personalised guidance.

The implications extend far beyond regulatory compliance. ACNU creates opportunities for pharmaceutical companies to expand market reach, improve patient access, and generate valuable real-world evidence about product use in diverse populations. Yet these opportunities come with significant responsibilities — and technical challenges that traditional IT infrastructure simply wasn't designed to address.

AEGIS bridges this gap by providing purpose-built technology that meets regulatory requirements whilst delivering exceptional user experiences. Our platform transforms the ACNU pathway from a theoretical possibility into a practical reality, enabling companies to move confidently from prescription to consumer markets with full regulatory integrity.

1

Prescription Product

Existing Rx medication with established safety profile

2

Digital Condition

AEGIS-powered intelligent assessment and education

3

OTC Access

Safe consumer availability with ongoing monitoring

Key Market Statistics

- 90% of consumers actively seek self-care options for managing their health
- 45% of existing Rx brands are potentially eligible for the ACNU pathway
- $30 billion+ estimated market expansion opportunity by 2030
- 18-24 months typical timeline from pilot to commercial launch

The Digital Condition

At the heart of ACNU lies a deceptively simple concept: a "digital condition of use" that ensures consumers can safely self-select and use medications without professional supervision. Yet implementing this concept requires sophisticated technology that balances multiple competing priorities: safety rigour, user experience, regulatory compliance, and operational scalability.

Intelligent Safety

Dynamic risk assessment that adapts to individual circumstances, clinical guidelines, and emerging safety data in real-time.

Transparent Education

Clear, accessible information delivery that ensures genuine comprehension without overwhelming users with medical jargon.

Continuous Verification

Ongoing monitoring and validation that confirms appropriate use patterns and identifies safety signals before they become problems.

Human-Centred Design

Interfaces built for real people in real situations, acknowledging diverse literacy levels, languages, and accessibility needs.

> *"Every ACNU flow is a conversation — not a checklist. AEGIS creates experiences that feel intuitive and supportive whilst maintaining the rigorous safety standards that regulators demand."*

These four pillars work in concert to create what we call "intelligent compliance" — systems that don't simply enforce rules, but actively support optimal outcomes for all stakeholders. Users receive personalised guidance that helps them make informed decisions. Manufacturers gain valuable insights into real-world product use. Regulators access comprehensive data demonstrating safety and appropriate access patterns. It's a genuinely win-win-win scenario, made possible by thoughtful technology design.

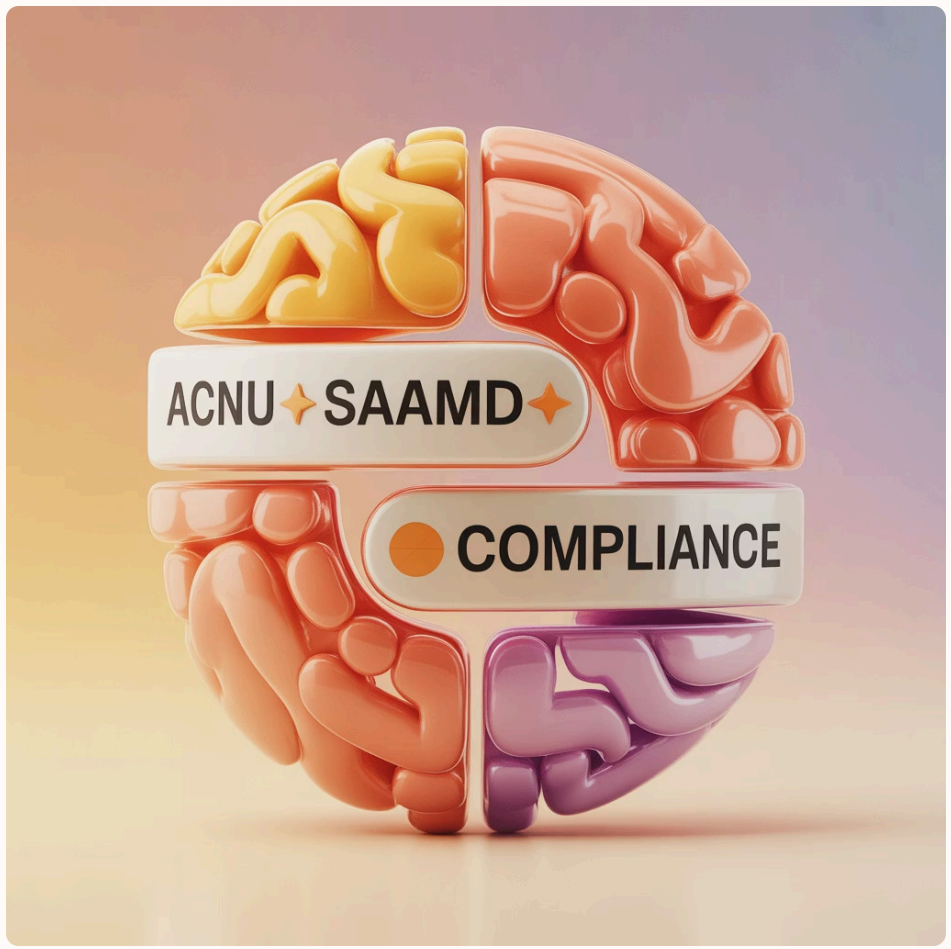
When ACNU Meets SaMD

AEGIS operates at the intersection of two critical regulatory frameworks: the FDA's ACNU pathway for Rx-to-OTC switches and the Software as a Medical Device (SaMD) requirements that govern healthcare software systems. This dual compliance creates unique challenges — and unique opportunities for excellence.

SaMD designation recognises that AEGIS doesn't merely present information; it makes clinically relevant assessments that influence healthcare decisions. This triggers requirements for software lifecycle management, risk analysis, quality systems, and comprehensive documentation that exceed typical commercial software standards. Rather than viewing these requirements as burdens, we've embraced them as foundations for building truly robust, trustworthy systems.

Our approach integrates multiple international standards and regulatory frameworks into a cohesive quality management system. IEC 62304 guides our software development lifecycle, ensuring systematic design, implementation, and maintenance processes. ISO 14971 informs our risk management methodology, helping us identify, analyse, and mitigate potential hazards. FDA's 21 CFR Part 11 governs our electronic records and signatures, ensuring data integrity and audit trail completeness.

This multi-layered compliance approach creates systems that are not just compliant but genuinely superior in reliability, security, and performance. When ACNU meets SaMD, the result is technology infrastructure that regulators trust, companies depend on, and users find delightfully easy to navigate.



Compliance Framework	Purpose
IEC 62304	Software lifecycle controls and development processes
ISO 14971	Risk management and hazard analysis
21 CFR Part 11	Electronic records and signatures integrity
ISO 13485	Quality management systems for medical devices
HIPAA/GDPR	Data privacy and security protections

Architecture of Trust

AEGIS is built on a five-tier architecture that separates concerns whilst maintaining seamless integration. Each layer serves specific purposes and can be independently validated, updated, and scaled without compromising system integrity.

Experience Layer

Responsive interfaces optimised for mobile, tablet, and desktop. Supports 12+ languages with culturally appropriate content adaptation.

Logic Layer

Clinical decision support algorithms that interpret user responses, assess contraindications, and personalise educational content.

Compliance Layer

Audit trails, electronic signatures, and comprehensive logging that meets regulatory requirements for record retention and data integrity.

Intelligence Layer

Analytics engine that identifies patterns, generates insights, and flags potential safety signals for proactive investigation.

Integration Layer

Secure APIs connecting to pharmacy systems, electronic health records, adverse event reporting, and regulatory submission platforms.

This architecture enables AEGIS to serve as both a consumer-facing application and an enterprise-grade compliance system. Users experience fast, intuitive interfaces that never hint at the complexity beneath. Meanwhile, pharmaceutical companies and regulators access comprehensive dashboards showing real-time data about usage patterns, safety metrics, and system performance.

10

Years

Minimum record retention with redundant backup systems

99.98%

Uptime

System availability across all infrastructure

SOC 2 Type II Certified: AEGIS has completed independent audits confirming our security, availability, processing integrity, confidentiality, and privacy controls meet the highest industry standards.

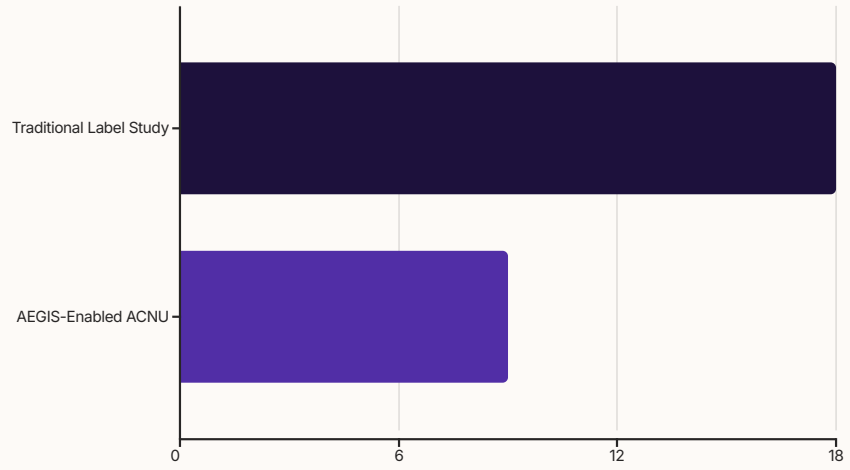
From Gatekeeping to Growth

Traditional Rx-to-OTC transitions have been characterised by lengthy timelines, significant uncertainty, and substantial upfront investment with no guarantee of regulatory approval. Label comprehension studies alone can consume 12-18 months and cost millions, with results that sometimes fail to demonstrate adequate consumer understanding, forcing companies back to the drawing board.

ACNU fundamentally changes this calculus by allowing digital conditions of use to replace or supplement traditional studies. However, this pathway's promise can only be realised with technology infrastructure capable of meeting rigorous regulatory standards whilst remaining practical to implement and scale.

AEGIS transforms the economics and timelines of Rx-to-OTC transitions by providing pre-validated technology that dramatically reduces time-to-market. Our modular approach allows rapid customisation for specific products whilst maintaining regulatory compliance. Companies can launch pilot programmes in months rather than years, gathering real-world evidence that supports regulatory submissions and informs commercial strategy.

More fundamentally, AEGIS shifts the compliance centre of gravity from cost to value creation. The data generated through AEGIS implementations provides actionable insights about consumer behaviour, unmet needs, and opportunities for product innovation. What was once a pure regulatory expense becomes an investment in market intelligence and competitive advantage.



50% reduction in time-to-market through pre-validated technology and streamlined regulatory pathways.

> "AEGIS turns the cost centre of compliance into a growth engine, generating valuable data whilst accelerating access to expanded markets."

Case Insight: The Cardio Pilot

Cardiovascular Medication ACNU Pilot Programme

Overview

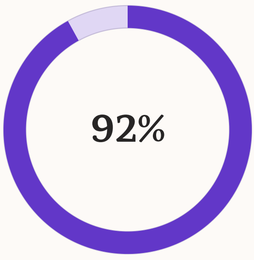
A leading pharmaceutical manufacturer partnered with Mahalo to pilot AEGIS for a cardiovascular medication transitioning from prescription to OTC status. The pilot spanned six months across three diverse metropolitan areas, engaging over 5,000 consumers through retail pharmacy partners.

The AEGIS implementation featured a tablet-based assessment tool deployed at pharmacy consultation counters. Consumers completed a guided self-assessment covering medical history, current medications, symptoms, and understanding of proper product use. Based on responses, AEGIS provided personalised recommendations: proceed with purchase and tailored usage guidance, consult with pharmacist for clarification, or recommendation to seek physician consultation.

Implementation Approach

- Custom clinical decision logic developed collaboratively with medical affairs team
- Integration with pharmacy point-of-sale systems for seamless checkout
- Real-time monitoring dashboard for safety signal detection
- Automated adverse event reporting workflows

Results

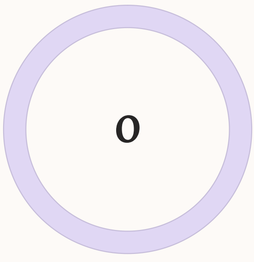


Correct Self-Selection

Consumers appropriately identified suitability

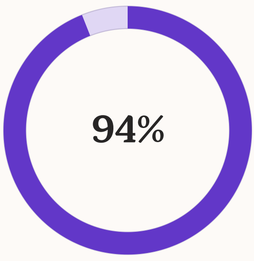
Months Saved

Accelerated development timeline versus traditional approach



Serious AEs

Zero serious adverse events reported during pilot



User Satisfaction

Would recommend experience to others

> **Medical Director, Pilot Sponsor:** *"AEGIS gave us confidence that consumers could safely self-select whilst providing the comprehensive data our regulatory team needed. The platform exceeded our expectations for both user experience and compliance documentation."*

Perhaps most importantly, the pilot generated a wealth of real-world evidence that informed both the regulatory submission and commercial launch strategy. Analytics revealed unexpected usage patterns, identified opportunities for enhanced patient education, and validated the safety profile in a diverse patient population — insights that would have been impossible to obtain through traditional label comprehension studies alone.

Designing for Trust

Trust isn't a feature that can be bolted onto a platform as an afterthought. It must be woven into every design decision, from information architecture to visual hierarchy to interaction patterns. AEGIS embodies trust through three interconnected design principles that inform everything we build.

Accessibility First

Healthcare information should be universally accessible regardless of literacy level, language, disability status, or technological sophistication. AEGIS meets WCAG 2.1 AA standards and supports screen readers, keyboard navigation, and adjustable text sizing. Content is written at appropriate reading levels with medical terminology explained in plain language.

Radical Transparency

Users deserve to understand what data is collected, how it's used, and why certain recommendations are made. AEGIS provides clear explanations for every assessment outcome, allows users to review and correct their responses, and explains the clinical reasoning behind recommendations in accessible terms.

Privacy by Design

Sensitive health information requires the highest levels of protection. AEGIS implements end-to-end encryption, minimises data collection to only what's clinically necessary, provides granular privacy controls, and supports user data export and deletion in compliance with GDPR and CCPA requirements.

The AEGIS Monitoring Loop

Trust is maintained through continuous vigilance. Our closed-loop monitoring system ensures ongoing safety and quality:

User Interaction

Consumer completes assessment and receives guidance

Platform Analysis

Automated systems analyse patterns and flag anomalies

Safety Reporting

Adverse events and concerns escalated to appropriate parties

Regulatory Review

Agencies access comprehensive compliance data

Continuous Improvement

Insights drive platform enhancements and updates

The Future: Adaptive Regulation

The ACNU pathway represents just the beginning of a broader transformation in how regulation approaches pharmaceutical access and safety. As digital health technologies mature and regulators gain confidence in their capabilities, we anticipate a shift toward increasingly adaptive, data-driven regulatory frameworks.

AEGIS is being designed with this future in mind. Our platform architecture supports capabilities that extend far beyond current ACNU requirements, positioning our partners to take advantage of emerging regulatory pathways and technologies as they become available.

Intelligent Systems on the Horizon

Machine learning algorithms will enable AEGIS to continuously refine risk assessment models based on real-world outcomes data. Rather than static clinical decision trees, the platform will employ adaptive logic that becomes more accurate and personalised over time, learning from millions of consumer interactions whilst maintaining explainability and regulatory oversight.

Cross-agency data sharing will enable more comprehensive safety monitoring and faster identification of emerging risks. AEGIS is building integration capabilities that allow secure, privacy-preserving data exchange between manufacturers, regulators, healthcare providers, and research institutions — creating a true pharmacovigilance network.

2025 — Adaptive Logic

Machine learning-enhanced risk assessment algorithms deployed in production environments

1

2026 — Cross-Agency Templates

Standardised ACNU implementation frameworks adopted across FDA centres and international regulators

2

2027 — Dynamic Labelling

Real-time updates to product information based on emerging safety data and usage patterns

3

2028+ — Predictive Compliance

AI systems anticipate regulatory questions and proactively generate supporting evidence

4

> *"This is not the end of regulation — it's the beginning of intelligent regulation. Systems that protect public health not through rigid gatekeeping, but through adaptive, evidence-based oversight that evolves as quickly as the science itself."*

The future of pharmaceutical regulation will be characterised by continuous learning, rapid adaptation, and unprecedented transparency. AEGIS is building the infrastructure to make this future possible, transforming compliance from a periodic hurdle into an ongoing conversation between all stakeholders in the healthcare ecosystem.

Redefine Safe Access

Build the Future with AEGIS

The pharmaceutical industry stands at a crossroads. The ACNU pathway opens unprecedented opportunities for expanding access, serving patients more effectively, and generating valuable real-world evidence. Yet realising these opportunities requires more than regulatory permission — it demands technology infrastructure capable of meeting rigorous safety and compliance standards whilst delivering exceptional user experiences.

AEGIS provides that infrastructure. Our platform transforms abstract regulatory requirements into concrete, deployable systems that work reliably at scale. We've done the difficult work of integrating multiple compliance frameworks, building robust quality management systems, and creating interfaces that real people find intuitive and trustworthy.

For Pharmaceutical Manufacturers

Accelerate time-to-market for Rx-to-OTC transitions, reduce development costs, and generate competitive intelligence through real-world evidence collection.

For Healthcare Providers

Support informed patient self-care decisions with confidence, knowing comprehensive safety assessments guide every recommendation.

For Consumers

Access effective treatments more conveniently whilst receiving personalised guidance that ensures safe, appropriate use.

Partner with Mahalo Health

Whether you're planning your first ACNU submission or seeking to optimise existing Rx-to-OTC programmes, Mahalo's team brings deep expertise in regulatory affairs, clinical decision support, and healthcare technology implementation. We don't just provide software — we partner with you to design, validate, and launch compliant digital condition of use programmes that achieve your strategic objectives.

Book a Strategy Call | Download Platform Overview PDF | Contact Mahalo

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Mahalo Health | Building intelligent compliance infrastructure for the future of pharmaceutical access

> This white paper is provided for informational purposes only and does not constitute medical, legal, or regulatory advice. Companies considering ACNU pathways should consult with qualified regulatory professionals regarding their specific circumstances. AEGIS is a Software as a Medical Device subject to regulatory oversight.

Content Strategy & Audience Targeting

The AEGIS white paper serves multiple stakeholder groups within the pharmaceutical industry, each with distinct priorities, concerns, and decision-making criteria. Our content strategy addresses these diverse audiences through layered messaging that allows readers to engage at their appropriate level of technical depth.

Regulatory Affairs Teams

Primary concerns: Compliance documentation, audit trails, FDA submission requirements

Key messages: AEGIS meets all SaMD requirements including IEC 62304, ISO 14971, and 21 CFR Part 11. Comprehensive validation packages expedite regulatory submissions. Pre-validated platform reduces compliance burden.

Content focus: Technical architecture, quality systems, regulatory pathway details

Business Development Executives

Primary concerns: Market opportunity, competitive advantage, ROI timelines

Key messages: ACNU pathway enables expansion into $30B+ market opportunity. AEGIS reduces time-to-market by 50%. Real-world evidence generates strategic insights beyond compliance.

Content focus: Market analysis, case studies, business impact metrics

Medical Affairs Professionals

Primary concerns: Patient safety, clinical decision support accuracy, adverse event monitoring

Key messages: Rigorous clinical logic development process. Continuous safety monitoring with proactive signal detection. Patient-centred design ensures appropriate use.

Content focus: Clinical validation, safety architecture, monitoring systems

Content Progression Strategy

The white paper follows a deliberate narrative arc that builds credibility and demonstrates comprehensive understanding:

1. **Context Setting** — Establishes the ACNU opportunity and regulatory landscape
2. **Challenge Definition** — Articulates technical and compliance complexities
3. **Solution Introduction** — Presents AEGIS architecture and capabilities
4. **Evidence & Validation** — Demonstrates real-world results through case study
5. **Future Vision** — Positions ongoing innovation and partnership value

The Platform That Makes Safe Access the New Standard

AEGIS by Mahalo

ACNU

Purpose-built for FDA's Alternative to Actual Use pathway, with comprehensive understanding of regulatory requirements and documentation standards.

SaMD

Full Software as a Medical Device compliance including quality management systems, risk analysis, and validated development processes.

Compliance

Unified platform architecture that maintains regulatory integrity whilst delivering exceptional user experiences and strategic business value.

50%	5000+	92%	$30B
Faster to Market	**Consumers Served**	**Self-Selection Accuracy**	**Market Opportunity**
Compared to traditional Rx-to-OTC pathways	In validated pilot programmes	Demonstrated in real-world deployments	Unlocked through ACNU pathways

Ready to Transform Pharmaceutical Access?

Join leading pharmaceutical companies in pioneering the future of safe, accessible healthcare. AEGIS provides the technology infrastructure, regulatory expertise, and proven track record you need to confidently navigate the ACNU pathway.

Get Started Today

Schedule a consultation with our regulatory and technical experts to explore how AEGIS can accelerate your Rx-to-OTC strategy.

hello@mahalo.health

Schedule Demo

Scan to Schedule Your Strategy Session

Building the Future of Intelligent Compliance

The pharmaceutical industry stands at the threshold of a profound transformation. The convergence of digital health technologies, evolving regulatory frameworks, and shifting consumer expectations creates unprecedented opportunities for companies willing to embrace innovation whilst maintaining unwavering commitment to safety and compliance.

AEGIS represents more than a technology platform — it embodies a philosophy about how pharmaceutical companies can and should engage with regulation in the 21st century. Rather than viewing compliance as a barrier to overcome, we see it as a foundation upon which to build competitive advantage, generate strategic insights, and deliver genuine value to patients and healthcare systems.

Our Commitment to Excellence

Mahalo Health was founded on the principle that healthcare technology should elevate standards rather than compromise them. Every line of code, every user interface decision, every architectural choice reflects our dedication to creating systems that regulators trust, companies depend on, and patients find empowering.

We understand that pharmaceutical companies entrust us with their most valuable assets: their brands, their regulatory standing, and ultimately the health and safety of the patients they serve. This responsibility drives our relentless focus on quality, security, and continuous improvement.

Partnership Beyond Technology

Successful ACNU implementations require more than software — they demand deep regulatory expertise, clinical knowledge, user experience design capabilities, and strategic insight. Mahalo brings together professionals from pharmaceutical companies, regulatory agencies, clinical practice, and technology leadership to provide truly comprehensive support.

When you partner with Mahalo, you gain access to a team that understands both the technical complexities of SaMD development and the strategic nuances of pharmaceutical business. We become an extension of your team, invested in your success.

Proven Track Record

Real-world deployments demonstrating safety, efficacy, and regulatory acceptance across diverse therapeutic categories and patient populations.

Continuous Innovation

Ongoing platform development incorporating emerging regulatory requirements, advancing technologies, and evolving best practices.

Comprehensive Support

From strategy development through implementation, validation, submission, and post-market surveillance — we're with you at every stage.

Industry Leadership

Active participation in regulatory dialogue, standards development, and industry forums shaping the future of digital health compliance.

Join the AEGIS Community

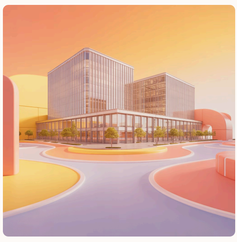
The most forward-thinking pharmaceutical companies are already leveraging AEGIS to accelerate their ACNU strategies and position themselves for the future of intelligent regulation. We invite you to explore how AEGIS can transform your approach to Rx-to-OTC transitions and broader digital health initiatives.


> **The future of pharmaceutical access is intelligent, adaptive, and human-centred.**
>
> *AEGIS makes that future available today.*

Connect With Us

Mahalo Health
Email: hello@mahalo.health
Web: https://aegis.mahalo.health

Follow our thought leadership on LinkedIn and Twitter for insights on ACNU implementation, digital health regulation, and pharmaceutical innovation.



About Mahalo Health: Mahalo Health develops intelligent compliance infrastructure for the pharmaceutical industry, specialising in Software as a Medical Device solutions that bridge regulatory requirements with exceptional user experiences. Our AEGIS platform enables pharmaceutical companies to implement FDA's ACNU pathway with confidence, accelerating access to effective treatments whilst maintaining the highest standards of safety and regulatory compliance.