MDDx.AI

Smarter Compliance. Safer Healthcare.

AI-Powered Solutions for MedTech Compliance and Innovation

Agenda

- Our Company Purpose – Problem and Solution
- Meet Our Team
- The Challenges and Our Solution
- Market Size
- Competitor Overview
- Product Development
- Revenue Forecast
- Sales and Go-to-Market Strategy
- Product Target Milestones & Metrics
- Closing Remarks

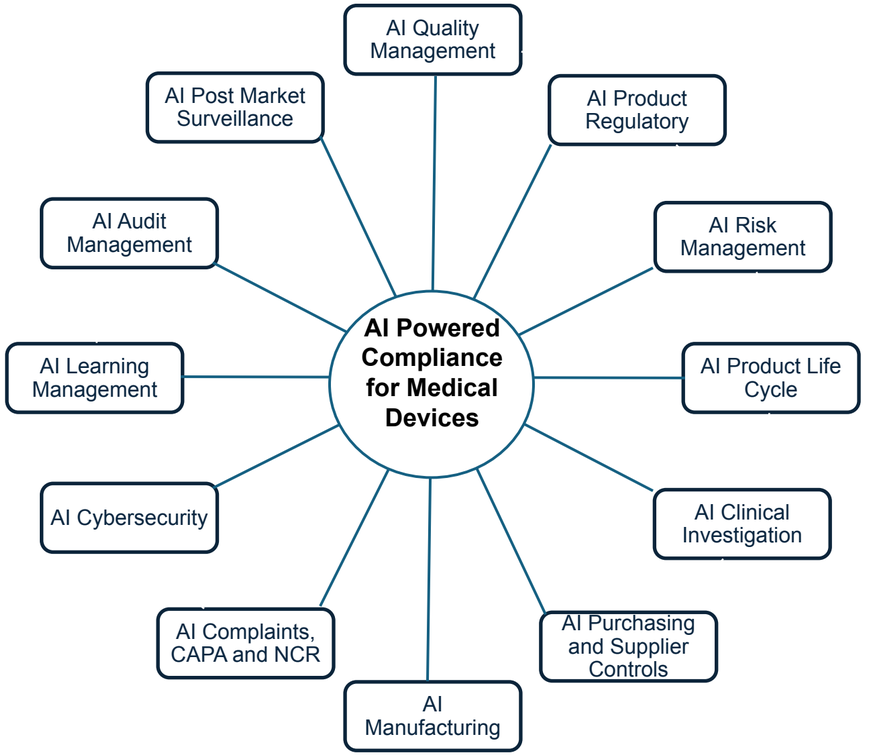
Our Company Purpose – Problem and Solution

The Problem:
Regulatory compliance software for biotechnology and MedTech companies is often outdated, and inefficient. Teams are forced to navigate complex file structures and disjointed systems to access the information they need—slowing innovation and increasing risk.

***Our Solution**:*

We offer an AI-powered compliance platform that unifies quality, regulatory, risk, and product processes—eliminating silos, reducing manual work, and making critical information easily accessible across the MedTech lifecycle.

***Mission**:*
We aim to empower MedTech innovators with AI-driven solutions that streamline compliance and accelerate development—setting the global benchmark for intelligent compliance and enabling safer, faster, and more accessible healthcare innovation worldwide.



Meet Our Team

Market Research

SBC Consulting

UC Berkeley Team – Market Research and Web Design

UC Berkeley Strategic Business Consulting Group.
User Insight Analysis
Web UI/UX Design
Competition Landscape
Key Differentiators
Market Segments

Product Development

Antrix Inc.

Investor, Business Models and Revenue Forecast

Antrix, Inc.
Initial Investor
Product Development,
Revenue Forecast
Go-to-Market Strategy
Product Target Milestones & Metrics

Marketing

Hemal Kurani

Marketing Specialist & Cofounder

Competitor Overview
Revenue Forecast
Clinical Laboratory Intern.
Patent Author/Inventor (12 Patents), Currently pursuing her Bachelor in Bioengineering + Business at UC Berkeley.

Bus. Development

Eveline Akkers

Business Development Consultant

Biotechnology and diagnostics expert with 17+ years in genomics and molecular diagnostics, driving global product launches, strategic market growth, and key partnerships.

Compliance

Bill Kurani

RA/QA/CA Compliance Guru & Founder

25+ years of experience in medical device regulated industry. Authored and received several regulatory approvals. Patent Author/Inventor, Books Author, Published Articles, UCSC Instructor, Prolific Speaker

The Challenges and Our Solution …1

The Challenges	Our Solution	Module Name
Setting up and maintaining a QMS involves regulatory complexity, cross-functional coordination, and continual updates.	Automated centralized QMS covering global standards with interfaces to regulatory databases and intelligence	AI Quality Management (Foundational)
Regulatory strategy, submissions, and filings are complex due to evolving global regulations and the need for precise, well-documented data.	Automates submissions, pre-subs, labeling and vigilance reporting for Recalls and MDRs with interfaces to regulatory databases to US FDA and EUDAMED	AI Product Regulatory
Risk analysis and management are challenging due to the need to address risks throughout the product lifecycle.	Automated risk analysis across product lifecycle with interfaces to design, development, manufacturing and post market surveillance	AI Risk Management
Product design, development, and lifecycle management are time-consuming due to complex regulations, evolving technology, detailed specifications, and cross-functional collaboration.	Automated medical device development from concept to commercialization which includes Design History File, Technical File and Design Controls with interfaces to GitHub, Atlassian, Jira etc.	AI Product Life Cycle
Clinical investigations face challenges including complex designs, regulatory hurdles, high costs, recruitment issues, and ensuring ethical compliance, data integrity, and diverse representation.	Automated clinical investigation comprising pre clinical, clinical and post clinical management. Auto generation of papers based on studies that can be sent to scientific journals for publications.	AI Clinical Investigation
Purchasing and supplier control challenges include ensuring supplier qualification, managing risks, audits, maintaining approved supplier list, monitoring and re-evaluations.	Automated Supplier Qualification, Approved Supplier List, Supplier Corrective Actions, Monitoring and Re-evaluations	AI Purchasing and Supplier Controls

The Challenges and Our Solution …2

The Challenges	Our Solution	Module Name
Manufacturing challenges include ensuring consistent product quality, validating processes, and managing production scaling, costs, supply chain disruptions, and infrastructure, equipment and personnel qualification.	Automated creation and maintenance of infrastructure, equipment and personnel qualification, Device Master Records (DMR), and Device History Records (DHR).	AI Manufacturing
Challenges with complaints, CAPA, and NCRs include timely investigations, root cause analysis, corrective actions, and ensuring documentation, regulatory compliance, and recurrence prevention.	Automated complaints, CAPA and NCR with interfaces to external systems such as Helpdesk, Zendesk, Jira etc.	AI Complaints, CAPA and NCR
Challenges with cybersecurity, SiMD, and SaMD include protecting patient data, ensuring software reliability, meeting regulatory requirements, and managing vulnerabilities, updates, and interoperability.	Automated SiMD/SaMD secure design, vulnerability tracking, and updates with interfaces to GitHub, Jira.	AI Cybersecurity
Challenges with job descriptions, roles and responsibilities, training, competency, maintaining training records, and verifying competencies for audits and compliance.	Automated job descriptions, roles and responsibilities, training, and competencies record maintenance with interfaces to Workday, ADP etc.	AI Learning Management
Audit management challenges include coordinating internal, FDA, Notified Body, customer, and supplier audits while ensuring readiness, compliance, and managing documentation, corrective actions, and schedules.	Automated Audit Management of Internal Audit, FDA Inspection, Notified Body, Customer Audit, and Supplier Audit.	AI Audit Management
Challenges with Post Market Clinical Follow-up and Post Market Surveillance reports include collecting reliable data, ensuring timely analysis for compliance, continuous monitoring, addressing safety signals, and updating documentation.	Automate Post Market Clinical Follow-up and Post Market Surveillance Reports with interfaces to regulatory databases	AI Post Market Surveillance

Market Size

Region	Market Size (2024)	Projected Market Size (2030-2032)	CAGR	Number of Manufacturers	Top Countries	Sources
United States	$256.2 billion	$360.1 billion (2030)	5.9% (2025-2030)	9,009 establishments (BLS), 972 businesses (IBISWorld) 6,500+ companies (AdvaMed)	United States	Grand View Research trade.gov BLS IBISWorld AdvaMed
Europe	€160 billion (~$151.7 billion)	$209.05 billion (2032)	4.09% (2024-2032)	33,000+ companies (95% SMEs)	Germany (26.4% share), France (14.4%), UK (10.1%)	medtecheurope.org Market Data Forecast Masson International
Global	$567 billion+	N/A	N/A	Not precisely available; industry valued at $567B+	North America accounts for 39% of market	Statista medtecheurope.org trade.gov

Competitor Overview

	Master Control	Greenlight Guru	Compliance Quest	Qualio	TrackWise	Veeva	Montrium
Description	Comprehensive QMS integrating quality processes to enhance compliance and operational efficiency.	Designed for medical device companies, aligning with FDA and ISO best practices for audit readiness.	AI-powered QMS on Salesforce, focused on lifecycle management and regulatory compliance.	Cloud-based QMS for small to mid-sized medical device firms, emphasizing ease of use and scalability.	Robust QMS for managing quality processes, including CAPA, audits, and compliance reporting.	Enterprise-wide cloud QMS with compliance, document control, and training management.	GxP-compliant QMS for life sciences, integrating document control, training, and compliance.
Limitations	Complex implementation and high costs for small businesses.	Limited customization options and high pricing for startups.	Heavy reliance on Salesforce ecosystem; costly for non-Salesforce users.	Lacks advanced AI automation; limited integration capabilities.	High maintenance and customization costs; complex UI.	Primarily for large enterprises; expensive for smaller companies.	Not as feature-rich as other QMS; limited AI-driven automation.
Revenue	$120 M	$31.6 M	$75 M	$22 M	$120 M*	$2.75 B	$15.6 M
No. of Customers	1000+	1100+	1000+	250+	700+	1432+	200+

MDDx.AI

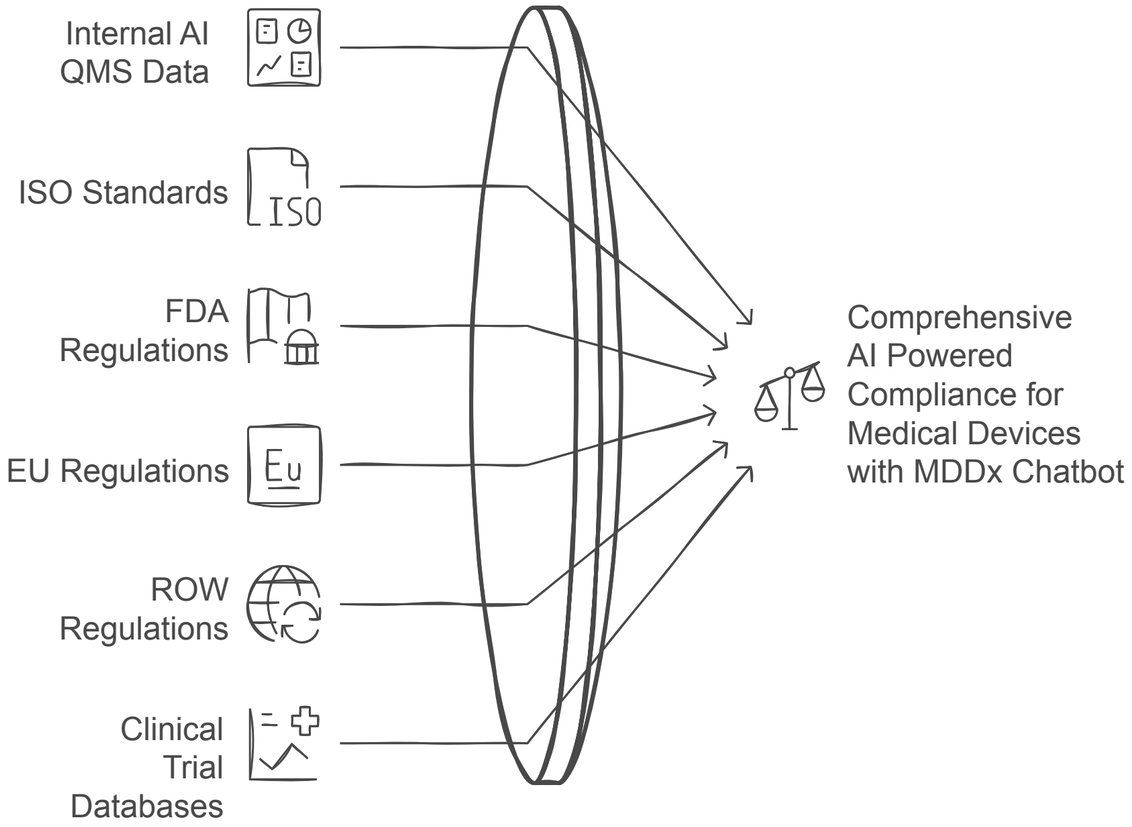
Our AI-powered governance platform automates medical device development reducing manual effort, cost and time to market while ensuring regulatory compliance. MDDx Chatbot with 3 machine learning models for Free, Small, Medium and Large Companies or Free, Silver, Gold, and Platinum. MDDX solutions results in **50% FTE Savings and 75% and Work Efficiency Improvement (WEI)**

MDDx Company Key Differentiation Compared to Competitors

Key Differentiator	MDDx	Competitors
Exclusive Compliance to 25+ AI-Specific ISO Standards	✅ Industry First	❌ Not Offered
Human-Centered & Ethical AI Design Compliance – AI QMS Interfaces similar to ChatGPT, Gemini, Grok, Deep Seek etc.	✅ Fully Integrated	❌ Not Considered
Modular, Scalable, and Customizable Architecture with interfaces to ERP, Workday, GitHub, Jira, Helpdesk, Zendesk etc.	✅ Fits Startups to Enterprises	❌ Rigid or Limited Scalability
Full AI Compliance Suite for Medical Device Lifecycle with interfaces to FDA, EU, ROW databases	✅ 12 Integrated AI Compliance Modules	❌ Fragmented Tools
ISO & Regulatory Compliance Automation	✅ Built-in Compliance Workflows	❌ Manual / Limited Automation
AI-First Approach to Quality, Risk & Lifecycle Management for Products and Clinical Trials	✅ Core to Platform	❌ Not AI-Driven
Coverage Across AI Governance, Cybersecurity, Ethics, and Data Integrity	✅ Comprehensive	❌ Partial or None
MDDx Chat Bot - FTE Savings and Work Efficiency Improvement (WEI)	✅ Comprehensive – 50% FTE – 75% WEI	❌ Partial or None
KPIs - Real-Time Insights & Predictive Analytics	✅ Embedded AI Dashboards	❌ Static Reporting
Global Regulatory Intelligence	✅ Continuously Updated	❌ Incomplete or Outdated

Product Development

Harmonizing Data for AI Based Medical Device Compliance



AI Architecture & Integration

1. **Scalable, Modular Architecture**: Designed with modular components (data ingestion, ML engines for free, small, medium and large companies, analytics, compliance layer) to support flexibility, scalability, and rapid adaptation to regulatory or business changes.

2. **Seamless System Integration**: Built to integrate with existing platforms and enterprise systems (Regulatory Databases US FDA, EU EUDAMED, ERP, LIMS, GitHub, Jira, Workday etc.) through secure APIs, ensuring smooth data flow and minimal disruption.

3. **Regulatory-Grade Data Management**: Enforces end-to-end data traceability, integrity, and audit readiness, aligned with compliance standards. Always Audit Ready.

4. **Augmented Intelligence**: Combines AI-powered insights using AI Chatbots with human validation to support decision-making in quality events like Complaints, CAPA, NCR, risk management for Recalls, MDR, Clinical Trials, Research Paper Publications and continuous improvement workflows.

Revenue Forecast

5 year - Revenue Forecast

Year	First Year License Fees	First Year Customization & Integration Fees	Annual Maintenance Fees	Annual User Charges	Totals
1	$ 362,500	$ 325,000	$ -	$ 795,000	$ 1,482,500
2	$ 1,262,500	$ 1,075,000	$ 70,000	$ 3,600,000	$ 6,007,500
3	$ 3,095,000	$ 2,900,000	$ 312,500	$ 10,020,000	$ 16,327,500
4	$ 6,612,500	$ 6,275,000	$ 911,500	$ 23,865,000	$ 37,664,000
5	$ 10,637,500	$ 9,325,000	$ 2,194,000	$ 76,410,000	$ 98,566,500

Input - Based on the following Customer Acquisition Forecast *excludes freemium

Company Size / AI Models	Year 1	Year 2	Year 3	Year 4	Year 5
Freemium	25	50	100	200	300
Small	5	15	54	115	145
Medium	2	6	15	36	50
Large	1	4	8	16	32
New Freemium only customers	25	50	100	200	300
New customers* excl. freemium	8	25	77	167	227
Total Nº Freemium only customers	25	75	175	375	675
Total Nº customers*	8	33	110	277	504

Note: If Pharmaceuticals, Biologics, Food and Cosmetics Manufacturers compliance is also included the revenue will be many fold

Input - Revenue forecasts based on the following average fee assumptions and average number of users

Company Size	Annual first year fee for all Modules	Avg one time license fee	Annual first year fee for customization & integration	Avg. first year customization and integration fee	Annual Maintenance Fee for all Modules – (20% of licensing fee)	Avg Annual Maintenance fee	Charges per user per month for all Modules	Avg charges per user per year for all Modules	Average number of users
Freemium	$0	$0	$0	$0	$0	$0	$0	$0	variable
Small (1–50 users)	$10,000 – $25,000	$17,500	$10,000 – $40,000	$25,000	$2000 - $5000	$3,500	$25 - $75	$600	25
Medium (51–200 users)	$25,000 – $75,000	$52,500	$25,000 – $75,000	$50,000	$5000 - $15,000	$10,000	$75 - $125	$1,200	125
Large (201+ users)	$75,000 – $250,000+	$175,000	$75,000 – $125,000+	$100,000	$15000 - $50,000+	$32,500	$125 - $275	$2,400	175

Sales & Go-to-Market Strategy

Customer Acquisition

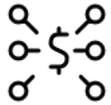
Targeted advertising and partnerships to reach decision makers

- **Targeted Advertising**: LinkedIn, Genome Web.
- **Account-Based Outreach**: Direct email campaigns and personalized engagement with Medical Devices and Medical Devices manufacturers.
- **Strategic Partnerships** with regulatory consultants, compliance firms, and industry associations for co-marketing and referrals.

Lead Generation & Value Offering

Freemium model and webinars to demonstrate value

- **Freemium Model:** Provide limited governance documentation to Medical Devices manufacturers to demonstrate platform value. Convert into small, medium, large paid customers.
- **Webinars & Thought Leadership**: Host industry webinars on compliance automation to drive inbound interest.
- **Industry Events & Conferences**: Exhibit at Medical Devices and regulatory science events for brand visibility.



Monetization & Revenue streams

Subscription and user fee-based models for revenue

- **Premium Subscription Model**: Charge manufacturing members for advanced governance tools, AI-powered regulatory insights, and automation features.
- **Tiered Pricing:** Offer Small (Silver), Medium (Gold), and (Large) Platinum plans based on company size and compliance needs.
- **Per-Use or Transaction-Based Fees:** Charge for specific regulatory strategy, submissions, MDR, compliance audits.

Scalability & Growth

International expansion and optimization for growth

- **International Expansion:** Adapt platform for EU Medical Devices, ISO compliance, and other global regulatory frameworks.
- **AI-Driven Optimization:** Enhance automation to improve efficiency and reduce manual compliance workload.
- **Referral & Affiliate Programs:** Incentivize satisfied customers and industry consultants to bring in new users.

Product Target Milestones & Metrics

31ST December 2025

AI Quality Management System

AI Product Regulatory Module

AI Product Life Cycle Module

AI Clinical Investigation Module

AI Complaints, CAPA and NCR Module

AI Post Market Surveillance Module

31ST July 2026

AI Risk Management Module

AI Cybersecurity Module

AI Purchasing & supplier Controls Module

AI Learning Management Module

AI Manufacturing Module

AI Audit Management Module

31ST December 2026

Product Enhancements based on Customer Feedback

Closing Remarks

“AI-driven compliance is transforming how medical devices, and also pharmaceuticals, biologics, food, and cosmetics manufacturers bring products to market — and MDDx.ai is positioned at the forefront. With a multi-billion-dollar market, accelerating regulatory complexity, early customer traction, and a scalable platform ready to capture global demand, now is the time to invest in a AI driven compliance leader.”

Thank you