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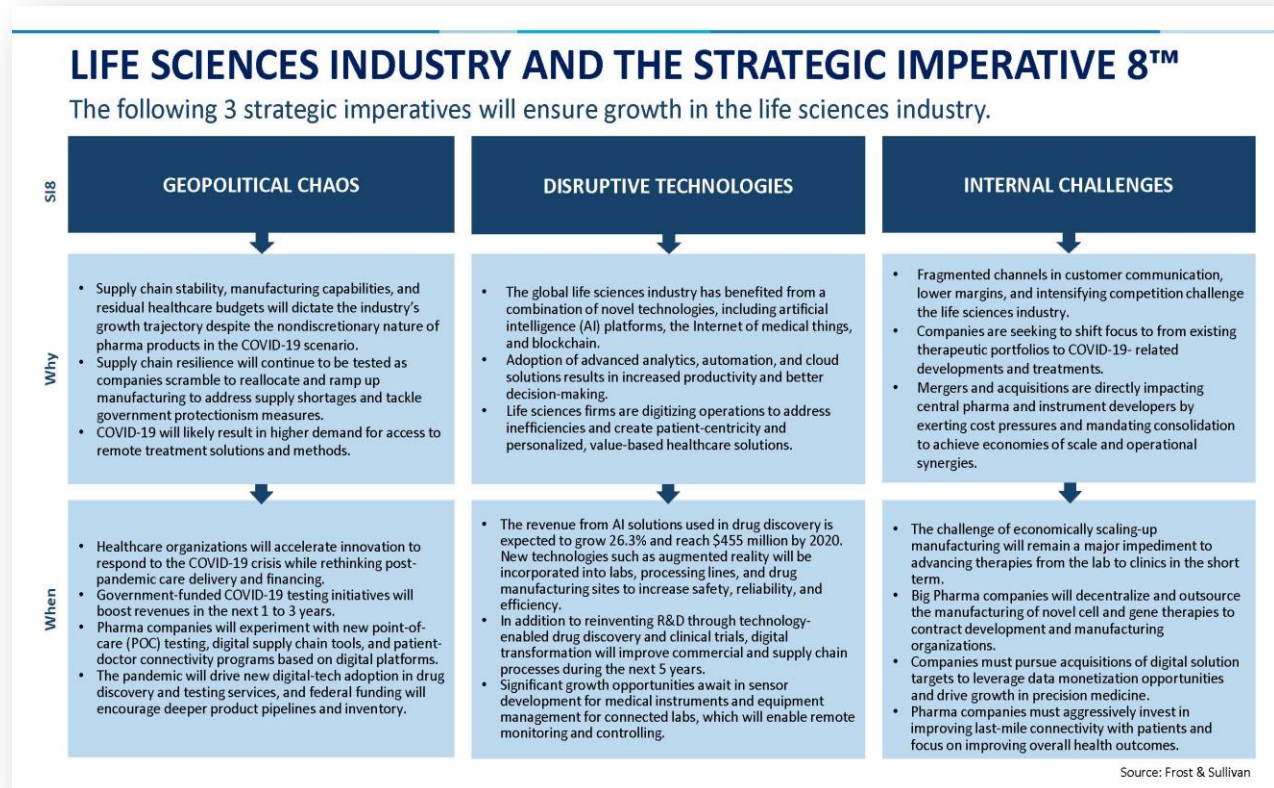## BEST PRACTICES

AWARDS

FROST & SULLIVAN

2020

BEST PRACTICES AWARD

aizon

2020 NORTH AMERICA ARTIFICIAL INTELLIGENCE FOR PRODUCTIVITY AND COMPLIANCE IN PHARMACEUTICALS ENABLING TECHNOLOGY LEADERSHIP AWARD

Strategic Imperatives

Frost & Sullivan identifies three key strategic imperatives that impact the life sciences industry: geopolitical chaos, disruptive technologies, and internal challenges. Every company that is competing in the life sciences space is obligated to address these imperatives proactively; failing to do so will almost certainly lead to stagnation or decline. Successful companies overcome the challenges posed by these imperatives and leverage them to drive innovation and growth. Frost & Sullivan's recognition of Aizon is a reflection of how well it is performing against the backdrop of these imperatives.

LIFE SCIENCES INDUSTRY AND THE STRATEGIC IMPERATIVE 8™

The following 3 strategic imperatives will ensure growth in the life sciences industry.

SI8	GEOPOLITICAL CHAOS	DISRUPTIVE TECHNOLOGIES	INTERNAL CHALLENGES
Why	• Supply chain stability, manufacturing capabilities, and residual healthcare budgets will dictate the industry's growth trajectory despite the nondiscretionary nature of pharma products in the COVID-19 scenario. • Supply chain resilience will continue to be tested as companies scramble to reallocate and ramp up manufacturing to address supply shortages and tackle government protectionism measures. • COVID-19 will likely result in higher demand for access to remote treatment solutions and methods.	• The global life sciences industry has benefited from a combination of novel technologies, including artificial intelligence (AI) platforms, the Internet of medical things, and blockchain. • Adoption of advanced analytics, automation, and cloud solutions results in increased productivity and better decision-making. • Life sciences firms are digitizing operations to address inefficiencies and create patient-centricity and personalized, value-based healthcare solutions.	• Fragmented channels in customer communication, lower margins, and intensifying competition challenge the life sciences industry. • Companies are seeking to shift focus to from existing therapeutic portfolios to COVID-19- related developments and treatments. • Mergers and acquisitions are directly impacting central pharma and instrument developers by exerting cost pressures and mandating consolidation to achieve economies of scale and operational synergies.
When	• Healthcare organizations will accelerate innovation to respond to the COVID-19 crisis while rethinking post-pandemic care delivery and financing. • Government-funded COVID-19 testing initiatives will boost revenues in the next 1 to 3 years. • Pharma companies will experiment with new point-of-care (POC) testing, digital supply chain tools, and patient-doctor connectivity programs based on digital platforms. • The pandemic will drive new digital-tech adoption in drug discovery and testing services, and federal funding will encourage deeper product pipelines and inventory.	• The revenue from AI solutions used in drug discovery is expected to grow 26.3% and reach $455 million by 2020. New technologies such as augmented reality will be incorporated into labs, processing lines, and drug manufacturing sites to increase safety, reliability, and efficiency. • In addition to reinventing R&D through technology-enabled drug discovery and clinical trials, digital transformation will improve commercial and supply chain processes during the next 5 years. • Significant growth opportunities await in sensor development for medical instruments and equipment management for connected labs, which will enable remote monitoring and controlling.	• The challenge of economically scaling-up manufacturing will remain a major impediment to advancing therapies from the lab to clinics in the short term. • Big Pharma companies will decentralize and outsource the manufacturing of novel cell and gene therapies to contract development and manufacturing organizations. • Companies must pursue acquisitions of digital solution targets to leverage data monetization opportunities and drive growth in precision medicine. • Pharma companies must aggressively invest in improving last-mile connectivity with patients and focus on improving overall health outcomes.

Source: Frost & Sullivan

Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each award category before determining the final award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. Aizon excels in many of the criteria in the AI for productivity and compliance in the pharmaceutical space.

AWARD CRITERIA

Technology Leverage	Customer Impact
Commitment to Innovation	Price/Performance Value
Commitment to Creativity	Customer Purchase Experience
Stage Gate Efficiency	Customer Ownership Experience
Commercialization Success	Customer Service Experience
Application Diversity	Brand Equity

Founded in 2014 and headquartered in San Francisco, US with a European office in Barcelona, Spain, Aizon provides software solutions leveraging the Internet of Things (IoT), cloud, advanced analytics, artificial intelligence (AI), and Pharma 4.0 technologies. The company harnesses manufacturing Big Data from unlimited sources to optimize processes, improve operational efficiency, address quality issues, and enhance regulatory compliance for pharmaceutical (pharma) and biotechnology (biotech) manufacturing operations. Aizon enables pharma and biotech to incorporate AI into their processes to meet market demand, enable real-time decision making, mitigate risk, and improve profitability. Earlier known as Bigfinite, the company recently rechristened to Aizon as part of its AI-focused branding strategy is leveraging its lead in providing GxP compliance-based solution to highly regulated industries on a global basis.

Proprietary Digital Platform Enabling to Meet Compliance and Improve Pharmaceutical Manufacturing Efficiency

Digital connectivity, exponential real-world data growth, and innovative technologies transform the life science industry and enable developing next-generation pharmaceuticals, challenged by complex and costly manufacturing processes, growing regulatory scrutiny, policy changes, and supply chain bottlenecks. Besides, manually managing the spread of complex data, deriving insights, and translating the information into critical clinical and business decisions are significant bottlenecks.[1] Additionally, as the shift towards Pharma 4.0 takes place, GxP compliance, data integrity, and regulations are vital in creating a digital strategy.

Aizon addresses these pharmaceutical manufacturing challenges through its disruptive solutions, serving its customers through the challenges and complexities of capturing data in this highly regulated industry. The company helps simplify their journey towards smart and continuous manufacturing. With three decades of pharma and information technology (IT) experience, Aizon aims to improve pharma manufacturing using Big Data, AI, and cloud technologies.

The company started developing their GxP AI platform, a software-as-a-service (SaaS) AI/ML-based analytics platform, to access various structured and unstructured manufacturing data from disparate sources.

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[1] *Artificial Intelligence Market—Key Application Areas for Growth in Healthcare IT, Forecast to 2022* (Frost & Sullivan, August 2018)

The platform analyzes the information to provide actionable insights, meeting regulatory compliance, and optimizing resources and processes to enhance efficiency and quality across all manufacturing sites. Aizon collaborated with the Amazon Web Services (AWS) healthcare and life-sciences team to build its innovative platform. It meets pharmaceutical manufacturers' extensive regulatory needs to ensure process compliance across the value chain, including laboratory (GLP), clinical (GCP), and manufacturing (GMP). The platform can store and investigate astronomical amounts of pharmaceutical-manufacturing and quality data from diverse sources such as laboratory information management systems, manufacturing execution systems, environmental control systems, historians, automated process equipment, and other manufacturing equipment connected to the cloud through AWS IoT and stored in a controlled data lake (Amazon Simple Storage Service). The platform conducts high-scale data analysis of the pharmaceutical-manufacturing Big Data, leveraging a secured AWS-powered highly technical architecture in a 24/7 environment, making audits easier. The company partners with international regulatory bodies to continuously train and qualify the algorithms as per requirements.

With seven patents to date, Aizon continues to propel innovation; the company developed an Innovation Laboratory that centers on thought leadership and advanced AI with a dual purpose of bringing advanced AI capabilities to market and helping drive the transformation of the industries they serve. The team focuses on prototyping and studying the market, leveraging customer and partner feedback, and creating a product-market fit to build on the platform quickly.

"The platform's robust capabilities provide true value to its customers, as demonstrated through several commercial collaborations and a proven track record in lowering costs and increasing manufacturing excellence while meeting compliance goals."

- Supriya Lala Kundu, Best Practices Research Analyst

Aizon recently developed an AI consulting services organization comprised of data scientists, solution architects, and strategy consultants to help its customers build a blueprint for using best practices while deploying AI across the enterprise.

The company embarks on the mission to make pharma manufacturing customers realize the true potential of AI as a classical statistical tool that considers multiple inputs simultaneously to make forecasting and recommendations, identify patterns, establish classification, provide predictive alerting, and not solely predictive techniques.

Addressing Pharma Manufacturing Challenges through Several Applications, Saving Costs

The SaaS platform's primary use cases encompass predictive maintenance, predictive improved overall equipment effectiveness (OEE), golden batch, energy efficiency, root cause analysis, and relevant factors identification in batch yield optimization. With the astronomically rising cost of drug development and time-to-market, pharma companies evaluate next-generation strategies to decrease costs and improve manufacturing efficiency. In such a scenario, AI and machine learning (ML) can leverage disparate data, reduce inefficiency, and obtain real-world evidence for timely and cost-effective drug development.

By applying advanced analytical techniques such as AI, ML, and neural networks, the Aizon system conducts data analysis to predict real-time manufacturing issues and help pharma companies address them proactively. For example, an unexpected machine breakage affects production, challenges seamless treatment delivery to patients in need, and affects pharmaceutical companies' profit margins.

To that end, the system can leverage ML to design models for equipment's predictive maintenance, such as identifying and indicating when the manufacturing equipment might fail or require cleaning. Such predictions save production costs from untimely equipment obsolescence and manufacturing disruption and prevent resource wastage. Besides, early aberration detection (vibration, noise, and temperature) maximizes machine use and ensures consistent product quality.

The platform's robust capabilities provide true value to its customers, as demonstrated through several commercial collaborations and a proven track record in lowering costs and increasing manufacturing excellence while meeting compliance goals. For example, Aizon enabled a Europe-based global pharmaceutical client to meet its emission norms and prevent regulatory action such as huge fines. The client was paying penalties due to exceeding the prescribed emission norms, negatively impacting the environment, potentially leading to eventual site closure. The company implemented a solution to assemble 35 bioreactors in a complex drug-development "supersystem" and control volatile organic compounds' (VOCs) emission from reactors, enable VOCs treatment before environmental release, and control the cooling system to improve energy efficiency. Aizon's platform analyzed raw production data to design manufacturing processes recommendations for the site to meet the VOC-emission limits. The solution reduced the cooling system's electrical usage to 17% of earlier consumption, saving significant regulatory penalties.

Frost & Sullivan notes that such examples are a case in point to validate Aizon's role in maximizing compliance, lowering risk, and saving costs by enhancing manufacturing efficiency, enabling the pharmaceutical industry to channelize and optimize resources towards innovation.

Process Monitoring System Aiding Decision-support to Maintain Consistent Quality

A configurable and scalable platform, Aizon allows clients to redesign and configure the system per newly discovered relevant factors, perform root cause analysis, and develop new capabilities through built-in solution design. The AI-powered, GxP-qualified platform allows customers to design real-time solutions to enhance product quality. The system helps in critical decision support of manufacturers; it foresees low-performing batches and recommends process improvement strategies to enhance performance. The technology, therefore, enables reduced variability and improved productivity.

The yield prediction functionality in the early stages of a manufacturing (fermentation) procedure allows the experts and manufacturing teams to warrant high-quality results batch-by-batch and discover the techniques to improve the current best-performing batches. The Aizon platform's ability to control the drug manufacturing process establishes quality assurance, supports quicker and improved Process Performance Qualification, and enables the manufacturing team to sustain stage 3 of the Food and Drug Administration's (FDA's) Validation Process Guidelines.

Positions as an Industry Accelerator by Creating a Partnership-based Ecosystem and Original Equipment Manufacturer Opportunities of the Platform

Aizon recently received Series B financing of $15 million from Atlantic Bridge, Honeywell Ventures, and Institut Català de Finances, bringing the total funding to $24 million. The company is using this investment to ensure customer success and to spur growth through direct sales, channel sales, and business development.

Aizon is ISO 27001/27017 and ISO 9001 certified and follows GAMP5 and GxP standards for development. The company also has a real focus on collaborating with life science companies and institutions where regulatory bodies like the FDA, MHRA, and WHO participate to benchmark best practices and set new industry regulations for the use of AI.

Therefore, an essential platform component is its ability to ingest the batch data in real-time in a massive way while creating a compliant data program with every single byte of data for an audit trail. The company's partnership with de facto players in labs, automation, and manufacturing execution systems further allows Aizon to connect and build disparately available data together in a compliant way, apply AI, and implement Pharma 4.0 for significant cost savings and heightened manufacturing efficiencies. For example, the company points that the daily cost of storing drug batches in the warehouse runs into an astronomical $7 billion with a delayed market release due to manual compliance and audit checks. Aizon's AI platform automates the audit processes and contributes to tremendous cost savings while enabling drugs to reach patients faster.

Moving at a rapid growth path, the company doubled its employee base by the first quarter of 2020. It hired top-level executives with deep industry experience to complement the founding team. The team seeks to expand into new markets and build ecosystems around Aizon for greater market penetration and technology adoption.

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- Supriya Lala Kundu, Best Practices Research Analyst

The company signed a global reseller agreement with the automation leader Honeywell, which will develop its market strategy around the company's platform and deliver innovative solutions to the life sciences and adjacent industries. The Honeywell collaboration further enables Aizon to design an ecosystem-based strategy built-out across the manufacturing lifecycle in pharma and biotech and use the data to power its AI platform. Above and beyond, the company plans to introduce new market products and applications (at the platform level) to expand its footprint.

Aizon realizes the focus of pharma-IT companies to provide enhanced value to its customers from its technology products and services offerings. To that end, the company presents its platform to the marketplace with original equipment manufacturer (OEM) opportunities; this approach enables pharma manufacturers to apply Aizon's technology to improve the currently deployed technology's efficiency and performance from other vendors. Hence, the company envisions a partner-based ecosystem that includes global system integrators leveraging Aizon's technology in their solutioning strategy and builds end-user based applications with enhanced value.

The company thus positions as a tech-enabler in the industry, seeking to harness the growing data and update their customers' existing capabilities with AI and ML. Aizon works with top pharma organizations, such as The Parenteral Drug Association (PDA) and The International Society for Pharmaceutical Engineering (ISPE). It provides thought leadership on AI applications in life sciences and AI-compliant environments as part of its core competency.

The company recently published a scientific paper on AI algorithms qualification via the PDA's *Journal of Pharmaceutical Science and Technology*. It focuses on individual companies, their processes, and how organizations and the FDA, ISPE, and PDA observe AI as an integral part of the next stage of the pharma industry.

Aizon discerns additional opportunities for its technology across adjacent markets, primarily chemical and chromatography, cosmetics, medical devices, and nutraceutical, and other AI applications that will continue to drive Manufacturing 4.0. The company continues to build a community around the technology, driving the pharma manufacturing industry to adopt AI and ML, map a strategy, follow best practices, and support the customers through their journey

Conclusion

To address the pharma industry's manufacturing and compliance challenges, Aizon developed its analytics platform powered by artificial intelligence (AI) and machine learning (ML) capabilities. The GxP-compliant, robust, and customizable platform integrates unlimited sources of structured and unstructured manufacturing Big Data and stores and investigates the data to deliver actionable insights across all manufacturing sites and simplify regulatory compliance.

The company offers an intuitive way to gain meaningful operational intelligence for decision-support that enables customers to improve manufacturing efficiency to meet market demand and deliver life-saving treatments quickly. The robust platform drives scale, maintains continuous quality within and between batches, and enables real-time visibility and predictive insights in a GxP compliant manner. Aizon acts as an accelerator of the pharma manufacturing industry by bolstering their currently deployed technology with AI and ML capabilities to lower production uncertainty and manufacturing risks, boosting production performance.

By focusing on a partnership-based ecosystem, Aizon collaborates with industry leaders, life science organizations, several de facto players, and system integrators to build customer-centric solutions and potentially help implement Pharma 4.0.

With its strong overall performance, Aizon earns Frost & Sullivan's 2020 North America Enabling Technology Leadership Award in AI for productivity and compliance in the pharma industry.

What You Need to Know about the Enabling Technology Leadership Recognition

Frost & Sullivan's Enabling Technology Leadership Award recognizes the company that applies its technology in new ways to improve existing products and services and elevate the customer experience.

Best Practices Award Analysis

For the Enabling Technology Leadership Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

Technology Leverage

Commitment to Innovation: Continuous emerging technology adoption and creation enables new product development and enhances product performance

Commitment to Creativity: Company leverages technology advancements to push the limits of form and function in the pursuit of white space innovation

Stage Gate Efficiency: Technology adoption enhances the stage gate process for launching new products and solutions

Commercialization Success: Company displays a proven track record of taking new technologies to market with a high success rate

Application Diversity: Company develops and/or integrates technology that serves multiple applications and multiple environments

Customer Impact

Price/Performance Value: Products or services provide the best value for the price compared to similar market offerings

Customer Purchase Experience: Quality of the purchase experience assures customers that they are buying the optimal solution for addressing their unique needs and constraints

Customer Ownership Experience: Customers proudly own the company's product or service and have a positive experience throughout the life of the product or service

Customer Service Experience: Customer service is accessible, fast, stress-free, and high quality

Brand Equity: Customers perceive the brand positively and exhibit high brand loyalty

About Frost & Sullivan

Frost & Sullivan is the Growth Pipeline Company™. We power our clients to a future shaped by growth. Our Growth Pipeline as a Service™ provides the CEO and the CEO's growth team with a continuous and rigorous platform of growth opportunities, ensuring long-term success. To achieve positive outcomes, our team leverages over 60 years of experience, coaching organizations of all types and sizes across 6 continents with our proven best practices. To power your Growth Pipeline future, visit Frost & Sullivan at http://www.frost.com.

The Growth Pipeline Engine™

Frost & Sullivan's proprietary model to systematically create on-going growth opportunities and strategies for our clients is fuelled by the Innovation Generator™. Learn more.

Key Impacts:

- **Growth Pipeline:** *Continuous flow of Growth opportunities*
- **Growth Strategies:** *Proven Best Practices*
- **Innovation Culture:** *Optimized Customer Experience*
- **ROI & Margin:** *Implementation Excellence*
- **Transformational Growth:** *Industry Leadership*

The Innovation Generator™

Our six analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.

Analytical Perspectives:

- **Mega Trend (MT)**
- **Business Model (BM)**
- **Technology (TE)**
- **Industries (IN)**
- **Customer (CU)**
- **Geographies (GE)**