AXENDIA™

AI DRIVES SHIFT FROM REACTIVE TO PREDICTIVE QUALITY

REGULATORY CONSIDERATION FOR AI-ENABLED QMS

An Axendia eBook Presented by Sparta Systems

Sparta Systems®

Introduction

In this eBook, we discuss how Life Science organizations can use AI to drive the shift from reactive to predictive quality management. We also address validation and regulatory considerations for AI-enabled QMS using Computer Software Assurance (CSA).

"Artificial intelligence and machine learning have the potential to fundamentally transform the delivery of healthcare. As technology and science advance, we can expect to see earlier disease detection, more accurate diagnosis, more targeted therapies and significant improvements in personalized medicine", commented Scott Gottlieb, M.D., 23rd US FDA Commissioner.

Artificial intelligence (AI) and machine learning (ML) can deliver innovative and important insights from the vast amount of data generated by Life Science manufacturers and Healthcare providers.

> The ability of artificial intelligence and machine learning software to learn from real-world feedback and improve its performance is spurring innovation and leading to the development of novel medical devices.
>
> — Dr. Scott Gottlieb, MD
> 23rd US FDA Commissioner

AI's ability to "learn" is also spurring Quality Management System (QMS) innovation. This technology is driving positive disruption, enabling the shift from reacting to quality events to predictive and proactive quality management.

To accelerate the adoption of these technologies, the FDA has proposed a framework for the use of AI/ML-based software when used as a Medical Device. The framework is founded on a Total Product Life Cycle (TPLC) approach that follows what the Agency terms: Good Machine Learning Practices (GMLP).

The FDA is also encouraging the use of modern technology in support of Manufacturing, Operations and Quality since it delivers significant advantages for Life Science companies. Additionally, the Agency recognizes that Computer System Validation (CSV) has been an obstacle to the implementation of automation systems and digital technologies in Life Sciences. (See Axendia's blog: Goodbye Computer System Validation...)

The FDA, recognizing the industry's CSV challenges, has announced new guidance on "Computer Software Assurance for Manufacturing, Operations, and Quality System Software." This guidance is on the Agency's "A-list" and is planned for release in FY 2019. Furthermore, the Agency is encouraging the use of AI and ML based on GMLP.

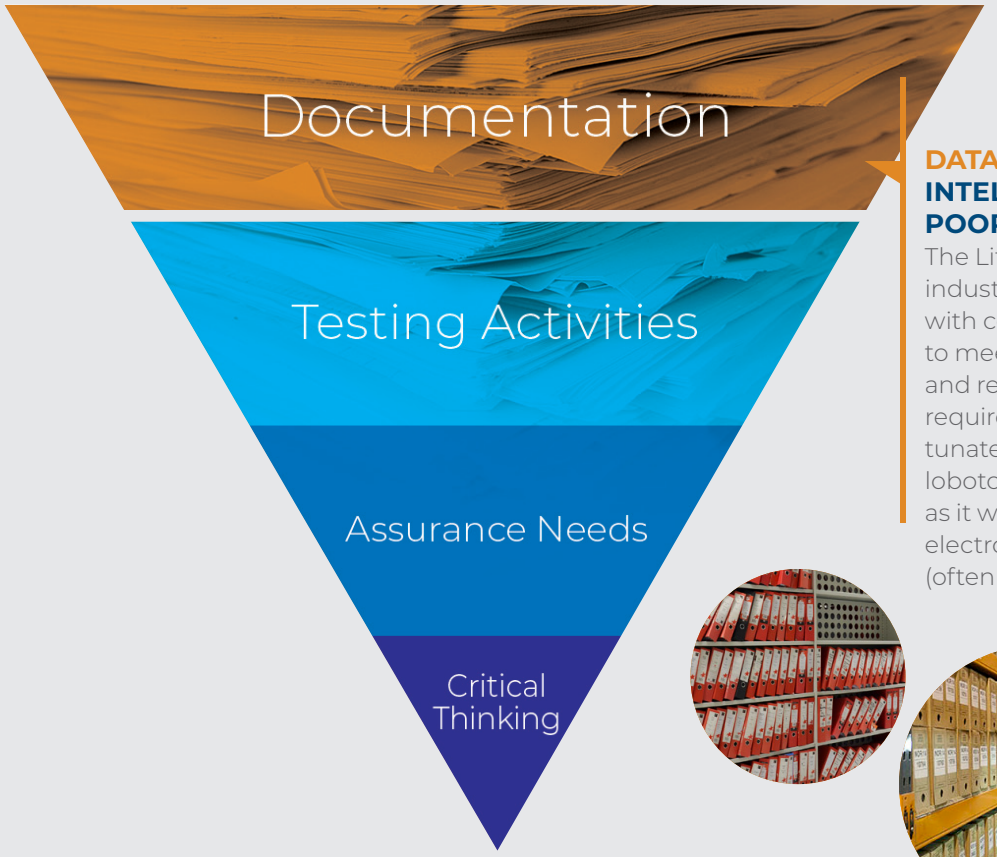
Turning Data into Intelligent and Actionable Insights

Our research shows that the Life Science industry is obsessed with collecting data, retaining and hoarding it to meet statutory and regulatory requirements. Unfortunately, most companies do not harness this data to improve product quality. As a result, our industry suffers from DRIP: Data Rich but Intelligence Poor.

But what has happened to this vast amount of data? Unfortunately, this data was lobotomized as soon as it was saved in static electronic documents (often PDFs).

Until now, this unstructured data sat idle, forgotten in vaults, or buried under digital dust in electronic storage devices, until the document retention policy forces the company to "purge" them. As a result, vast amounts of product and process intelligence that could be gleaned from this data goes unused.

OLD COMPUTER SYSTEM VALIDATION (CSV) MODEL



DATA RICH BUT INTELLIGENCE POOR

The Life Science industry is obsessed with collecting data to meet statutory and regulatory requirements. Unfortunately, this data was lobotomized as soon as it was saved as static electronic documents (often PDFs).

Turning Data into Intelligent and Actionable Insights

The use of AI and ML can enable Life Science organizations to harness data and turn it into intelligent and actionable insights that enable predictive quality. AI systems can process data from point solutions to glean intelligence and support decision-making.

According to Dr. Gottlieb, "Artificial intelligence has helped transform industries like finance and manufacturing, and I'm confident that these technologies will have a profound and positive impact on health care. I can envision a world where, one day, artificial intelligence can help detect and treat challenging health problems, for example by recognizing the signs of disease well in advance of what we can do today. These tools can provide more time for intervention, identifying effective therapies and ultimately saving lives."

As technology innovation continues to accelerate, the FDA is enabling innovation and modernization across the Life Science industry. Keeping up with the future requires the use of modern technologies – such as Cloud Computing, AI, ML, Big Data and Analytics and the Internet of Medical Things (IoMT) – working together effortlessly and seamlessly to capitalize on new opportunities and address emerging challenges.

You Can't Validate AI with Outdated CSV Models

For decades CSV has been an obstacle to the implementation of automation and digital technologies in Life Science. This is primarily due to a misconception that extensive structured testing and documentation are required to demonstrate the validation of computer systems used in support of Manufacturing, Operations and Quality System software.

The FDA recognizes that the adoption of modern technologies requires a different approach to computer system validation (watch webinar The FDA Shares a New Approach to CSV).

Axendia's eBook, Goodbye CSV...Hello CSA? details the FDA's new approach: Computer System Assurance (CSA). CSA is a set of activities or actions that are performed to give confidence that the software functions as intended and meets the organization's needs.

CSA is a risk-based approach founded on critical thinking (not documentation!), on which there is an evaluation of assurance needs, followed by a determination of the appropriate level of testing activities and finally identification of the right level of testing (and record keeping) that is necessary to provide the appropriate assurance evidence. CSA focuses on the impact of each feature, operation or function on patient safety, product quality and quality system integrity. CSA adjusts the rigor of validation/assurance activities according to this risk.

NEW CSA MODEL

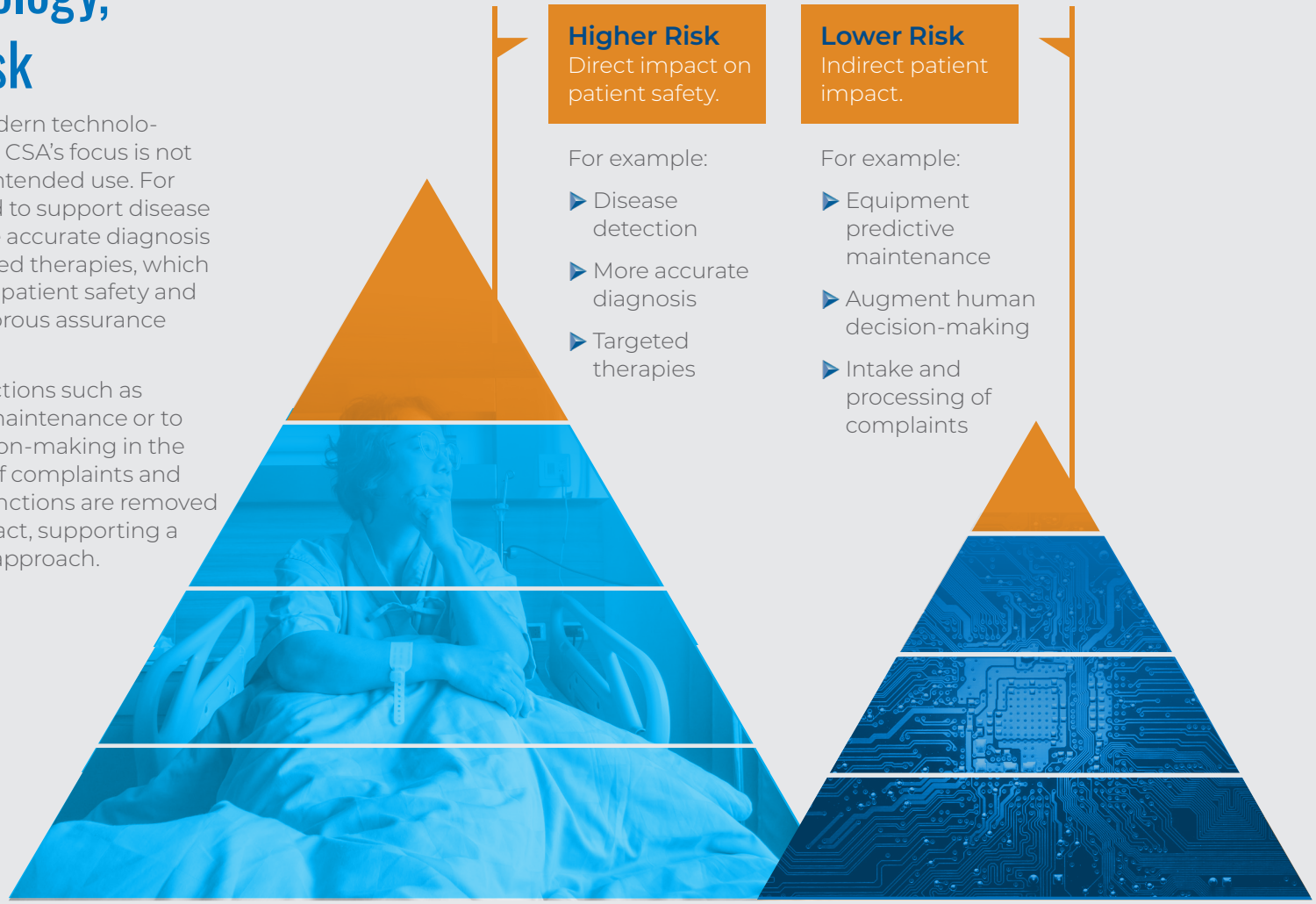
A risk-based approach founded on critical thinking on which there is :

1. An evaluation of assurance needs
2. A determination of the appropriate level of testing activities
3. Identification of the right level of record keeping

Same Technology, Different Risk

CSA is applicable to modern technologies like AI and ML as its CSA's focus is not the technology but its intended use. For example, AI can be used to support disease detection, provide more accurate diagnosis and recommend targeted therapies, which have a direct impact on patient safety and would require more rigorous assurance activities.

AI can also support functions such as equipment predictive maintenance or to augment human decision-making in the intake and processing of complaints and quality events. These functions are removed from direct patient impact, supporting a more streamlined CSA approach.



AI Enables the Shift to Predictive Quality Management

A key component of AI and ML is the ability to "learn" from experience. According to the FDA, "The ability for AI/ML software to learn from real-world feedback (training) and improve its performance (adaptation) makes these technologies uniquely situated among software..."

To encourage the use of and AI and ML in the Life Sciences industry, the FDA published a "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)."

Axendia's analysis of the FDA's AI/ML frameworks shows that the traditional regulatory paradigm was not designed to support adaptive artificial intelligence and machine learning technologies.

The Agency proposes a total product life cycle (TPLC) regulatory approach based on what the FDA calls: Good Machine Learning Practices (GMLP). This iterative approach would realize the power of AI/ML learning algorithms by facilitating a rapid cycle of product improvement while providing effective safeguards.

The ability for AI software to learn from real-world feedback and improve its performance is enabling the shift to a predictive quality approach. AI can help detect and address challenging quality problems by recognizing signals and quality issues well in advance of what we can do today.

AI is enabling Life Science organizations to shift to predictive quality management, turning data into intelligent and actionable insights.

For example:

Natural Language Processing can extract context from static electronic documents to support deviation, auto classification, intake/quality event triage and complaints triage.

Correlation & Root Cause Analysis across multiple variables can be used to understand root cause of events.

Trending & Signal Detection can identify trends in data and textual content to understand consumer sentiment, spot quality events and detect anomalies in process control and conduct trend analysis.

Deviation Root Cause Analysis can parse through current and historical data to make predictions about future or otherwise unknown events.

Implications for Industry

Companies like Amazon, Uber, Google and Apple have disrupted their respective industries by continuously embracing technologies like cloud computing, data analytics, modeling & simulation and artificial intelligence.

Artificial intelligence and machine learning have the potential to fundamentally transform the delivery of healthcare. The shift from selling medical products to providing patient-centric value-based care is creating an inflection point for transformation.

Innovative Life Science companies must adopt a predictive quality approach that improves outcomes while providing value.

Leveraging the FDA's Good Machine Learning Practices regulatory framework, innovative Life Science organizations must embrace AI and ML to drive improved productivity and intelligent decision-making across the organization. Through the use of these modern technologies, organizations can detect and address quality problems well in advance of what we can do today, supporting a shift to proactive and predictive approaches to quality management.

To achieve Positive Disruption, Life Science organizations must:

- Embrace modern technologies
- Focus on predictive quality, not simply compliance
- Support visibility and digital continuity across the product life cycle
- Provide digital evidence
- Drive improved patient outcomes and value-based care

Organizations that do not embrace modern technologies to achieve positive disruption will be disrupted!

Acknowledgments

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Sparta Systems is the world's premier provider of cloud and on-premise quality management software. We offer the solutions, analytics, and expertise that speed up quality and compliance. Our solutions help to lower risk, increase efficiency, and keep consumers safe while allowing manufacturers, suppliers, and distributors to collaborate in a seamless and integrated environment. Sparta is privately owned and headquartered in Hamilton N.J., with offices across Europe and Asia. We support close to 1 million users across 700+ implementations, in more than 30 countries. Companies in life sciences, consumer products, discrete manufacturing and more, rely on Sparta.

For more information, visit www.spartasystems.com

About Axendia

Axendia is a leading analyst and strategic advisory firm focused exclusively on the Life-Sciences and Healthcare markets. Industry stakeholders and regulators rely on Axendia for trusted advice on Business, Regulatory and Technology issues and trends based on trusted sources. Axendia was recognized by CIOReview as a one of the 20 Most Promising Life Sciences Technology and Services providers.

For more information, visit **axendia.com**
Read Axendia's blog: Life-Science Panorama

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