



SAFHE 2026

SOUTHERN AFRICAN
HEALTHCARE CONFERENCE

SYNERGY
IN ACTION:

SHAPING THE FUTURE OF
HEALTHCARE TOGETHER



9 – 10 JUNE 2026



CTICC 2 CAPE TOWN

AI is revolutionizing Medical Device user operations



CHAIRPERSON (2021-2025) MDMSA , CHAIRPERSON, Vice (2022/3) MDPG

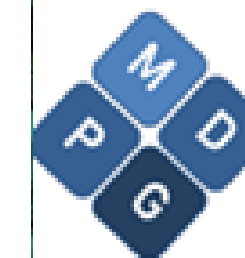
RUDOLPH-SHORTT Consultancy CC

t/a ISOhealthSA, PeonyCo & Compliance Projects



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Medical
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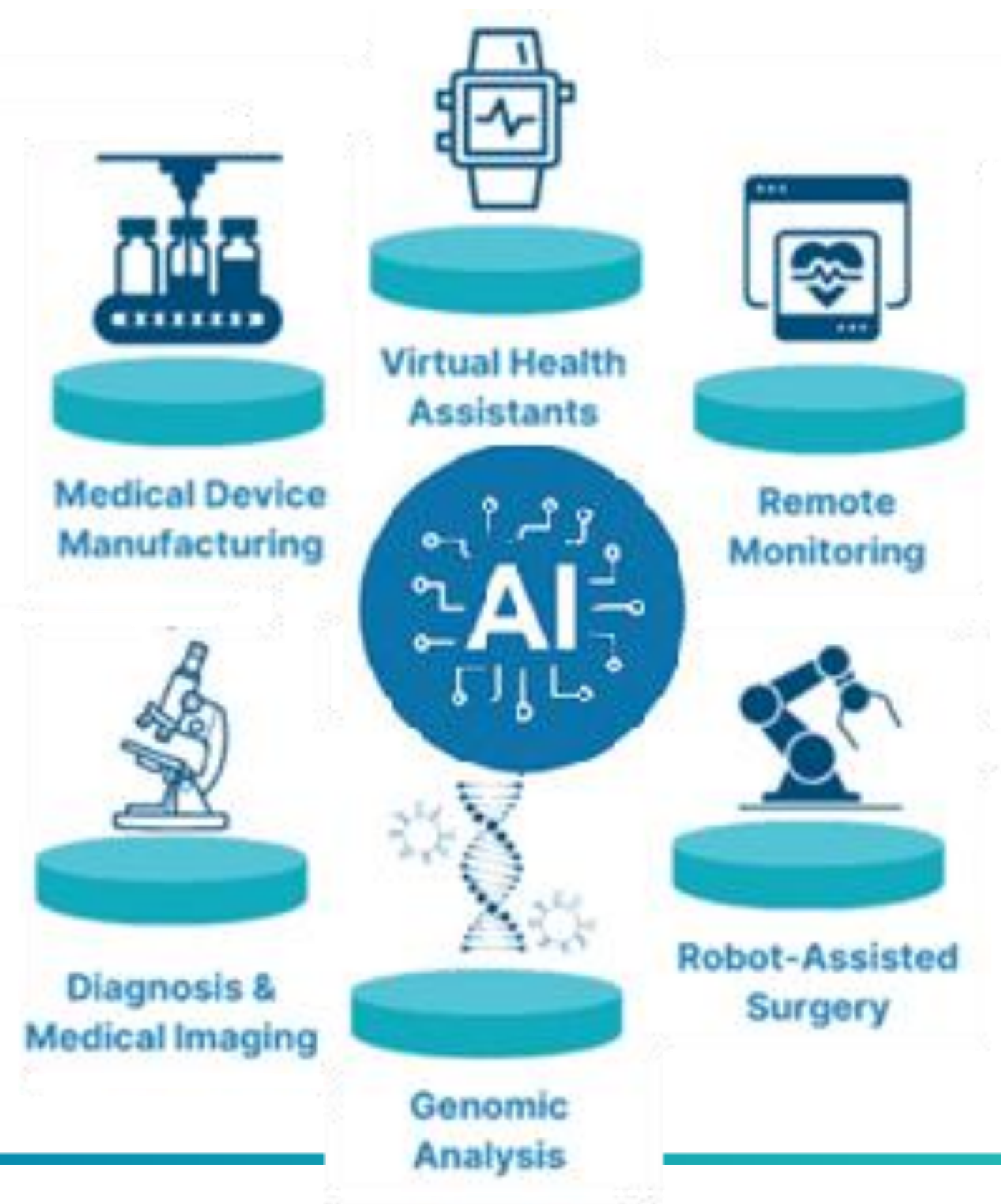


SAAPI



Medical Device Manufacturers of South Africa

Artificial Intelligence USED in Medical Devices & Quality Systems



**Transforming Products,
R&D, QMS, and Production**

AI in QMS

- **Quality Management system is the foundation of excellence with a good practices used to navigate, engineer and follow processes with informed instructions and using verification and validation techniques.**
- **Adopting artificial intelligence can align policies and enable activities for effective and timely outcomes**

Principles of QMS

1. Customer

2. Leader

3. People

4. Process

5. System

6. Supplier

7. Facts

8. Improve

9. Risk

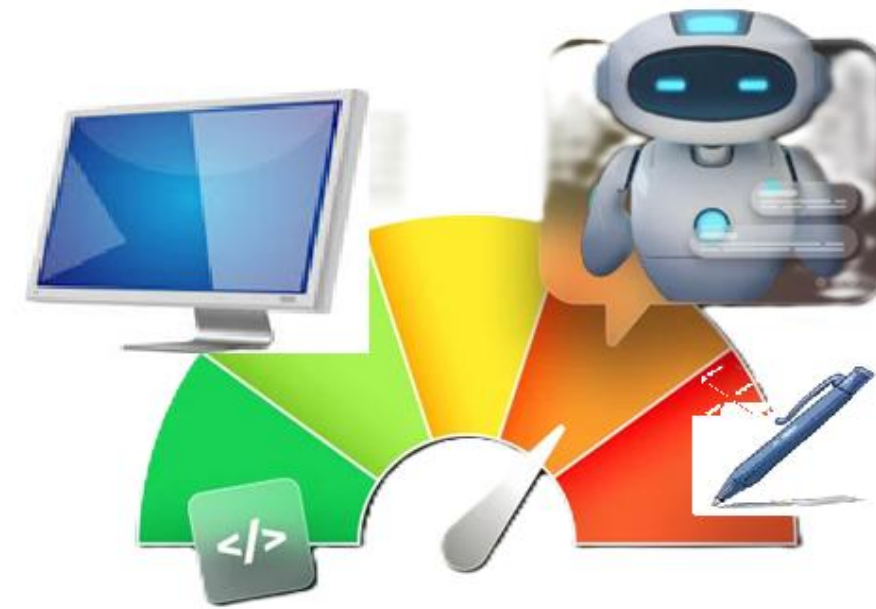


Benefits of AI in QMS



Area	AI Contribution	Impact
Compliance	Automated checks against regulatory frameworks	Reduced risk of violations
Efficiency	Real-time process adjustments	Higher throughput
Quality	AI-powered defect detection	Lower rejection rates
Responsiveness	Adaptive scheduling and forecasting	Faster delivery
Sustainability	Waste reduction through optimized resource use	Lower costs, greener production

Effective delivery techniques



By utilizing AI for

- simulation,
- test case generation, and
- real-world performance monitoring, manufacturers can reduce testing time and decrease manual effort, while simultaneously ensuring compliance with compliance and technical standards

Artificial Intelligence (AI) enables effective and timely verification [Ve] and validation [Va] (V&V) of medical device products and production [P&P] by transitioning the process from manual, document-intensive, and reactive tasks to proactive, automated, and continuous workflows.

Artificial Intelligence in PRACTICE

Enabling Production efficacy

Industry	AI Application	Benefit
Manufacturing	Predictive maintenance, defect detection	Reduced downtime, higher quality
Healthcare products (used in hospitals)	AI-driven diagnostics, workflow automation	Faster, more accurate outcomes
Energy	Smart grid optimization, load balancing	Efficiency, sustainability
Logistics	Route optimization, demand forecasting	Cost savings, timely delivery

**How AI
enables
effective
and timely
Ve &Va
processing**

IN

- 1. Designing Processes**
- 2. Controlling Processes**
- 3. Improving Processes**

What is a process

- A stepwise activity or actions to achieve and output using and controlling resources (people, time, methods, equipment, infrastructure)



1. Designing Processes

- **Data-Driven Modeling:** AI analyzes historical and real-time data to design processes that minimize risks and maximize efficiency.
- **Simulation & Digital Twins:** AI-powered models simulate production or service environments, allowing organizations to test scenarios before implementation – what-if.
- **Requirement Alignment:** AI ensures process designs meet regulatory and quality standards by cross-checking against compliance frameworks.



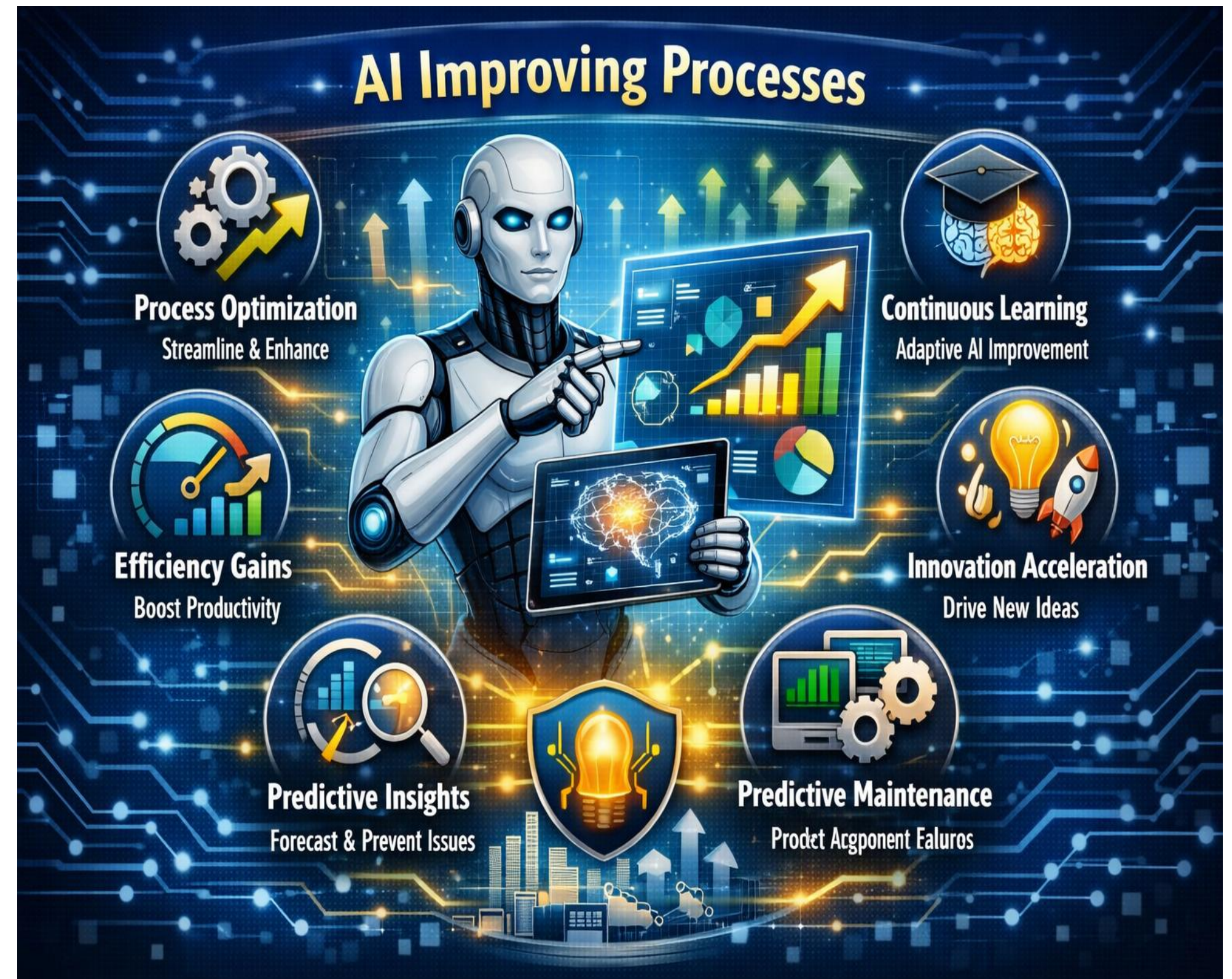
2. Controlling Processes

- **Adaptive Control Systems:** AI algorithms adjust parameters dynamically to maintain optimal performance under changing conditions – smart ventilators / heart monitors
- **Predictive Maintenance:** Machine learning predicts equipment failures, reducing downtime and ensuring reliability – monitors age of parts.
- **Fault Detection:** AI identifies anomalies in real time, enabling corrective action before issues escalate – quality controls.
- **Closed-Loop Automation:** AI integrates with sensors and IoT [Internet of Things] devices to continuously regulate processes without human intervention – HVAC systems with seasonal fluctuations / smart devices.



3. Improving Processes

- **Continuous Learning:** AI refines models through iterative feedback, improving accuracy and efficiency over time.
- **Quality Control:** AI enhances inspection and testing by detecting defects faster and more accurately than manual methods.
- **Demand Forecasting:** AI predicts market trends and resource needs, aligning production with demand.
- **Process Optimization:** Algorithms identify bottlenecks and recommend adjustments to reduce waste and improve throughput.



how AI enables effective and timely Ve & Va for medical device P&P



Are we building it RIGHT [Ve]
- Does it meet the standard /
User Specification
Requirement
Are we building the RIGHT
product [Va]
-intended use / installation
/Operation

Ve

TEST CASE is a structured scenario used to confirm that a system, product, or process is both correctly built (Verification) and fit for its intended purpose (validation)

Verification of algorithms for

-medical equipment / products

-Infrastructure , installation qualification and

-preventive maintenance

- **normally provided by the device manufacturer with operator training and operational monitoring using AI can transform the landscape of**

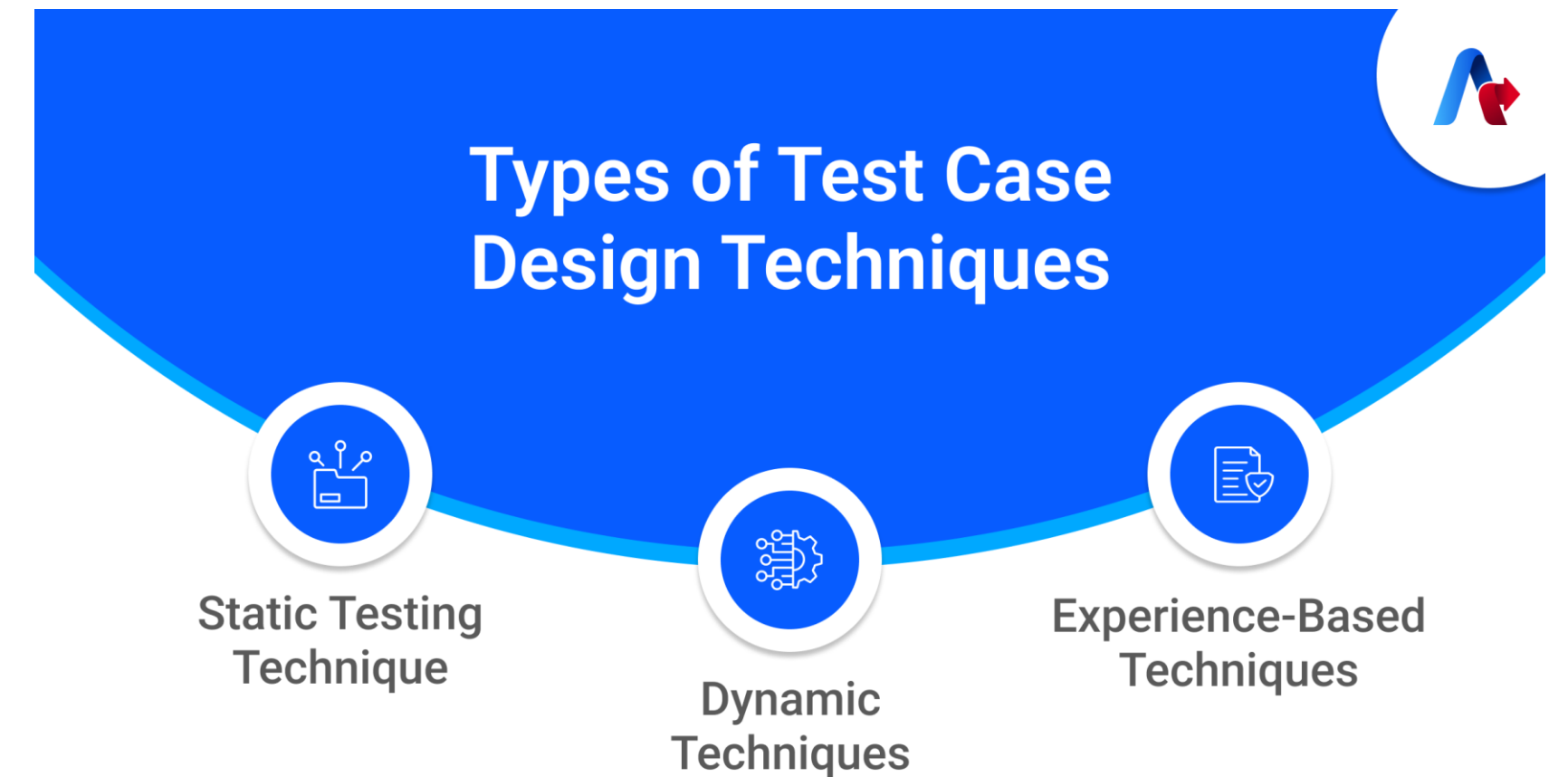
-corporate governance, risk management, and compliance by reducing the manual labor associated with monitoring, measurement, and auditing

AI V&V imminent CHANGES

- 1. Automation of Testing and Test Case Generation**
- 2. Enhanced Quality Control and Risk Mitigation**
- 3. Continuous and Real-World Validation**
- 4. Regulatory Compliance and Documentation**
- 5. Specialized AI V&V Applications**

1. Automation of Testing and Test Case Generation

- **Automated Test Case Creation:** AI tools can analyze requirements and software code to automatically generate comprehensive test cases, including complex edge cases that manual methods might miss.
- **Intelligent Test Execution:** AI-driven controllers can automate the execution of thousands of test cases in parallel, significantly speeding up regression testing.
- **Self-Healing Tests:** AI-powered systems can automatically update, or "self-heal," test scripts when the software's UI or functionality changes, reducing maintenance time.



2. Enhanced Quality Control and Risk Mitigation

- **Predictive Defect Detection:** AI can analyze code and system architecture to predict areas with high defect probability, enabling testing teams to focus on the riskiest components early.
- **AI-Powered Visual Inspection:** In manufacturing, AI vision systems can identify defects in implants or surgical instruments at a micron level, improving upon manual inspection accuracy and reducing recalls.
- **Synthetic Data Generation:** Generative models can produce realistic synthetic data to test device performance across diverse patient demographics, reducing reliance on hard-to-acquire, sensitive patient data.



3. Continuous and Real-World Validation

- **Post-Market Surveillance:** AI enables continuous monitoring of device performance in real-world clinical settings, detecting "model drift" (when accuracy decreases over time) before it compromises patient safety.
- **Real-Time Data Analysis:** AI systems can process massive datasets from IoT sensors or wearable devices in real-time, providing immediate feedback on device performance



4. Regulatory Compliance & Documentation

- **Automated Traceability Matrix:** AI tools can automatically generate and maintain the Requirements Traceability Matrix (RTM), ensuring that every user need is mapped to a test case, which simplifies Regulatory and ISO compliance.
- **Pre-emptive Compliance:** AI acts as an internal auditor, scanning for regulatory gaps in documentation and ensuring that technical files are audit-ready.



5. Specialized AI V&V applications

- **Digital Twins for Maintenance:** AI can create a "digital twin" of complex devices (e.g., MRI machines) to monitor components and detect potential issues, increasing equipment uptime.
- **Explainable AI (XAI):** XAI techniques are used to ensure that the AI's decision-making process is transparent, allowing for human oversight, which is critical for high risk medical devices.



Summary Key Benefits to AI

1. **Faster Time-to-Market:** Reduces the validation timeline.
2. **Cost Savings:** Decreases the cost of manual testing and prevents costly, late-stage recalls.
3. **Improved Accuracy:** Reduces human error and provides more consistent, reliable outcomes.
4. **While AI enhances V&V, it is not a complete replacement for human expertise but serves as an assistive tool to complement human judgment, particularly in maintaining high-stakes patient safety and compliance**



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Thank you Simone Rudolph-Shortt



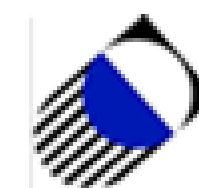
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