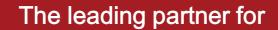


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SMART MANUFACTURING SYSTEMS



# **ABOUT US**

Founded in 2020, IMPACT Systems is a specialized provider of fully integrated automation, instrumentation, and industrial control solutions. We have quickly earned the trust of leading manufacturers across Egypt and the MENA region by delivering innovative technologies, reliable services, and high-quality spare parts.

Today, we are recognized as a key enabler of digital transformation in pharmaceutical manufacturing. Our expertise includes Industrial IoT (IIoT), SCADA systems, PLC integration, Al-driven monitoring, regulatory compliance, and customized solutions for pharmaceutical industries, all aligned with FDA and GMP standards. We partner with leading global brands to deliver scalable, compliant, and intelligent solutions.

## **OVERVIEW**

IMPACT Systems specializes exclusively in the pharmaceutical industry. We design, implement, and support customized machinery systems and automation systems that enhance production, improve quality control, and ensure regulatory compliance. Our solutions are built on platforms from global leaders like Siemens, Schneider Electric, Omron, Cognex, ABB, Rockwell Automation, Inductive Automation, Advantech, Kuka, and Kawasaki Robotics.

With deep domain expertise and localized experience, our team helps clients navigate the technical and regulatory complexities of modern pharmaceutical production. From batch traceability to 21 CFR Part 11 compliance, we deliver robust solutions that accelerate operational excellence.

## **OUR COMMITMENT**

We understand the critical importance of data integrity, traceability, and system validation in pharmaceutical environments. All of our systems are designed to comply with FDA guidelines including 21 CFR Part 11 for electronic records and signatures, and Good Manufacturing Practices (GMP). Cybersecurity, documentation, and validation are embedded in every solution we offer. We are committed to helping our clients build robust, compliant, and future-proof manufacturing operations.

# **OUR MISSION**

To empower pharmaceutical manufacturers with cutting-edge automation and digital solutions that drive productivity, reduce costs, and ensure quality and compliance in line with global standards.

# **OUR VISION**

To be the most trusted partner in digital transformation for pharmaceutical companies delivering Al-powered efficiency, regulatory excellence, and innovation through smart automation.



# **CORE COMPETENCIES**

#### WHAT SETS US APART:

**Pharma-Only Focus** We serve only the pharmaceutical sector, ensuring deep domain expertise.

**Regulatory Precision** Our systems are purpose-built for GMP and 21 CFR Part 11 compliance.

Smart Automation IIOT, Al-driven monitoring, predictive analytics, and machine vision boost your plant

intelligence.

Localized Excellence Global standards, localized integration. We understand Egyptian regulations, market

needs, and infrastructure.

Scalable & Cost-Effective From lab-scale to enterprise-wide deployments, our modular solutions grow with you.

# **SERVICE PORTFOLIO**

We offer a comprehensive suite of integrated automation and digital solutions specifically tailored for pharmaceutical manufacturing. Our portfolio enhances every stage of the production lifecycle—from raw material intake to finished product release—while ensuring full compliance with FDA, GMP, and 21 CFR Part 11 standards.





# LEADERSHIP MESSAGE

At IMPACT Systems, we do more than deliver technology ...... we deliver trust. We are committed to understanding the details that matter most in pharmaceutical operations, and we partner with you to build smarter, safer, and more efficient manufacturing systems.

Let us shape the future of pharmaceutical automation, together.

Tamer Hendi



# **CORE SOLUTIONS**

#### PHARMACEUTICAL AUTOMATION SOLUTIONS

Revolutionizing pharmaceutical manufacturing through intelligent automation—maximizing efficiency, guaranteeing compliance, and ensuring uncompromised quality at every stage of production.



IMPACT Systems delivers end-to-end pharmaceutical automation — from process design and device development to final packaging. Our tailored solutions ensure full compliance with international standards, backed by proven expertise and trusted by repeat clients.



#### **Automation & Control**

IMPACT systems is using the latest state art of technologies and up to date inventtions. Great thanks to our international partners research and advanced core solutions.

IMPACT systems has deep experience in machinery and robotic solutions supported with the valuable, well-known partners in Europe & Japan



## Machine Refurbish

We specialize in restoring old machines to peak performance by refurbishing electro-mechanical systems & integrating modern solutions — ensuring validation and full compliance.

# PHARMACUTICAL MANUFACTURING SYSTEMS

Tailor-made pharmaceutical manufacturing systems—engineered for precision, built for compliance, and custom-designed to fit your vision of the optimum process.

In partnership with our clients, IMPACT Systems designs, builds, installs, and integrates customized pharmaceutical manufacturing solutions that ensure speed, accuracy, and full compliance with GMP and FDA standards. From material handling and dispensing to fill-finish and high-volume production, we optimize every stage and close the gaps in your process.

#### **Customized Systems**

IMPACT Systems has a proven track record in designing and building compliant, validated electromechanical systems that add significant value to machines and close critical gaps in the manufacturing process.



#### Solutions Include:

- Automation Systems Refurbishment
- ➤ Machine Control Upgradation
- SCADA & HMI Integration
- Machine Vision Solutions
- Motion and Drives Solutions
- Tracking & Traceability Solutions
- Automated Conveyor Solutions
- Robotic Packaging Solutions
- Robotic Palletizing Solutions



- Conveyor & Sortation Systems
- Machine Vision for Solid, Simi-Solid
- Machine Vision for Syrup / Vial / Ampoule
- Final Product Inspection Systems
- > Tablet Compression Systems
- Liquid Dosing Systems
- > Drug Delivery Systems
- > Incubation Systems
- > Primary / Secondary Packaging Systems
- > Palletizing / Pallet Exchange Systems
- ...and much more!

# **SMART CORE SOLUTIONS**

### **SMART MONITORING & DIGITAL TRANSFORMATION**

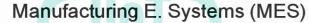
Digitize pharmaceutical operations with real-time insights, audit trails, and compliant control systems.



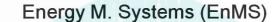


#### **IIoT Solutions**

Connect factory cleanroom and process equipment securely to enable remote analysis, diagnostics and predictive insights.



Achieve operational excellence, increase the effectiveness of your pharma supply chain, comply with ever-increasing regulations, improve time to market, and meet your business goals



Optimize energy use in pharmaceutical facilities while meeting sustainability and compliance targets for ISO 50001.

## Environmental M. Systems (EMS)

Ensure GMP-compliant cleanroom control with realtime monitoring of temperature, pressure, humidity, and particulates and be ready for ISO 14001.

#### **OEE & Performance Monitoring**

Improve equipment efficiency, reduce downtime, and maximize throughput with pharma-focused OEE tools.





## AI-DRIVEN QUALITY ASSURANCE & COMPLIANCE

Ensure flawless quality and full compliance in pharmaceutical manufacturing with Al-powered inspection, control, and predictive solutions.

## Vision Inspection Systems

High-speed, Al-based inspection for pharma packaging, labeling, and product integrity.

## **AI-Based Quality Control**

Real-time detection of quality deviations to ensure consistent, compliant production.



#### **Predictive Maintenance**

Pharma-grade Al models that predict failures, extend equipment life, and reduce unplanned downtime.



### INDUSTRIAL AUTOMATION SOLUTIONS

Achieve precise, compliant, and efficient control with industrial automation solutions engineered for regulated pharmaceutical environments.

## SCADA, HMI & PLC Integration

Validated control systems tailored for pharmaceutical manufacturing and cleanroom operations.



## **GMP-Compliant Control Panels**

Custom-built panels using global brands, fully compliant with GMP and FDA requirements.



## **Process Control & Optimization**

Automate critical pharma processes with precise, recipe-driven control and batch sequencing.





Cloud









# **DEDICATED PHARMA-SYSTEMS**

## **Vial Handling Systems**

Our vial handling solutions are custom-designed and dedicated to automate vial orientation, sorting, and transfer across sterile processes using Siemens or Beckhoff Automation and motion platforms. Features include servo conveyors, rotating tables, and synchronization with upstream/downstream equipment.

- ✓ Cleanroom-ready and high-speed with GMP compatibility
- ✓ Handles bulk and nested formats
- ✓ Includes accumulation buffers and smart rejection modules
- ✓ SCADA control and compliance with FDA 21 CFR Part 11 Guidelines
- √ Special handling modules for Loading/Unloading Manual/Automatic LYO systems

## Reference Project

### Automated Vial Handling Line in Sterile Are

Design, supply, installation, programming, testing, commissioning, and validation of a complete automated vial handling system (loading/unloading to/from lyophilized machine up to sterile crimping). Fully compliant with FDA 21 CFR Part 11 & GMP standards. *Hikma pharmaceuticals - 2022* 





## Automated Vial / Ampoule Lines Modernization & Data Integrity

We provide complete refurbishment services for vial and ampoule production lines, extending equipment lifetime while enhancing efficiency, compliance, and reliability. Our solutions ensure adherence to GMP standards, reduce downtime, and deliver cost-effective modernization. Additionally, we implement advanced Data Integrity solutions to secure electronic records and ensure full compliance with 21 CFR Part 11 and global regulatory requirements.

## Reference Project

#### Upgrade of Oncology Vial/Ampoule Filling & Packaging Production Lines

Refurbishment of two ROTA production lines (washing, filling, crimping, labeling). Upgraded and validated control systems as a part of the client data integrity project. *Hikma pharmaceuticals - 2021* 

- ✓ Integration of advanced, validated control systems aligned with Data Integrity requirements.
- Implementation of secure electronic records and audit trails, ensuring full compliance with FDA 21 CFR Part 11 and GMP standards.
- Comprehensive qualification and validation (IQ/OQ/PQ) to guarantee regulatory approval and operational reliability.



# Automated Tablet / Capsule Lines Modernization & Data Integrity

We are specialized in refurbishing pharmaceutical solid product lines, extending equipment lifetime and improving efficiency. Our upgrades include modern control systems with full Data Integrity solutions to secure electronic records. All refurbishments are validated to meet FDA, GMP, and 21 CFR Part 11 compliance requirements.

## **Reference Project**

#### **Upgrade of Tablet / Capsule Production Lines**

Refurbishment of two solid-dose production lines, including capsule filling (PAM), coating (Gansons), tablet pressing (Accura and KILIAN), and blistering (Hoonga). Systems validated per 21 CFR Part 11 & GMP. Hikma pharmaceuticals - 2022

- ✓ Integration of advanced, validated HMI units aligned with Data Integrity requirements.
- ✓ Implementation of secure electronic records and audit trails, ensuring full compliance with FDA 21 CFR Part 11 and GMP standards.
- Comprehensive qualification and validation (IQ/OQ/PQ) to guarantee regulatory approval and operational reliability.

# **DEDICATED PHARMA-SYSTEMS**

## Machine Vision Inspection & Rejection Systems

We provide high-speed, Al-enabled vision systems for real-time inspection and rejection of defective products. Using Cognex, Keyence, and Omron technologies, we detect issues like fill discrepancies, label misalignment, contamination, and product defects—ensuring flawless output without production delays. Promoted solutions could by complied with FDA guidelines, serialization and trackability options when needed. Por solutions cover and not limited to:

- ✓ Solid & Semi-Solid Lines: Detects defects in tablets, capsules, and ointment tubes (shape, cracks, sealing).
- ✓ Vial & Ampoule Lines: Inspects for particles, fill volume, sealing integrity, labeling, and surface issues.
- ✓ Syrup Lines: Checks bottle quality, liquid levels, cap torque, and label accuracy.

## Reference Project

#### Machine vision solution for Syrup Production Line

Complete vision-based inspection and rejection solution (Omron platform), including electrical panel, smart vision camera, monitoring and reporting computer, and mechanical rejection system, delivered turnkey and fully validated. <u>DABUR Amla - 2022</u>



# **DEDICATED PHARMA-SYSTEMS**

# **Modernization of Incubation Systems**

Our systems deliver precise control of temperature, CO<sub>2</sub>, humidity, and lighting for microbiological and stability testing in QC and R&D labs. Built on Siemens S7-1500 or Omron NX platforms, they support multi-chamber setups and Part 11-compliant logging.

- √ Remote monitoring and deviation alerts
- ✓ Audit-ready data reporting

## Reference Project

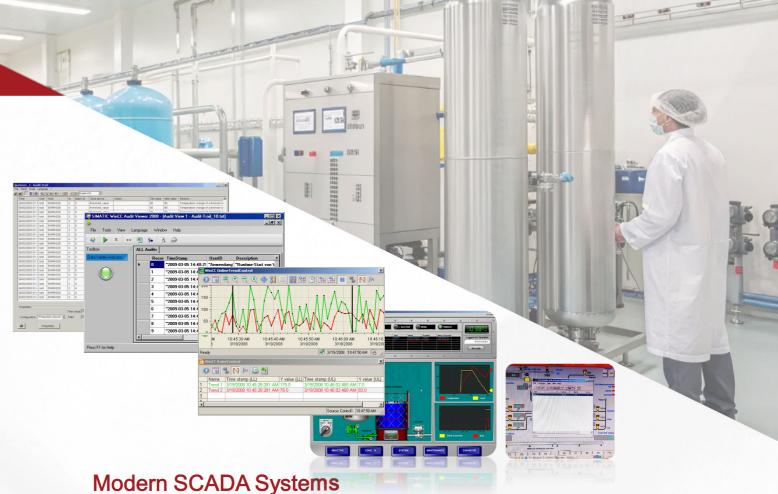
#### **Cooling Incubators Upgradation**

Refurbishment and validation of two cooling incubators, Made by BINDER, ensuring full compliance with FDA 21 CFR Part 11 guidelines. ACDIMA - 2023

- Replacement and upgrading of obsolete components with modern, reliable systems.
- Integration of advanced, validated control systems aligned with Data Integrity requirements.
- Implementation of secure electronic records and audit trails, ensuring full compliance with FDA 21 CFR Part 11 and GMP standards.

Comprehensive qualification and validation (IQ/OQ/PQ) to guarantee regulatory approval and





We deliver advanced SCADA solutions designed to optimize pharmaceutical manufacturing and monitoring processes. Our systems provide real-time data visualization, batch traceability, and seamless integration with MES and ERP platforms. Fully compliant with FDA, GMP, and 21 CFR Part 11, they ensure secure data integrity and regulatory readiness.

## Reference Project

## **New Central SCADA systems**

Implementation of two validated central SCADA systems (Siemens WinCC platform) for pharmaceutical production control and monitoring. Hikma pharmaceuticals - 2021

#### SCADA System Upgradation

Modernization of SCADA system (Schneider / Wonderware Intouch), including reprogramming, testing, and commissioning for process optimization for Tomato Sauce production Line. Faragalla - 2021



## Robotic Solutions for Automated Pharma Packaging

We design and implement advanced robotic solutions tailored for pharmaceutical packaging lines, ensuring flexibility, precision, and regulatory compliance. Our systems handle a wide range of products including blister packs, bottles, ampoules, vials, and tubes, while supporting secondary packaging operations such as case packing, labeling, and integration with serialization systems.

#### **Key Features:**

- √ Vision-guided pick-and-place with high accuracy and adaptability.
- ✓ Scalable modular design for future production expansion.
- ✓ Reduced operational costs through optimized automation and minimized errors.
- ✓ Enhanced traceability and electronic batch record support for full data integrity.
- √ High class branded robotic solutions such as Kuka, Kawasaki, Omron and ABB







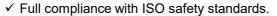
# **DEDICATED PHARMA-SYSTEMS**

## **Robotic Palletizing Systems**

We deliver automated palletizing systems for cartons, crates, and shrink-wrapped products, ensuring stable, accurate stacking and maximum throughput. Integrated with WMS, our solutions streamline end-of-line operations and enhance efficiency with reliable 24/7 operation. Powered by KUKA, Fanuc, or Kawasaki robots, they combine high performance with ISO-compliant safety features.

#### Key Features:

- ✓ Automated pallet handling with dispensers and stretch wrapping.
- ✓ Intelligent grippers adaptable to multiple product formats.
- ✓ Seamless WMS/ERP integration for optimized logistics.
- ✓ High-speed, accurate stacking with consistent load stability.





# **BRANDS**



# **SIEMENS**































# **M**aintain your industry for getting Precise operational technology According to industry 4.0 with Calculated ROI and accepted cost.



# **OUR CUSTOMERS**























































































Our proven history of success

products to achieve customers

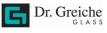
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reflects our commitment to supply

exceptional services and high-quality

























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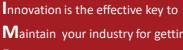












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