PACIV

A GLOBAL LEADER

IN INDUSTRIAL AUTOMATION SOLUTIONS

PACIV STANDS FOR:
PROCESS AUTOMATION, CONTROLS, INSTRUMENTATION & VALIDATION.

PACIV was founded in Puerto Rico in 1997 by Jorge L. Rodriguez.

With their related experience in Instrumentation and Controls (I&C) for major biopharmaceuticals in the United States and Puerto Rico, Jorge found common ground with Rick Straw to launch a successful, growing partnership with PACIV USA LLC in 2003.

Rick had served for over 11 years in the biopharmaceutical sector prior to joining Jorge and PACIV. Located in Indiana, PACIV USA perfectly fit the clients' desire for a local provider of both industrial automation and regulatory compliance solutions. PACIV USA was able to fulfill these service needs while assisting in the standardization among their facilities. By 2011, PACIV went international by opening offices in Hampshire, England as PACIV UK.

After gaining solid and intense experience in England, PACIV UK propelled the company to the next step in Europe, with the opening of the physical office for PACIV Ireland in County Cork.

After 23 years of business, PACIV's primary function continues to be providing unparalleled control systems, instrumentation, and regulatory compliance services to the biotechnology, pharmaceutical, medical device, water / wastewater, food and beverage, energy, and other process industries in a cost-effective manner.

PACIV'S DIFFERENTIATION IS OUR UNIQUE MIX OF TECHNICAL EXPERTISE, UNPARALLELED CUSTOMER SERVICE, AND TRUSTED BRAND.

Our powerful combination of automation and instrumentation knowledge with regulatory compliance experience makes us a compelling value proposition in delivering clients process control and instrumentation needs.
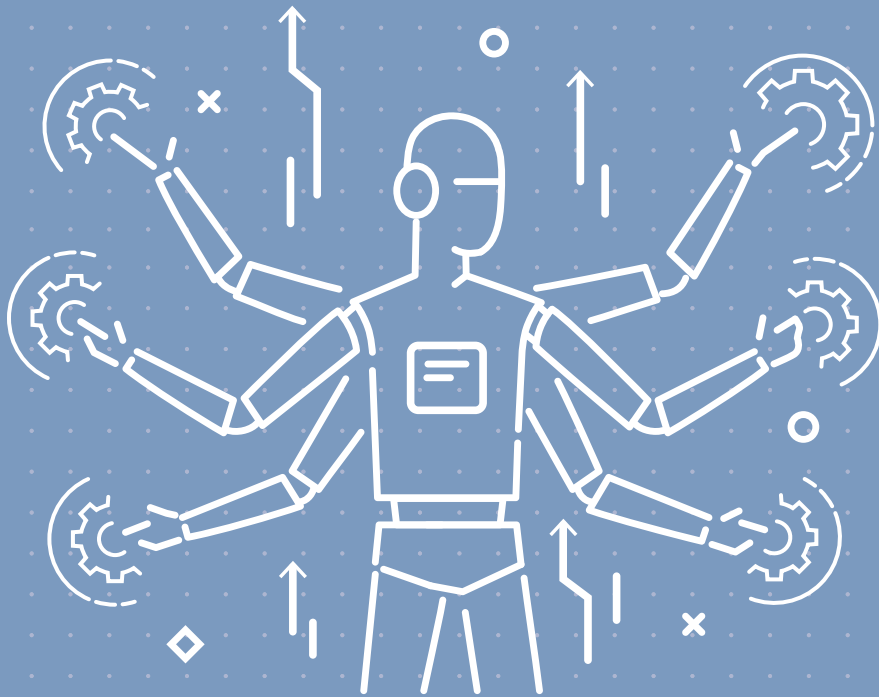
Our factory-trained and certified engineers get projects conceptualized, designed, built, configured, installed, and commissioned quickly. We are also available for operational support, maintenance support, and site services such as outsourcing services, staff augmentation and/or emergency calls.

WE'VE GOT YOU COVERED WITH CUTTING EDGE AUTOMATION TECHNOLOGY

Improving Efficiency, Productivity and Quality

- Over 23 years in Industrial Automation and Control System Integration
- Global Presence – Puerto Rico, USA (Midwest, Northeast) and Europe (Ireland, UK)
- One of the Largest System Integrators in Puerto Rico and the central US.
- 120+ engineers providing system integration services and support
- Unique blend of talent – chemical, electrical, mechanical & computer science
- Highly experienced, Factory certified and licensed (P.E.) engineers
- Control System Integrators Association – Associate Member
- CGMPs, FDA Regulations and Industry Standards (ISPE GAMP, ISA S95, S88)
- Certified Minority Business Enterprise (MBE) in PR and the USA
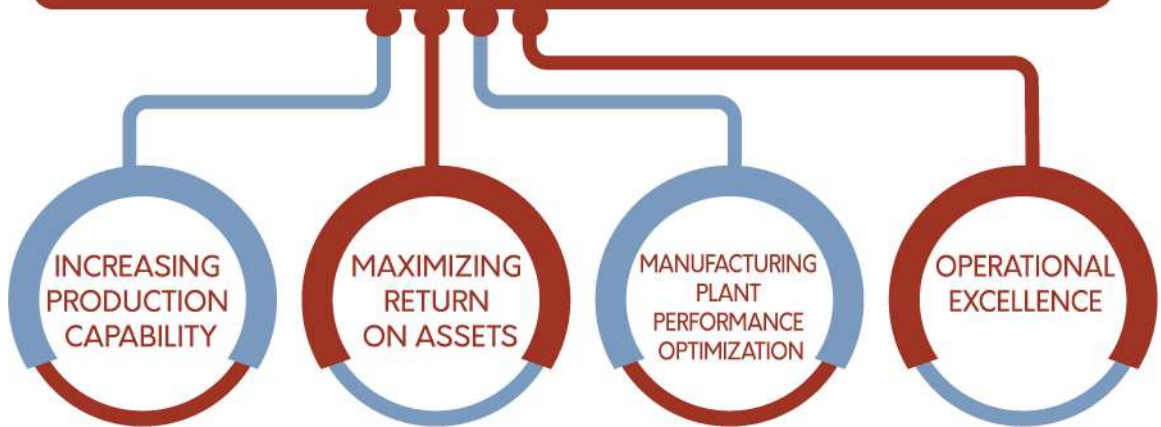- A Harvard Business School case study

AUTOMATION

PACIV'S INDUSTRIAL AUTOMATION SERVICES ARE AT THE CORE OF OUR BUSINESS.

PACIV has been globally implementing new automation systems, upgrading old systems and making changes to existing systems for over 20 years now. We specialize in the design, configuration, and successful implementation of automation systems utilized on both batch and continuous process projects for the world's leading Life Science companies. We leverage your existing infrastructure to implement process automation solutions designed for your manufacturing and processing needs. We work with our customers to ensure that every automation project runs smoothly, remains on time and within budget.
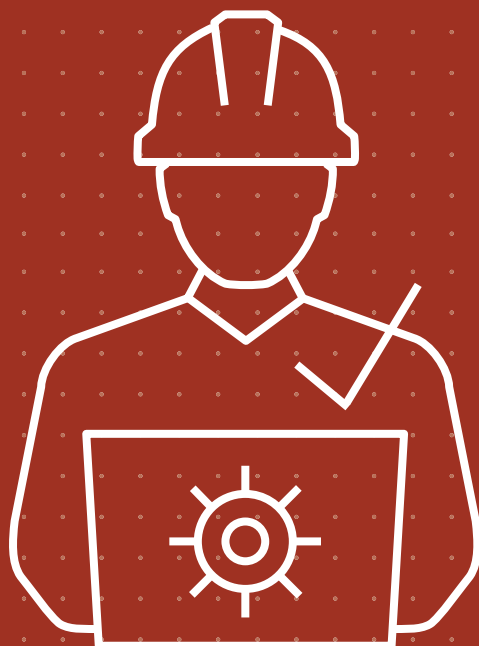
Our cross-functional and multi-disciplined teams employ knowledgeable automation engineers with the industry proven experience and agility to deliver world leading right-sized solutions within the various technology platforms used by our clients. We work with our clients on all project sizes, from a single-loop controller to plant-wide automation systems.

THE AUTOMATION SOLUTIONS WE OFFER ALLOW OUR CLIENTS TO ACHIEVE THEIR OPERATIONAL STRATEGIC OBJECTIVES WHILE SIGNIFICANTLY REDUCING OVERALL COSTS BY:

- INCREASING PRODUCTION CAPABILITY
- MAXIMIZING RETURN ON ASSETS
- MANUFACTURING PLANT PERFORMANCE OPTIMIZATION
- OPERATIONAL EXCELLENCE

OUR INDUSTRIAL AUTOMATION SERVICES COVER:

- Vendor independence – focused on delivering the best solution
- Multi-platform capabilities with access to OEMs through relationships
- Evaluation, including the technical and business impact of control system choices
- Site-wide Automation Strategy Consultancy
- Automation Project Management

VALIDATION

At PACIV, we verify through documented evidence that a system meets its functional intent and adheres to the requirements and approved design to deliver a sustainable and reliable solution. Our Commissioning and Qualification (C&Q) and Computer System Validation (CSV) services make certain that the development and implementation process runs smoothly. From initial planning and design concept throughout the System Development Lifecycle (SDLC), we ensure that systems are properly handed over so they can be maintained in a validated state through their useful lifecycle up to retirement.

OUR C&Q AND CSV SERVICES INCLUDE:

- Commissioning and Validation SDLC services leveraging risk-based Management Process following FDA, ICH Q9, ASTM 2500, and ISPE (GAMP and C&Q) guidelines to provide full CSV/C&Q Life Cycle Services for:
  - Automated in-process Filling, Assembly, and Delivery lines
  - Packaging Systems (e.g. Cartoners, Palletizers, Print/Verify, etc.)
  - Facilities/Utilities (e.g. SIP/CIP, BMS/CMS, AHUs, Metasys, NAE controllers, etc.),
  - Lab Equipment (e.g. Homogenizers, Spectrophotometers, Balances, Freezers, Coolers, etc.)
- Gap and Risk Assessments
- Consultancy for FDA 483's and/or Warning Letters handling (responses and remediation initiatives)
- Vendor Evaluations and Qualifications
- Validation Operation and Configuration Services (i.e. System Administration, Configuration Management, Security Administration, etc.)
- Maintaining a Validated State (i.e. Backup/Restore, Disaster/Recovery, Business Continuity Plan, Periodic Review, etc.)
- Cleaning Validation
- Data Migration, Integrity, and Retention Verification Services

AT PACIV, WE VERIFY THROUGH DOCUMENTED EVIDENCE THAT A SYSTEM MEETS ITS FUNCTIONAL INTENT AND ADHERES TO THE REQUIREMENTS AND APPROVED DESIGN TO DELIVER A SUSTAINABLE AND RELIABLE SOLUTION

PROGRAMMING

TESTING

DEVELOPMENT

PLANNING

IMPLEMENTATION

DESIGN

VALIDATION AND VERIFICATION

ANALYZE

Our Commissioning and Qualification (C&Q) and Computer System Validation (CSV) services make certain that the development and implementation process runs smoothly. From initial planning and design concept throughout the System Development Lifecycle (SDLC), we ensure that systems are properly handed over so they can be maintained in a validated state through their useful lifecycle up to retirement.

Our full C&Q/CSV System Development Life Cycle (SDLC) services include consultancy, planning, development, and execution tailored to meet your corporate policies, procedures, and validation methods while applying ISPE GAMP™ and C&Q Guidelines.
Whether it is a new product line and design concept, or modification to an existing system (i.e. capacity expansion, design or process improvement, etc.), PACIV can meet all your C&Q and CSV needs with over two decades of expertise and hands-on implementation and delivery.
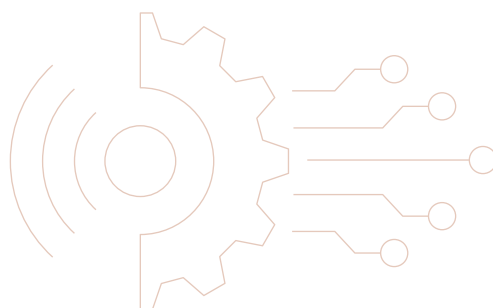
INSTRUMENTATION

PACIV can address any instrumentation needs from specification and procurement to installation and field calibration for all types of process instrument technologies ("smart", electronic, pneumatic).

We combine best-practice expertise with broad service flexibility to meet your needs. We are platform-independent so we can work on a wide range of technologies in your facility.

We can calibrate instruments according to your specific plant standards and maintenance schedules. We will work around your hours and project requirements, dispatching the right number of technicians with the matching skills for the job and the right fit for your company culture. We can perform calibrations on new instrument installations and support your existing operation and maintenance calibration needs Our instruments calibration technicians can be equipped with calibration standards that are traceable to NIST. We perform calibrations in all industrial instrumentation such as temperature (including recorders and mapping), level, pressure, pH, flow, and conductivity among others.

Our Technicians are trained to install all needed instrumentation and other I&C equipment (e.g. control panels, junction boxes, and marshalling panels). We are certified to perform installations and certifications on industrial control networks such as DeviceNet and FOUNDATION Fieldbus. We will work around your production needs to minimize disruptions. Whether your project entails I&C upgrades / retrofits or new construction, we can work with you to ensure proper installation and start-up, including necessary commission testing. With multiple office locations and different resource capabilities, we can bring the proper resources into the project to attend to any particular need at the appropriate time.

- Procurement, expedite and coordinate delivery with project team
- Receipt Verification (RV) as per specification/data sheets
- Manage and resolve all NCR's (Non-Conformances)
- Electrical instrumentation and piping drawings
- Installation
- Verification and inspection of equipment installed against P&IDs ("walkdowns")
- Conduit and Wiring Termination
- Calibration Certification as per our or client procedures (using NITS certified instruments standards)
- 24 / 7 On-Site Support and maintenance
- Instruments data entry into Computer Maintenance Management Systems (CMMS) (e.g. MAXIMO)

INSTRUMENT SERVICE PROVIDER (ISP PROVIDER)

Turnkey Instrumentation Services including our unique inspection and verification services to ensure Regulatory Compliance of process plant instruments and components (from temperature, pressure and analytical measurements to valves and pumps) for your project. We manage everything from ordering to delivery to your site when your team is ready to install.

We do it all so that you never get to project commissioning and realize that you don't have critical documentation for the systems to be tested and documented properly or that the wrong instrument was installed costing time and money for specialized instruments to be reordered and replaced.

- Order placement after instrument tender bid selection phase.

- Expediting of delivery process.

- Storage in a controlled warehouse space.

- Receipt Verification/ Inspection of instrument.

- Generation of regulatory compliance inspection pack per instrument.

- Generation of documentation Turn Over Packages (TOP).

- Just in time Delivery service to Project main Contractors (skid and stick build) of instruments to suit construction schedules.

- Ensures full compliance of Corporate/site instrument standards across all project contractors/ skid vendors.

INDUSTRIAL CONTROL PANEL SHOP SERVICES

We will design, fabricate, and/or install any type of panels to fulfill our clients' control system and communications needs. Our panels are fabricated as per clients' requirements and can cover any type of process area classification.

Our industrial panels can be designed as Main Control, Extended/Remote I/O, Power Distribution, Network Cabinets or any other manufacturing application-type panels to satisfy the client's project needs. We procure all materials in-house required to fabricate the panels, perform and document all check-out/testing (FAT), and provide panel installation and field wiring termination as required at the site.

In addition to new panel fabrication, we can also retrofit existing panels in the field to ensure the most up-to-date and current PLC, HMI, and Network versions and solutions are being utilized.

Our PACIV-USA office is a UL508A-approved Industrial Control Panel Shop.

Our Control Panel Shop Services include:

- Generation of Control Panel Engineering Design and Specifications, including Panel Layout and Electrical and Wiring Schematic Drawings
- Fabrication of new PLC/DCS and Power Distribution Panels (Low/Voltage, VFD/Motor Control, etc.)
- Network Communication Technologies (i.e. Industrial Ethernet, Radio, 4G, ControlNet, DeviceNet, Serial, etc.)
- Procurement of Panel Hardware, Software, and Components
- Programming and Configuration of PLC and HMI Systems widely used across global manufacturing platforms (i.e. Rockwell, DeltaV, Omron, Siemens, Etc.)

- Panel Commissioning Services
- UL508A Standards Conformance and Panel UL Certification/Labelling
- Delivery to Client Site and Start-up Testing (Field I/O, Loop Check, Software/Network/VFD Configuration, etc.)

PACIV-USA office is approved as a UL508A listed shop.

VISION

Keep improving our global leadership in industrial automation solutions for the life science's industry

MISSION

To be the preferred industrial automation service company of our life science's clients by applying our unique combination of technical expertise and commitment culture. We will achieve unparalleled cost-effective and reliable solutions for our life sciences' business partners while being a great company in which to work and a valuable corporate citizen to our communities.

VALUES

- Excellence and Innovation in all we do
- Honesty and Integrity are the foundation of who we are
- Relentless Commitment to serve is our way of life
- Listen to our client's and associate's needs
- We are a family; Respect, Loyalty and Teamwork is our company culture
- We are an Integral part of the Communities in which we live

OUR CREDO

We will strive to be the preeminent global provider of control systems, instrumentation, commissioning, qualification, and computer system validation services.

We will perform our services reliably, on-time, and with the highest degree of integrity, commitment, teamwork and dedication, completely satisfying our customer's needs and expectations.

We will conduct our business in a manner that produces exceptional value or both our associates and our clients while challenging every member of our team to seek the highest level of integrity, technical competency, drive, and focus.

We will uphold the high ideals that continue to make PACIV the company of choice for our business partners as well as for our associates.

FAST FACTS

- Founded in 1997 – over 23 years in the Life Sciences industrial automation arena
- Global presence (Puerto Rico, USA and Ireland)
- Largest system integrator in Puerto Rico and Indiana
- 120+ full-time associates providing system integration services and support
- Unique blend of talent – chemical, electrical, mechanical & computer science
- Highly experienced, Factory certified and licensed (P.E.) engineers
- Rockwell Recognized System Integrator, Factory Certified (e.g. DeltaV, Foxboro, iFIX, OSIPI, Wonderware)
- Knowledge and experience in cGMP's, FDA Regulations and Industry Standards (ISPE GAMP, ISA S95, S88)
- Full range of instrument standards (NIST Certified)
- Control System Integrators Association – Associate Member
- Certified Minority Business Enterprise (MBE)

We will strive to be the preeminent global provider of control systems, instrumentation, commissioning, qualification, and computer system validation services.

- Harvard Business School Case Study
- Global Supplier of the Year for Eli Lilly & Co.
- 20 Best Employers in Puerto Rico
- Top 400 Companies in Puerto Rico – Caribbean Businesses
- Top 10 Highest Growing Companies in Puerto Rico – Caribbean Business

PACIV

A Global Leader in Industrial Automation Solutions

PLEASE CONTACT
PACIV TODAY
TO EXPLORE HOW
WE CAN DESIGN
AND SUPPORT
YOUR AUTOMATION
SYSTEMS:

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