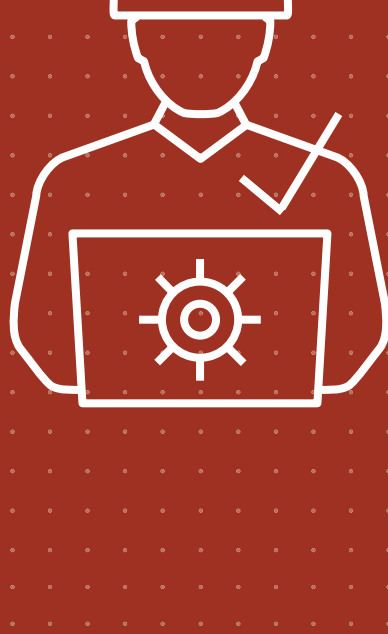


VALIDATION

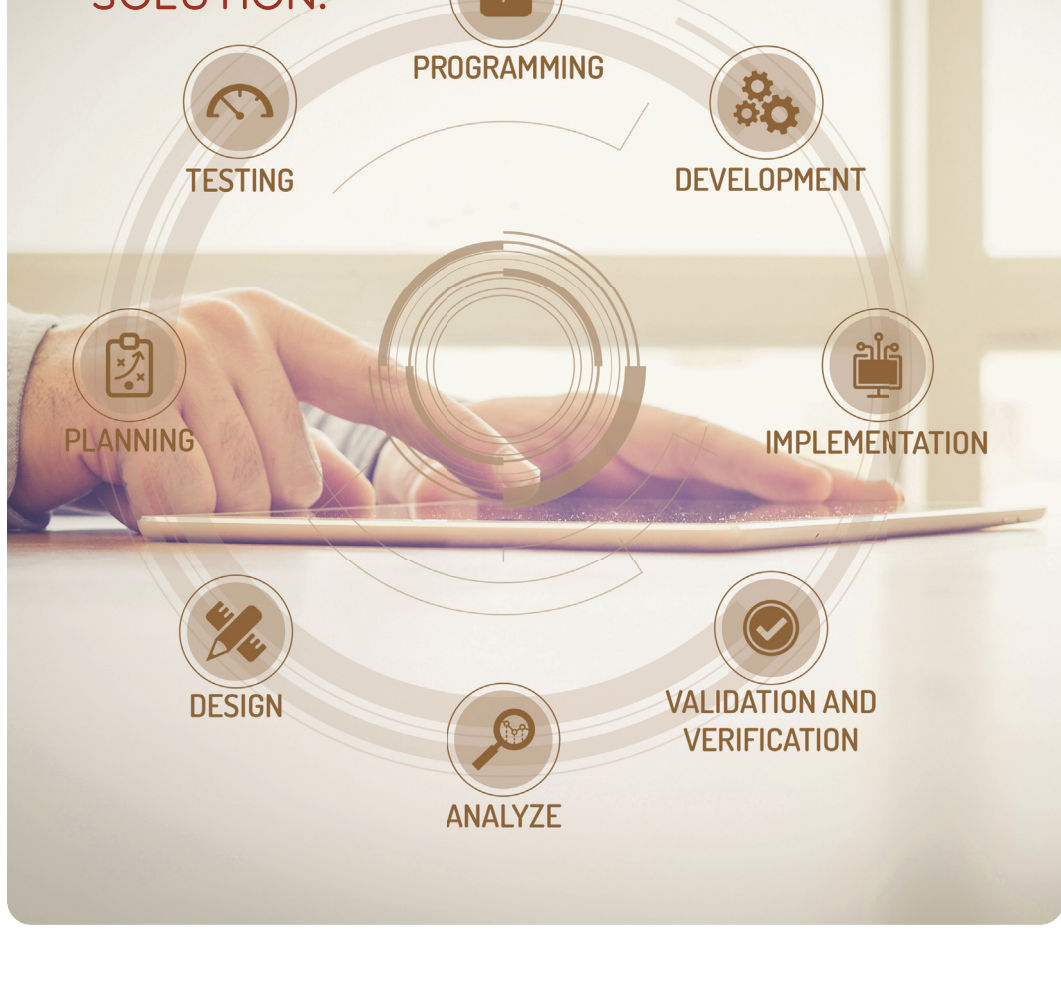


PACIV

A GLOBAL LEADER
IN INDUSTRIAL AUTOMATION
SOLUTIONS

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

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 through over two decades of expertise and hands-on implementation and delivery.

PACIV

A Global Leader in Industrial Automation Solutions

PLEASE CONTACT
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TO EXPLORE HOW
WE CAN DESIGN
AND SUPPORT
YOUR VALIDATION
SYSTEMS:



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