



PINNACLE
INDUSTRIAL CONTROLS

System Integration

Lifesciences

Solutions for automation in the Lifescience industry. With expertise of over 20 years and domain expertise with complete solutions derived from *GAMP5*.

About Us

Pinnacle Industrial Controls is an established industrial automation and control system solutions company. With over 20 years of experience. We partner with clients spread across the world, ranging from mid-sized companies to MNCs from OEMs to end users. Our engineers are well equipped to execute customized integration needs of the pharmaceutical industry world. They are well equipped with knowledge base across various software, hardware, operating systems, network and manufacturing processes.



System Integration Expertise

Lifesciences Experience

We have install base of our automation solutions for Lifesciences industry in the top 20 Pharma and Biopharma companies in India. We work closely with many of the consultants and process OEMs. We also have many global installations of our automation systems.

We have tremendous experience in executing systems based on GAMP5 guidelines. We also take care of complete life cycle of the project, from preparation of URS to finalization of performance qualification.

We understand the challenges of each of the persons involved in the factory, viz. Production, Quality, IT, Projects and Pharmacists.

Our goal is to get maximum ROI for the customer and get maximum production as per global standards.

WHAT WE OFFER

- Automation solutions / Hygienic Instruments
- Domain expertise and skilled resources
- Technical know-how various platforms
- Understanding of the international guidelines
- Always available, support to End Users
- Complete 21CFRPart11 implementation
- Consultancy for fully compliant system
- Support throughout the lifecycle of the product
- Legacy systems support

Domain Expertise

Liquid manufacturing

- Creams / ointments manufacturing lines
- Vials / ampoules manufacturing lines
- Large volume and small volume parenteral
- Vaccines projects
- Integrated systems for sterile mfg with CIP/SIP
- Liquid orals with integrated CIP
- Blending, mixing, filtration and storage
- Oncology and ophthalmic lines

Packaging

- Cartoning
- Blister Packaging
- Tube filling
- Tablet / liquid /capsule filling and capping
- Tablet counting/insertion
- Labelling
- Injectable filling
- Powder filling
- Pick and place
- Sorting

Solids manufacturing

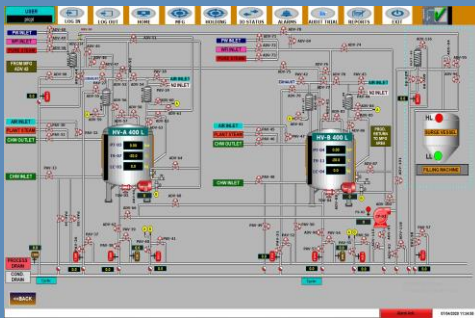
- Tablet coating
- Rapid Mixer Granulators
- Fluid Bed Driers
- Blender
- Complete integrated granulations lines
- Co-mill/Sifter
- Product transfer systems
- Tablet press

Sterilizers and dryers

- Steam sterilizer
- Dry heat sterilizer
- Autoclave / Bung processor
- Pure steam generators & MCDP
- Lyophiliser

High purity water

- Generation & distribution for WFI, PW, softener, UF, RO-EDI, DM



MFG AREA AUDIT REPORT			
Start Date and Time :		08/11/2019 16:00:00	
End Date and Time :		08/11/2019 17:00:00	
DATE TIME	DESCRIPTION	COMMENT	USERNAME
08/11/2019 16:01:18	Line 'B' tagged on with alarm 'Signal'		System
08/11/2019 16:01:18	Line tagged off		System
08/11/2019 16:01:18	Line 'A' tagged on with alarm 'Signal'		System
08/11/2019 16:01:18	Line 'A' tagged on with alarm 'Signal'		System
08/11/2019 16:01:18	Line 'B' tagged on with alarm 'Signal'		System
08/11/2019 16:01:18	Line 'C' tagged on with alarm 'Signal'		System
08/11/2019 16:01:18	Line 'D' tagged on with alarm 'Signal'		System
08/11/2019 16:01:18	Line 'E' tagged on with alarm 'Signal'		System
08/11/2019 16:01:18	Line 'F' tagged on with alarm 'Signal'		System
08/11/2019 16:01:18	Line 'G' tagged on with alarm 'Signal'		System
08/11/2019 16:01:18	Line 'H' tagged on with alarm 'Signal'		System
08/11/2019 16:01:18	Line 'I' tagged on with alarm 'Signal'		System
08/11/2019 16:01:18	Line 'J' tagged on with alarm 'Signal'		System
08/11/2019 16:01:18	Line 'K' tagged on with alarm 'Signal'		System
08/11/2019 16:01:18	Line 'L' tagged on with alarm 'Signal'		System
08/11/2019 16:01:18	Line 'M' tagged on with alarm 'Signal'		System
08/11/2019 16:01:18	Line 'N' tagged on with alarm 'Signal'		System
08/11/2019 16:01:18	Line 'O' tagged on with alarm 'Signal'		System
08/11/2019 16:01:18	Line 'P' tagged on with alarm 'Signal'		System
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08/11/2019 16:01:18	Line 'R' tagged on with alarm 'Signal'		System
08/11/2019 16:01:18	Line 'S' tagged on with alarm 'Signal'		System
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08/11/2019 16:01:18	Line 'X' tagged on with alarm 'Signal'		System
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08/11/2019 16:01:18	Line 'Z' tagged on with alarm 'Signal'		System

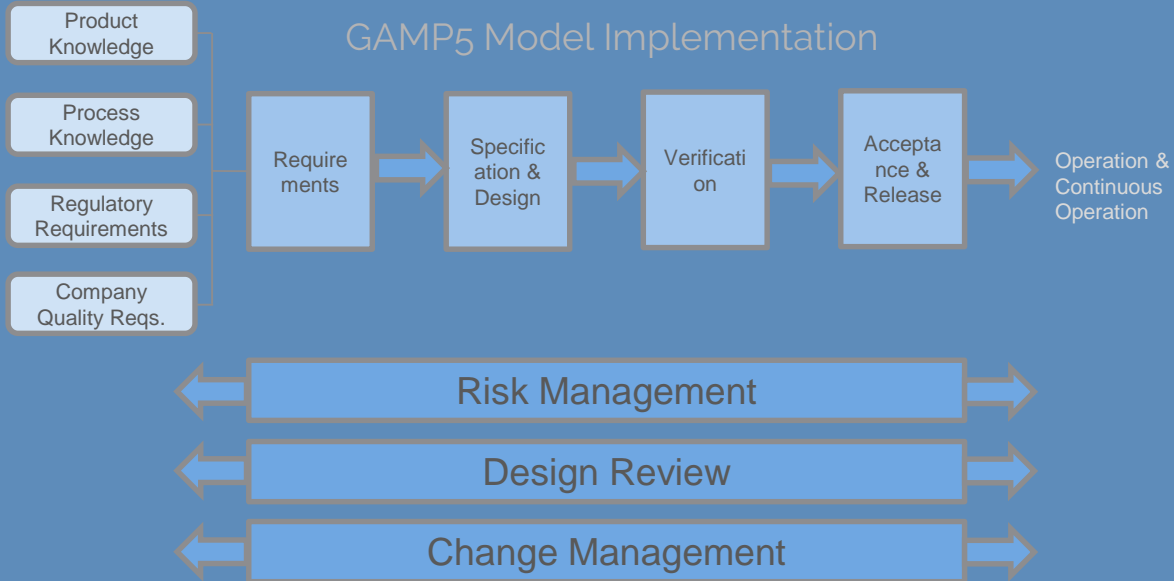
Documentation

- Compliance of the URS
- Functional Design Specifications (FDS)
- Logic flow / Valve matrix
- Security matrix
- System architecture
- Design Qualification (DQ)
- Risk Assessment (RI)

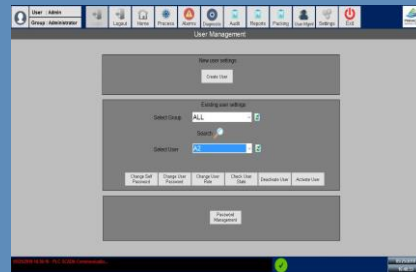
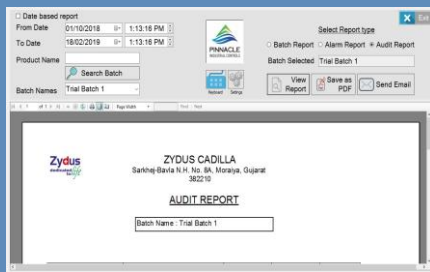
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Factory Acceptance Test (FAT)
- Simulation
- Disaster Recovery Management
- Electrical Panel Drawings
- User Manual

21 CFR Part 11 compliance and solutions

Our first 21CFR Part 11 SCADA package was installed way back in 2007 in Serum Institute, Pune. We have over 12 years experience working with 21CFR systems in the industry. We understand and comply all URS's of 21CFR Part 11, USFDA and Eudralex. Along with automation and SCADA we also understand the challenges of IT infra and configuration requirements of the customer, which enables to comply 100% with the URS.



We help End Users and Original Equipment Manufacturers (OEM) in this industry to comply with the most stringent norms that 21CFR Part 11 demands. We have absolute clarity on this subject and with our experience of working in the Life sciences industry for more than 20 years, we can deliver systems with no liability to the end user from auditors.



Security & E-Signatures features
Audit and Alarm Reports
Electronic Records, Batch Reports
Auto Data Backup
RAID Hardware

Validation Documentation
IT System / OS Security Requirement
Complete GAMP5 Implementation
Signature Manifestations
Custom Reports

Customer Base



INNOVATION

DRIVES OUR AUTOMATION



PINNACLE
INDUSTRIAL CONTROLS

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