

CTP SYSTEM

INTEGRATED COMPETENCES

Nuestra misión es integrar nuestros conocimientos y recursos con los de nuestros clientes, creando así una compañía integrada.

Nos llamamos a nosotros mismos "SYSTEM" porque somos un mecanismo donde el conocimiento y la experiencia aprovechan al máximo todos los aspectos técnicos y de calidad.

CTP SYSTEM presenta su brand para Latinoamérica:



Latino América Consultores (LAC) es una empresa del grupo CTP que se dedica a brindar servicios de consultoría para la industria farmacéutica en Latinoamérica, en la cual integramos competencias, conocimientos y experiencia para ponerlos al servicio de nuestros clientes. Nos basamos en los conceptos **CALIDAD y RESPETO** que –además de requisitos indispensables-, son nuestra filosofía de trabajo.

Contamos con un grupo de profesionales relacionados con la industria farmacéutica que están al servicio de las necesidades de nuestros clientes, cumpliendo con las normativas de calidad nacionales e internacionales, garantizando así que nuestros procedimientos estén respaldados por alta tecnología y normas específicas. Nuestro "know-how" se debe a nuestro amplio conocimiento, nuestra red de expertos internacionales y la constante participación en la actualización de técnicas y metodologías, pero por sobre todo creemos en las personas y en las ideas.



INGENIERIA

- Project Management
- Value Engineering
- Feasibility Studies
- Conceptual, Basic & Detail Design
- Manufacturing Equipment & Critical System
Supplier Selection
- Commissioning
- FAT / SAT

SERVICIOS REGULATORIOS PARA EMPRESAS EXPORTADORAS

- EMEA and FDA Product Registration
- Documentation for Drug Product Submission
(CTD)
- eSubmission
- Assistance for Documentation Submission to the
Health Authority
- NDA & DMF Preparation
- Site Master File Preparation
- GxP Audits (local or international auditors)
- Risk Assessment
- GxP & 21CFR Part11 Assessment
- Health Authority Inspection Preparation & Support
- Documentation Preparation & Management
- Quality System Design
- Process Documentation Preparation

VALIDACIÓN DE SOFTWARE

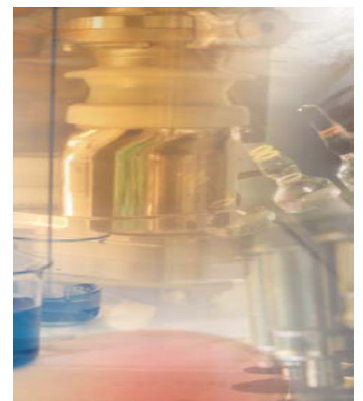
- GxP Software Assessment & Feasibility Studies
- IT Compliance
- Computer System Validation
- GxP Risk Assessment
- 21CFR Part11 Compliance
- ERP and LIMS Qualifications
- Network Qualification
- Training

SERVICIOS DE VALIDACIÓN

- GAP Analysis
- Risk Analysis / Impact Assessment
- Design Qualification
- Validation Master Plan Preparation
- IQ / OQ / PQ of Manufacturing Equipment &
Critical Systems
- Analytical Equipment Qualification
- Maintenance & Calibration (Metrology Plan,
Preventive Maintenance Plan, SOPs)
- Cleaning Validation
- Technology Transfer
- Process Validation

GXP TRAINING

- Multi-user Courses
- Tailored Courses for Companies
- Basic Training



Componentes del Sistema



UNI EN ISO 9001:2000
SA 8000



Leader in GMP Compliance Services for equipments and production processes

Two internal Departments.

Engineering & Validation, Strategic Approach Definition and Support for New Projects, Conceptual, Basic & Detail Design, Project Management, GMP Supervision and Support. Project Risk Assessment, Design Qualification. Critical Utilities Qualification, Production Equipments, Control Systems

Process & Quality, Management and execution of Validation Programs for Production and Cleaning Processes. Consultant Support for Quality Assurance, Quality Control, Production, Regulatory Affairs, Research & Development.



Chemical Laboratory

Chemical Methods Development and Validation, ICH Stability Programs, GLP Support, NIR Methods Development & Consultancy, Pharmacokinetic and Bioequivalence Studies, Residual Studies, Analytical Support.



Microbiological Laboratory

Microbiological Methods Development and Validation, Microbiological Support & Consultancy, HACCP Support & Consultancy, Environmental Monitoring Consultancy, Sanitizing Agents Qualification, Analytical Support.

OPERATING IN COMPLIANCE WITH UNI EN ISO 17025 STANDARD



Metrology, Calibration and Technical Services Company

Metrology & Calibration Services, Preventive Maintenance, Technical Services and high specialization in Vacuum Technologies and Thermography.



Leader in Information Technology Supply & Compliance in GxP Environment

Two internal Departments.

Compliance, Validation Policies and Validation Master Plans Definition, GxP Risk Assessment, 21CFR Part11 Training & Consultancy, Audit to Automated Systems Suppliers, Information Systems and Control Systems Validation, Network qualification, Validation of Software Interfaces (data transport and data migration), Feasibility Studies and User Requirement Specification (URS) definition for GxP critical SW Projects, Software Selection, Project Management.

Project & Solution, Software Solutions Development & Implementation for Knowledge and Document Management, eSubmission and Dossier Management, Business Intelligence, Enterprise Application Integration, Quality Control Support Solution, IT Consultancy for IT Strategy and IT Security.



Partner of CTP Tecnologie di Processo for South America.



Subsidiary of CTP Tecnologie di Processo for central/eastern Europe



Partner of CTP Tecnologie di Processo & ICS Pegaso for central/western Europe



Integrated, value-added services for the Pharmaceutical Industry

Manufacturing & Technology Support, Regulatory Support, Business Management & Business Development Support.

Competencias Integradas



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