

PROCESS & QUALITY UNIT

CTP SYSTEM INTEGRATED COMPETENCES

VISION

Essere partner attraverso la competenza integrata affiancando strutture ed aziende per la compliance verso le GMP in un processo di miglioramento continuo del life-cycle dei prodotti.

MISSION

Essere il supporto operativo e strategico delle società GMP-oriented, la soluzione ideale per le necessità di Assicurazione e Controllo Qualità, Affari Regolatori e aspetti di Produzione.



CTP Tecnologie di Processo S.p.A. è la capogruppo di CTP SYSTEM



CTP Lab, il laboratorio microbiologico di CTP SYSTEM è accreditato GMP



CTP Chem, il laboratorio chimico di CTP SYSTEM è accreditato GLP e GMP



QUALITY ASSURANCE

- GxP Audits
- Remediation Plans Design & Execution
- Health Authority Inspection Preparation & Support
- Documentation Preparation & Management & Review
 - Standard Operating Procedures
 - Batch Records
 - Change Control
 - Deviations
 - Out of Specifications
- Risk Analysis
- Validation of “Active” instrument
- GxP Training & Training Management
- Annual / Product Quality Review Preparation
- Suppliers Qualification

QUALITY CONTROL

- GLP/GMP support
- USP/EU Compendial Services
- Non Compendial Methods Development & Validation
- Sanitizing Agents Qualification
- NIR Methods Development & Consultancy
- RAW Materials & Packaging Analysis
- Air & Utilities Monitory Plan Design & Execution
- Identification of the isolated microbial flora (bacteria, moulds and yeasts)
- Analytical Transfer
- Water Assessment according to USP <1112>
- Analytical Equipment Qualification and test execution (IQ, OQ, PQ)



REGULATORY AFFAIRS

- Dossier Audit
- Remediation Plans Design & Execution
- Documentation for Drug Substance / Product Submission: CTD Preparation & Reviewing
- eSubmission
- Assistance for Documentation Submission to the Health Authority
- NDA & DMF Preparation & Reviewing
- Site Master File Preparation & Reviewing
- Variations submission
- 510 K documentation Preparation & Reviewing
- Regulatory Affairs in out-sourcing
- ICH Stability Study
- Analytical Support
- Residual Studies in biological liquids and animal tissues

PRODUCTION

- Preparation of Process Management & Control Documentation (SOPs, Batch records)
- Quality by Design / Robust Approach
- Process Development And Optimization
- Formulative Development
- Production Processes Supervision
- Planning and Execution of environmental samples
- Scale-up & Technology Transfer
- Process Validation
- Cleaning & Cleaning Validation
- Process Analytical Technology (PAT)
- Supplying and analysis of validation bioindicators



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UNIT

PERCHE' ...

... lavoriamo da 20 anni nel settore,

... la nostra storia ci ha permesso di diventare il più grande gruppo di consulenza GMP in Italia,

... flessibilità dell'offerta,

... personalizzazione del servizio,

... unicità della struttura,

... team multi-disciplinari,

...per noi non esistono clienti ma solo partner!

