CTP SYSTEM
INTEGRATED COMPETENCES

PROCESS & QUALITY UNIT

VISION

Essere partner attraverso le **COMPETENZE INTEGRATE**, affiancando strutture e 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.

perché …

… lavoriamo da oltre 20 anni nel settore,

… la nostra storia ci ha reso 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!

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” instruments
- 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 Equipments 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

- Dossier Audit
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