

# CTP SYSTEM

## INTEGRATED COMPETENCES

### LABORATORY SERVICES



**GMP certification: n. aM-186/2008 according to D.lgs 219/2006**

**GLP certification: n. 19/25/2006 according to D.lgs 50/2007**



**GMP certification: n. aM-176/2008 according to D.lgs 219/2006**



### RESEARCH & DEVELOPMENT

- Development and validation of *compendial* and *non-compendial* analytical (chemical-physical and microbiological) methods
- Validation of sanitizing agents (in vitro and on surfaces)
- Validation of methods for quantification of sanitizer residual
- Neutralizer Efficacy Testing
- Identification of Microbial isolates (bacteria, moulds and yeasts)
- Recovery Studies
- Analytical Methods transfer and laboratories qualification
- Analytical services in support of complaints
- Pharmaceutical pre-formulation and formulation development
- Water Activity Determination according to USP <1112>
- *Extractables* and *Leachables* testing



## GMP AREA

- Chemical and physical analysis (Titrations, TOC, HPLC, GC, Dissolution Test, Atomic Absorption, IR)
- Microbiological analysis (Lal test by kinetic-chromogenic method, Mycoplasma detection, TMC, Growth promotion test, bacteriostasis and fungistasis test, microbial identifications, Preservatives efficacy test)
- Chemical-physical and microbiological analysis of compressed gases
- Supplying and analysis of bioindicators for validation
- Analysis of raw materials and packaging materials
- D-value determination (test performed in third-party laboratory)
- Holding time evaluation
- Environment validation: microbiological sampling and testing of air and surfaces
- Validation of personnel garments
- NIRS libraries development and NIRS quantitative methods validation
- Stability Studies according to ICH/ASEAN Guidelines
- Residual Studies in biological fluids and animal tissues
- Analytical activities in support of raw materials suppliers qualification according to D.lgs 219/06
- Analytical activities in support of regulatory documentation (CTD, Variation Type IA/ IB/ II)
- Bioequivalence studies by comparative testing based on F1 and F2 values
- Document preparation based on the CTD granularity requirements
- Equipment qualification (IQ, OQ, PQ)

## CONSULTING ACTIVITIES

- Training (Quality Control, Analytical Research and Pharmaceutical Development areas)
- Statistical application in pharmaceutical area
- Raw materials suppliers Auditing
- Consulting activities in support of QA department
- Development of Remediation Plans in compliance with 21CFR Part11 and Annex 11
- Standard Operating Procedure preparation and review
- Project Management in compliance with quality and regulatory requirements
- Consulting activities in support of GLP certification and Auditing
- Consulting activities in support of Risk Assessment for environmental monitoring program
- Consulting activities in support of microbiological analysis of water for pharmaceutical purposes (establishment of alert and action levels based on trend analysis of total microbial count)
- Analytical and consulting activities by CTP CHEM and CTP LAB qualified personnel at Customer's site



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