



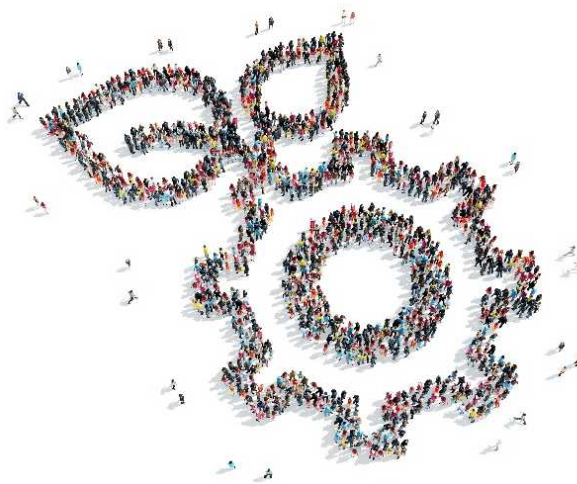
# CTP SYSTEM

INTEGRATED COMPETENCES

AKKA TECHNOLOGIES GROUP

*for*

# LIFE SCIENCES



[CTPSYSTEM.COM](http://CTPSYSTEM.COM)

# THE RIGHT INTEGRATION OF COMPETENCE, KNOWLEDGE AND EXPERIENCE IN A WINNING SYSTEM OF SKILLS.

## OUR COMPETENCE

### OUR STORY

**CTP SYSTEM Srl**, founded in 1990, is leader in Italy and one of the most important companies in Europe for the **PHARMACEUTICAL, CHEMICAL, HEALTHCARE, COSMETICS, FOOD, and VETERINARY FIELD**.

In 2017, **CTP SYSTEM** enters **AKKA TECHNOLOGIES Group**, already a leader in the development of technology services for the **Automotive, Railway, Aeronautics, Space & Defense, Oil & Gas** sectors.

The integration of **CTP SYSTEM** within the **AKKA Group** allows enhancing in synergy each other's competence, also creating a specialized network for the Life Sciences world.

**CTP SYSTEM** provides management and delivers consulting services to support the customers in **each step of the product life cycle**, from Research & Development to Process & Plant Engineering, Technology Transfer, Regulatory Support, Process & Plant Qualification, enabling IT Solutions.

### OUR VALUES

- ✓ Creating value to our customers for continuous **updating** and **improvement** of regulatory and technical activities related to **development, manufacturing** and **release** of drugs and health products.
- ✓ Guaranteeing high quality, continuity, competence, experience, rapid answer and a wide range of **top level services**.
- ✓ Assuring efficiency and competitiveness, always in compliance with **national and international requirements**.



### OUR SKILLS

More than 160 high-specialized consultants and the dedicated employee's team of **CTP SYSTEM**, in addition to over 350 experts of **AKKA Group**, create a winning **NETWORK** that grows over time:

- Graduated Engineers
- Pharmaceutical Consultants
- Biologists & Chemists
- Software Specialists
- Validation Consultants
- Project Technicians

The professional staff consists of dynamic people, sharing competence, values and specific know-how, for a better coordination and supervision of all the services provided.

### OUR APPROACH

**CTP SYSTEM** strongly believes in the integration of competences, and always applies this approach, following every step of production and manufacturing process, from raw materials to product.



### SHARING YOUR GOALS

- ✓ work with a group of expertise, covering all critical aspects of production with a single supplier
- ✓ find the right solution for every problem occurring during the pharmaceutical production, both in compliance with EU GMP and FDA regulations
- ✓ enter in a network of international services able to develop your business in the major pharmaceutical markets
- ✓ choose the best quality

## COMMISSIONING & VALIDATION

**CTP SYSTEM** supports its customers in managing and directly performing all the Validation phases and Qualification activities for all kinds of equipment, systems and utilities in Pharmaceutical and related companies.

We have extensive experience in the preparation of **Validation Master Plans** at all levels, whether for an establishment or for single project, on behalf of the main international companies for all types of pharmaceutical products (APIs, solid and liquid forms, sterile products and more). We perform the **Qualification & Validation for all the automation systems**, from a single equipment control system of a single machine to complex Distributed Control Systems (DCS) and Building Management Systems (BMS).

## PROCESS & QUALITY

**CTP SYSTEM** has the right experience and know-how for companies that require **Quality Services**, support to **Production Dynamics, Quality Assurance** and **Regulatory activities**. We offer real value to our customers for a continuous updating and improvement of technical and regulatory activities, as for development, manufacturing and release of drugs and health products.

## ENGINEERING

**CTP SYSTEM** thoroughly knows how important it is to apply **GMP requirements in pharmaceutical and healthcare fields**. Our best solution for plant design in pharmaceutical industry combines profound respect of regulations and availability of resources, with the goal of quality for the final product. We offer the bases to develop a project according to the concepts of **Quality Engineering**: a clear definition of the needs, an application of the right functional Quality Assurance notions and innovative technologies.

## IT COMPLIANCE

**CTP SYSTEM** offers experience in Mastery and Validation of all the **IT and Automation Systems**, supporting strategic decisions and on-site project management, with a deep knowledge of technology, process and regulations.

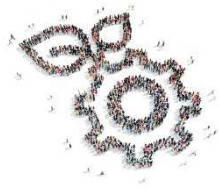


## TRAINING

**CTP SYSTEM** has punctually met the formative request of its customers through the creation of **GxP Training**, a brand that combines all the training activities supplied by its highly specialized staff. The formative proposal of **CTP SYSTEM** is subdivided into many Course typologies:

- MULTI-USERS COURSES
- BASIC TRAINING
- TRAINING ON DEMAND
- PANEL DISCUSSIONS
- ON-LINE TRAINING





**CTP SYSTEM** is able to manage **TIME & MATERIALS** activities or **WORK PACKAGE** projects, according to the Client's needs.

## for COMMISSIONING & VALIDATION

- GAP Analysis
- Risk Analysis / Impact Assessment
- Validation Master Plan Preparation
- IQ / OQ / PQ of Manufacturing Equipment & Critical System
- Analytical Equipment Qualification
- Maintenance & Calibration
- Metrology Plan
- Preventive Maintenance Plan
- Specialized services (vacuum, thermography...)
- Troubleshooting
- SOPs



## for PROCESS & QUALITY

- **QUALITY ASSURANCE**
  - Documentation Preparation and Review
  - Auditing Activity
  - Risk Management & Risk Analysis
  - GMP & ISO Consultancy
- **PRODUCTION**
  - Process Development & Scale Up
  - Technology Transfer
  - Process & Cleaning Validation
  - Process Improvement
- **REGULATORY AFFAIRS**
  - Regulatory Documentation Preparation
  - Submission Support
  - Strategic consulting at European level
- **LICENSING STRATEGY**

## for ENGINEERING

- URS
- Project Management
- GMP review, Risk Assessment, Value Engineering
- Feasibility Studies, preliminary budgeting
- Conceptual, Basic & Detail Design
- Design Qualification
- Tendering & Purchasing Support and Coordination
- Manufacturing Equipment & Critical System Supplier Selection
- Start-up, Commissioning, Construction Supervision, Coordination, Direction
- FAT / SAT

## for IT COMPLIANCE

- **COMPLIANCE PROGRAMME**
  - Assessment of compliance of computerized systems
  - Data Integrity Assessment (paper and electronic data)
  - Support for remediation activities
- **COMPLIANT SOLUTION**
  - Business/GxP process analysis and definition of User Requirement Specifications
  - Supplier and software selection
  - Supplier audit
- **VALIDATION OF COMPUTERIZED SYSTEMS**
  - Validation Lifecycle Procedure and Policies
  - Definition of approach
  - Validation deliverables and activities execution
  - Risk assessment (project, requirements, functional level)
  - Training
  - Support for Standard Operating Procedures
- **IT SUPPORT**
  - Network Qualification
  - Multicompliance Quality Systems



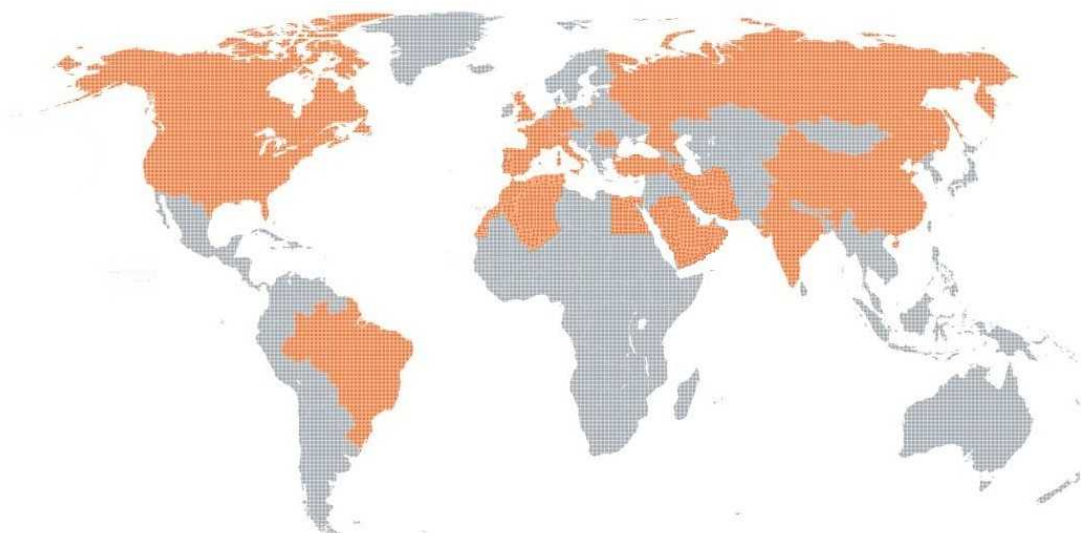
# PLACES



## CTP SYSTEM IN ITALY



## AKKA TECHNOLOGIES IN THE WORLD



A.G.E.O.P. RICERCA ONLUS, AAA, ABBOTT, ABBVIE, ABC FARMACEUTICI, ABIOGEN, ABOCA, ACOM, ACOTEC, ACRAF, ACTAVIS, ADEODATA, ADISCO, ADVANCED ACCELERATOR APPLICATIONS, ADVENT, ADWYA, AGENNIX INC., AGI THERAPEUTICS, AIR LIQUIDE, ALFA OMEGA, ALFA WASSERMANN, ALTERGON, AMERSHAM HEALTH, AMINO CHEMICALS, ANGELANTONI, ANTIBIOTICOS, APSARA, ARCHIMICA, ARDA NATURA, ARGOS ZYKLOTRON, ASTELLAS PHARMA, AT GRADE, AVERROES, AZIENDA OSPEDALIERO-UNIVERSITARIA MEYER, BAREKAT, BAUSCH&LOMB, BAXTER, BAYER, BEA TECHNOLOGIES, BERLIN CHEMIE MENARINI, BIEFFE MEDITAL, BIOCELL CENTER, BIOCLASS, BIOFARM, BIOFER, BIOINDUSTRIA L.I.M., BOKOSMES, BIOLOGICI ITALIA LABORATORIES, BIOPHARMA, BIOPROGRESS, BIOREP, BIOSCIENCE INSTITUTE, BIOSINT, BIOSKILLS, BIOSUN PHARMED, BOEHRINGER INGELHEIM, BOIRON, BOUTY HEALTHCARE, BRACCO, BRISTOL MYERS SQUIBB, BSP PHARMACEUTICALS, C.O.C. FARMACEUTICI, CADENCE PHARMACEUTICALS INC, CAMBREX, CARDIO CENTRO TICINO, CASA RUBIO, CASTAGNETTI, CELL F & B, CENTRO CARDIOLOGICO MONZINO, CENTRO DI RIFERIMENTO ONCOLOGICO, CENTRO SPERIMENTALE DEL LATTE, CERBIOS PHARMA, CHELAB, CHEMIFARMA, CHIESI FARMACEUTICI, CILAG GMBH INTERNATIONAL, COMECER, CONSULT SERVICE, COR CON INTERNATIONAL, CORDEN PHARMA, COSMA, COSMO PHARMACEUTICALS, COSNESSENS, COSTER, CUBIST PHARMACEUTICAL, CYTOPHARMA, D.O.C. GENERICI, DAR ESSAYDALI, DE.CA, DHL, DIATHEVA, DIESSE - DIAGNOSTICA SENESE, DIPHARMA, DOC GENERICI, DOMPE', DOPPEL, DOX-AL, DSM CAPUA, EBM, ECOBIE, ELEA, ELI LILLY, EMERSON, E-PHARMA, ERBA VITA, ESOFORM, ETICHETTE DI RIGA, EUROCLONE, EUROFINS BIOLAB, EUROGAS, FAMAR, FARCHEMIA, FARMABIOS, FARMAC ZABBAN, FARMIGEIA, FARMILATHEA, FASINTERNATIONAL, FEBRAFARMA, FERLITO FARMACEUTICI, FIDIA, FIDIA ADVANCED BIOPOLYMERS, FINE FOODS, FKV, FONDAZIONE CELLULE STAMINALI TERNI, FONDAZIONE SAN RAFFAELE, FONDAZIONE SDN, FORMENTI, FOUNDATION CARDIOLOGICAL RESEARCH, FRESENIUS KABI, FRIULCHEM, GALENICA SENESE, GAMMATOM, GB PHARMA, GE HEALTHCARE, GEDEON RICHTER, GELFIPHARMA, GEMA BIOTECH, GIPHARMA, GLAXO SMITH KLINE, GNOSIS, GRANAROLO, GRIFOLS, GROUPE SAIDAL, GRÜNENTHAL-FORMENTI, GUNA, HARDIS, HAUPT PHARMA, HELSINN CHEMICALS, HIKMA, HIPPOCRATES RESEARCH, HITEC, HOLLIDAY SCOTT, HOSPIRA, HPB HUMAN BIOPLAZMA, IASON, IBA RADIOISOTOPI ITALIA, IBN SAVIO, IBSA, ICF, ICI RENDE, IDI, IEO - ISTITUTO EUROPEO DI ONCOLOGIA, IMA, IMA LIFE, IMS, INAIL, INFOR, INFRA, INGEGNERIA BIOMEDICA SANTA LUCIA, INGHENIA, INJECTALIA, INNOPHARMA, INSTITUT PASTEUR, IOR BOLOGNA, IPT, IRST, ISTITUTO NAZIONALE PER LA RICERCA SUL CANCRO, ISTITUTI FISIOTERAPICI OSPEDALIERI, ISTITUTO DE ANGELI, ISTITUTO DI FISILOGIA CLINICA - CNR, ISTITUTO SUPERIORE DI SANITÀ, ITALFARMACO, ITEL, IVERS LEE, JANSSEN-CILAG, JOHNSON&JOHNSON, JOINET, KEDRION, KLINVER, KW, LA.FA.RE, LABORATOIRES BOIRON ITALIA, LABORATORIO ARISTON, LABORATORIO FARMACOLOGICO MILANESE, LABORATORIO HIDALGO, LAMEPLAST, LAMP, LDM LABORATORIO DIAGNOSTICA MOLECOLARE, LOFARMA, MAGIS FARMACEUTICI, MANETTI & ROBERTS, MEAD JOHNSON, MEDICAIR ITALIA, MEDICAL RESEARCH, MEDICEF, MEDIPASS, MEDIS, MEGA PHARMA, MENARINI, MERCK SERONO, Merial, MINISTERO DELLA SALUTE, MIPHARM, MOLMED, MOLteni, MONICO, NEUROTHON ONLUS, NEWCORTEC, NORDTEST, NOVARTIS, NSA, NUOVA OMPI, O.T.I. - OFFICINA TERAPIE INNOVATIVE, OPALIA, OPCRIN, OSMOPHARM, OSSIGAS, OSTEOINVENT ITALIA, OSTEOMEDIK, PATHEON, PCA PRODOTTI CHIMICI ALIMENTARI, PFIZER, PHARMAGREB, PHARMANESS, PHARMATECH, PHARMINTRACO, PHIDEA MARVIN, PHILOGEN, PIERRE FABRE, PIERREL, PLASTIAPE, POLICHIMICA, PROCOS, PROMOCHEMICA, RAV, RAYMOS, RECORDATI, REMEDE PHARMA, RIYADH PHARMA, ROCHE, ROVAFARM, RS SERVIZI, S&B , S.C.M. - SOCIETÀ CHIMICA MUGELLO, S.I.M.S., S.D.N., SANDOZ, SANOFI-AVENTIS, SAPA, SAPIO, SAUDI ARABIAN JAPANESE (AR SAU), SCHERING PLOUGH, SECURE LIFE, SFDA CINA, SIAD HEALTHCARE, SIEGFRIED GENERICS, SIFFRA, SIFI ITALIA, SIGMA-TAU, SINDUSFARMA, SOCIETÀ ITALO BRITANNICA, SOFAMM, SOFFIERIA MEZZADRI, SOIMAR, SOL, SOPHA, SORIN GROUP, SPIN, SSA, STERLING, STEVANATO GROUP, SWISS STEM CELLS BANK, SWISSLOG, TAMCO, TATTILE ANTARES, TEAM SYSTEM, TECNOGEN, TEHRAN CHEMIE, TEMA SINERGIE, TEMMLER, TERAPIA/RANBAXY, TEVA PHARMACEUTICAL WORKS, TRE I, TUBILUX PHARMA, UCL, UFI FILTERS, UNIDO, UNIMED, UNITECH, VALPHARMA, VAMFARMA, VAR LIFE, VARIATI, WINTHROP, WORLD SERVICES ITALIA, WYETH LEDERLE, XENESYS, ZACH SYSTEM, ZAMBON



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