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Der Produktionsbereich unterteilt sich in die Herstellung folgender pharmazeutischer Formen:

- Unter den oralen Formen sind die Granulate in Beuteln (*Inpharzam* ist einer der grössten Produzenten Europas dieses Konfektionstyps) und die Brausetabletten von grösster Wichtigkeit.
- Bei den injizierbaren Formen handelt es sich um Penicillin-Antibiotika, die in einem sehr modernen, speziell für sie bestimmten Trakt der Produktionsanlage hergestellt werden.

Das Qualitätssystem der *Inpharzam* steht im Einklang mit den höchst restriktiven Santitätsnormen. 15% der gesamten Arbeitskräfte sind in den Laboratorien der Qualitätskontrolle tätig.

Konkrete Projekte, die sich in fortgeschrittener Entwicklungsphase befinden, sehen die Herstellung von verschiedenen pharmazeutischen Spezialitäten vor, die für den Export in die USA bestimmt sind.

Die *Zambon Group* (Mailand, Italien) ist ein internationales Pharmaunternehmen, das 1906 gegründet worden ist und sich durch seine Forschungsaktivitäten auszeichnet. Die durch die konzerneigene Forschung entwickelten Produkte realisieren über 70% des Gesamtumsatzes. Die Beiträge des Konzerns zugunsten der Forschung beanspruchen einen hohen Prozentsatz der Investitionsmittel.

Ca. 2 500 Personen in drei Kontinenten tragen zum internationalen Erfolg der *Zambon Group* bei. Integriert in modernste Strukturen, sind sie in den folgenden Ländern tätig:

	a	b	c	d	e	f
Italien	•	•	•	•	•	•
Schweiz		•	•	•		
Spanien		•	•	•		
Portugal		•	•			
Frankreich		•	•			•
Deutschland		•	•			
Belgien		•	•			
Holland		•	•			
USA		•				
Brasilien		•	•	•		
Kolumbien		•	•			

a: Pharmaceutical Research
b: Clinical Research
c: Registration and Marketing
d: Pharmaceutical Production
e: Chemical Research Production
f: Hospital Home-Care

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*I.P.A.S. SA Institute for Pharmacokinetic and Analytical Studies**

A Highly Specialised Company Covering Phase I Clinical Studies

I.P.A.S. SA is a new contract research organisation (CRO) sited in Stabio, Canton Ticino, Switzerland, working in Phase I clinical trials, namely pharmacokinetic, bioavailability, bioequivalence, and tolerability investigations. This kind of investigations are now particularly requested from pharmaceutical companies for IND (investigation of new drugs) and/or NDA (new drug application) procedures.

Recently, Agencies of EU (European Unit) and Switzerland have published GCP (Good Clinical Practice) procedures which are consistent with previously approved GMP (Good Manufacturing Practice) and GLP (Good Laboratory Practice) procedures; this means that throughout all the investigations pharmaceutical companies and investigators must fully comply with the above procedures.

I.P.A.S. SA offers high quality services in compliance with the above procedures, internal SOPs (Standard Operating Procedures) and Ethics requirements (declaration of Helsinki and further amendments). In details, clinical trials are comprehensively planned in study protocols, which are approved by the Ethics Committee and by Central Authorities (IKS); after then studies are carried out in a comfortable clinic under permanent supervision of specialised physicians and nurses. Blood biochemical parameters, vital signs and ECG (safety data) are carefully monitored before, during and after the trial. Before starting the trial, volunteers sign an informed consent form which contains detailed information on the drug, its effects and possible adverse events, procedures and restrictions planned in the protocol.

A relevant part of this kind of investigations is the bioassay in biological fluids (blood, plasma, or serum) of the drug administered and its metabolite(s) which involves analytical micromethods fully validated to appreciate concentrations in the picogram or nanogram range. Analytics is performed by specialised *I.P.A.S.* operators at the *LA* (*Laboratorio Analisi Speciali Chimico-Cliniche SA*, Ligornetto), through a joint-venture between the two companies, which allows *I.P.A.S.* to profit the very relevant analytical equipments. *LA* indeed covers also the safety analysis of these investigations, namely blood and urine biochemical parameters, now considered of prime interest in any clinical trial.

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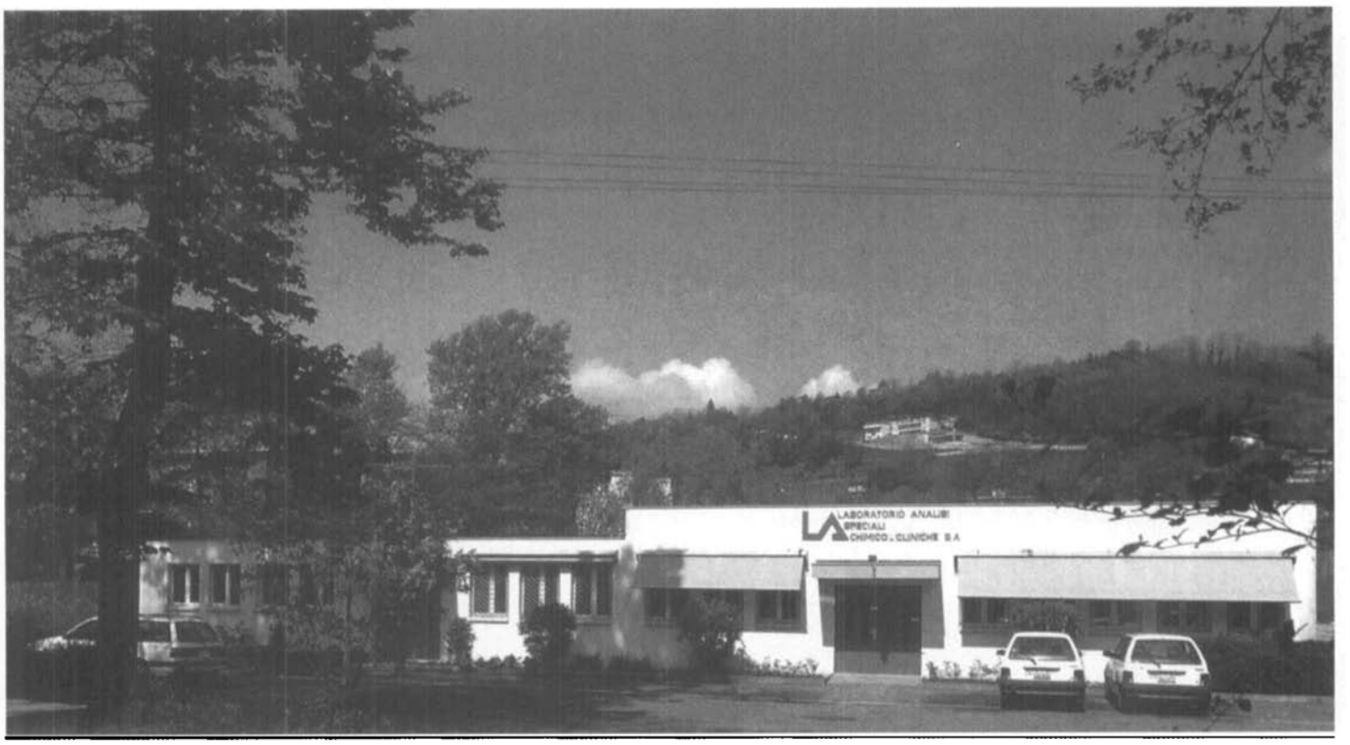

Figure. *Laboratory facility of* I.P.A.S. SA

Analytical studies in pharmacokinetics are carried out with chromatographic apparatuses, namely HPLC (high-performance liquid chromatography) and GC (gas chromatography) using several appropriate selective detectors.

Concentrations in biological fluids are then processed according to the accepted statistical criteria to investigate pharmacokinetics, bioavalability, bioequivalence, tolerability. Data obtained are comprehensively presented and discussed in a Research Report issued according to the up-to-date criteria suggested by European and USA FDA (Food and Drug Administration) Agencies.

The site of *I.P.A.S.*, in the centre of Europe, and the international vocation of Switzerland, facilitate contracts with Sponsors from all the Europe and USA. Activity of *I.P.A.S.*, in fact, despite its recent foundation, is in continuous increasing rate, mainly in the generic applications, which require a bioequivalence study comparing the new *vs.* the original formulation marketed by the innovator company.

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Laboratorio Analisi Speciali Chimico-cliniche SA*

The *Laboratorio Analisi Speciali* (*LA*) is a 20-years-old facility, originally located in Mendrisio, in the southern of Canton Ticino.

Since 1990 it moved to Ligornetto, a small village near to Mendrisio, in a markedly bigger facility. Until now its evolution was rapid and new fields of activity were implemented.

At the present the *LA* is able to perform biomedical, chemical and microbiological analysis.

The main area, that of biomedical analysis, is divided into four sections:
- clinical chemistry
- haematology
- serology and immunology
- microbiology

providing complete tools for physicians and hospitals.

In addition to instruments for routine analysis the *LA* have instruments for special analysis like:
- atomic absorption spectrometer for detection of metals in body fluids
- HPLC and GC for monitoring drugs, hormones, haemoglobin and its fractions or vitamins in body fluids
- laser-flow cytometer for immuno pheno typing of leucocites
- thermal cycler for PCR (polymerase chain reaction) for research of infective agents.

Other customers are industries, hotels, pubs, and refectories mainly for sanitary controls of the workers and the working areas.

The analytical chemistry section was set up to meet requests from the Chemical Industries for analysis at different stage of the production, *e.g.*, controls of raw mate-

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