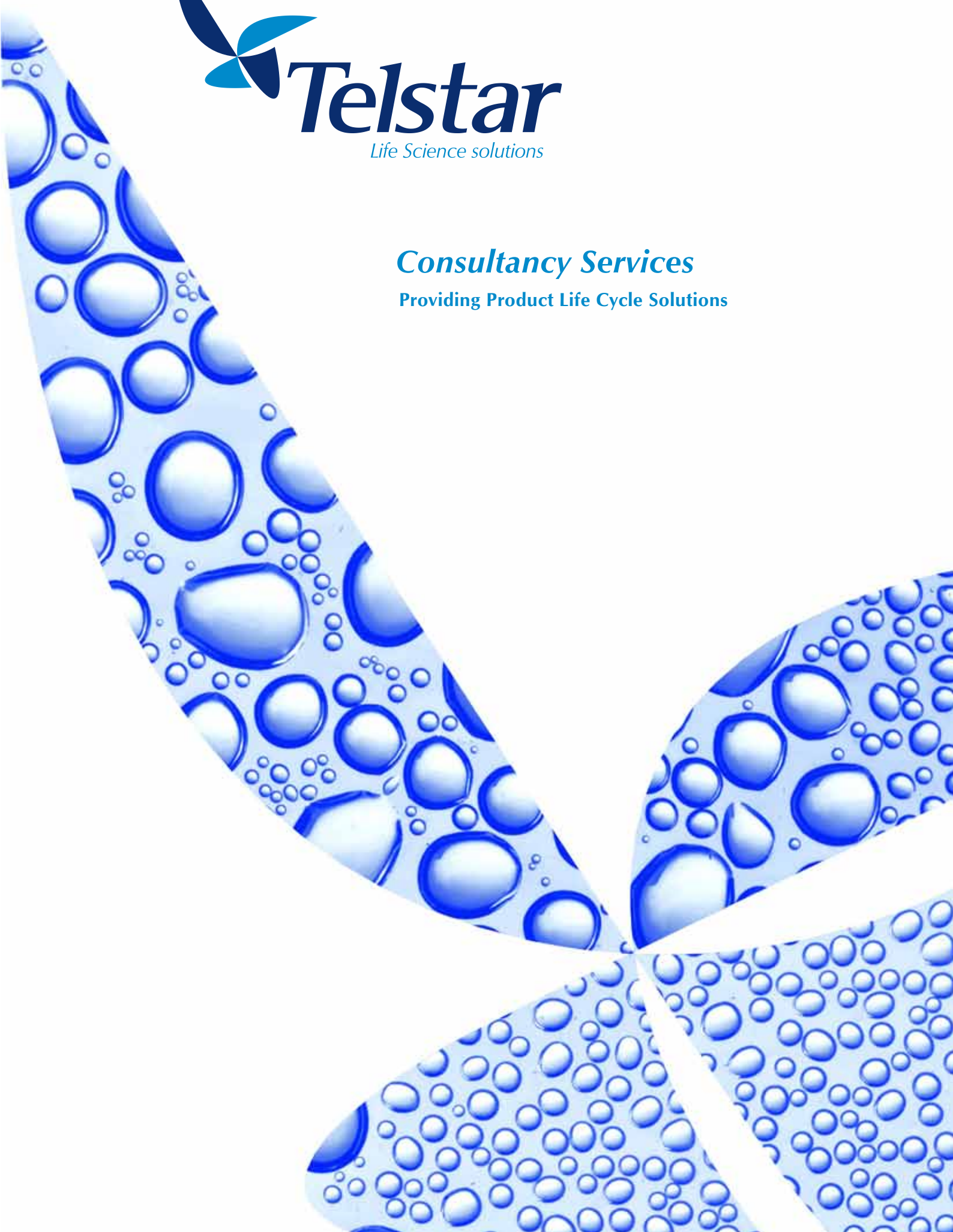
Telstar

Life Science solutions

Consultancy Services

Providing Product Life Cycle Solutions



Research and development

Preclinical and clinical advice	• Development Plan Design • Selection CRO´s • Study Protocol & Report evaluation • Investigational New Drug Application (IND) or Clinical Trial Application (CTA)
Good Laboratory Practices (Quality in Preclinical Research)	• GLP system implementation and SOP preparation • CRO's evaluation • Studies audit • Computer System Validation

Quality in Clinical Research	• GCP system implementation
	• Evaluation and audits of:
	  • Phase I Units, Studies (Centers/Investigation)
	  • Central and Bioanalytical Laboratories
	  • Data Management and Statistics
	  • Audit of IMP manufacturers (Annex 13 GMP)
	• Computer System Validation (GCP and Pharmacovigilance)

Pharmaceutical Development	• Implementation of Quality by Design for drug products and drug substances (ICH Q8 & Q11):
	  • Risk Analysis and knowledge management
	  • Design of Experiments (DoE)
	  • PAT (Process Analytical Technologies)
	  • MVDA Multivariate Analysis of data and development of predictive models.
	  • Technology transfer
	  • Quality systems integration ICH Q10

Design and implementation of non-regulated Quality Systems for R&D departments

Regulatory affairs

Active ingredients	• DMF guidance / preparation / variation (EU / USA) • Guidance, strategy, variations and support documentation to obtain CEP (EDQM)
Medicinal products	• Registration strategy and dossier submissions in Europe and FDA • Dossier writting and compilation • Variations, revalidation, readability testing, e-CTD formatting, NeeS.... • eXtended Medicinal Product Dictionary (XEVMPD). Article 57(2) compliant laboratories and products registration processes • Laboratory authorization processes guidance
Medical devices	• Strategic Advice on CE marking and Notified Bodies selection • Risk Analysis and Technical Files preparation • Software Verification/Validation • Activity license support (manufacturing, importer, distributor...) • Market release communication • Medical Device Vigilance

Cosmetic / Aesthetic / hygene products	• Product Information Filing – Safety Assessment • Labelling review and market release communication • Responsible Inscription support • Cosmetic Vigilance
Food suplements	• Advice on the submission process of applications to Health Authorities • Submission and maintenance "key 26" (manufacturer / marketer)
IT Tools	• Supplier of Extedo Tools; eCTDmanager
Biocides	• Advice, preparation and dossier registration

Industrial

Quality assurance system	• Internal Audits, GAP Analysis and implementation of Quality Systems
	  • GMP (EU, FDA...)
	  • ISO 13485 for Medical Devices
	  • ISO 22716 for Cosmetics...
	• Preparation and Support on FDA Pre Approval Inspections (PAI)
	• Risk Management (ICH Q9)

Operational Excellence	• Process design, monitoring and control to improve efficiency and quality indicators. Leading to;
	  • Regulatory flexibility; reduced number of variations
	  • Non quality cost reduction: capable and stable processes
	• Automation and real-time release: introduction of PAT (Process Analytical Technologies)
	Methodologies used:
	  • Lean-Six Sigma
	  • Quality by Design (process reengineering)
	  • Strategic Plan / Balanced Scorecard

Third party quality audits	• Active Pharmaceutical Ingredients (API) and Excipients manufacturers • Packaging material manufacturers • Contract Manufacturers • Services suppliers (analytical laboratories, warehouses, logistics, etc.)

Validation and qualification

Industrial
- Gap Analysis & Risk Analysis
- Commissioning
- Equipment and industrial services qualification
- Process validation (manufacturing, cleaning...)
- Validation lifecycle approaches: continued process verification, ASTM 2500

Laboratory
- Analytical Methods development, validation and transfer.

Computer System Validation
- IT gap analysis and corrective actions
- Policies and SOP advice / implementation.
- GXP compliance advice (21 CFR part 11, Annex 11 GMP..)

Pharmacovigilance

FV Services	• Pharmacovigilance System Implementation • Internal and Supplier Audits • Computer Systems Validation • Act as PhV European responsible or Contact Person in Spain • Management of adverse reactions (with the support of a physician)

Training

Ad-hoc Training	• Quality Systems (GLP, GCP, GMP, GDP, ISO...) • Regulatory Affairs • Quality by Design • Validation & Qualification

Business Development

Business Plan	• Licensing in & out • Search of partners (manufacturers, holders...) • Technology Transfers • Evaluation/ audit of products: dossier audits • Technical Due Diligences: Technical advice during acquisitions of products/companies

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ISO 9001: Certified Company