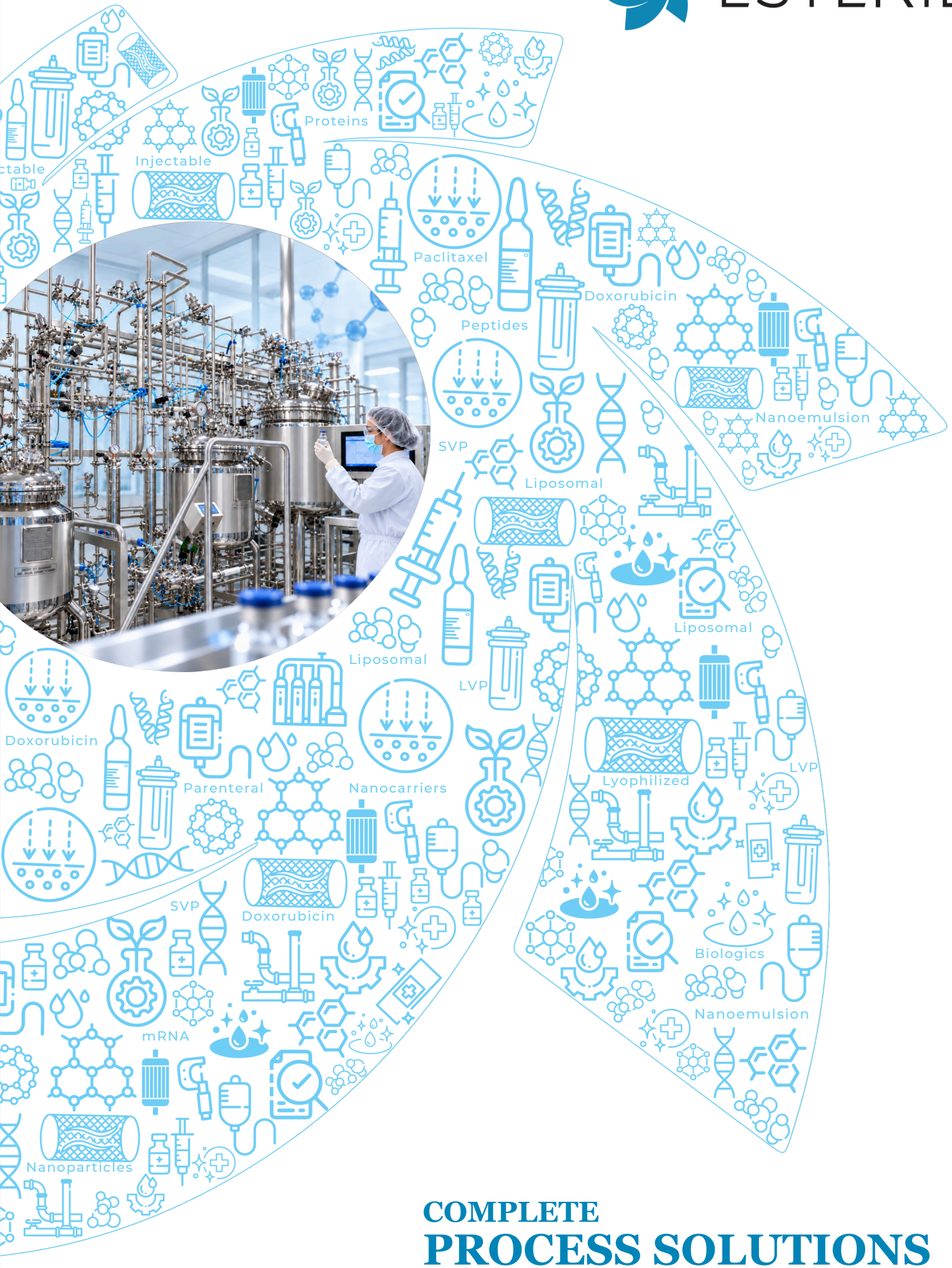
ESTERIL



COMPLETE
PROCESS SOLUTIONS

ENGINEERING PROCESS SOLUTIONS FOR

STERILE MANUFACTURING

Esteril Process Solutions engineers integrated process systems for sterile and high-purity pharmaceutical manufacturing, combining process engineering, equipment, piping, instrumentation and automation into complete manufacturing solutions.

PROCESS SYSTEM CAPACITY

3 L – 25,000 L



APPLICATION EXPERTISE

- SMALL VOLUME PARENTERALS
- LARGE VOLUME PARENTERALS
- COMPLEX MOLECULES
- GENERAL INJECTABLES
- OPHTHALMICS & OTIC
- STERILE APIS

OUR CORE SOLUTIONS

Integrated engineering systems for sterile and high-purity pharmaceutical manufacturing

- COMPLEX INJECTABLE PROCESS SKIDS
- AUTOMATION & CONTROL INTEGRATION
- MANUFACTURING & FILTRATION VESSELS / SKIDS
- INTEGRATED PIPING & TRANSFER SYSTEMS
- IN-SITU CIP/SIP SKIDS & PUPSIT SYSTEMS

COMPLEX & ADVANCED FORMULATIONS

- LIPID EMULSIONS & NANOEMULSIONS
- LIPOSOMAL & LIPID NANOCARRIER SYSTEMS
- LONG-ACTING DEPOT FORMULATIONS
- LYOPHILIZED STERILE INJECTABLES
- NANOPARTICLE DRUG DELIVERY SYSTEMS
- STERILE PARENTERAL SOLUTIONS
- PRESSURIZED METERED-DOSE INHALERS (pMDIs)
- STERILE INJECTABLE SUSPENSIONS



CLEANING, FILTRATION & PROCESS CONTROL

Systems engineered for cleaning, sterilization, sterile filtration, process control and data integrity.

Automated CIP/SIP • Recipe-Based Cycles • Valve Sequencing • Cycle Monitoring

FILTRATION & INTEGRITY TESTING

Sterile Filtration | PUPSIT | Controlled Filtration Parameters

TESTING & VERIFICATION

Riboflavin Coverage Test • CIP Cycle Verification • SIP Temperature Distribution • Drainability Verification

Hydrostatic / Pressure Testing • Pneumatic / Leak Testing • Helium Leak Testing

Surface Roughness (Ra) • Passivation Verification • Weld / Borescope Inspection • Dye Penetrant Testing • Radiographic Testing • Instrument Calibration

AUTOMATION

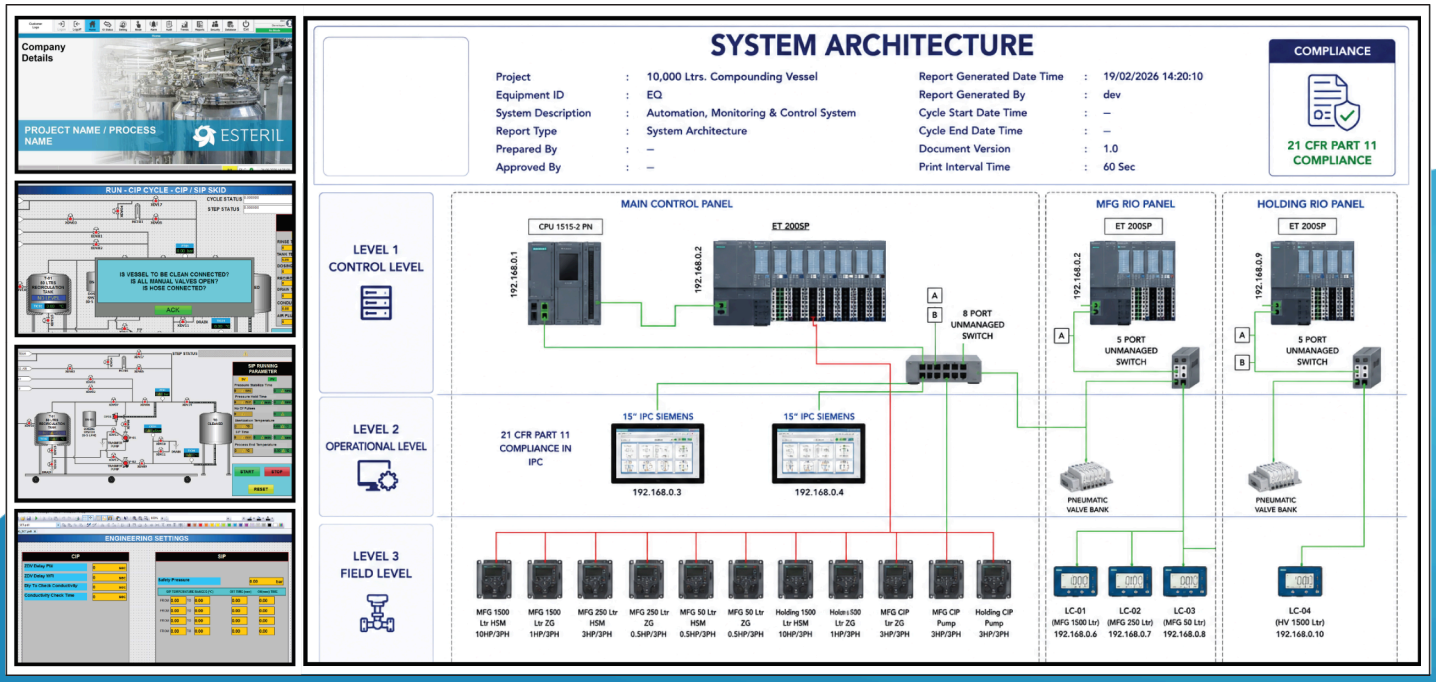
PLC • HMI • SCADA • DCS

Siemens • Schneider Electric • Allen-Bradley • Mitsubishi

21 CFR Part 11 • Multilevel User Access • Audit Trail Reports • Online Parameter Monitoring

DOCUMENTATION & REPORTING

CIP Batch Reports • SIP Batch Reports • Pressure Hold Test Reports • Semi-Automatic Batch Reports • Functional Design Specifications • Requirement Traceability Matrix • Risk Assessment • System Architecture



ENGINEERED FROM CONCEPT TO OPERATION

End-to-end engineering and project execution for pharmaceutical process systems.



ENGINEERING DELIVERABLES

PFDs & P&IDs · Process Calculations · GA & Layouts
· Equipment Specifications · Instrumentation · Control Philosophy

DOCUMENTATION & QUALIFICATION

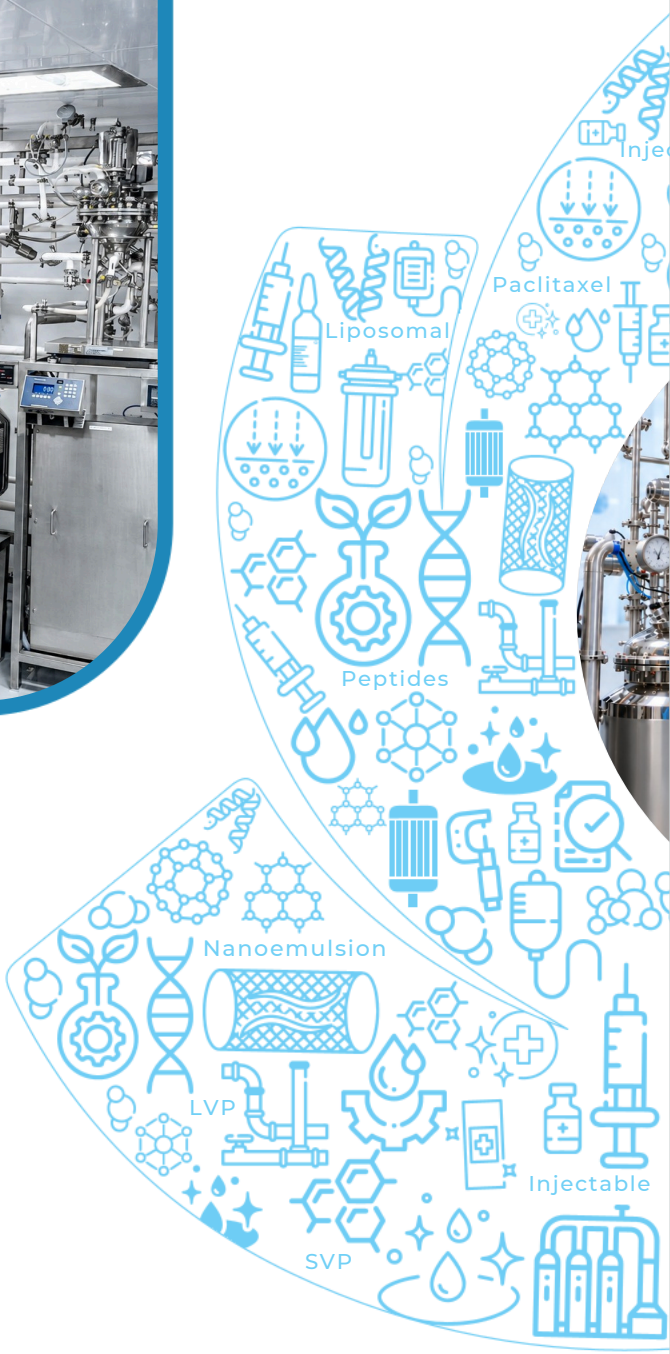
Material Traceability · Welding Documentation · Calibration
· Test Reports · FAT / SAT · IQ / OQ Support · As-Built Documentation

STANDARDS & ENGINEERING FRAMEWORKS

cGMP · EU GMP Annex 1 · GAMP 5 · 21 CFR Part 11 · ASME BPE







ESTERIL

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