



REALISATIONS

➤ **VALIDATION (IQ/OQ) and START-UP of a new sterile-injectable production plant:**

Special Note: This is a 40 million project! It's by far our biggest project. Imagine... a brand new pharmaceutical facility and ONLY LCV PHARMA had the responsibility for all the equipments: from technical validation (IQ/OQ protocol (write and execute), writing CALIBRATION protocol, to START-UP and SOLVE all problems that occurred on the different equipments). This is the PROOF that we can handle EVERY PROJECT you can have! References available....

- Utilities (PSG, PSC, WFI, Pure water, etc.);
- Cleaning systems (SIP, CIP);
- Parts Washer (Steris);
- Finn-Aqua Autoclaves;
- Automated Formulation Rooms and Tanks;
- MAR Aseptic Filler with Capper and Tray Loader;
- Ampoule and vials filling lines (IMA & Bosch);
- Vial Washer and Sterilizing Tunnel (Steriline, IMA, Bosch);
- Eisai Particulate Inspection;
- Optel Vision systems;
- Mediseal Thermoformer;
- Cartoning Machines (Mediseal, Dividella);
- Labellers (Libra, Neri).

Behind the Image, Know – How and Perfection

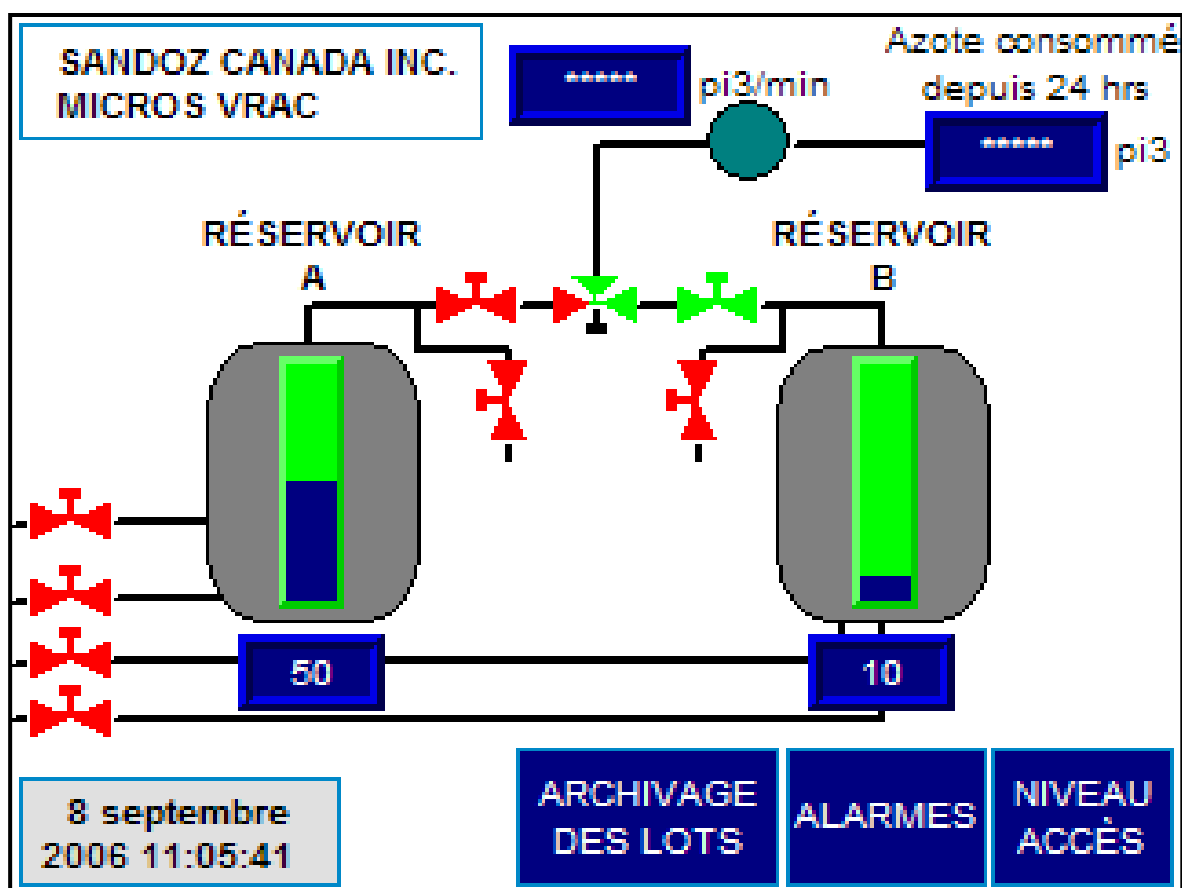
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➤ **DESIGN and INSTALLATION of a nitrogen distribution system including sampling and quarantine management:**

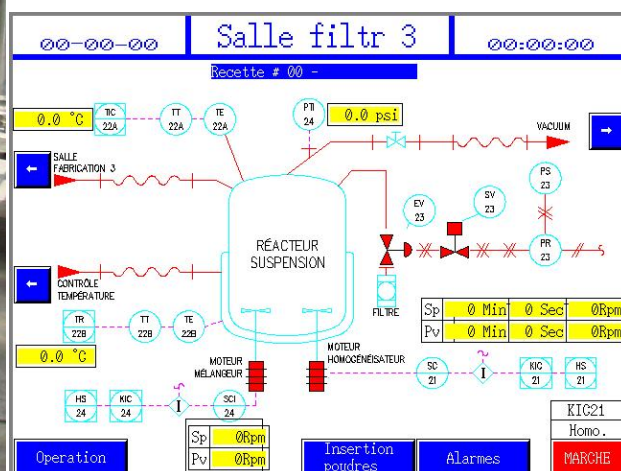
- Electrical drawings;
- Validation documents (FSDS, Tests Script);
- Control Panel fabrication;
- Installation and Start-Up.





➤ **DESIGN and FABRICATION of Manufacturing Tank Reactors:**

- Automation of process to link tank to existing Formulation Room control panel;
- Instrumentation selection;
- Electrical drawings design;
- Omron PLC and HMI programming;
- Electrical installation;
- Start-up and Control System Validation.





➤ **CRITICAL instruments CALIBRATION for a new sterile-injectable production plant:**

- Calibration procedure drafting for all types of instruments (temperature, pressure, conductivity, flow, pH, speed, position, level, etc);
- Calibration execution;
- Training of internal personnel;

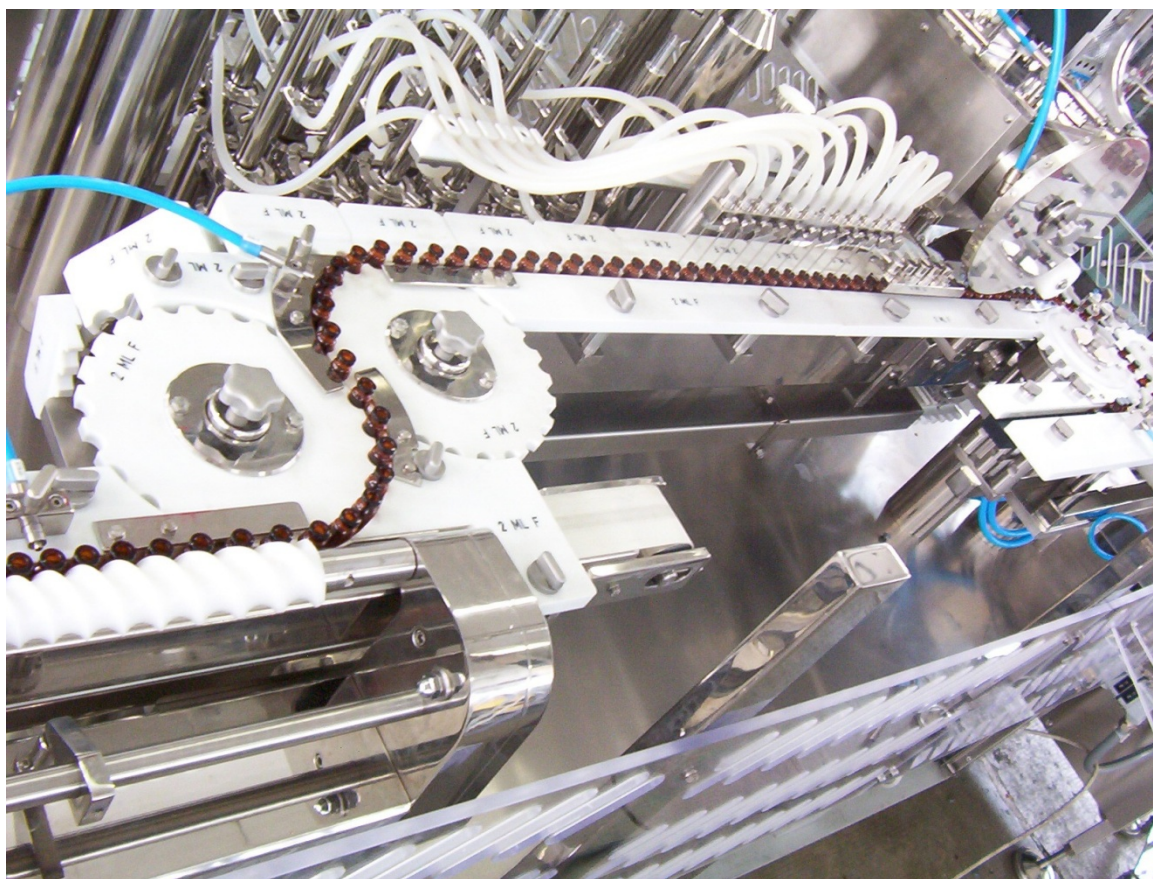
➤ **DESIGN of a powder pre-wetting system for pharmaceutical products manufacturing:**

- Electrical design;
- Programming and start-up;
- Validation.



➤ **Modifications of MAR fillers to incorporate control of external recirculation pump and reactors:**

- Modify electrical schematics of 3 fillers and 2 reactors to be able to exchange equipment;
- Write calibration procedure;
- Electrical installation and start-up;
- Programming and Control System Validation.





➤ Integration of a servo-torque unit to a MAR filler to improve capping quality:

- Electrical design;
- Programming and start-up;
- Validation.





➤ **Elaborate a TRAINING plan for technicians on new equipments:**

- Train electrical technicians on Eisai and MAR machines to help them in troubleshooting.





➤ **INTEGRATE, PROGRAMMING of aseptic fillers:**

- Change access management on a Capmatic filler (Omron);
- Add an encoder and bottle and stopper sensor on a Capmatic filler (Omron);
- Add recipe storing capability on Cozzoli filler (Omron);





➤ **VISION SYSTEM for LOT and EXPIRATION DATE inspection (IMA):**

- Preliminary testing;
- Electrical modification;
- Allen-Bradley PLC and HMI programming;
- Validation.





➤ **INTEGRATION of equipments for in-line installation (washers, inspection machines & labelers)**

- Electrical drawings;
- Electrical installation;
- Programming and validation for accumulation management and line output optimization.

➤ **Execution of CHANGE CONTROL of Automation Department:**

- Functional and Design Specification redaction;
- Impact of change evaluation;
- FRA and RTM;
- Redaction of required tests protocols;
- Execution and support during validation.

➤ **Modification of Differential Pressure Acquisition System to update points (Omron and Access):**

- Remove unused wiring;
- Install new transmitters;
- Calibration;
- PC and PLC programming modification;



➤ **MODIFY existing filler (MAR 52 line):**

- Rewrite program of the filler
- Synchronisation problem on Libra labellers;





➤ **STERILINE washer and tunnel:**

- Modify program to minimize water in evacuation duct (Allen-Bradley);
- Print air speed and temperature every 5 minutes (Ifix);
- Add emergency stop buttons between washer and tunnel;
- Change accumulation sensor type on tunnel inlet belt;
- Write a URS to install an emergency supply on the control system;

