



ELECTROL SPECIALTIES COMPANY

Electrol Specialties Company
441 Clark Street
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Tel 815-389-2291 – Fax 815-389-2294
www.esc4cip.com

ESC Sanitary Design & CIP Consulting Capabilities

Electrol Specialties Company (ESC) is a 70 plus year old employee owned company. ESC is the recognized leader in clean-in-place (CIP) technology, and has been working in this field for over 40 years.

As a full service resource to the Dairy/Food and Biopharm Industries, ESC offers consulting services as well as equipment and start up services to assure the client optimal results by proper integration of process and CIP, (Clean in Place,).

Sanitary Design & CIP Consulting Core Competency

The ESC Sanitary Design & CIP Consulting Group performs fee-based technical consulting to ensure optimized integrated cleaning of biopharm processes.

Consulting capabilities include the following:

- Integrated sanitary design and CIP/SIP, (Clean in Place/Steam in Place,) for new projects, as well as retrofit facility upgrades.
- P&ID and specification review to ensure optimized effective process/CIP/SIP integration.
- Piping model and installation drawing reviews to ensure proper CIP/SIP concept.
- Vendor drawing reviews for equipment cleanability, spray device placement and spray specification.
- Develop an overall process/CIP schematic flow diagram, depicting the integrated cleanable process design.
- Develop CIP circuit designs and valve sequence matrices.
- Produce sequential process/CIP/SIP schematic extractions to facilitate and simplify project communication through the design, software development, documentation, and commissioning phases.
- Create/review user requirement specifications (URS), functional requirement specifications (FRS), software detailed design specifications (SDDS), software factory acceptance testing (SFAT), site acceptance test (SAT), design qualification (DQ), installation qualification (IQ), and operational qualification (OQ) documents.
- Develop cGMP process and CIP software (21 CFR Part 11, GAMP, S88).

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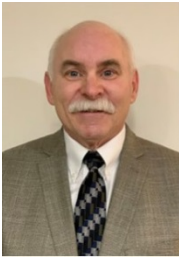
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Field service on-site engineering capabilities include the following:

- Facility site observation of existing or under-construction facilities to ensure proper sanitary installation.
- Process/CIP/SIP operations audits to optimize system performance while minimizing utility and chemical usage and waste generation.
- Conduct spray performance and riboflavin tests, evaluate results, and define remediation to obtain the desired cleanability results.
- Provide start-up, commissioning, and execution of qualification protocols.
- Process/CIP/SIP training, providing both classroom and hands-on experience.

Lead Consultants

Project work by the ESC Sanitary Design & CIP, (Clean in Place,) Consulting Group is under the direction of the following lead consultants:



Lyle W. Clem-Director of Engineering and Consultant. Lyle has 40 years of in-depth process design and project management experience in the life sciences industry. His expertise in engineering and technological innovation for clean in place processes has proven quite valuable for clients by providing products and services that reduce their overall costs and increase their efficiency. He brings extensive experience in process engineering, process automation, and project management for fluid handling in

pharmaceutical and biotechnology applications. He also offers in-depth experience in system design, construction and commissioning CIP and related systems in the life sciences industries. He participates in several sanitary design standards committees, within 3A, is a Certified Conformance Evaluator, and is a board member of that organization.



Sam Lebowitz-Technical Services Manager. Sam has over 30 years of biopharm experience. Prior to employment with ESC, he was with a major A&E firm as a Biopharmaceutical Process Engineer. He provides technical information in the preliminary design phase, coordinates detailed design, and provides field engineering, commissioning and validation services. He has several publications on the subject of integrated sanitary design with CIP and has frequent speaking and teaching engagements. Sam is currently the

document leader for 3A Accepted Practice 605- Permanently Installed Product and Solution Pipelines and Cleaning Systems.



Kindt Nielson-Electrical Engineering Manager. Kindt earned a B.S. in Electrical Engineering from Brigham Young University in Provo, UT. Kindt has 13 years of experience with electrical design and application programming along with the requisite software-related documentation for ESC manufactured equipment. He has been involved with a great variety of process and CIP applications, utilizing a variety of PLC & HMI platforms.

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Project Experience

Representative ESC sanitary design & CIP, (Clean in Place,) consulting experience include these client projects:

Abgenix, Fremont, CA (now Boehringer Ingelheim facility)–

Process/CIP/SIP design consultation, designed and fabricated 5 CIP skids, valve groups, transfer panels, spray balls, and provided start up services.

BiogenIdec, Oceanside, CA (now Genentech facility) –

Process/CIP/SIP design consultation, designed and fabricated 5 CIP skids, designed and fabricated custom spray balls, provided start up services.

Cook Pharmica, Bloomington IN (New Catalent Facility) –

Process/CIP/SIP design consultation, designed and fabricated CIP & process system components, designed and fabricated custom spray devices.

CRB, St. Louis, MO–

As a subcontractor for multiple client projects, ESC has provided Process/CIP/SIP design consultation.

Eli Lilly, Indianapolis, IN –

Process/CIP/SIP design consultation, designed and fabricated multiple CIP systems, and designed and fabricated custom spray devices over several years for multiple campus locations. Projects include both biotech and API processes.

Fluor Daniel, Greenville, SC –

As a subcontractor for multiple client projects, ESC has provided Process/CIP/SIP design consultation.

Genentech, S. San Francisco, CA –

Process/CIP/SIP design consultation, designed and fabricated multiple CIP systems, and designed and fabricated customer spray devices over several years for multiple campus locations.



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Jacobs Engineering, Conshohocken, PA –

As a subcontractor for multiple client projects, ESC has provided Process/CIP/SIP design consultation.

Lonza, Portsmouth, NH –

Process/CIP/SIP design consultation, performance audit services for existing CIP systems, designed and fabricated 13 CIP skids, provided start up services on a most recent project.

Noramco, Athens, GA –

Process/CIP design consultation for retrofit API process, including sanitary design review of vendor-provided systems and integration of CIP with process. Custom Hastelloy spray device design requirements.

Talecris, Clayton, NC (former Bayer Biologics facility) –

Process/CIP/SIP operations audits to improve cleaning and optimize system performance. Spray performance and riboflavin tests, evaluate results, and provide new spray device design to obtain the desired cleanability results.

Bioport Corporation, Lansing, MI (now Emergent Biosolutions)-

Process/CIP design for pilot plant and production scale vaccine manufacturing. CIP integration with existing process and for new BSL-3 manufacturing.

Contact Information

For further information, contact...

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