



...ensuring the function of your facility meets the requirements of your operations.

WHY CEPRO INC. FOR USP <797><800> COMPLIANCE

CEPro, Inc.

3350 Salt Creek Lane - Suite 116
Arlington Heights, IL 60005

Phone: 847.636-7710
Fax: 847.655.6087
www.ceproinc.com



TABLE OF CONTENTS

	<u>Page</u>
Project Team/Experience.....	1
Case Studies & Experience	2
Relevant Healthcare Cleanroom Projects	2
Proven Trends and Success Strategies.....	9
Approach and Management	11

Project Team/Experience

CEPro's staff has extensive expertise in the design, construction and service of highly critical facilities. We employ the latest and most effective techniques to maximize the benefits of the construction process employed by architects, contractors, engineers and all project team members.

Decades of hands-on, pragmatic experience working in critical facilities has resulted in an intimate knowledge of the assessment, design, construction, certification, operation and maintenance of these types of facilities, which makes our offering unique in the industry. We have worked at all levels in the Healthcare, Bio-Research, Pharmaceutical Manufacturing and Research Industries. We have assessed, designed, built, commissioned, and even managed the maintenance programs for various types of critical Facilities throughout the United States and abroad, internationally, including development of Standard Operating Procedures (SOP's) for the operation, maintenance, and periodic certification of these facilities.

Case Studies & Experience

Relevant Healthcare Cleanroom Projects

CEPro has provided numerous healthcare systems and facilities with a comprehensive gap analysis of their Pharmacy Compounding Areas in an effort to assist them with preparing for the upcoming implementation of USP <797/800> effective in December of 2019. Our knowledge of HVAC mechanical and controls systems has enabled us to provide an in-depth analysis of these facilities, which has provided these organizations the information needed to properly plan the upgrades of their compounding areas to meet these stringent requirements. Our intimate understanding of USP <797/800> has been instrumental to the success of this process, and has allowed CEPro to provide practical recommendations that could be implemented efficiently and effectively without breaking the bank.

CEPro's unique combined proficiency in HVAC, Controls, HEPA Filtration, Cleanrooms, and Pharmacy Compounding Environmental requirements sets us apart from all other consulting, design, testing and service firms in the world, we truly offer a unique perspective due to our A-to-Z approach to our solutions process.

Our gap analysis/assessment process is only the first step in a multi-step process to walk our clients through the upgrade project, which often includes planning and construction of temporary compounding facilities for use during the construction project. Our in-house Test & Balance technicians are intimately familiar with Cleanroom Environments and Healthcare Facilities, and allow us to quickly gather all of the necessary site conditions, limiting our invasiveness of the cleanroom operations during the field-testing portion of our gap analysis.

The next phase of our process is the design, which incorporates consideration for all aspects of our clients requirements, including Beyond Use Dating (BUD), staffing, volume of CSP's, and existing infrastructure, which can have a significant impact on the overall cost of the project. Our understanding of the compounding process enables us to effectively communicate with the pharmacy staff and provide an efficient space plan that will provide an efficient working environment for the staff. Our in-depth understanding of HVAC and Mechanical Systems has enabled us to provide design recommendations that result in upgraded facilities that have minimal impact to existing facility infrastructure.

Construction process...

- Schedule
- Pre-construction
 - Long-lead items / Product substitution due to lead time
 - ICRA Compliance
 - Clean Construction
 - Working in occupied space

WHY CEPRO INC. FOR USP <797><800> COMPLIANCE

- “Cleanroom Construction” – use of cleanroom wall/ceiling systems
- Controls – define and drive parameters
- Commissioning – above ceiling
- Oversight of MEP install
- “White Glove Delivery” of entire construction process
- 3-D look at ALL systems
- 10 lbs of shit in a 5 lb bag – most efficient use of space, including above ceiling
- RFI process a process of solutions, saving time in the overall construction project
- Black box

Occupancy/Certification process...

- Test & Balance integral to the success of the certification process
 - Controls
 - Room Pressures / Alarms
- Deep Clean
 - Sterilization
- Certification
 - Equipment
 - HEPA Filter Challenging
 - Viables
- Training
 - Pharmacy Staff
 - In-house engineering staff

Throughout all phases of the process, consideration is always given operational impact, budget and final compliance requirements, with the fundamental mentality to “keep it simple”, which leads to a facility that is cost effective to maintain by both the pharmacy and facility operations staff, and meets all compliance requirements.

We have developed

See comprehensive list of recent healthcare cleanroom projects CEPro, Inc. has been involved with in various capacities within the past five years.

- Advocate Beverly Oncology Center Pharmacy Commissioning / Certification
- Advocate Lutheran General Hospital Pharmacy Compliance Design/Build
- Advocate Sherman Hospital Pharmacy Compliance Design/Build
- Advocate Christ Hospital Design Consulting/Commissioning

WHY CEPRO INC. FOR USP <797><800> COMPLIANCE

- Advocate Good Samaritan Design Consulting
- Advocate Illinois Masonic Cancer Care Center Design Consulting / Commissioning
- Advocate Central Service Center Pharmacy Commissioning
- Advocate Integrated Service Center Design Consulting / Commissioning
- Amita Health Alexian Brothers Compliance Assessment/Design/Build
- Amita Health St. Alexia Medical Center Compliance Assessment
- Carle Foundation - System Wide (6) site Compliance Assessment/Design/Build
- Centegra Hospitals - System Wide (4) site Compliance Assessment/Design/Build
- Daviess Community Hospital (Indiana) Pharmacy Compliance Design/Build
- DuPage Medical Group - System Wide (4) site Compliance Assessment/Design/Build
- Franciscan Alliance - System Wide (23) site Compliance Assessment/Design/Build
- Goshen Health (Indiana) Pharmacy Design Consulting
- Home Infusion Solutions Pharmacy Compliance Design/Build
- Hospital Sisters Health System - System Wide (14) site Compliance Assessment / Design / Build
- Logansport Memorial Hospital Pharmacy Design Consulting / Build
- Loretto Hospital Pharmacy Compliance Design/Build
- Mercy Medical Center Pharmacy Compliance Design/Build
- Methodist Hospitals (Indiana) Compliance Assessment / Design / Build
- Mt. Sinai Hospital Compliance Assessment / Design / Build
- North Shore Health System - System Wide (7) site Compliance Assessment
- Northwestern Medicine
- Norwegian American Hospital Pharmacy Compliance Assessment / Design / Build
- Presence Health - Resurrection Hospital Pharmacy Compliance Assessment / Design / Build
- Presence Health - Skokie Oncology Clinic Pharmacy Design Consulting / Build
- Presence Health - System Wide (19) site Compliance Plan / Design / Build
- Riverside Healthcare - Riverside Medical Center Pharmacy Compliance Assessment / Design / Build
- Riverside Healthcare – Watseka Oncology Center Compliance Assessment / Design / Build
- Rush University Medical Center Pharmacy - Design Consulting / Build (three locations)
- Rush-Copley Pharmacy - Compliance Assessment / Design / Build (two locations)
- Trinity Health – Loyola Hickory Hills Oncology - Compliance Assessment / Design/Build
- Trinity Health – Gottlieb Hospital - Compliance Assessment / Design/Build
- Trinity Health – MacNeil Hospital - Compliance Assessment / Design/Build
- University of Chicago Medicine - (10) site Compliance Assessment Plan / Budget Development / Design / Build
- University of Illinois, Chicago – Certification

WHY CEPRO INC. FOR USP <797><800> COMPLIANCE

Loretto Hospital, Pharmacy Renovation (USP<797/800> Compliant), Chicago

Budget: \$444,000

Project team: Critical Environments Professionals, Inc., Arlington Heights, IL (design/build contractor)

Description: Existing Pharmacy located on the first floor of the main hospital with basement storage connected by stairs. Relocated staff and Pharmacy operations to sixth floor with interim IV Prep area. Entire space was renovated including Pharmacy work area, basement storeroom and cleanrooms to meet USP <797> and USP <800> compliance.



CEPro Responsibility: CEPro provided and/or managed all aspects of this project, including existing site evaluation, space planning, budgeting, design, demolition, abatement, construction management, commissioning and certification.

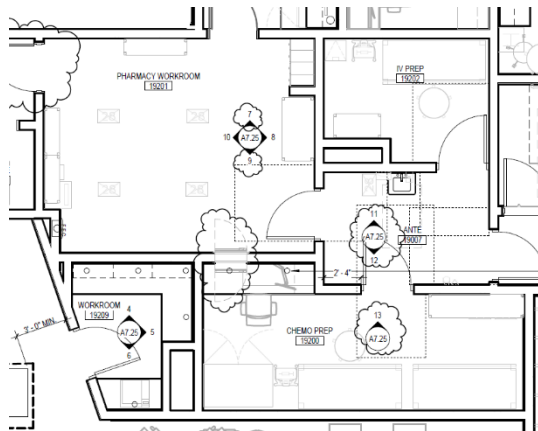
CEPro Team Members: Michael Kosinski – Sr. Consultant / Project Executive. Edward Kaminski – Project Manager

Client Reference: Dr. Sonia Mehta - CMO/CEO, James Renneker – CNO (312-626-4200), Lisa Raff – Director of Pharmacy (847-577-0620 ext. 1212)

Advocate Illinois Masonic, Center for Advanced Care, Chicago

Budget: \$100M

Project team: Smith Group, Chicago, IL. (architect); KJWW Engineering, Chicago (engineer); Turner Construction, Chicago (General Contractor); Critical Environments Professionals, Inc., Arlington Heights, IL (Cleanroom Consultant/Commissioning Authority)



Description: Construction of a pharmacy cleanroom within the nearly 164,000 ft² Center for Advanced Care. The cleanroom space was designed to support the treatment of cancer patients in the newly construction infusion center. Due to the need to prepare chemo-therapy medications as well as other HD's, it was crucial for the facility to be compliant with both USP <797> and USP <800>.

CEPro Responsibility: CEPro provided design consulting, commissioning and certification services pertaining to the pharmacy cleanroom space.

CEPro Team Members: Michael Kosinski – Sr. Consultant. Edward Kaminski – Project Manager

Client Reference: Tom Wheeler – Previous Pharmacy Director (312) 942-2781

Mercy Medical Center, Pharmacy Cleanroom (USP<797> Compliant), Chicago

WHY CEPRO INC. FOR USP <797><800> COMPLIANCE

Budget: \$275,000

Project team: Fox Valley Engineering, Fox River Grove, IL (engineer); Critical Environments Professionals, Inc. (design/build contractor)

Description: Cleanroom located in the lower level of the 15 story main hospital building, was designed and built by CEPro, Inc. A location for temporary relocation of the cleanroom was not available, so a 31-day construction window was available for the completion of the work. Final USP <797> certification of the cleanroom and equipment was completed on New Year's Eve, just 30 days after the construction began.



CEPro Responsibility: CEPro provided and/or managed all aspects of this project, including existing site evaluation, space planning, budgeting, design, demolition, abatement, construction management, commissioning and certification.

CEPro Team Members: Michael Kosinski – Sr. Consultant / Project Executive. Edward Kaminski – Project Manager

Client Reference: Mike Walsh (312-428-2795)

DuPage Medical Group, Pharmacy Cleanroom (USP<797> Compliant), Lisle, IL

Budget: \$2.2 million



Project team: Eckenhauf Saunders Architects, IL (architect); Affiliated Engineers, Chicago, IL (engineer); Loepardo Construction, Hoffman Estates, IL (general contractor); Critical Environments Professionals, Inc., Arlington Heights, IL (Cleanroom Consultant / Commissioning Authority)

Description: Cleanroom built as a joint-venture between Rush University Medical Center and DuPage Medical Group, this USP <797/800> compliant pharmacy cleanroom is used for preparation of both IV drug preparation and chemotherapy drug preparation for outpatient treatment.

CEPro Responsibility: CEPro provided design consulting, cleanroom build, commissioning and certification services pertaining to the pharmacy cleanroom space.

CEPro Team Members: Michael Kosinski – Sr. Consultant. Edward Kaminski – Project Manager

Client Reference: Jigar Thakker (312-428-2795)

WHY CEPRO INC. FOR USP <797><800> COMPLIANCE

Northwestern Memorial Hospital, cGMP Cell Therapy Processing Facility, Chicago

Budget: \$6.9 million.



Project team: Anderson Mikos Ltd., Oakbrook Terrace, IL. (architect); Henneman Engineering Inc., Chicago (engineer); Bulley & Andrews LLC, Chicago (design/build contractor); Critical Environments Professionals, Inc., Arlington Heights, IL (Cleanroom Consultant/Commissioning Authority)

Description: Facility on the seventh floor of the Olson Pavilion at the hospital recently won second place in the ASHRAE 2010 Technology Awards competition (institutional buildings category). The

compact lab is used for collecting, processing and manufacturing human cells, tissues, and cellular and tissue-based projects. ASHRAE recognized the facility's achievements in the area of occupant comfort, indoor air quality and energy conservation, based on the design as well as a year of verifiable operating data.

CEPro Responsibility: CEPro provided design consulting, commissioning Test & Balance, Regulatory Validation, Laboratory Controls and certification services pertaining to the cleanroom space.

CEPro Team Members: Michael Kosinski – Sr. Consultant. Edward Kaminski – Project Manager. Ronnie Wells – FDA Regulatory Compliance / Validation Director

Client Reference: All project clients have relocated

Proven Trends and Success Strategies

CEPro's approach to a project is unique in that we start with an understanding of the regulatory requirements, specifically USP <797> and USP <800> as it pertains to this project. A practical understanding of pharmacy operations, procedures and needs helps us to merge those needs to the regulatory requirements, resulting in a functional facility that is fully compliant. Our exhaustive understanding of the regulatory requirements goes well beyond the environmental applications, but encompasses procedural requirements as well, such as gowning, raw material handling and storage, Beyond-Use-Dating (BUD), sterility, cleaning, ingress/egress, to name a few. We consider the following three principles foundational in our approach to each cleanroom project we are involved in. These principles set us apart and drive our deliverables, they are our "must haves" when it comes to this type of project.

- 1. Functional not beautiful** – While there is nothing wrong with a beautiful cleanroom, functionality must take priority. All too often cleanrooms are designed with elaborate casework, expensive fixtures and furniture, and fancy layouts that all lead to a facility that is hard to clean and maintain. Cleanrooms with numerous corners, laminated wooden casework with drawers that are difficult to clean behind, and wall-hung shelving make the routine cleaning process challenging. Flooring that is flashed around the floor mounted cabinets makes even the daily floor cleaning a laborious task. Cleanrooms should be simple in design, configured to minimize corners in the flooring and should have flat walls with shelving that can be easily moved away from the walls to make the routine cleaning process fast and efficient.
- 2. Keep it simple** – Often these types of facilities are over-engineered with elaborate (and costly) mechanical and airflow controls with airflow tracking and room pressure controls, including systems that adjust airflow when doors are opened. All of this "complexity" can lead to instability in control. USP <797/800> have relatively tight environmental requirements for these spaces, and instability or "hunting" controls can lead to out-of-compliance conditions and nuisance alarms. Cleanrooms should have simple a simple control strategy, which is much more likely to be stable.
- 3. Build a Cleanroom, not a clean room** – A cleanroom should be designed not only to be clean and easily cleanable as mentioned above, but it should also be designed to keep itself clean, as much as possible anyway. While HEPA filtration and air changes are required in a cleanroom, dilution and directional airflow is equally important to a room keeping itself clean. Each air change "scrubs" the air and removes particulate. Placement of the supply HEPA filters and low level return/exhaust grills directly impact the dilution of the air in the room. Materials selected for the construction of a cleanroom should be non-particulate shedding materials, and should be robust enough to withstand the continuous cleaning with chemical and bumping of carts, chairs, furniture, etc. Anyone who has been on a construction site knows that drywall creates an incredible amount of dust,

WHY CEPRO INC. FOR USP <797><800> COMPLIANCE

especially during the taping and sanding phase of the project. When used for the construction of a cleanroom, that dust will continue to shed into the cleanroom space, increasing the cleaning requirements and reducing the life of the HEPA filtration systems. Painting, even with epoxy paint, only traps that particulate for a short time until it is bumped with a cart and the paint chips resulting in exposed drywall in the cleanroom. We recommend the use of cleanroom wall systems because they are designed specifically for the cleanroom application and meet all of the requirements of USP <797/800>: Surfaces are flat, scrubbable and impervious to chemicals used for routine cleaning. While installed costs may not necessarily be lower than typical “stick-built” construction, life-cycle costs are significantly reduced when using cleanroom wall systems due to efficiencies gained in the cleaning process, elimination of the need to “touch-up” the walls when damaged by carts/equipment, and elimination of a significant particulate generating material within the space which not only reduces the cleaning requirements, but also extends the life of the HEPA filtration systems.

Our ability to collaborate and communicate effectively with all project team members including the pharmacy staff, facilities engineers, project management, architects, engineers, commissioning agents, contractors and even the controls contractors and cleaning staff allows us to be effective and makes us an invaluable part of the project team throughout all phases of the project, and gives us the ability to provide a turn-key comprehensive project for customers that need that level of support. To aid in the space programming phase of the project, we have participated in mocked-up cleanrooms to allow for a physical walk-through of the space, providing a much more real-life feel to what the final product may look like. Our understating of the final certification requirements of the space allow us to build those requirements into the design, eliminating the costly changes often seen when the certifier arrives onsite for the initial certification. Our Test & Balance staff will work hand-in-hand with our certification technicians to ensure the facility is certified on the first visit.

Approach and Management

Meeting project challenges and schedules as well as Owner expectations:

- Validate strategic alignment of detailed project deliverables with end user operations and their senior leadership
- Identify risks and perform qualitative/quantitative risk analysis developing risk management strategies driven by the more risk points/greater the consequences, the more strategic planning time allocated
- Provide schedule specification and process with all team members
- Expedite team selection
- Collaborate on expediting Functional and Space Program narrative, Design and OPR
- Hyper focus on due diligence testing process with team following Function/Space Program, Design and OPR
- Align Commissioning process with all activities, start to finish
- Get design input from all prospective contractors before bidding process
- Team meet with prospective contractors under CEPro/GC to validate scope of work deliverables bid to eliminate any chance of scope creep. Entertain multiple sub's as competitive bidding requirements dictate
- Expedite equipment submittals, define specific requirements from suppliers of submittal review/approval process and provide in writing delivery dates
- Every contractor to provide a detailed project schedule synchronized with baseline schedule
- Determine equipment storage area needs and how equipment/materials will be physically brought into space during phases of construction
- Involve the city/township early on in the process to achieve complete understanding of permitting thru final inspection process
- Offer financial incentives to provide value adds and meeting/exceeding completion dates.