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Pharmacy Solution Set

Siemens Pharmacy Solution Set is a bundled offering of products, systems, technologies, programs, and services specifically designed to help organizations meet the environmental requirements of USP 797 and 800. Our solution is built with flexibility in mind, allowing us to assemble a customized solution to meet each customer's unique requirements, depending on their current level of compliance.

This document is based on the proposed requirements of:

- USP 797 : Pharmaceutical Compounding – Sterile Preparations (Proposed Revisions - September 2015)
- USP 800 : Hazardous Drugs – Handling in Healthcare Settings (Proposed Revisions - February 2016)

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Pharmacy Solution Set Matrix

USP-NF Chapter 797 / 800 Requirement	Evaluation	Engineered Services and Solutions	Building System Information Management	Service Solutions
<p>Environmental Controls</p> <p>Primary Engineering Controls (PECs) All CSPs must be prepared in an ISO Class 5 environment. Class 5 standards are achieved through the use of a PEC or an Isolator.</p> <p>Containment Primary Engineering Controls (C-PECs) All sterile and non-sterile Hazardous drugs as defined by NIOSH¹ must be compounded within a C-PEC. The C-PEC must operate continuously if used for sterile compounding or if it supplies negative pressure.</p> <p>Buffer / Clean Room Areas^{2,3} PECs need to be located within a Buffer or clean-room area with at least ISO Class 7 air quality. An ante-area provides access to the buffer area and must meet at least ISO 8 standards (ISO 7 standards for sterile HD preparations).</p> <p>Containment Secondary Engineering Controls (C-SEC) C-PECs must be located with a C-SEC. The C-SEC must be:</p>	<ul style="list-style-type: none"> • Pre-Assessment Questionnaire • Assessment of Current Environment <ul style="list-style-type: none"> ▪ Air Cleanliness ▪ Room Construction ▪ Exhaust System ▪ Mechanical System ▪ Temperature and Humidity ▪ Ventilation • Pharmacy Assessment Report 	<ul style="list-style-type: none"> • Design, install and commission (enhanced) room controls for the buffer and anteroom areas, to achieve desired airborne particle count, air changes per hour, differential pressure, temperature, and humidity levels. Note: For sterile HD compounding, C-PECs must be externally vented. • Fire Alarm System per local codes • Back-up to EES (Essential Electrical System) Power per NFPA 99 	<ul style="list-style-type: none"> • Design, install and commission building system information management elements: <ul style="list-style-type: none"> ▪ The Desigo CC workstation serves as the primary interface into the building automation system for real-time monitoring, troubleshooting, controlling building systems, managing alarms, collecting trend data (i.e., temperature, humidity, pressure, air changes per hour, alarm statuses). ▪ The RENO, Remote Notification Option for Desigo CC, allows notification of Alarm, Status and System Event information to be sent via e-mail, pagers, and phones via SMS (Short Message Service) for all points integrated into the system. ▪ Desigo CC provides a means of archiving, managing, processing and retrieving business critical data for a range of information management / reporting needs including analysis, compliance and management reporting. 	<ul style="list-style-type: none"> • Compliance Services: <ul style="list-style-type: none"> ▪ Clean Room Testing and Certification ▪ Cabinet Testing and Certification ▪ Calibration ▪ Training ▪ Documentation • Facility Information Services: <ul style="list-style-type: none"> ▪ Environmental Reporting and Consulting ▪ Custom Report Design and Creation (Temperature, Humidity, ACH, Positively Pressurized.) If equipment is integrated, reports can also include; refrigerator / freezer temperatures and particle counter readings. ▪ Data Archiving and Retrieval ▪ User Training

¹ National Institute for Occupational Safety and Health.

² If used to prepare only Category 1 CSPs, the PEC may be located in an unclassified area, without a buffer or ante-area. The area must be a Segregated Compounding Area.

³ If ISO class 5 is achieved using an isolator..., the isolator can be located in an ISO Class 8 area and used to prepare Category 2 CSPs.

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<ul style="list-style-type: none"> • Externally vented through HEPA filters • Be physically separated • Pressure between -.03 to -.01 in WC <p>The ante-room which provides entry into an HD buffer room must have:</p> <ul style="list-style-type: none"> • HEPA Filter supplied 30 ACPH • Positive pressure of .02 in WC relative to all adjacent unclassified spaces • ISO Class 7 or higher <p>Contained Segregated Compounding Area (C-SCA) C-PEC may be placed in an unclassified C-SCA if the following is met:</p> <ul style="list-style-type: none"> • HEPA Filter supplied 12 ACPH • Pressure between -.03 to -.01 in WC to adjacent spaces • Low and Medium risk HD CSPs <p>Workbenches / Barrier Isolators PECs generally include laminar airflow workbenches, biological safety cabinets, and isolators.</p> <p>Compounding facilities must be designed and controlled to provide a well-lit and comfortable working environment. The room must be maintained at a temperature of 20C or cooler and a humidity below 60% at all times.</p>				

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<p>Security</p> <p>Access of personnel to controlled areas must be restricted. The PEC must be located in a controlled access buffer area.</p> <p>Airlocks and interlocking doors can be used to facilitate better control of air balance between higher classified area and an area of lesser air quality (e.g., between the buffer area and ante-area), or between a classified area and an unclassified area</p> <p>When designing the facility, hands-free access doors are preferred.</p> <p>Access to areas where HDs are handled must be restricted to authorized personnel.</p>	<ul style="list-style-type: none"> Assessment 	<ul style="list-style-type: none"> Secure access into the controlled area via: <ul style="list-style-type: none"> Card Access CCTV Digital Recording Door interlocks Hands-free doors 	<ul style="list-style-type: none"> Intrusion Monitoring and Alarming Door status Door access restrictions Door interlocks 	<ul style="list-style-type: none"> Security Services
<p>Environmental Monitoring (of Room)</p> <p>ISO Class 7 Buffer or ante-area supplied with HEPA filtered air must measure be minimum of 30 ACPH.</p> <p>A minimum D/P of .02in WC is required between ISO classifications and the buffer area and the pharmacy. A pressure gauge or velocity meter must be used to monitor the D/P or airflow between the Buffer and anti-room and between the anti-room and the general</p>	<ul style="list-style-type: none"> Assessment 	<ul style="list-style-type: none"> Design, install and commission (enhanced) room controls for the buffer and anteroom areas, to achieve desired airborne particle count, air changes per hour, differential pressure, temperature, and humidity levels 	<ul style="list-style-type: none"> The Desigo CC workstation serves as the primary interface into the building automation system for real-time monitoring, troubleshooting, controlling building systems, managing alarms, collecting trend data (i.e., temperature, humidity, pressure, air changes per hour, alarm statuses). 	<ul style="list-style-type: none"> Facility Information Services <ul style="list-style-type: none"> Environmental Reporting and Consulting Custom Report Design and Creation (Temperature, Humidity, ACH, Positively Pressurized.) If equipment is integrated, reports can also include: refrigerator / freezer temperatures and particle counter readings. Data archiving and retrieval User Training

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<p>environment. The results must be logged daily or recorded by a continuous monitoring device.</p> <p>Total (non-viable) particle counts on ISO areas must be conducted during operations every 6 months.</p> <p>The air quality of the buffer, PEC and anteroom area is evaluated by a qualified operator(s) for conformance to ISO Class requirements, as appropriate, at least every six months and when renovations occur. All certification and re-certification records must be reviewed by supervising personnel or other designated employees to ensure the environments comply with proper standards.</p>				<ul style="list-style-type: none"> • Clean room Testing and Certification (may include following tests): <ul style="list-style-type: none"> ▪ Air volume and velocity ▪ HEPA filter Integrity test ▪ Pressurization (includes room air exchange rates) ▪ Airborne particle count ▪ Smoke testing ▪ Recovery test ▪ Temperature and humidity
<p>Controlled Storage Areas</p> <p>CSPs may be stored under different storage conditions before they are used. The following storage conditions apply:</p> <ul style="list-style-type: none"> • Controlled Room Temp; 20 – 25C • Refrigerator; 2-8 C • Freezer; -25 to -10 C <p>To help ensure CSP quality, personnel must monitor conditions in the storage areas. Controlled temperature must be checked at least daily and the results must be documented in a temperature log. If a continuous recording device is in use, personnel must check at least daily that it is functional.</p>		<ul style="list-style-type: none"> • Data integration of refrigerators / freezers into Desigo CC for monitoring, documenting and alarming. 	<ul style="list-style-type: none"> • Building Automation System collects trend data and alarm statuses from integrated equipment • Remote notification of alarm conditions can be provided to Pharmacy and Facility Staff 	<ul style="list-style-type: none"> • Facility Information Services <ul style="list-style-type: none"> ▪ Environmental Reporting and Consulting ▪ Custom Report Design and Creation (Temperature, Humidity, ACH, Positively Pressurized.) If equipment is integrated, reports can also include; refrigerator / freezer temperatures and particle counter readings. ▪ Data Archiving and Retrieval ▪ User Training

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<p>CSPs that are exposed to temperatures that exceed storage temperature limits shall be discarded.</p> <p>HDs must be stored in a negative pressure room with at least 12 ACPH. HDs used in sterile compounding may be stored in the negative pressure buffer room.</p> <p>Refrigerated HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH.</p>				
<p>Standard Operating Procedures The compounding facility must establish and follow written standard operating procedures (SOPs) designed to ensure the quality of the CSP.</p> <p>Documentation Standards All records must be retained for at least 3 years or as required by the state laws and regulations, whichever is longer.</p>			<ul style="list-style-type: none"> • Desigo CC provides a means of archiving, managing, processing and retrieving business critical data for a range of information management / reporting needs including analysis, compliance and management reporting. 	<ul style="list-style-type: none"> • Training • Documentation

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