

NUMBER	CHANGE CATEGORY	2021 REQUESTED CHANGE	REASON FOR CHANGE	IMPACT	APPROXIMATE DATE IMPLEMENTED
CC01587	Equipment	Replacement peristaltic pump installation for isolator E-1700	Old peristaltic pump will no longer be supported by manufacture. New pump has additional features for better speed control and pressure sensor for added safety.	No downtime	12-Feb-21
CC01588	Organization	Salt Lake City Organizational changes	Org changes are being made to improve customer service, science leadership, standardization, efficiency and flexibility	No external client impact; org changes are occurring at director level and below and not SLT level	In-process
CC01589	Facilities	Children's Room Update, Mother's room relocation, QA/Reporting final report drop off location	Moves will allow closer proximity and teamwork for Reporting and QA, while still allowing privacy and accommodations for employees in need of Mothers' room facility.	N/A	23-Mar-21
CC01590	Facilities	BET Prep Lab B	Currently unable to work at full capacity with shift work and space restrictions. The extra lab space will allow shift work to start earlier and give appropriate space for COVID distancing requirements.	No external customer impact	18-Feb-21
CC01591	Accreditation/Certification	ISO 17025 Scope of Accreditation Additions	Additions to the ISO 17025 scope are needed to add STP0085 and clarification for STP0004, Delta P testing. ASCA program added to the scope. SOP0180 removed.	Additional methods are now ISO 17025 Accredited. NL is now ASCA accredited for Biocompatibility testing. The PCD process (SOP0180) is no longer accredited.	In-process
CC01592	QMS, Product Offerings & Services	Simplification of the sample receiving process after login-Kaizen event	Current login process is overly complex and causing delays. Simplification is needed for scalability with future growth	Samples not counted at login, shipping boxes will not be broken down, Temp for TOC samples no longer taken at login	In-process
CC01594	Computerized Quality System	Master Control Upgrade from 11.4 to Classic 20	Version 11.4 is outdated that will no longer be supported by MasterControl. Upgrading to the new version will also allow for implementation at other sites.	QMS revamp and updates and to improve processes and make our systems efficient and scalable for other sites	In-process

CC01596	Quality and Global Compliance	VP Role Consolidation; Quality and Science	Strengthen technical leadership while building strong links for our core science team to our quality and commercial growth efforts and build the foundations of our science and quality pillars.	Change in executive management	In-process
CC01597	Organization	Restructure of MMO Department for North America	To better align job functions for future growth and support of all North American/global facilities.	Internal restructure of MMO for North America locations	In-process
CC01598	Sterility Assurance, ISO Bioburden Radiation	Phase 2 Sterility Uniflow Automation for the Cleanroom and Isolator	Validated checks to the testing data now collected in UNIFLOW from Phase 1	N/A - No external customer impact. Downtime 2 hours on a Saturday night 27 Feb 2021	15-Mar-21
CC01599	Product Offering and Service, Method	Update to the eSSF to include packaging label	Eliminate the need for login to open packages and prioritize. Hazardous materials will be identified on the label, increasing employee safety.	Sponsors will print and attach a packaging label to the shipping container. Login employees will identify prioritization, routing, and safety information on the packaging label	In-process
CC01601	Facilities	Cleanroom maintenance and semi-annual requalification shutdown	Five testing rooms (CR4-CR8) will be reclassified to ISO Class 6 Maintenance and requalification are part of routine practices for the cleanroom.	Cleanroom operation will be suspended temporarily while maintenance and requalification are performed	In-process
CC01602	Product Offering and Service, Method	Discontinuation of PCD #1 and PCD #3	The previous cap used in PCD #1 and 3 are not made by the vendor anymore and therefore PCDs will not longer be made.	PCDs #1 and 3 will be discontinued. Alternative PCDs will be available.	In-process
CC01605	Equipment	Relocation of Environmental Chamber 1801	Current location B169 does not satisfy operational logistics.	N/A additional chambers available for use	In-process
CC01606	Equipment	Installation/ Validation Nicolet iS50 FTIR	Update of equipment needed as older equipment will no longer be supported and to support the company's initiative to upgrade software to Windows 10	Impacts Routine Chemistry, FTIR testing will be on hold until qualification is completed. Notified applicable external customers of downtime.	17-Jun-21

CC01607	Equipment	Installing additional Gas Chromatigraph (8890)	Current equipment is reaching end of life and support by the vendor. New equipment will provide additional testing capacity and provide greater reliability/flexibility if current equipment goes down.	N/A No impact to clients as new equipment will not impact current used equipment.No changes to the established method.	In-process
CC01620	Equipment	Relocation of Single Door Fr	This freezer E-1841 is no longer needed in RW5, RW2 can use this freezer for sample storage and has available space for the freezer.	N/A There is no impact to sponsor testing. Chemistry (RW5) emptied the freezer, and placed what they needed in another freezer	In-process
CC01621	Equipment	RWV E-2169 Fridge Move	E-2169 (single door cooler located in RWV-HALL) will be moved "in-use" down the hall to accommodate space needed for newly acquired double door cooler (E-6659).	This change is needed to accommodate section growth.	In-process
CC01622	Equipment	Log in Freezer E-2882 and Fridge E-1840 relocation	Move freezer E-2882 from the south side of the new dividing wall in B130 to the north side of the wall in the Log in room and move E-1840 to east wall in same room. The E-1840 will need a 24 hour before and after Rees report and can be done in use and E-2882 will require a 24 hour profile (chamber mapping) and can be done in use.	It will reduce traffic, improve the work flow and reduce foot traffic through the door into the receiving area. Moving E-1840 across the room to the east wall will give us more area to receive pallets.	In-process

