


SITE EVALUATION GAP - CANCER THERAPIES





 United States - Confidential Client

PROJECT DESCRIPTION

Hyde performed a thorough gap analysis of the Cleaning Program for a drug product in short supply that was being manufactured at a contract manufacturing facility under consent decree.

Hyde's work on the project involved Hyde CORE Lab studies, cleaning verification program development and execution as well as cycle development and operational qualification.

SCOPE AND DELIVERABLES

-  **Cleaning Process Design of Experiments (DOE) Study**
-  **Swab Method Validation**
-  **Surface Swab Recovery Validation**
-  **Visual Residue Limit Supply**

CLEANING VERIFICATION



Surface Area Calculations / Maximum Allowable Carry-over calculations (MAC).



Development of acceptance criteria (and, as applicable, alert and action limits) for cleaning.



Statistical Analysis technical reports of data gathered during verification



Protocol development, execution, and summary reports.

REQUIREMENTS							
PURE STEAM GENERATOR							
URS Req #	DESCRIPTION	QRA	FAT	SAT	IQ	OQ	PQ
2	OPERATIONAL REQUIREMENTS						
2.1	Capacity						
1	CSG rated for NL T 1000 lbs with 3.0-4.3 bar clean steam pressure distribution, and NIST 8 Bar plant steam pressure at discharge	NCOP	DOC	TEST			
2	Supply Clean Steam to Autoclaves	CFP		TEST			
4	Supply Clean Steam to twelve Autoclaves	CFP		TEST			
2.2	Process Requirements						
1	Clean Steam when condensed and EU 2018/2025/2018	COP					TEST
2	Clean Steam condenser	COP					TEST
13	Clean Steam - Process	COP				TEST	
18	Degreaser for Non Condensable Gases	CFP	TEST				
2.3	Process Control						
1	Automated Unattended Control	NCOP	TEST				
3	CSG shall be controlled and monitored	NCOP	TEST				
4	Shutdown and Alarm based on Run	COP		TEST			
2.4	Cleaning						
1	Equipment and piping shall be Cleaned and Passivated after FAT	CFP		DOC			
5	All surfaces contacted by product to be 316L SS 15-20 Kt EP Finish, or S.S. unpolished PTFE (Teflon)	CFP	TEST				
3	U.L. Leaking	NCPP	DOC				
9	Instruments Calibrated under periodic program	NCPP			DOC		

Identifies required test functions
Identifies when testing will be executed
FAT, SAT, IQ, OQ, PQ