

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 Analytical 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
OPERATIONAL REQUIREMENTS							
2.1	Capacity						
1	CSG stand for NL T 5000 lbs/hr with 3.0-4.3 Bar clean steam pressure distribution, and NMT 8 Bar plant steam pressure at equipment	NCOP	DOC	TEST			
2	Supply Clean Steam to Autoclaves	CFP		TEST			
4	Supply Clean Steam to twelve A/C	CFP		TEST			
Process Requirements							
1	Clean Steam when condensed and EU per ICH Q3B R2	COP					TEST
2	Clean Steam condenser	COP					TEST
13	Clean Steam - Process	COP				TEST	
18	Degasser for Non Cond	CFP	TEST				
Process Control							
1	Automated Unattended Operation	NCOP	TEST				
3	CSG shall be controlled and	NCOP	TEST				
4	Shutdown and Alarm based on KPI	COP		TEST			
Cleaning							
1	Equipment and piping shall be Cleaned and Passivated after FAT	CFP		DOC			
5	All surfaces contacted by product to be 316L SS 13-20 Kt EP Finish, or 3.5. impregnated PTFE (Teflon)	CFP	TEST				
3	U.L. Listing	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