DCS Framework

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Project	Document No.	Revision
M2项目下游工艺管罐系统与工艺自控系统工程	**PP20-0098-T-000482**	**2.0**

	Initials	Date	Signature
~~Morimatsu prepared:~~	杜林茂	2021-04-26	张蓉蓉
Morimatsu approved:	杜林茂	2021-04-26	张蓉蓉
Innovent reviewed:			

Innovent approved:			

1. Purpose

The DCS Framework provides an overview on the entities of the Physical Model (Unit Classes, Equipment Module Classes) and the entities of the Procedural Model (Phase Classes) to be implemented in the DeltaV DCS Software for the stainless steel media and buffer systems.
A separate DCS Framework will be provided for the single-use Process Units.
The Automation Framework will be a living document, which will be updated and extented as required during the specification and implementation of the DCS Software.

2. Method

The Automation Framework is an Excel spread sheet that is subdivided in two sections for the Physical Model and the Procedural Model.

The section for the Physical Model identifies all Unit Classes with Unit Instances and all Equipment Module Classes and the location of the Equipment Module Classes.
The spread sheet identifies by **X** all Equipment Modules that belong to one particular Unit.
The spread sheet identifies by **S** all Equipment Modules that are shared Equipment Modules, which do not belong to one particular Unit but can be acquired from Phases that run on particular Units.

The section for the Procedural Model is a Phase Map that identifies all required Phases.
The spread sheet identifies by **X** all Units at which the Phase can be executed .
The spread sheet identifies by **X** or by **S** all Equipment Modules that will be acquired from the Phase.

The following information is provided in the individual columns of the Spread Sheet:

Index	Numerical index for further reference	
Phase Name	Phase Name per Naming Conventions	
Phase Descriptions	Short description of functionality of the Phase	
Ref. PFD	Reference to Page of marked up PFD's, that show SIP, CIP, XFER flow paths	
Phase is executed at Unit	Identification of Units at which an instance of the Phase will be executed	
Phase acquires Equipment Modules	Identification of all Equipment Modules that will be acquired by the Phase per following keys	
	X	Euipment Module from own Unit is acquired
	S	Equipment Module from another Unit or from no Unit (Shared EM) is acquired

3. Naming Conventions

Entity	Naming Convention	Example
Phase	max. 16 characters, capital letters, _ for delimiter	SIP_TANK_EMPTY
Unit	Free text	Buffer Hold Tank 1
EM	max. 16 characters, capital letters, _ for delimiter, EM_.....	EM_Bottom_Group

4. Change Log

The Automation Framework is a living document, that will be updated as required.
Changes to last version will be identified with text in red letters.
Major revisions will be done only if structural elements (Units, Equipment Modules, Phases) are added or deleted, and for milestones in project execution. All intermediate versions are indicated by the major revision and subsequent number, e.g. 02-2

Rev.	Date	Name	Description
0	2020-10-28	张予婧	draft
0.1a	2020-11-06	张予婧	add UF phase
0.1b	2020-11-18	张予婧	更新部分描述增加层析排气phase
0.1c	2020-11-20	张予婧	BP_BH launch unit 更新
0.1d	2020-11-25	张予婧	launch unit 更新 add abbreviation list
0.1e	2020-12-10	张予婧	add alarm phase
1.0	2021-03-03	杜林茂	新增PH_S_PUR_PA，PH_X_PT_DF，PH_X_PT_VF，PH_PRES_CONT
2.0	2021-04-26	杜林茂	新增PH_BUF_VD_TM，PH_PUR_VD_TM；删除PH_SET_STATE

5 Acronyms and Abbreviations

Abbreviation	
S	SIP
C	CIP
LT	Leak test
DR	Drain
X	Transfer
P	Preparation
TC	Temperature control
VAL	Validition
BP	Buffer preparation tank
BH	Buffer holding tank
PUR	Purification tank
CHT	Chromatography
DF	Depth filter
VF	Virus filter
UF	Ultra filter
POU	Point of use
ALW	Alkali and WFI
DIS	Distribution pipe
GEL	Gel tank
PU	Pump
HV	Harvest tank
VT	Vent
Sample	Sample
INST	Install
STOR	Storage
MSG	Message
AG	Agitator
TK	Tank
ALK	Alkali
RTN	Return
WT	Wash tank
RT	Rinse tank
AT	Alkali tank
DSF	Drug substance filling

SECTION 1		PHYSICAL MODEL (UNIT CLASSES AND EQUIPMENT MODULE CLASSES)	Unit
Unit	Unit Classs	Unit Description	DSX-TA12 / DSX-TA13 / DSX-TA14 / DSX-TA15 / DSX-TA16 / DSX-TA17 / DSX-TA18 / DSX-TA19 / DSX-TA20 (工艺用水罐) / DSX-TA21 / DSX-TA22 / DSX-TA23 / DSX-TA24 / DSX-TA26 / DSX-TA27 / DSX-TA28 / DSX-TA29 / DSX-TA30 / DSX-TA31 / DSX-TA32 / DSX-TA33 / DSX-TA34 / DSX-TA35 / DSX-TA02 / DSX-TA03 / DSX-TA04 / DSX-TA05 / DSX-TA06 / DSX-TA08 / DSX-TA07 (匀浆罐) / DSX-DF03 / DSX-VF01 / DSX-CHT01 / DSX-CHT02 / DSX-CHT03 / DSY-UF01 / DSY-UF02 / DSZ-UF01 / DSX-PT07 / DSX-CIP02 / DSX-CIP03 / DSX-CIP05 / ALK
DSX-TA12	BP Tank	3000L BUFFER PREPARATION TANK UNIT TA12	X
DSX-TA13		3000L BUFFER PREPARATION TANK UNIT TA13	X
DSX-TA14		6000L BUFFER PREPARATION TANK UNIT TA14	X
DSX-TA15		9000L BUFFER PREPARATION TANK UNIT TA15	X
DSX-TA16	BH Tank	3000L BUFFER HOLDING TANK UNIT TA16	X
DSX-TA17		3000L BUFFER HOLDING TANK UNIT TA17	X
DSX-TA18		3000L BUFFER HOLDING TANK UNIT TA18	X
DSX-TA19		3000L BUFFER HOLDING TANK UNIT TA19	X
DSX-TA20		3000L PROCESS WATER TANK UNIT TA20	X
DSX-TA21		3000L BUFFER HOLDING TANK UNIT TA21	X
DSX-TA22		3000L BUFFER HOLDING TANK UNIT TA22	X
DSX-TA23		3000L BUFFER HOLDING TANK UNIT TA23	X
DSX-TA24		3000L BUFFER HOLDING TANK UNIT TA24	X
DSX-TA26		6000L BUFFER HOLDING TANK UNIT TA26	X
DSX-TA27		6000L BUFFER HOLDING TANK UNIT TA27	X
DSX-TA28		6000L BUFFER HOLDING TANK UNIT TA28	X
DSX-TA29		6000L BUFFER HOLDING TANK UNIT TA29	X
DSX-TA30		3000L BUFFER HOLDING TANK UNIT TA30	X
DSX-TA31		6000L BUFFER HOLDING TANK UNIT TA31	X
DSX-TA32		9000L 0.5M NaOH TANK UNIT TA32	X
DSX-TA33		9000L BUFFER HOLDING TANK UNIT TA33	X
DSX-TA34		9000L BUFFER HOLDING TANK UNIT TA34	X
DSX-TA35		9000L BUFFER HOLDING TANK UNIT TA35	X
DSX-TA02	Process Tank(DPS)	4000L HARVEST TANK UNIT TA02	X
DSX-TA03		4000L PURIFICATION TANK UNIT TA03	X
DSX-TA04		4000L PURIFICATION TANK UNIT TA04	X
DSX-TA05		4000L PURIFICATION TANK UNIT TA05	X
DSX-TA06		3000L PURIFICATION TANK UNIT TA06	X
DSX-TA08		3000L PURIFICATION TANK UNIT TA08	X
DSX-TA07	Slurry Tank匀浆罐	1500L Slurry TANK UNIT TA07	X
DSX-DF03	Process Equipment 无需信号交互	DEPTH FILTRATION UNIT DF03	X
DSX-VF01		NF WORK UNIT NF01	X
DSX-CHT01	Process Equipment 都是DCS系统，内部交互	HPLC #1 WORK UNIT CHT01	X
DSX-CHT02		HPLC #2 WORK UNIT CHT02	X
DSX-CHT03		HPLC #3 WORK UNIT CHT03	X
DS1_3-UF01	超滤 都是DCS系统，内部交互	UF/DF WORK UNIT UF01 for Line 1 and Line 3	X
DS1_3-UF02		UF/DF WORK UNIT UF02 for Line 1 and Line 3	X
DSZ_4-UF01		UF/DF WORK UNIT UF01 for Line 2 and Line 4	X
原液分装系统	都是DCS系统，内部交互	PALLET TANK DS1-PT07	X
DSX-CIP02	CIP Station 都是DCS系统，内部交互	CIP02 UNIT TA-CIP0201	X
DSX-CIP03		CIP03 UNIT TA-CIP0301	X
DSX-CIP05		CIP05 UNIT TA-CIP0501	X
ALK		2500L CONCENTRATED ALKALI TANK UNIT XXX	X

SECTION 2		PROCEDURAL MODEL (PHASES)	
IndeX	Phase Class	Phase Description	
1	SIP Phases		
1-1	PH_S_BUF	Sterilization of buffer tank with cooling by chilled water or glycol ; tank heated by plant steam. 缓冲液罐子灭菌	DSX-TA12 / DSX-TA13 / DSX-TA14 / DSX-TA15 / DSX-TA16 / DSX-TA17 / DSX-TA18 / DSX-TA19 / DSX-TA20 (工艺用水罐) / DSX-TA21 / DSX-TA22 / DSX-TA23 / DSX-TA24 / DSX-TA26 / DSX-TA27 / DSX-TA28 / DSX-TA29 / DSX-TA30 / DSX-TA31 / DSX-TA32 / DSX-TA33 / DSX-TA34 / DSX-TA35
1-2	PH_S_PUR_CHT	Sterilization of buffer tank and transfer pipe to chromatography with cooling by chilled water or glycol ; tank heated by plant steam. 纯化罐子及出料到层析的管道灭菌。3种选项	DSX-TA02 / DSX-TA04 / DSX-TA05
1-3	PH_S_PUR_DF	Sterilization of buffer tank and transfer pipe to DF with cooling by chilled water or glycol ; tank heated by plant steam. 纯化罐子及出料到深层过滤的管道灭菌。3种选项	DSX-TA03
1-4	PH_S_PUR_VF	Sterilization of buffer tank and transfer pipe to VF with cooling by chilled water or glycol ; tank heated by plant steam. 纯化罐子及出料到除病毒过滤的管道灭菌。3种选项	DSX-TA05 / DSX-TA06
1-5	PH_S_PUR_UF	Sterilization of buffer tank and transfer pipe to UF with cooling by chilled water or glycol ; tank heated by plant steam. 纯化罐子及出料到超滤的管道灭菌。1种选项	DSX-TA05 / DSX-TA08
1-6	PH_S_BP_BH	Sterilization transfer line of buffer preparation tank with filters. 根据出料对象做不同选项 TA12&TA13，出料管路SIP分别有15个选项 TA14的出料管路SIP有18个选项 TA15的出料管路SIP有9个选项	DSX-TA12 / DSX-TA13 / DSX-TA14 / DSX-TA15
1-7	PH_S_BH_POU_DS1_3	Sterilization transfer line from holding tank to purification. 从缓冲液储存罐出料管路到纯化系统。 包括到上游缓冲液（通过PCS7信号交互）	DSX-TA16 / DSX-TA17 / DSX-TA18 / DSX-TA19 / DSX-TA21 / DSX-TA22 / DSX-TA23 / DSX-TA24 / DSX-TA27 / DSX-TA28 / DSX-TA29 / DSX-TA30 / DSX-TA31 / DSX-TA32 / DSX-TA33 / DSX-TA34 / DSX-TA35
1-8	PH_S_BH_POU_DS2_4	Sterilization transfer line from holding tank to purification. 从缓冲液储存罐出料管路到纯化系统。 包括到上游缓冲液（通过PCS7信号交互）	DSX-TA16 / DSX-TA17 / DSX-TA18 / DSX-TA19 / DSX-TA21 / DSX-TA22 / DSX-TA23 / DSX-TA24 / DSX-TA26 / DSX-TA27 / DSX-TA28 / DSX-TA29 / DSX-TA30 / DSX-TA31 / DSX-TA32 / DSX-TA33 / DSX-TA34 / DSX-TA35
1-9	PH_S_ALW_DIS1_3	Sterilization transfer line from holding tank bottom to main pipe. （TA20/TA26/TA32） 缓冲液出料管路从罐底灭菌到缓冲液分配阀组。	DSX-TA20 / DSX-TA26 / DSX-TA32
1-10	PH_S_ALW_DIS2_4	Sterilization transfer line from holding tank bottom to main pipe. （TA20/TA26/TA32） 缓冲液出料管路从罐底灭菌到缓冲液分配阀组。	DSX-TA20 / DSX-TA26 / DSX-TA32
1-11	PH_S_POU_DIS1_3	Sterilization transfer line from purification to buffer holding main pipe. 缓冲液出料管路从纯化系统反灭到缓冲液分配阀组。	DSX-TA03 / DSX-TA04 / DSX-TA16 / DSX-TA17 / DSX-TA18 / DSX-TA19 / DSX-TA21 / DSX-TA22 / DSX-TA23 / DSX-TA24 / DSX-TA27 / DSX-TA28 / DSX-TA29
1-12	PH_S_POU_DIS2_4	Sterilization transfer line from purification to buffer holding main pipe. 缓冲液出料管路从纯化系统反灭到缓冲液分配阀组。	DSX-TA03 / DSX-TA04 / DSX-TA16 / DSX-TA17 / DSX-TA18 / DSX-TA19 / DSX-TA21 / DSX-TA22 / DSX-TA23 / DSX-TA24 / DSX-TA27 / DSX-TA28 / DSX-TA29
1-13	PH_S_CHT_PUR	Sterilization of transfer line from chromatography to tank. 层析出料到罐体进口管路	DSX-CHT01 / DSX-CHT02 / DSX-CHT03
1-13	PH_S_PUR_PA	Sterilization of process air filter of harvest tank. 收获罐气体过滤器灭菌	DSX-TA02
2	CIP Phases		
2-1	PH_C_BP	CIP Buffer preparation tank, include agitation if have 缓冲液配制罐清洗分为碱循环洗，纯水冲洗和注射用水润洗，吹扫排尽包含上以上步骤中，搅拌也包含在phase中。	DSX-TA12 / DSX-TA13 / DSX-TA14 / DSX-TA15
2-2	PH_C_BH	CIP Buffer holding tank, include agitation if have 缓冲液储罐清洗分为碱循环洗，纯水冲洗和注射用水润洗，吹扫排尽包含上以上步骤中，搅拌也包含在phase中。	DSX-TA16 / DSX-TA17 / DSX-TA18 / DSX-TA19 / DSX-TA20 (工艺用水罐) / DSX-TA21 / DSX-TA22 / DSX-TA23 / DSX-TA24 / DSX-TA26 / DSX-TA27 / DSX-TA28 / DSX-TA29 / DSX-TA30 / DSX-TA31 / DSX-TA32 / DSX-TA33 / DSX-TA34 / DSX-TA35
2-3	PH_C_PUR	CIP purification tank, include agitation if have 纯化罐清洗分为碱循环洗，纯水冲洗和注射用水润洗，吹扫排尽包含上以上步骤中，搅拌也包含在phase中。	DSX-TA02 / DSX-TA03 / DSX-TA04 / DSX-TA05 / DSX-TA06 / DSX-TA08 / DSX-TA07 (匀浆罐) / DSX-DF03 / DSX-VF01 / DSX-CHT01 / DSX-CHT02 / DSX-CHT03 / DSY-UF01 / DSY-UF02 / DSZ-UF01

SECTION 1		PHYSICAL MODEL (UNIT CLASSES AND EQUIPMENT MODULE CLASSES)	Unit																																											
Unit	Unit Classs	Unit Description	DSX-TA12	DSX-TA13	DSX-TA14	DSX-TA15	DSX-TA16	DSX-TA17	DSX-TA18	DSX-TA19	DSX-TA20 （工艺用水罐）	DSX-TA21	DSX-TA22	DSX-TA23	DSX-TA24	DSX-TA26	DSX-TA27	DSX-TA28	DSX-TA29	DSX-TA30	DSX-TA31	DSX-TA32	DSX-TA33	DSX-TA34	DSX-TA35	DSX-TA02	DSX-TA03	DSX-TA04	DSX-TA05	DSX-TA06	DSX-TA08	DSX-TA07 （匀浆罐）	DSX-DF03	DSX-VF01	DSX-CHT01	DSX-CHT02	DSX-CHT03	DSY-UF01	DSY-UF02	DSZ-UF01	DSX-PT07	DSX-CIP02	DSX-CIP03	DSX-CIP05	ALK
DSX-TA12	BP Tank	3000L BUFFER PREPARATION TANK UNIT TA12	X																																											
DSX-TA13		3000L BUFFER PREPARATION TANK UNIT TA13		X																																										
DSX-TA14		6000L BUFFER PREPARATION TANK UNIT TA14			X																																									
DSX-TA15		9000L BUFFER PREPARATION TANK UNIT TA15				X																																								
DSX-TA16	BH Tank	3000L BUFFER HOLDING TANK UNIT TA16					X																																							
DSX-TA17		3000L BUFFER HOLDING TANK UNIT TA17						X																																						
DSX-TA18		3000L BUFFER HOLDING TANK UNIT TA18							X																																					
DSX-TA19		3000L BUFFER HOLDING TANK UNIT TA19								X																																				
DSX-TA20		3000L PROCESS WATER TANK UNIT TA20									X																																			
DSX-TA21		3000L BUFFER HOLDING TANK UNIT TA21										X																																		
DSX-TA22		3000L BUFFER HOLDING TANK UNIT TA22											X																																	
DSX-TA23		3000L BUFFER HOLDING TANK UNIT TA23												X																																
DSX-TA24		3000L BUFFER HOLDING TANK UNIT TA24													X																															
DSX-TA26		6000L BUFFER HOLDING TANK UNIT TA26														X																														
DSX-TA27		6000L BUFFER HOLDING TANK UNIT TA27															X																													
DSX-TA28		6000L BUFFER HOLDING TANK UNIT TA28																X																												
DSX-TA29		6000L BUFFER HOLDING TANK UNIT TA29																	X																											
DSX-TA30		3000L BUFFER HOLDING TANK UNIT TA30																		X																										
DSX-TA31		6000L BUFFER HOLDING TANK UNIT TA31																			X																									
DSX-TA32		9000L 0.5M NaOH TANK UNIT TA32																				X																								
DSX-TA33		9000L BUFFER HOLDING TANK UNIT TA33																					X																							
DSX-TA34		9000L BUFFER HOLDING TANK UNIT TA34																						X																						
DSX-TA35		9000L BUFFER HOLDING TANK UNIT TA35																							X																					
DSX-TA02	Process Tank(DPS)	4000L HARVEST TANK UNIT TA02																								X																				
DSX-TA03		4000L PURIFICATION TANK UNIT TA03																									X																			
DSX-TA04		4000L PURIFICATION TANK UNIT TA04																										X																		
DSX-TA05		4000L PURIFICATION TANK UNIT TA05																											X																	
DSX-TA06		3000L PURIFICATION TANK UNIT TA06																												X																
DSX-TA08		3000L PURIFICATION TANK UNIT TA08																													X															
DSX-TA07	Slurry Tank匀浆罐	1500L Slurry TANK UNIT TA07																														X														
DSX-DF03	Process Equipment 无需信号交互	DEPTH FILTRATION UNIT DF03																															X													
DSX-VF01		NF WORK UNIT NF01																																X												
DSX-CHT01	Process Equipment 都是DCS系统，内部交互	HPLC #1 WORK UNIT CHT01																																	X											
DSX-CHT02		HPLC #2 WORK UNIT CHT02																																		X										
DSX-CHT03		HPLC #3 WORK UNIT CHT03																																			X									
DS1_3-UF01	超滤 都是DCS系统，内部交互	UF/DF WORK UNIT UF01 for Line 1 and Line 3																																				X								
DS1_3-UF02		UF/DF WORK UNIT UF02 for Line 1 and Line 3																																					X							
DSZ_4-UF01		UF/DF WORK UNIT UF01 for Line 2 and Line 4																																						X						
原液分装系统	都是DCS系统，内部交互	PALLET TANK DS1-PT07																																							X					
DSX-CIP02	CIP Station 都是DCS系统，内部交互	CIP02 UNIT TA-CIP0201																																								X				
DSX-CIP03		CIP03 UNIT TA-CIP0301																																									X			
DSX-CIP05		CIP05 UNIT TA-CIP0501																																										X		
ALK		2500L CONCENTRATED ALKALI TANK UNIT XXX																																											X	
SECTION 2		PROCEDURAL MODEL (PHASES)																																											
IndeX	Phase Class	Phase Description																																											
1	SIP Phases																																												
2-4	PH_C_GEL	CIP GEL tank, include agitation if have 匀浆罐清洗分为碱循环洗，纯水冲洗和注射用水润洗，吹扫排尽包含上以上步骤中，搅拌也包含在phase中。																														X													
2-5	PH_C_BP_BH	CIP transfer line of buffer preparation tank with filters. 根据出料对象做不同选项 TA12&TA13，出料管路CIP分别有15个选项 TA14的出料管路CIP有18个选项 TA15的出料管路CIP有9个选项	X	X	X	X																																							
2-6	PH_C_BH_POU1_3	CIP transfer line of buffer holding tank. 从缓冲液储存罐出料管路到纯化系统。 包括到上游缓冲液（通过PCS7信号交互）					X	X	X	X		X	X	X	X		X	X	X	X	X		X	X	X																				
2-7	PH_C_BH_POU2_4	CIP transfer line of buffer holding tank. 从缓冲液储存罐出料管路到纯化系统。 包括到上游缓冲液（通过PCS7信号交互）					X	X	X	X		X	X	X	X		X	X	X	X	X		X	X	X																				
2-8	PH_C_ALW_DIS1_3	CIP transfer line from holding tank bottom to main pipe. （TA20/TA26/TA32） 缓冲液出料管路从罐底清洗到缓冲液分配阀组。									X					X						X																							
2-9	PH_C_ALW_DIS2_4	CIP transfer line from holding tank bottom to main pipe. （TA20/TA26/TA32） 缓冲液出料管路从罐底清洗到缓冲液分配阀组。									X					X						X																							
2-10	PH_C_POU_DIS1_3	CIP transfer line from purification point of use to buffer holding main pipe. 缓冲液出料管路从纯化系统反洗到缓冲液分配阀组。																									X	X					X	X	X	X	X	X	X	X					
2-11	PH_C_POU_DIS2_4	CIP transfer line from purification point of use to buffer holding main pipe. 缓冲液出料管路从纯化系统反洗到缓冲液分配阀组。																									X	X					X	X	X	X	X	X	X	X					
2-12	PH_C_PUR_CHT	CIP of transfer line from purification tank to chromatography. TA02及出料到CHT01管道； TA04及出料到CHT02管道； TA05及出料到CHT03管道；																								X		X	X																
2-13	PH_C_DF	CIP of depth filter and liquid filter. 深层过滤及液体过滤器灭菌（TA03出料管道）																															X												
2-14	PH_C_VF_PU	CIP of diagramp pump before virus filter 清洗除病毒过滤器前的隔膜泵																																X											
2-15	PH_C_VF	CIP of virus filter（反向清洗） 除病毒过滤模块清洗																																X											
2-16	PH_C_UF_DS1_3	CIP of UF（反向清洗） 超滤管道清洗																																				X	X						
2-17	PH_C_UF_DS2_4	CIP of UF（反向清洗） 超滤管道清洗																																						X						
2-18	PH_C_CHT_PUR	CIP of transfer line from chromatography to tank. 清洗层析出口产品管路																																	X	X	X								
2-19	PH_C_TA08_TA06	CIP of transfer line fromTA08 to TA06. 清洗TA08出料到TA06的管道																													X														
3	Product Phases																																												
3-1	PH_P_BP	Preparation of buffer prep tank 配制罐配料	X	X	X	X																																							
3-2	PH_TA20_WFI_IN	Add WFI into TA20 TA20罐注水									X																																		
3-3	PH_X_BP_BH	Buffer transfer from Buffer Preparation Tank to Holding tank 缓冲液配制到缓冲液储存转移（包括缓冲液罐排放）	X	X	X	X																																							

SECTION 1		PHYSICAL MODEL (UNIT CLASSES AND EQUIPMENT MODULE CLASSES)	Unit																																										
Unit	Unit Classs	Unit Description	DSX-TA12	DSX-TA13	DSX-TA14	DSX-TA15	DSX-TA16	DSX-TA17	DSX-TA18	DSX-TA19	DSX-TA20（工艺用水罐）	DSX-TA21	DSX-TA22	DSX-TA23	DSX-TA24	DSX-TA26	DSX-TA27	DSX-TA28	DSX-TA29	DSX-TA30	DSX-TA31	DSX-TA32	DSX-TA33	DSX-TA34	DSX-TA35	DSX-TA02	DSX-TA03	DSX-TA04	DSX-TA05	DSX-TA06	DSX-TA08	DSX-TA07（匀浆罐）	DSX-DF03	DSX-VF01	DSX-CHT01	DSX-CHT02	DSX-CHT03	DSY-UF01	DSY-UF02	DSZ-UF01	DSX-PT07	DSX-CIP02	DSX-CIP03	DSX-CIP05	ALK
DSX-TA12	BP Tank	3000L BUFFER PREPARATION TANK UNIT TA12	X																																										
DSX-TA13		3000L BUFFER PREPARATION TANK UNIT TA13		X																																									
DSX-TA14		6000L BUFFER PREPARATION TANK UNIT TA14			X																																								
DSX-TA15		9000L BUFFER PREPARATION TANK UNIT TA15				X																																							
DSX-TA16	BH Tank	3000L BUFFER HOLDING TANK UNIT TA16					X																																						
DSX-TA17		3000L BUFFER HOLDING TANK UNIT TA17						X																																					
DSX-TA18		3000L BUFFER HOLDING TANK UNIT TA18							X																																				
DSX-TA19		3000L BUFFER HOLDING TANK UNIT TA19								X																																			
DSX-TA20		3000L PROCESS WATER TANK UNIT TA20									X																																		
DSX-TA21		3000L BUFFER HOLDING TANK UNIT TA21										X																																	
DSX-TA22		3000L BUFFER HOLDING TANK UNIT TA22											X																																
DSX-TA23		3000L BUFFER HOLDING TANK UNIT TA23												X																															
DSX-TA24		3000L BUFFER HOLDING TANK UNIT TA24													X																														
DSX-TA26		6000L BUFFER HOLDING TANK UNIT TA26														X																													
DSX-TA27		6000L BUFFER HOLDING TANK UNIT TA27															X																												
DSX-TA28		6000L BUFFER HOLDING TANK UNIT TA28																X																											
DSX-TA29		6000L BUFFER HOLDING TANK UNIT TA29																	X																										
DSX-TA30		3000L BUFFER HOLDING TANK UNIT TA30																		X																									
DSX-TA31		6000L BUFFER HOLDING TANK UNIT TA31																			X																								
DSX-TA32		9000L 0.5M NaOH TANK UNIT TA32																				X																							
DSX-TA33		9000L BUFFER HOLDING TANK UNIT TA33																					X																						
DSX-TA34		9000L BUFFER HOLDING TANK UNIT TA34																						X																					
DSX-TA35		9000L BUFFER HOLDING TANK UNIT TA35																							X																				
DSX-TA02	Process Tank(DPS)	4000L HARVEST TANK UNIT TA02																								X																			
DSX-TA03		4000L PURIFICATION TANK UNIT TA03																									X																		
DSX-TA04		4000L PURIFICATION TANK UNIT TA04																										X																	
DSX-TA05		4000L PURIFICATION TANK UNIT TA05																											X																
DSX-TA06		3000L PURIFICATION TANK UNIT TA06																												X															
DSX-TA08		3000L PURIFICATION TANK UNIT TA08																													X														
DSX-TA07	Slurry Tank匀浆罐	1500L Slurry TANK UNIT TA07																														X													
DSX-DF03	Process Equipment 无需信号交互	DEPTH FILTRATION UNIT DF03																															X												
DSX-VF01		NF WORK UNIT NF01																																X											
DSX-CHT01	Process Equipment 都是DCS系统，内部交互	HPLC #1 WORK UNIT CHT01																																	X										
DSX-CHT02		HPLC #2 WORK UNIT CHT02																																		X									
DSX-CHT03		HPLC #3 WORK UNIT CHT03																																			X								
DS1_3-UF01	超滤 都是DCS系统，内部交互	UF/DF WORK UNIT UF01 for Line 1 and Line 3																																				X							
DS1_3-UF02		UF/DF WORK UNIT UF02 for Line 1 and Line 3																																					X						
DSZ_4-UF01		UF/DF WORK UNIT UF01 for Line 2 and Line 4																																						X					
原液分装系统	都是DCS系统，内部交互	PALLET TANK DS1-PT07																																							X				
DSX-CIP02	CIP Station 都是DCS系统，内部交互	CIP02 UNIT TA-CIP0201																																								X			
DSX-CIP03		CIP03 UNIT TA-CIP0301																																									X		
DSX-CIP05		CIP05 UNIT TA-CIP0501																																										X	
ALK		2500L CONCENTRATED ALKALI TANK UNIT XXX																																											X
SECTION 2		PROCEDURAL MODEL (PHASES)																																											
IndeX	Phase Class	Phase Description																																											
1	SIP Phases																																												
3-4	PH_X_BH_DIS	Buffer transfer from Buffer holding to main distribution piping. 缓冲液储存出料主管，可以被不同分支调用（包括缓冲液罐排放）。 包括到上游缓冲液（通过与PCS7信号交互）					X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X																				
3-5	PH_X_BH_CHT	Buffer from buffer distribution to chromatography. 缓冲液从出料分支到层析系统																																	X	X	X								
3-6	PH_X_BH_DF	Buffer from buffer distribution to depth filter . 缓冲液从出料分支到深层过滤系统																															X												
3-7	PH_X_BH_VF	Buffer from buffer distribution to virus filter . 缓冲液从出料分支到除病毒过滤系统																																X											
3-8	PH_X_BH_PUR	Buffer from buffer distribution to purification tank . 缓冲液从出料分支到纯化罐																									X	X	X	X															
3-9	PH_X_BH_UF_DS1_3	Buffer from buffer distribution to UF . 缓冲液从出料分支到超滤																																				X	X						
3-10	PH_X_BH_UF_DS2_4	Buffer from buffer distribution to UF . 缓冲液从出料分支到超滤																																						X					
3-11	PH_X_BH_TA01	Buffer from buffer distribution to TA01 . 缓冲液从出料分支到TA01					X																X																						
3-12	PH_X_DIS_CHT	CIP of chromatography inlet valve. 层析系统前分配阀组清洗																																	X	X	X								
3-12	PH_X_HV	Product from upstream to harvest tank. 接收上游的产品（通过与PCS7信号交互）																								X																			
3-13	PH_X_PUR_CHT	product from purification tank to chromatography. 产品出料从纯化罐到层析																																	X	X	X								
3-14	PH_X_PUR_DF	product from purification tank to depth filter. 产品出料从纯化罐到深层过滤																															X												
3-15	PH_X_PUR_VF	product from purification tank to virus filter. 产品出料从纯化罐到除病毒过滤																																X											
3-16	PH_X_TA08_TA06	product from purification tank TA08 to purification tank TA06. 产品出料从纯化罐TA08到纯化罐TA06																													X														
3-17	PH_X_PUR_UF_DS1_3	product from purification tank to ultra filter. 产品出料从纯化罐到超滤																																				X	X						
3-18	PH_X_PUR_UF_DS2_4	product from purification tank to ultra filter. 产品出料从纯化罐到超滤																																						X					
3-19	PH_X_CHT_PUR	Transfer product chromatography to tank. 从层析出料到纯化罐。																																	X	X	X								
3-20	PH_X_CHT_VT	Chromatography vent 层析排气																																	X	X	X								
3-21	PH_WFI_SAMPLE	Sample of WFI WFI取样	X	X	X	X					X																																		
3-22	PH_P_GEL_INST	Install column of gel tank 匀浆罐配液																														X													
3-23	PH_P_GEL_STOR	Storage column of gel tank 匀浆罐配液																														X													
3-24	PH_DSF_WE_VERIFY	Verify scale 矫正称重																																							X				
3-25	PH_DSF_GENERAL	General weigh 一般称重																																							X				
3-26	PH_DSF_PRE	Preparation of drug substance filling 原液分装准备																																							X				
3-27	PH_DSF_PROCESS	Drug substance filling 原液分装																																							X				
3-28	PH_X_PT_DF	Transfer product from pallet tank to depth filter 产品出料从托盘到深层过滤																															X	X											

SECTION 1		PHYSICAL MODEL (UNIT CLASSES AND EQUIPMENT MODULE CLASSES)	Unit																																									
Unit	Unit Classs	Unit Description	DSX-TA12	DSX-TA13	DSX-TA14	DSX-TA15	DSX-TA16	DSX-TA17	DSX-TA18	DSX-TA19	DSX-TA20 （工艺用水罐）	DSX-TA21	DSX-TA22	DSX-TA23	DSX-TA24	DSX-TA26	DSX-TA27	DSX-TA28	DSX-TA29	DSX-TA30	DSX-TA31	DSX-TA32	DSX-TA33	DSX-TA34	DSX-TA35	DSX-TA02	DSX-TA03	DSX-TA04	DSX-TA05	DSX-TA06	DSX-TA08	DSX-TA07 （匀浆罐）	DSX-DF03	DSX-VF01	DSX-CHT01	DSX-CHT02	DSX-CHT03	DSY-UF01	DSY-UF02	DSZ-UF01	DSX-PT07	DSX-CIP02	DSX-CIP03	DSX-CIP05	ALK
DSX-TA12	BP Tank	3000L BUFFER PREPARATION TANK UNIT TA12	X																																								
DSX-TA13		3000L BUFFER PREPARATION TANK UNIT TA13		X																																							
DSX-TA14		6000L BUFFER PREPARATION TANK UNIT TA14			X																																						
DSX-TA15		9000L BUFFER PREPARATION TANK UNIT TA15				X																																					
DSX-TA16	BH Tank	3000L BUFFER HOLDING TANK UNIT TA16					X																																				
DSX-TA17		3000L BUFFER HOLDING TANK UNIT TA17						X																																			
DSX-TA18		3000L BUFFER HOLDING TANK UNIT TA18							X																																		
DSX-TA19		3000L BUFFER HOLDING TANK UNIT TA19								X																																	
DSX-TA20		3000L PROCESS WATER TANK UNIT TA20									X																																
DSX-TA21		3000L BUFFER HOLDING TANK UNIT TA21										X																															
DSX-TA22		3000L BUFFER HOLDING TANK UNIT TA22											X																														
DSX-TA23		3000L BUFFER HOLDING TANK UNIT TA23												X																													
DSX-TA24		3000L BUFFER HOLDING TANK UNIT TA24													X																												
DSX-TA26		6000L BUFFER HOLDING TANK UNIT TA26														X																											
DSX-TA27		6000L BUFFER HOLDING TANK UNIT TA27															X																										
DSX-TA28		6000L BUFFER HOLDING TANK UNIT TA28																X																									
DSX-TA29		6000L BUFFER HOLDING TANK UNIT TA29																	X																								
DSX-TA30		3000L BUFFER HOLDING TANK UNIT TA30																		X																							
DSX-TA31		6000L BUFFER HOLDING TANK UNIT TA31																			X																						
DSX-TA32		9000L 0.5M NaOH TANK UNIT TA32																				X																					
DSX-TA33		9000L BUFFER HOLDING TANK UNIT TA33																					X																				
DSX-TA34		9000L BUFFER HOLDING TANK UNIT TA34																						X																			
DSX-TA35		9000L BUFFER HOLDING TANK UNIT TA35																							X																		
DSX-TA02	Process Tank(DPS)	4000L HARVEST TANK UNIT TA02																							X																		
DSX-TA03		4000L PURIFICATION TANK UNIT TA03																								X																	
DSX-TA04		4000L PURIFICATION TANK UNIT TA04																									X																
DSX-TA05		4000L PURIFICATION TANK UNIT TA05																										X															
DSX-TA06		3000L PURIFICATION TANK UNIT TA06																											X														
DSX-TA08		3000L PURIFICATION TANK UNIT TA08																												X													
DSX-TA07	Slurry Tank匀浆罐	1500L Slurry TANK UNIT TA07																													X												
DSX-DF03	Process Equipment 无需信号交互	DEPTH FILTRATION UNIT DF03																														X											
DSX-VF01		NF WORK UNIT NF01																															X										
DSX-CHT01	Process Equipment 都是DCS系统，内部交互	HPLC #1 WORK UNIT CHT01																																X									
DSX-CHT02		HPLC #2 WORK UNIT CHT02																																	X								
DSX-CHT03		HPLC #3 WORK UNIT CHT03																																		X							
DS1_3-UF01	超滤 都是DCS系统，内部交互	UF/DF WORK UNIT UF01 for Line 1 and Line 3																																			X						
DS1_3-UF02		UF/DF WORK UNIT UF02 for Line 1 and Line 3																																				X					
DSZ_4-UF01		UF/DF WORK UNIT UF01 for Line 2 and Line 4																																					X				
原液分装系统	都是DCS系统，内部交互	PALLET TANK DS1-PT07																																						X			
DSX-CIP02	CIP Station 都是DCS系统，内部交互	CIP02 UNIT TA-CIP0201																																							X		
DSX-CIP03		CIP03 UNIT TA-CIP0301																																								X	
DSX-CIP05		CIP05 UNIT TA-CIP0501																																									X
ALK		2500L CONCENTRATED ALKALI TANK UNIT XXX																																									X
SECTION 2		PROCEDURAL MODEL (PHASES)																																									
IndeX	Phase Class	Phase Description																																									
1	SIP Phases																																										
3-29	PH_X_PT_VF	Transfer product from pallet tank to nano filter 产品出料从托盘到除病毒过滤																													X	X											
4	Other Phases																																										
4-1	PH_MSG	Promot operator information 例如取样，投料，调pH等提示	X	X	X	X																				X	X	X	X	X	X	X												
4-2	PH_TIMER	Timer. 计时	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X												
4-3	PH_AG	Tank agitator control. 罐搅拌控制	X	X	X	X																				X	X	X	X	X	X	X												X
4-4	PH_TC_TK	Jacket heating by TCM or cooling by glycol/chilled water during product.																							X	X	X	X	X	X														
4-5	PH_LT_BUF	Hermetic leak test of tank with breath filter.	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X																			
4-6	PH_LT_PUR	Hermetic leak test of tank with transfer pipe.																							X	X	X	X	X	X														
4-7	PH_D_BUF	Drain buffer tank with transfer pipe.	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X																			
4-8	PH_D_PUR	Drain purification tank with transfer pipe.																							X	X	X	X	X	X														
4-9	PH_VAL_CWFI_BUF	Validate by CWFI	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X																			
4-10	PH_VAL_CWFI_PUR	Validate by CWFI																							X	X	X	X	X	X														
4-11	PH_ALM_RA	Ration alarm																							X																			
4-12	PH_ALM	PH, CT and temperature alarm																							X	X	X	X	X	X														
4-13	PH_PRES_CONT	Process tank pressure control																							X	X	X	X	X	X														
4-14	PH_BUF_VD_TM	Buffer system validation time management	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X																			
4-15	PH_PUR_VD_TM	Purification system validation time management																							X	X	X	X	X	X	X	X	X	X	X	X	X	X	X					
~~4-14~~	~~PH_SET_STATE~~	~~Set state~~																														~~X~~		~~X~~	~~X~~	~~X~~								
5	CIP Skid Phases																																										
5-1	SUPPLY_PW	Supply pw and drain at POU																																						X	X	X	
5-2	SUPPLY_PW_DRN	Supply pw and drain at cip skid																																						X	X	X	
5-3	SUPPLY_ALK	Supply alkali and drain at POU																																						X	X	X	
5-4	SUPPLY_ALK_DRN	Supply alkali and drain at cip skid																																						X	X	X	
5-5	SUPPLY_ALK_RTN	Supply alkali and return to washtank																																						X	X	X	
5-6	SUPPLY_WFI	Supply wfi and drain at POU																																						X	X	X	
5-7	SUPPLY_WFI_DRN	Supply wfi and drain at cip skid																																						X	X	X	
5-8	AIR_BLOW	Air blow and drain at pou																																						X	X	X	
5-9	AIR_BLOW_DRN	Air blow and drain at cip skid																																						X	X	X	
5-10	PREP_PW	Preparation pw																																						X	X	X	
5-11	PREP_ALK	Preparation Alkali																																						X	X	X	
5-12	PREP_WFI	Preparation wfi																																						X	X	X	
5-13	PH_C_WT	Washtank selfclean																																						X	X	X	
5-14	PH_C_RT	Rinsetank selfclean																																						X	X	X	

SECTION 1		PHYSICAL MODEL (UNIT CLASSES AND EQUIPMENT MODULE CLASSES)	Unit																																											
Unit	Unit Classs	Unit Description	DSX-TA12	DSX-TA13	DSX-TA14	DSX-TA15	DSX-TA16	DSX-TA17	DSX-TA18	DSX-TA19	DSX-TA20 (工艺用水罐)	DSX-TA21	DSX-TA22	DSX-TA23	DSX-TA24	DSX-TA26	DSX-TA27	DSX-TA28	DSX-TA29	DSX-TA30	DSX-TA31	DSX-TA32	DSX-TA33	DSX-TA34	DSX-TA35	DSX-TA02	DSX-TA03	DSX-TA04	DSX-TA05	DSX-TA06	DSX-TA08	DSX-TA07 (匀浆罐)	DSX-DF03	DSX-VF01	DSX-CHT01	DSX-CHT02	DSX-CHT03	DSY-UF01	DSY-UF02	DSZ-UF01	DSX-PT07	DSX-CIP02	DSX-CIP03	DSX-CIP05	ALK
DSX-TA12	BP Tank	3000L BUFFER PREPARATION TANK UNIT TA12	X																																										
DSX-TA13		3000L BUFFER PREPARATION TANK UNIT TA13		X																																									
DSX-TA14		6000L BUFFER PREPARATION TANK UNIT TA14			X																																								
DSX-TA15		9000L BUFFER PREPARATION TANK UNIT TA15				X																																							
DSX-TA16	BH Tank	3000L BUFFER HOLDING TANK UNIT TA16					X																																						
DSX-TA17		3000L BUFFER HOLDING TANK UNIT TA17						X																																					
DSX-TA18		3000L BUFFER HOLDING TANK UNIT TA18							X																																				
DSX-TA19		3000L BUFFER HOLDING TANK UNIT TA19								X																																			
DSX-TA20		3000L PROCESS WATER TANK UNIT TA20									X																																		
DSX-TA21		3000L BUFFER HOLDING TANK UNIT TA21										X																																	
DSX-TA22		3000L BUFFER HOLDING TANK UNIT TA22											X																																
DSX-TA23		3000L BUFFER HOLDING TANK UNIT TA23												X																															
DSX-TA24		3000L BUFFER HOLDING TANK UNIT TA24													X																														
DSX-TA26		6000L BUFFER HOLDING TANK UNIT TA26														X																													
DSX-TA27		6000L BUFFER HOLDING TANK UNIT TA27															X																												
DSX-TA28		6000L BUFFER HOLDING TANK UNIT TA28																X																											
DSX-TA29		6000L BUFFER HOLDING TANK UNIT TA29																	X																										
DSX-TA30		3000L BUFFER HOLDING TANK UNIT TA30																		X																									
DSX-TA31		6000L BUFFER HOLDING TANK UNIT TA31																			X																								
DSX-TA32		9000L 0.5M NaOH TANK UNIT TA32																				X																							
DSX-TA33		9000L BUFFER HOLDING TANK UNIT TA33																					X																						
DSX-TA34		9000L BUFFER HOLDING TANK UNIT TA34																						X																					
DSX-TA35		9000L BUFFER HOLDING TANK UNIT TA35																							X																				
DSX-TA02	Process Tank(DPS)	4000L HARVEST TANK UNIT TA02																								X																			
DSX-TA03		4000L PURIFICATION TANK UNIT TA03																									X																		
DSX-TA04		4000L PURIFICATION TANK UNIT TA04																										X																	
DSX-TA05		4000L PURIFICATION TANK UNIT TA05																											X																
DSX-TA06		3000L PURIFICATION TANK UNIT TA06																												X															
DSX-TA08		3000L PURIFICATION TANK UNIT TA08																													X														
DSX-TA07	Slurry Tank匀浆罐	1500L Slurry TANK UNIT TA07																														X													
DSX-DF03	Process Equipment 无需信号交互	DEPTH FILTRATION UNIT DF03																															X												
DSX-VF01		NF WORK UNIT NF01																																X											
DSX-CHT01	Process Equipment 都是DCS系统，内部交互	HPLC #1 WORK UNIT CHT01																																	X										
DSX-CHT02		HPLC #2 WORK UNIT CHT02																																		X									
DSX-CHT03		HPLC #3 WORK UNIT CHT03																																			X								
DS1_3-UF01	超滤 都是DCS系统，内部交互	UF/DF WORK UNIT UF01 for Line 1 and Line 3																																				X							
DS1_3-UF02		UF/DF WORK UNIT UF02 for Line 1 and Line 3																																					X						
DSZ_4-UF01		UF/DF WORK UNIT UF01 for Line 2 and Line 4																																						X					
原液分装系统	都是DCS系统，内部交互	PALLET TANK DS1-PT07																																							X				
DSX-CIP02	CIP Station 都是DCS系统，内部交互	CIP02 UNIT TA-CIP0201																																								X			
DSX-CIP03		CIP03 UNIT TA-CIP0301																																									X		
DSX-CIP05		CIP05 UNIT TA-CIP0501																																										X	
ALK		2500L CONCENTRATED ALKALI TANK UNIT XXX																																											X
SECTION 2		PROCEDURAL MODEL (PHASES)																																											
IndeX	Phase Class	Phase Description																																											
1	SIP Phases																																												
5-15	PH_D_WT	Washtank drain																																								X	X	X	
5-16	PH_D_RT	Rinsetank drain																																								X	X	X	
5-17	PH_S_RT	Rinsetank SIP																																								X	X	X	
5-18	PH_C_AT	Alkalitank selfclean																																											X
5-19	PH_D_AT	Alkalitank drain																																											X
5-20	PH_P_AT	Preparation alkali																																											X