Presentation of QbD Application in Aseptic Filling Line

Jackson Zhao
2019-11-26

EXPERTISE IN PHARMACEUTICAL INDUSTRY

www.tofflon.com

Tofflon

Tofflon Since 1993

CONTENTS

1 Filling Linkage Line in Injectable Solution System

Filling Linkage in Injectable System Solution

(1) Mini KUFILL

KUFill——The Advanced Aseptic Processing System Integrated with Isolator

(2) KUFILL

(3) Flexible Manufacturing System Solution

(4) Vials Lyophilized System Solution

(5) Vials Liquid System Solution

(6) Ampoules Liquid System Solution

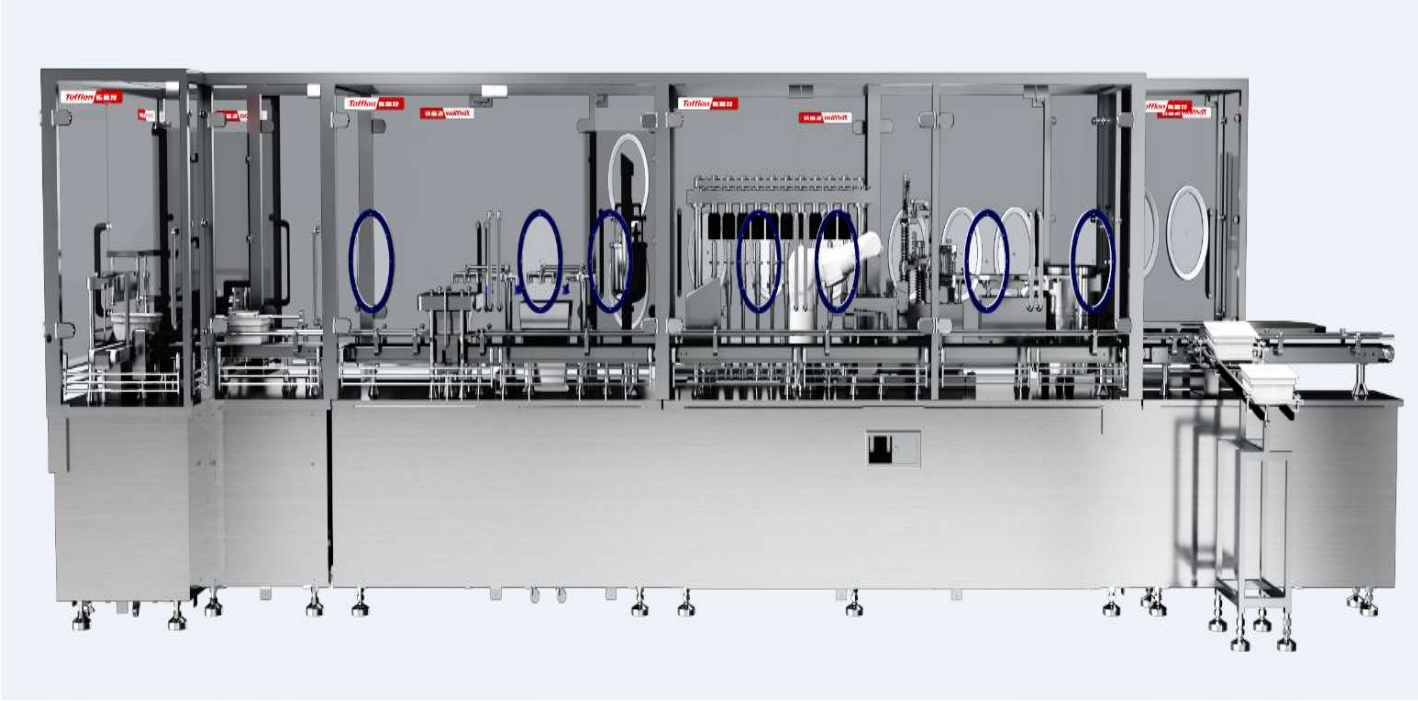
(7) Vials Powder Filling System Solution

Mini KUFILL

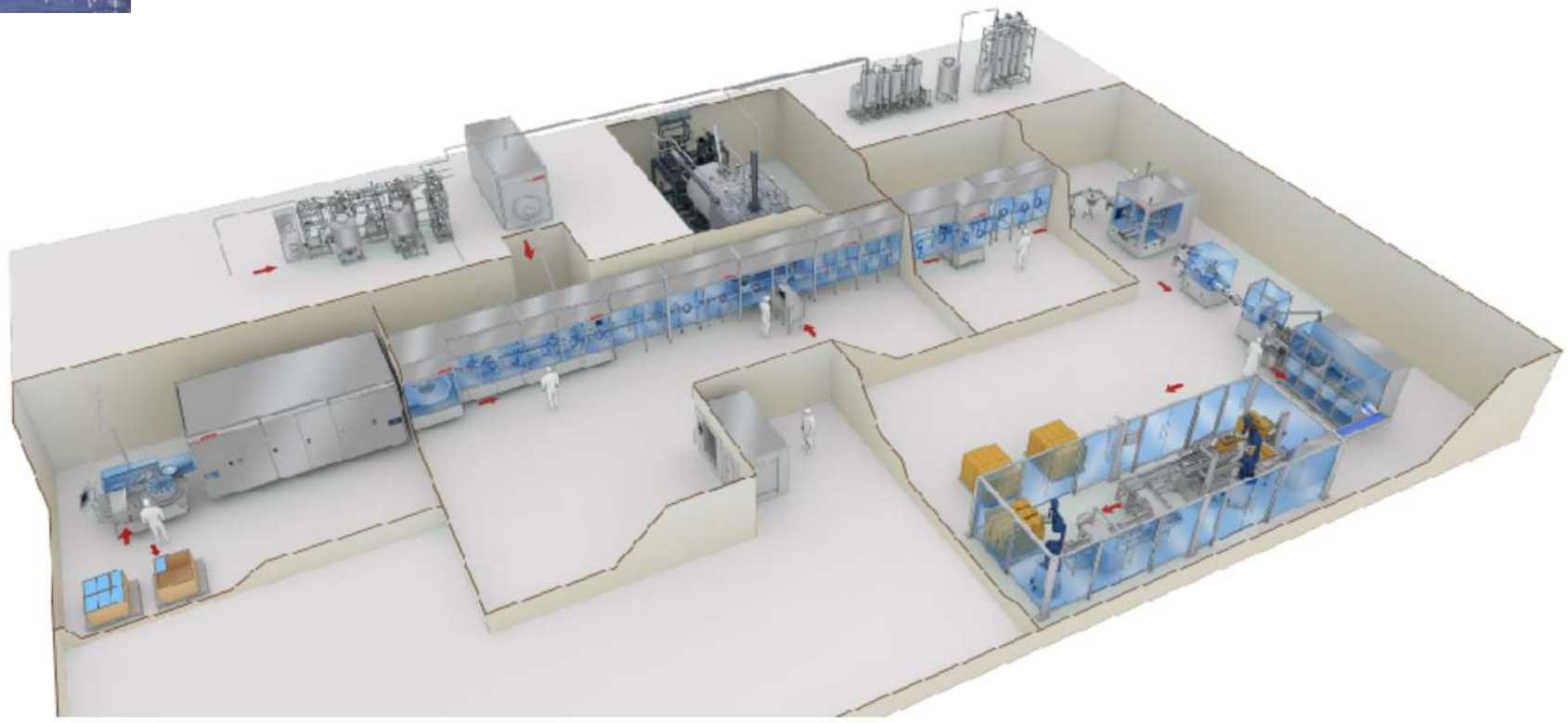
www.tofflon.com

KUFILL

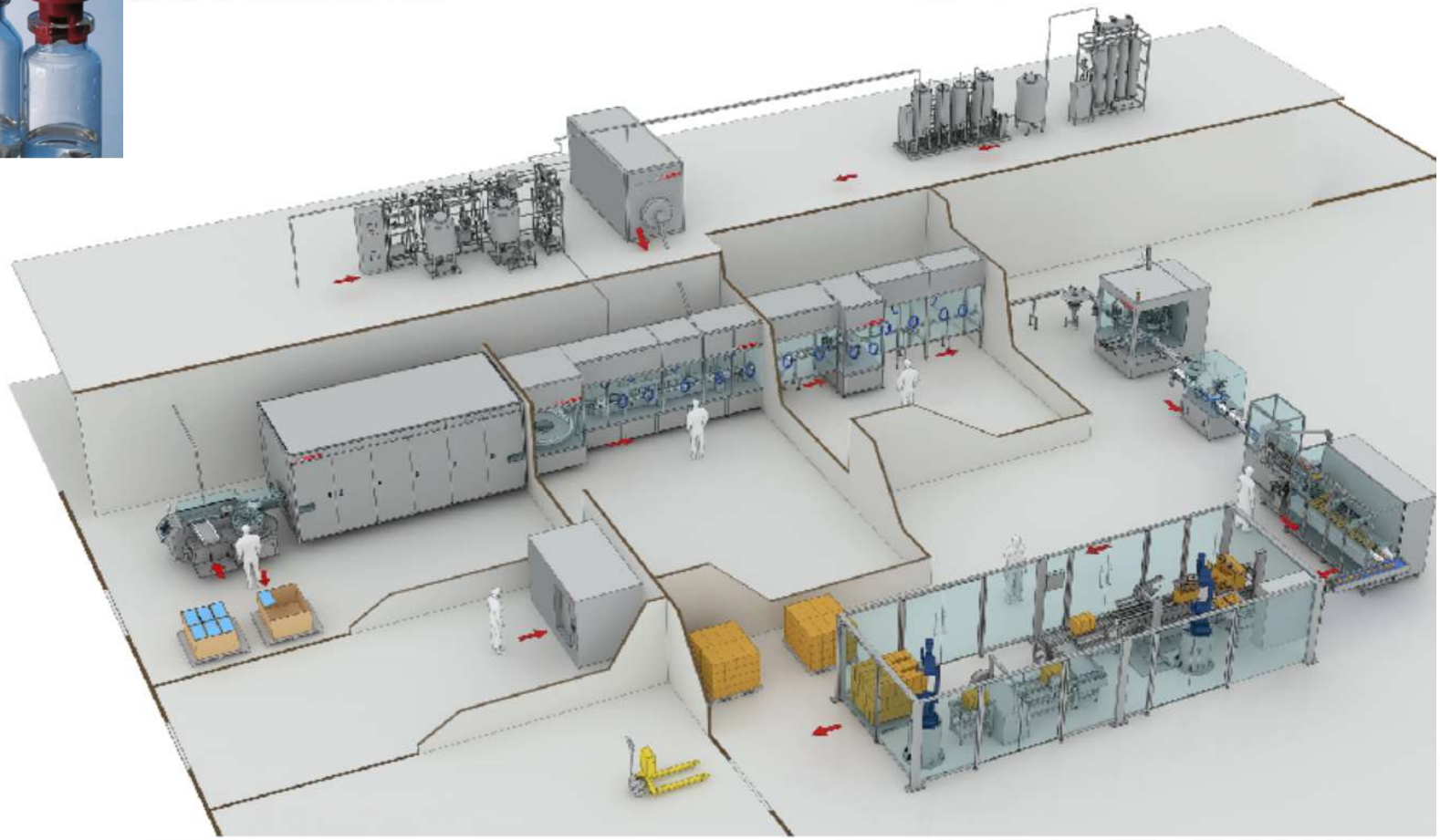
Flexible Manufacturing System Solution



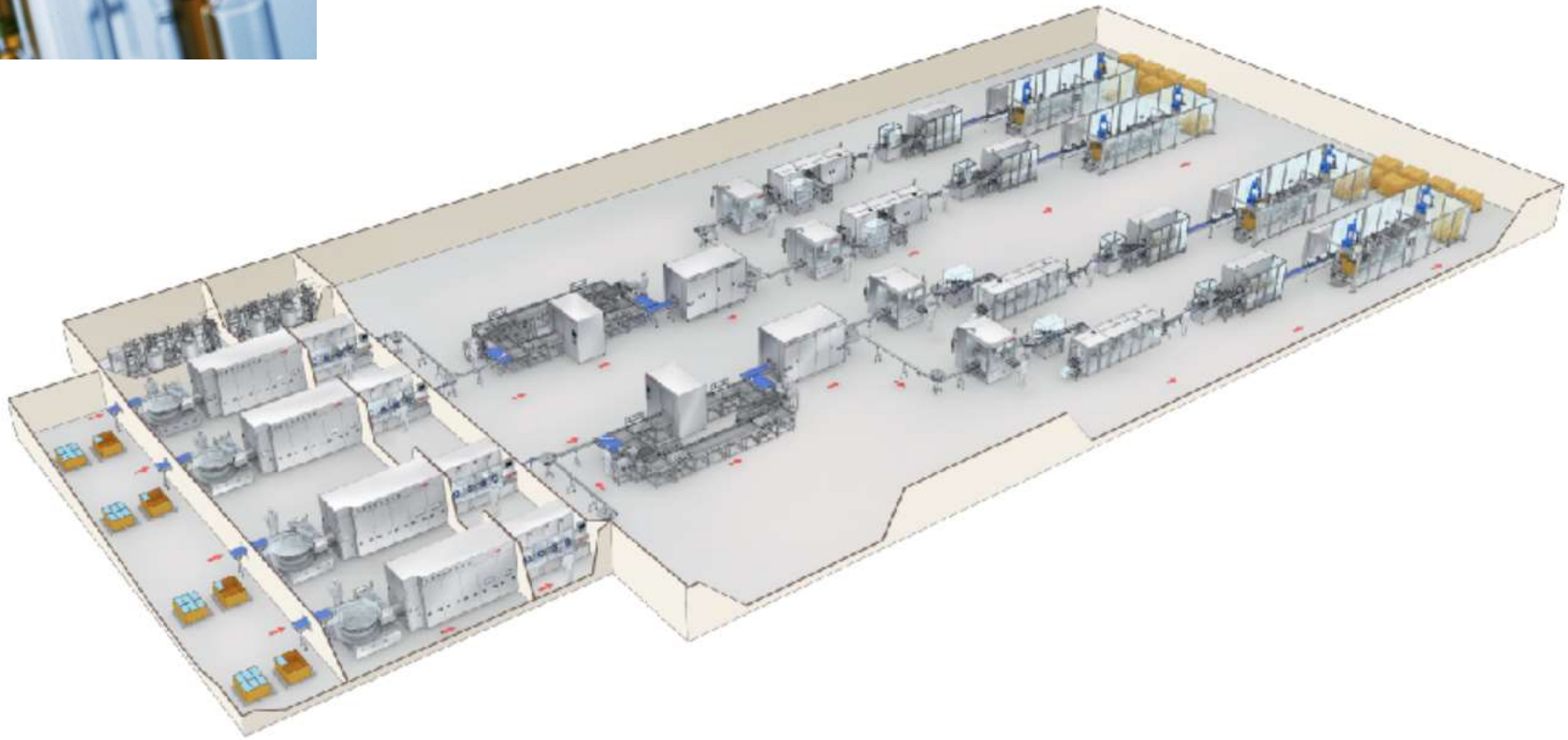
Vials Lyophilized System Solution



Vials Liquid System Solution



Ampoules Liquid System Solution



Vials Powder Filling System Solution

2 Quality by Design

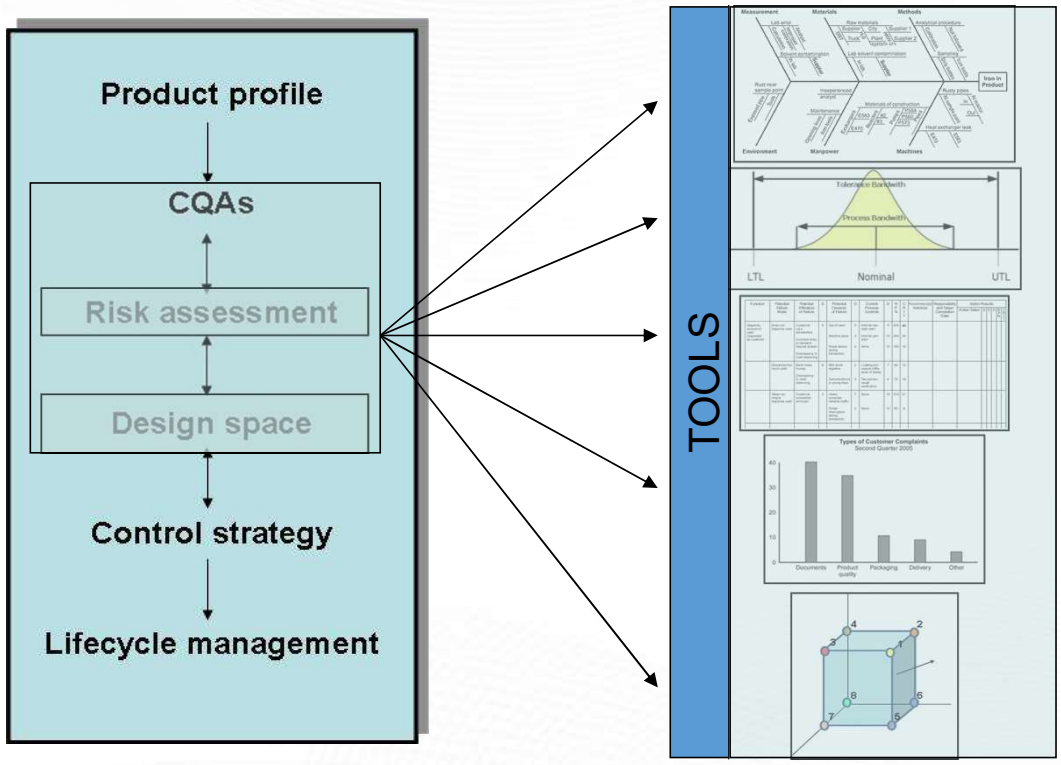
Quality by Design

Product Quality Lifecycle Implementation (PQLI)

Quality by Design: A systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management.

Quality by Design

A Systematic Approach



Ishikawa

Capability

FMEA

Pareto

DOE

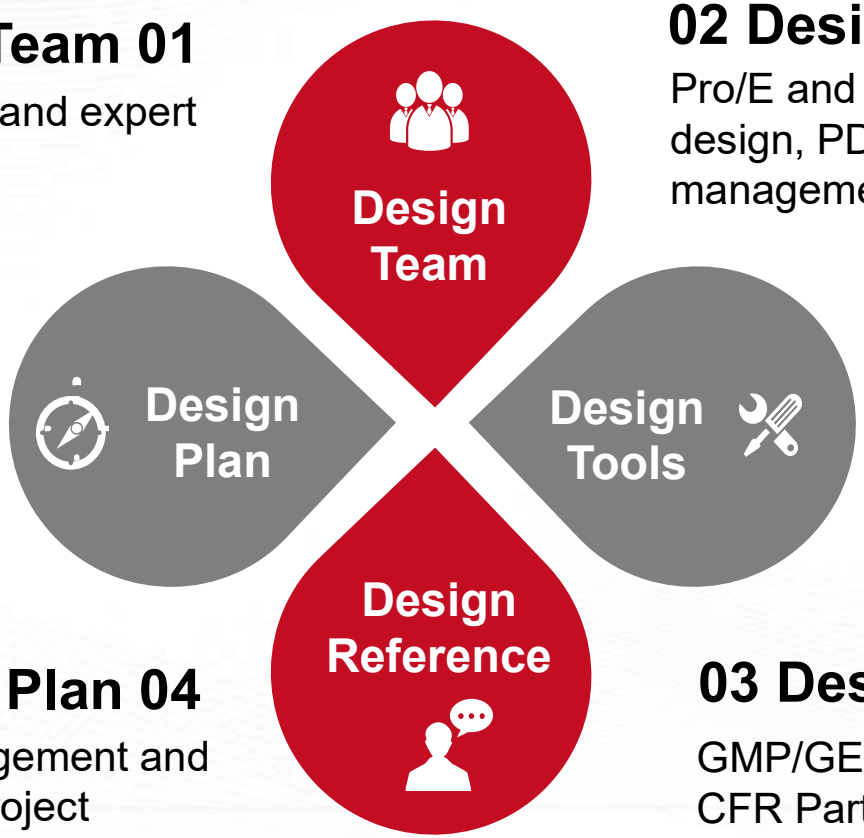
- Target the product profile
- Determine Critical Quality Attributes (CQAs)
- Link input material attributes and process parameters to CQAs and perform risk assessment
- Develop a design space
- Design and implement a control strategy
- Manage product lifecycle, including continual improvement

Design Management

Aseptic Filling Line

Design Team 01

Experienced engineers and expert advisors



02 Design Tools

Pro/E and Inventor/CAD used for 2D/3D design, PDM and OA used for drawings management.

Design Plan 04

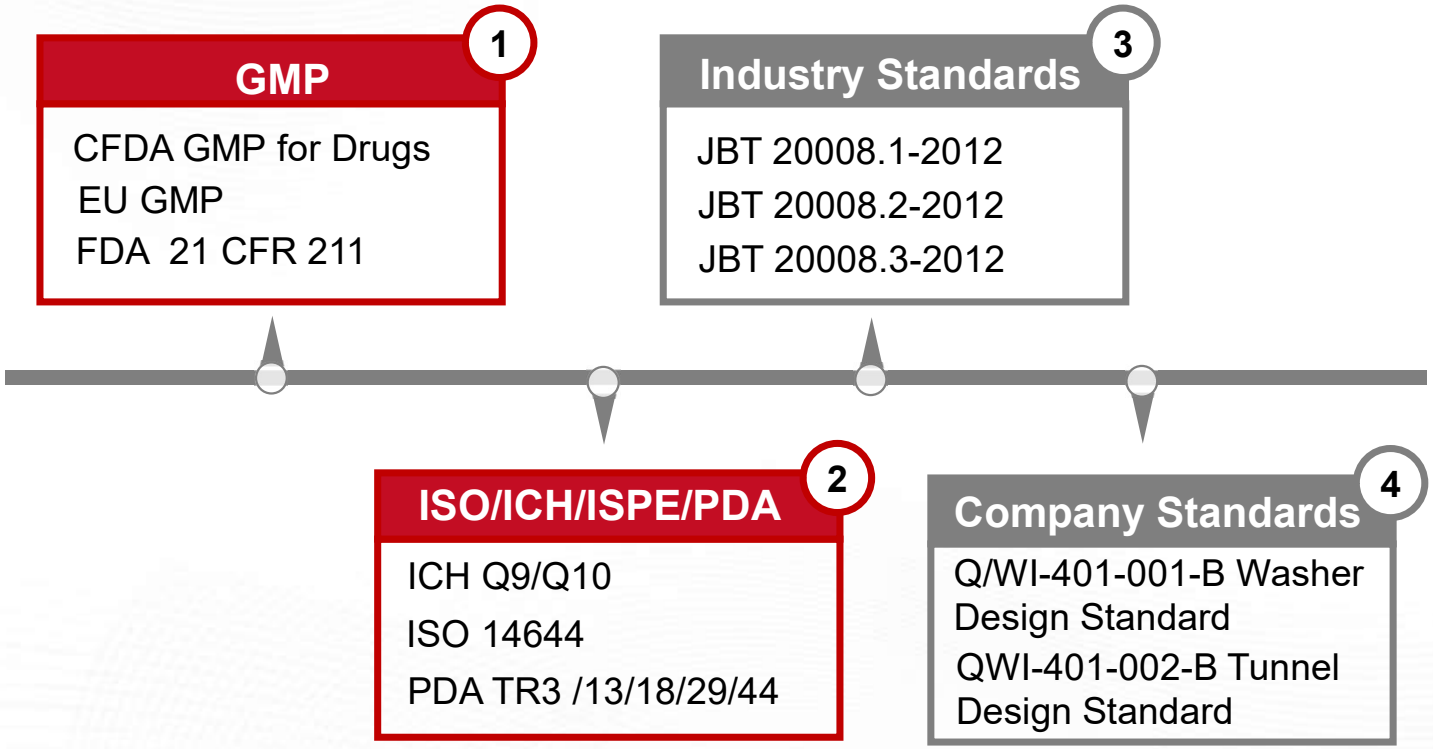
A precise plan, plan management and quick response for each project according to the design flow chart.

03 Design Reference

GMP/GEP/GAMP5 guidelines and 21 CFR Part 211 and Part 11, etc.

Design Management

Design Reference



Design Management

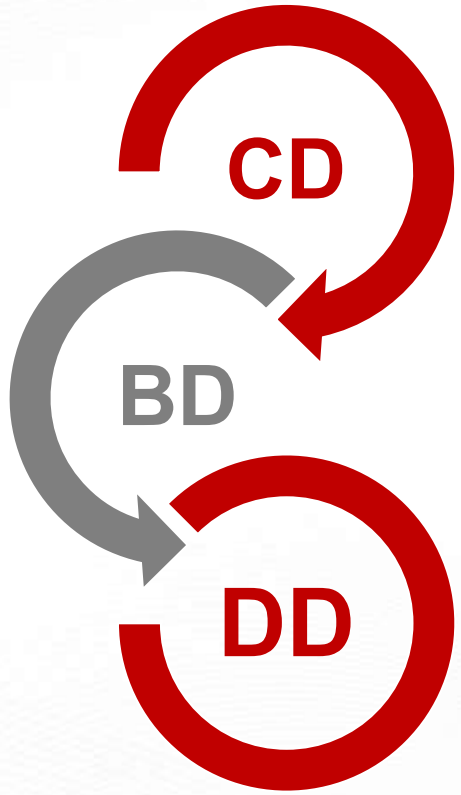
Design Plan

Conception Design

Prepare the Functional and Design Specification/P&ID/Layout according to URS/TS/URS Deviation/Plant Layout/MOMs

Basic Design

Prepare the Hardware Specification/ Software Specification / Wiring Drawing and others.

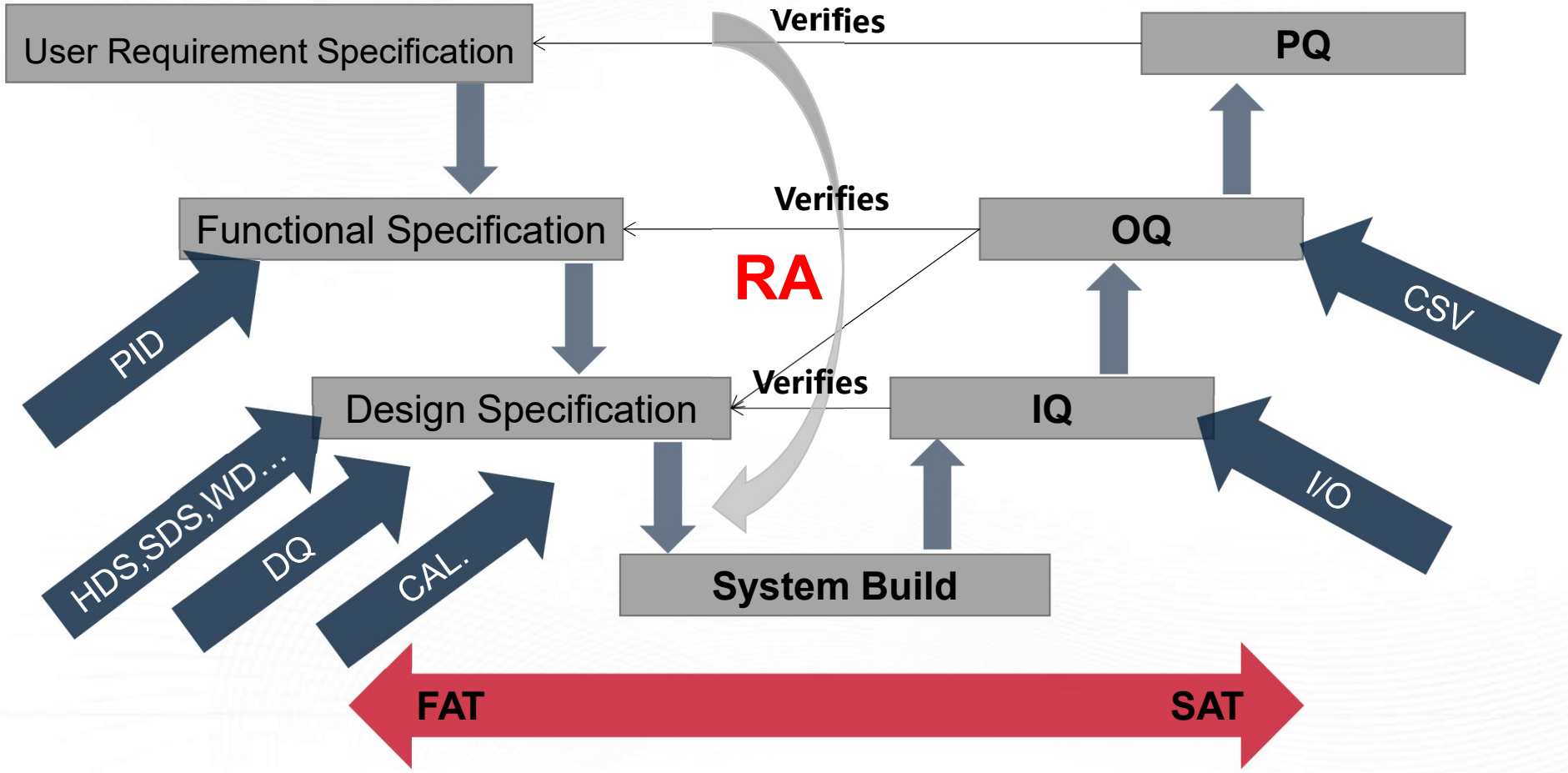


Detailed Design

Approve and release the FS/DS/HDS/SDS/P&ID /Layout/WD and Drawings.

Design Management

Lifecycle



Design Management

Review/Approve/Release

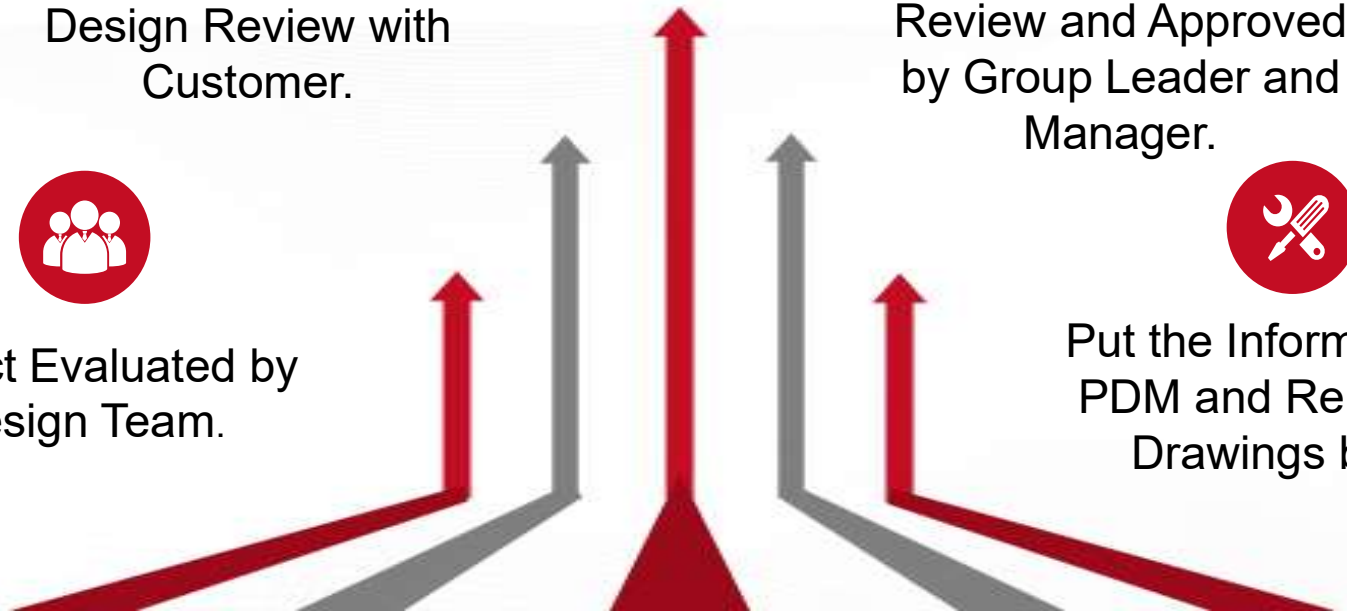
Self Checked by Design Engineer according to ICD List

Design Review with Customer.

Review and Approved by Group Leader and Manager.

Project Evaluated by Design Team.

Put the Information into PDM and Release the Drawings by OA.



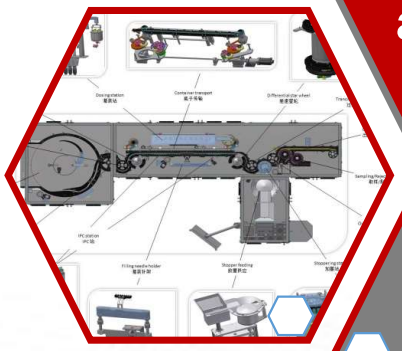
Design Management

Technical Clarification

Manufacturing Process

for 400VPM Filling Machine

Assembly Instructions and Testing Protocols

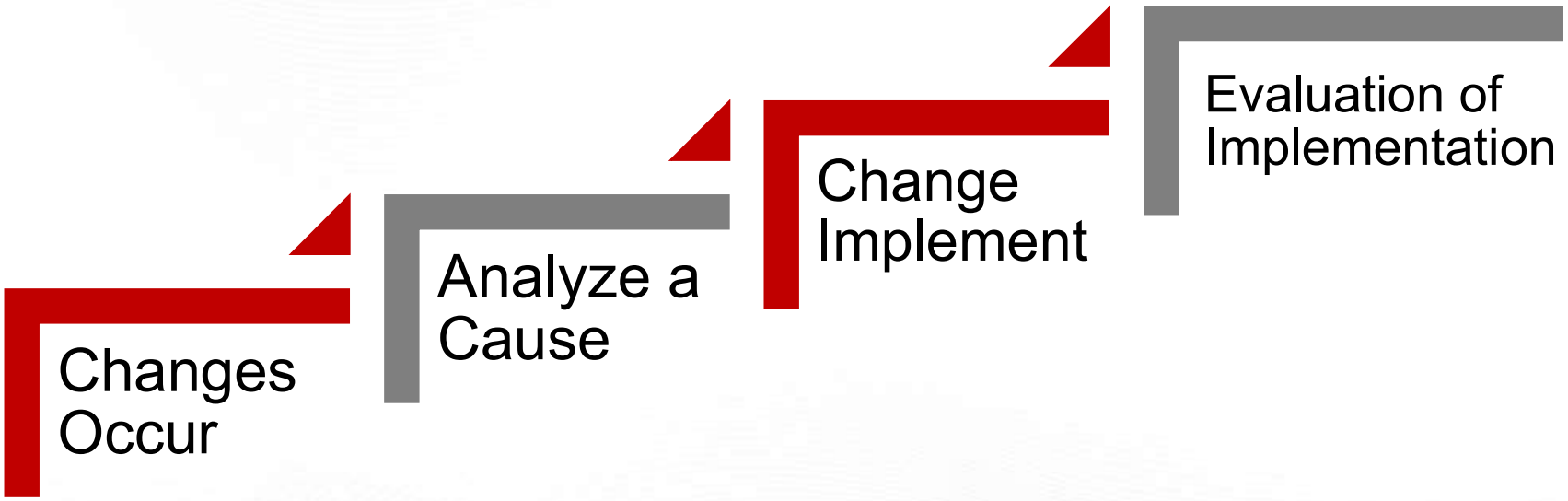


Trained by Design Engineer on Site

2D and 3D Assembly Guidance

Design Management

Change Control



- Here we introduce the QbD concept to the Quality Control of the Aseptic Filling Line

- QbD Three main tools:

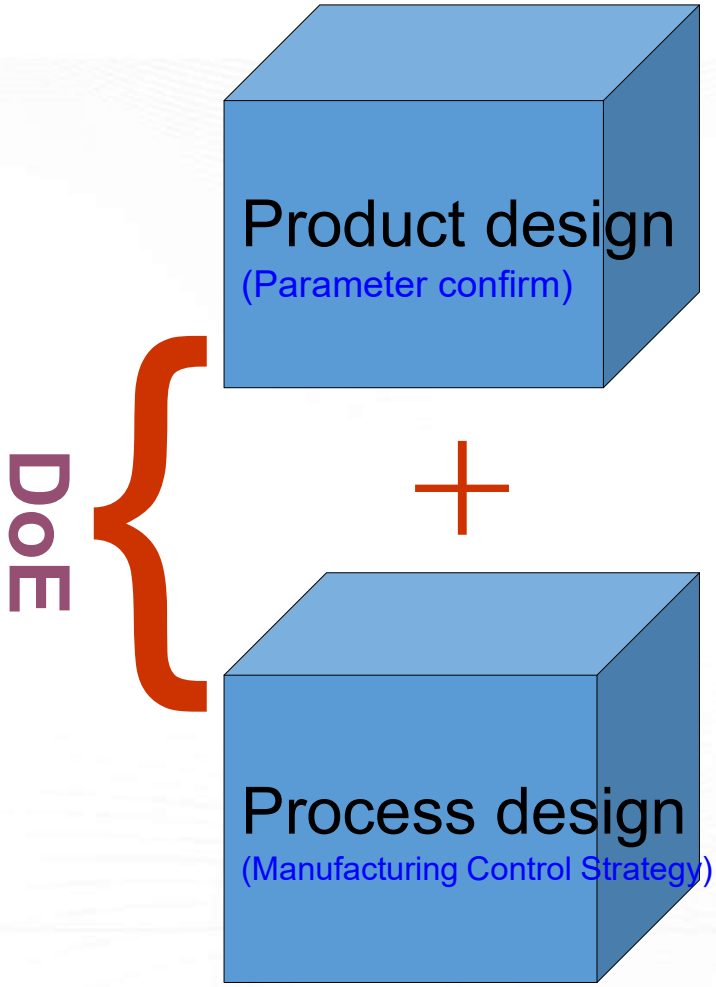
❖Design Of Experiments(DoE)

❖Failure Mode and Effects Analysis(FMEA)

❖Process Analytical Technology(PAT)

The First QbD tool: DoE

QbD-DoE



To build a design space and calculate parameter of the whole filling line accurately and ensure stability, reliability and safety of equipment

Product Performance (FS DS HDS SDS)

Process Performance (IQ OQ PQ Test Protocol)

Good SOPs and perform SOPs during fabricating process

Product Design

Technical Data

Technical Data For Washing Machine

Tofflon®	No. : TFL/	
	Ver. : B	Page : 2 / 11
Title : TD for Washing machine	Owner : Shanghai Tofflon Science & Technology Co., Ltd.	

INDEX

Technical Data For Sterilizing Depyrogenation Tunnel

Tofflon®	No. : TFL/	
	Ver. : C	Page : 2 / 15
Title : TD for Tunnel	Owner : Shanghai Tofflon Science & Technology Co., Ltd.	

Technical Data For Filling and Stoppering Machine

Tofflon®	No. : TFL/	
	Ver. : C	Page : 2 / 23
Title : TD for Filling and Stoppering Machine	Owner : Shanghai Tofflon Science & Technology Co., Ltd.	

INDEX

Product Design

FS/DS/HDS/SDS/DQ

Tofflon

FUNCTIONAL DESIGN SPECIFICATION
功能设计规格书

SUPPLIER NAME/供应商: Shanghai Tofflon Science & Technology Co., Ltd. 上海东富龙科技股份有限公司	CUSTOMER NAME/客户名称: Zhejiang Medicine Co., Ltd Xinchang Pharmaceutical Factory 浙江医药股份有限公司新昌制药厂
	NO./编号: 2016-028LF
	MODEL/型号: FFVLP50/01-01
FUNCTIONAL DESIGN SPECIFICATION FOR FILLING AND STOPPERING MACHINE 灌装压塞机功能设计规格书	

Tofflon

HARDWARE DESIGN SPECIFICATION
硬件设计规格书

SUPPLIER NAME/供应商: Shanghai Tofflon Science & Technology Co., Ltd. 上海东富龙科技股份有限公司	CUSTOMER NAME/客户名称: Zhejiang Medicine Co., Ltd Xinchang Pharmaceutical Factory 浙江医药股份有限公司新昌制药厂
	NO./编号: 2016-028LF
	MODEL/型号: FFVLP50/01-01
HARDWARE DESIGN SPECIFICATION FOR FILLING AND STOPPERING MACHINE 灌装压塞机硬件设计规格书	

Tofflon

SOFTWARE DESIGN SPECIFICATION
软件设计规格书

SUPPLIER NAME/供应商: Shanghai Tofflon Science & Technology Co., Ltd. 上海东富龙科技股份有限公司	CUSTOMER NAME/客户名称: Zhejiang Medicine Co., Ltd Xinchang Pharmaceutical Factory 浙江医药股份有限公司新昌制药厂
	NO./编号: 2016-028LF
	MODEL/型号: FFVLP50/01-01
SOFTWARE DESIGN SPECIFICATION FOR FILLING AND STOPPERING MACHINE 灌装压塞机软件设计规格书	

Tofflon

DESIGN QUALIFICATION
设计确认

SUPPLIER NAME/供应商: Shanghai Tofflon Science & Technology Co., Ltd. 上海东富龙科技股份有限公司	CUSTOMER NAME/客户名称: Zhejiang Medicine Co., Ltd Xinchang Pharmaceutical Factory 浙江医药股份有限公司新昌制药厂
	NO./编号: 2016-028LF
	MODEL/型号: FFVLP50/01-01
DESIGN QUALIFICATION FOR FILLING AND STOPPERING MACHINE 灌装压塞机设计确认	

Process Design-Manufacturing Quality Control

Manufacturing Quality Control

SOP + Check Lists + Test Instruments

Good SOPs

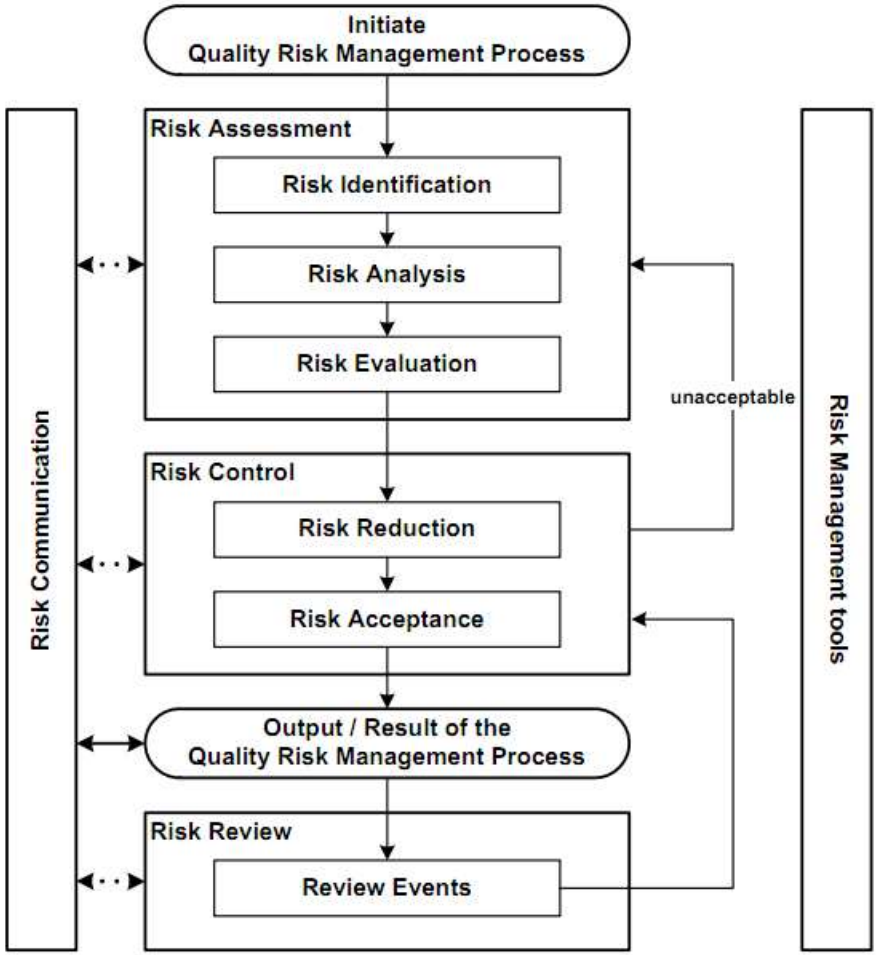
and perform SOPs during fabricating process

IQC (Incoming Quality Control)
IPQC（InPut Process Quality Cortrol）
FQC (Finish or Final Quality Control)
OQC（Outgoing Quality Control ）

The Second QbD tool: FMEA

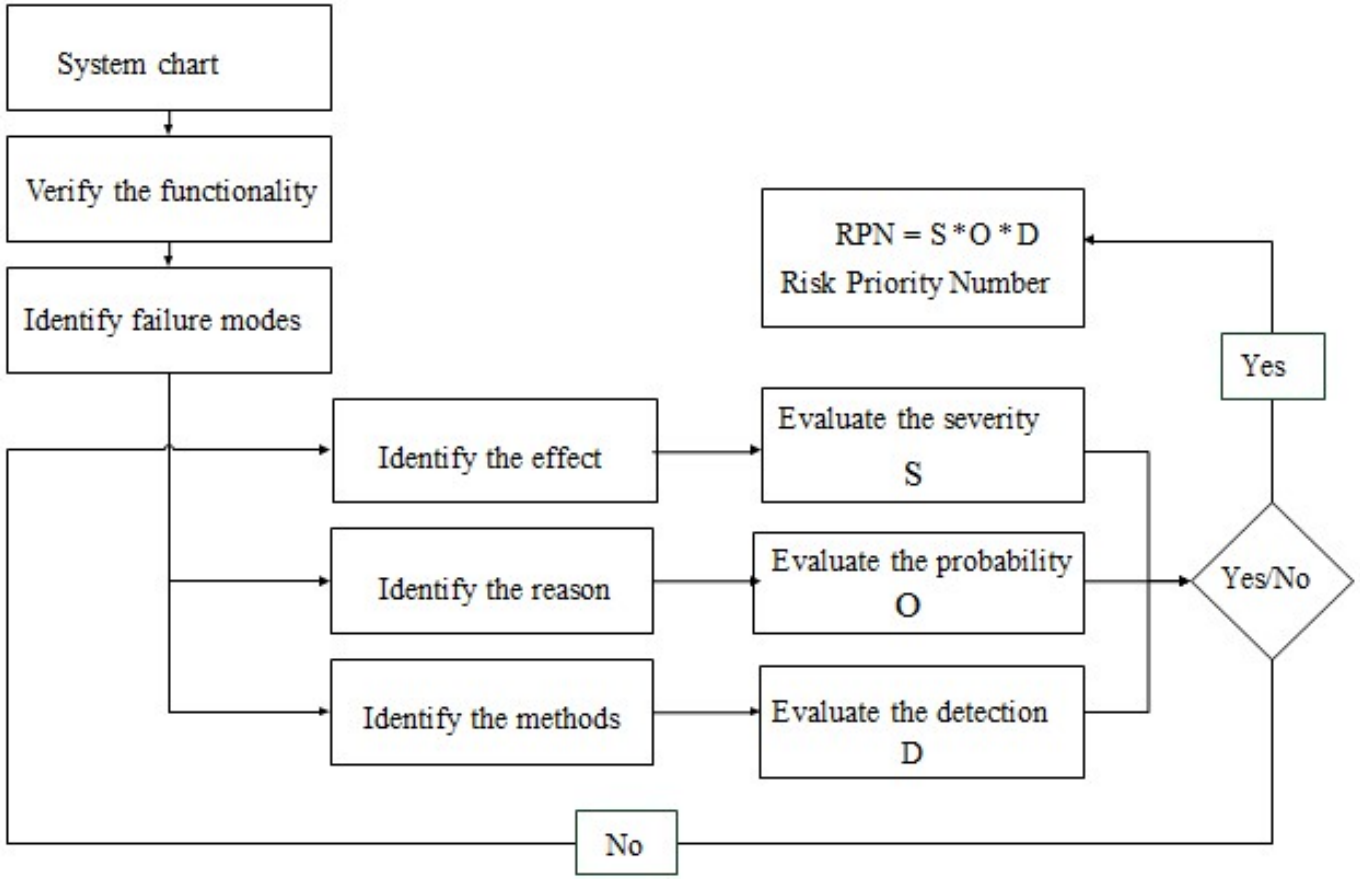
Quality by Design

ICH Q9 Quality Risk Management



Quality by Design

FMEA



S:**S**everity O:**O**ccurrence D: **D**etection

Quality by Design

SIA/CCA

Tofflon

SYSTEM IMPACT ASSESSMENT
系统影响性评估

SUPPLIER NAME/供应商: Shanghai Tofflon Science & Technology Co., Ltd. 上海东富龙科技股份有限公司	CUSTOMER NAME/客户名称: Zhejiang Medicine Co., Ltd Xinchang Pharmaceutical Factory 浙江医药股份有限公司新昌制药厂
	PROJECT NO. /项目编号: TFL-IPS-2016-034
	CONTRACT NO./合同编号: ZMCBE1-1609005
SYSTEM IMPACT ASSESSMENT 系统影响性评估	

Tofflon

COMPONENT CRITICALITY ASSESSMENT
部件关键性评估

SUPPLIER NAME/供应商: Shanghai Tofflon Science & Technology Co., Ltd. 上海东富龙科技股份有限公司	CUSTOMER NAME/客户名称: Zhejiang Medicine Co., Ltd Xinchang Pharmaceutical Factory 浙江医药股份有限公司新昌制药厂
	NO./编号: 2016-028LF
	MODEL/型号: FFVLP50/01-01
COMPONENT CRITICALITY ASSESSMENT FOR FILLING AND STOPPERING MACHINE 灌装压塞机部件关键性评估	

Quality by Design

RA

Tofflon

RISK ASSESSMENT
风险评估

SUPPLIER NAME/供应商: **Shanghai Tofflon Science & Technology Co., Ltd.** **上海东富龙科技股份有限公司**	CUSTOMER NAME/客户名称: **Zhejiang Medicine Co., Ltd** **Xinchang Pharmaceutical Factory** **浙江医药股份有限公司新昌制药厂**
	NO. /编号: **2016-028LF**
	MODEL/型号: **FFVLP50/01-01**

RISK ASSESSMENT FOR
FILLING AND STOPPERING MACHINE
灌装压塞机风险评估

Quality by Design

RA

Tofflon	RA	Doc. No. 文件编号	2016-028LF-RA
		Model 型号	FFVLP50/01-01
Shanghai Tofflon Science & Technology Co., Ltd. 上海东富龙科技股份有限公司	Risk Assessment for Filling and Stoppering Machine 灌装压塞机风险评估	Version 版本号	V 1.0
		Page 页码	14 of 40

9. Risk Assessment Implementation and Record 风险分析执行及记录

Number 编号	Component/ Function 部件/功能	Potential failure mode 潜在失效模式	Potential failure consequences 潜在失效后果	S	Potential failure cause 潜在失效原因	O	D	RPN	Control Measure 控制措施	Qualification Activity 确认活动	PS	PO	PD	PRPN	Whether accept 是否接受	Execution confirmation 执行情况确认
YS251	Minimum load sensor 缺瓶传感器	Error display 显示错误	Affect the normal operation of machine 影响设备正常运行	5	Program failure or sensor failure 程序故障或传感器故障	1	1	5	Alarm confirmation. 进行报警测试	1.OQ	5	1	1	5	Y 是	
YS006	Minimum amount of warning sensor 最小量预警传感器	Error display 显示错误	Affect the normal operation of machine 影响设备正常运行	5	Program failure or sensor failure 程序故障或传感器故障	1	1	5	Alarm confirmation. 进行报警测试	1.OQ	5	1	1	5	Y 是	
YS005	Minimum load sensor 缺瓶停机传感器	Error display 显示错误	Affect the normal operation of machine 影响设备正常运行	5	Program failure or sensor failure 程序故障或传感器故障	1	1	5	Alarm confirmation. 进行报警测试	1..OQ	5	1	1	5	Y 是	
M178	Main motor 主电机	Transports insufficient capacity	Affect the normal operation of machine,eg,	5	Improper motor selection 电机选型不当	1	3	15	Correct installation confirmation 正确安装确认	1.IQ	5	1	1	5	Y 是	

The Third QbD tool: PAT

- **Here We Use the Following List of Instruments to Ensure the Quality of Aseptic Filling Line.**

Manufacturing Quality Control

IQC

S.N.	IQC SOPs and Check Lists
01	IQC SOP
	SOP
	Flow chart
02	Key parts inspection SOP
	Weighing module
	Manifold
	Filling needles
	buffer tank
	Stoppering air chamber
	Rejection air chamber
	.....
03	Packing materials management
	SOP
	Flow chart
	Check list
04	Materials management
	Stainless steel management SOP
	Mental parts (Stainless steel) and non-mental parts SOP
05	Unqualified parts handling
06	Supplier management
	Flow chart and requirement for inspection at supplier site
	Inspection by supplier SOP
	Quality assurance agreement
	Supplier processing requirement

Manufacturing Quality Control

IQC-Material Certification Management-URS Review

N°	Requirement description	Criticality (Yes/No)
	Generalities	
U.5.2.1	Electrical panels must be made of steel.	No(2)
U.5.2.2	All metal parts in direct product contact or in contact with the stoppers must be made of stainless steel 316L (1.4404). Material Certificate of Conformity 3.1 must be provided. The surface finish / rugosity must be lower or equal to 0.6µm.	Yes
U.5.2.3	All non-metal parts must be in conformity with the USP class VI (certificates must be provided)	Yes
U.5.2.4	QSMP sheets must be provided for all parts and elements (hoses) in direct product contact.	Yes
U.5.2.5	All metal parts in direct contact with process compressed air must be in stainless steel 316L (1.4404). Material Certificate of Conformity 3.1 must be provided. The surface finish / rugosity must be lower or equal to 0.8 µm.	Yes

Manufacturing Quality Control

IQC-Material Certification Management

❑ Material Management Flow Chart

Manufacturing Quality Control

IQC-Material Certification Management

Material introduction inside the RABS Cabinet (Conveyor and Filling machine)					
No.	**Item/Name**	**MOC/Spec./Desc.**	**Desc. For Contact**	**Location**	**Reference(certification)**
1	Infeed starwheel	POM	Contact with external of the vial	Infeed system	FDA / ISO
2	Filling needles	SS 316L	contact with Product	Filling system	GB/T 20878-2007
3	Manifolds and pipes	SS 316L	contact with Product	Filling system	ASME BPE
4	Filling hoses	Silicone	contact with Product	Filling system	FDA / USP Class VI
5	Filling needles for gas flushing	SS 316L	contact with Product	Filling system	GB/T 20878-2007
6	Manifolds and pipes for gas flushing	SS 316L	contact with Product	Filling system	ASME BPE
7	Filling hoses for gas flushing	Silicone	contact with Product	Filling system	FDA / USP Class VI
8	Body of diaphragm valve	SS 316L	contact with Product	Filling system	EN10204 3.1
9	Diaphragm of diaphragm valve	EPDM/PTFE	contact with Product	Filling system	FDA/BSE/TSE/USP Class VI
10	Buffer tank	SS 316L	contact with stopper	Filling system	GB24511-2009 / ASTM-A240-316L / GB/T 25198-2010
11	Pipelines for WFI, sterile compressed air and pure steam	SS 316L	contact with Product	CIP/SIP system	ASME BPE
12	Pipelines for Product	SS 316L	contact with Product	CIP/SIP system	ASME BPE
13	Filter housing	SS 316L	contact with Product	CIP/SIP system	Statement / EN10204 3.1
14	Body of diaphragm valve	SS 316L	contact with Product	CIP/SIP system	EN10204 3.1
15	Diaphragm of diaphragm valve	EPDM/PTFE	contact with Product	CIP/SIP system	FDA/BSE/TSE/USP Class VI
16	Sealing ring	PTFE	contact with Product	CIP/SIP system	FDA / USP Class VI
17	Bowl and chute	SS 316L	contact with stopper	Stoppering system	ASTM A240 ASME SA-240 / EN10204 3.1
18	Stoppering plate	SS 316L	contact with stopper	Stoppering system	ASTM A-240M/480M / EN10204 3.1
19	Accelerative wheel	POM/SS304	Contact with external of the vial	Main transmission system	FDA / ISO
20	Transfer toothed plate	SS 304	Contact with external of the vial	Main transmission system	EN10028-7:2007 / EN10204 3.1
21	Rejection starwheel	POM	Contact with external of the vial	Rejection system	FDA / ISO
22	Discharging starwheel	POM	Contact with external of the vial	Outfeed system	FDA / ISO
23	Discharge belt	POM	Contact with external of the vial	Outfeed system	FDA / ISO
24	Guide	POM /PE	Contact with external of the vial	Outfeed system	FDA / ISO
25					

Manufacturing Quality Control

IQC-Material Certification Management

Shanghai Tofflon Science & Technology Co.,Ltd. 上海东富龙科技股份有限公司	DQ	Doc. No. 文件编号	2017-017LFc-DQ
	Design Qualification for Filling and Stoppering Machine 灌装压塞机设计确认	Model 型号	FFVLP40/01-01
		Version 版本号	V 1.0
		Page 页码	61 of 73

10.6. Materials and Surface Finishes Qualification 材料和表面

Purpose 目的

Verify whether materials of surface that direct or indirect c
cGMP/URS/TS requirements.
确认与产品直接或间接接触的材料是否符合 cGMP/L

Acceptance Criteria 可接受标准

All materials of surface that direct or indirect c
irements.
品直接或间接接触的材料

			Design 设计情况	Yes/No 是否符合要求
				Yes (√) No ( )
				Yes (√) No ( )
			a<0.8	Yes (√) No ( )
			ube	Yes (√) No ( )
				Yes (√) No ( )
			L	Yes (√) No ( )
			316L	Yes (√) No ( )
			EPDM	Yes (√) No ( )
			SS 316 L	Yes (√) No ( )
		SS 304/POM	SS 304	Yes (√) No ( )
TS4.4.12 TS4.4.13	Starwheel 星轮	POM	POM	Yes (√) No ( )
TS4.4.11	V-block 输入块	POM	POM	Yes (√) No ( )
TS4.4.14	Belt 网带	POM	POM	Yes (√) No ( )

EXPERTISE IN PHARMACEUTICAL INDUSTRY
专业技术服务于制药工业

Yuki. Wu 2018. 10. 17

Tofflon	DQ	Doc. No. 文件编号	2017-017LFc-DQ
		Model 型号	FFVLP40/01-01
Shanghai Tofflon Science & Technology Co.,Ltd. 上海东富龙科技股份有限公司	Design Qualification for Filling and Stoppering Machine 灌装压塞机设计确认	Version 版本号	V 1.0
		Page 页码	63 of 73

Conclusion/Remarks 结论/备注

Conclusion 结论

Remark 备注:

The acceptance criteria is fulfilled. no deviation is found.

Ep 2018.10.17

Conformity 符合性

Yes/是 (√)	No/否 ( )	Deviation No.偏差编号 N/A
Executed by / Date: 执行人/日期	Yuki. Wu 2018. 10. 17	Ep 2018.10.17
Reviewed by/ Date: 审核人/日期	19.10.2018	17.10.2018 17.10.2018

EXPERTISE IN PHARMACEUTICAL INDUSTRY
专业技术服务于制药工业

www.tofflon.com

Manufacturing Quality Control

IQC-Material Certification Management

Tofflon

MATERIAL OF CERTIFICATE
材质证明

SUPPLIER NAME/供应商: **Shanghai Tofflon Science&Technology Co.,Ltd. 上海东富龙科技股份有限公司**	CUSTOMER NAME/客户名称: ****** NO./编号: **2017-017LFc** MODEL/型号: **FFVLP40/01-01**
MATERIAL OF CERTIFICATE FOR FILLING AND STOPPERING MACHINE 灌装压塞机材质证明	

EXPERTISE IN PHARMACEUTICAL INDUSTRY

ADD: 139, DUHUI RD.,SHANGHAI -201108 CHINA
TEL: +86 21 64909996
FAX: +86 21 64908881
Http: // www.tofflon.com

Material of Certificate List
材质证明清单

No. 序号	Component 部件	Material 材质	Critical or Non-critical (C or NC) 关键或非关键	Remark 备注
1	Filling needles 灌装针	SS316L	C	
2	Manifold 分配管	SS316L	C	
3	Pipeline 管路	SS316L	C	
4	Filling tubes 灌装软管	Silicone tube 硅胶管	C	
5	Filling pump 灌装泵	SS 316L	C	
6	Buffer tank 缓冲罐	SS316L	C	
7	Body of diaphragm valve 隔膜阀本体	SS 316L	C	
8	Diaphragm of diaphragm valve 隔膜阀膜片	EPDM	C	
9	The stopper feed bowl and feed tracks 胶塞料斗和供料轨道	SS 316 L	C	
10	Turn table plate 转盘板	SS 304	C	

Manufacturing Quality Control

IQC-Material Certification Management

MATERIAL CERTIFICATE

Customer:	东富龙	Certificate No.:	180622-412
Customer Order No.:	3215TFLF180517001	Date of Certificate:	2018-06-22
Part No.:	FFF17019201400901	Production Batch No.:	N/A
Part Description:	10 头分配管 Dosing vessel.		

Raw Material Specification

Heat Number	Material Specification	Material suppliers	Material Description	C	Si	Mn	P	S	Ni	Cr	N	Mo
160325W07	Ø55	浦青	316L	0.020	0.32	0.96	0.037	0.0066	10.08	16.24		2.02
17ZT0107	Ø12	浙泰不锈钢	316L	0.016	0.30	0.92	0.036	0.008	10.08	16.37		2.01
51076	Ø38.1*1.65	凌士通	316L	0.020	0.48	0.88	0.035	0.007	10.00	16.60	0.042	2.04

Mechanical Test

Heat Number	Yield Rp 0.2		Yield Rp 1.0		Tensile Strength		Hardness	Reduction	Elongation	Impact Test
	N/mm2	PSI	N/mm2	PSI	N/mm2	PSI	HRB/HB	%	%	20℃-J
160325W07	-				-		-		-	
17ZT0107	-				-		-		-	
51076	295				625		82		56	

Mechanical Test

Heat Number	Eddy Current Test	Visual & Dimensional Test	Flaring Test	Flattening Test	Intergranular Corrosion Test	Material Identification Test
160325W07	OK	OK	OK	OK	-	OK
17ZT0107	OK	OK	OK	OK	-	OK
51076	OK	OK	OK	OK	-	OK

We certify that this information is a true representation of the data that has been furnished by our raw material suppliers. We have no knowledge of any mercury of low melting contamination.
Examined according to quality system ISO 9001:2008 by QAI. Certificate number: QAIC / CN / 121530
This certified Mill Test Report is computer generated and meet EN 10204 3.1
This Certificate was made by use of a computer system and is valid without signature.

Expert Quality Approved

ASME BPE Compliant

Expert Precision Material Engineering & Technical Ltd.

Manufacturing Quality Control

IQC-Material Certification Management

SAINT-GOBAIN

Manufacturer:
34 rue du Moulin aux Aulnaies
89120 Charny-Orée-de-Puisaye , France

Certificate of Conformance

Part Number/ Revision:	*760268*	**Customer Part Number/ Revision:**	*84-311-032 Cdc rev.02*
Description:	*T.VERSILIC 3.2X6.4- 25M MARQUE - DOUBLE SACS*		
Lot Number:	*1959481*	**Lot Quantity:**	*4000 m*
Date of Manufacture: (DD/MMM/YYYY)	*24/04/2018*	**Expiration Date: (DD/MMM/YYYY)**	*24/10/2020*
Post processing Run Number: (Refer to the attached Certificate of Processing for Additional Detail)	*N/A*		

We certify the material listed above conforms in full with the following specifications:

All items have been manufactured, inspected, tested, and accepted in accordance with our Quality Management System certi
certification i

All materials
and notes in
Regulatory In
manufacture
Plastics, Clas
Saint-Gobain
conduct tests
Gobain's sol
requirements of the buyer, and from defects in material and workmanship. This warranty is expressly made in lieu of any and all other warranties and Saint-Gobain's sole liability shall be to replace any product not in conformance with the specification and requirements of the buyer.

All materials and processes used in manufacturing conform to the materials and/or manufacturing specifications and notes indicated on the purchase order, drawing, specifications, quality assurance requirements, Versilic® Regulatory Information Overview (RIO), Revision 0, or other applicable approved documents effective on the date of manufacture. The ASTM plaques of Versilic® silicone meet the requirements of the USP, Biological Test for Plastics, Class VI.

Quality Approval:	Christelle PEDROSO	**Date:**	*27/04/2018*

Filling Tubes:
Silicone

Manufacturing Quality Control

IPQC-Mechanical Installation

TFL/RD7.5-01-22A-LF

Tofflon 灌装机装配检查表

客户名称		机器型号	
机器编号		WBS(组件)	灌装机关键部位

检查项目	参考值	实际值	执行人	过程检
图1 测量图1机架各段的长度，对角线，保证符合设计尺寸，误差≤1MM	≤1MM			
图2 测量图2机架面板整体水平，应每米≤0.5MM。（安装包覆板之前）	≤0.5MM			
图3所示，测量各类面板侧边槽位，应≤0.2MM	≤0.5MM			
图4所示，测量各类面板平面拼接处高低槽位应≤0.2MM	≤0.2MM			

1 / 9

TFL/RD7.5-01-22A-LF

Tofflon 灌装机装配检查表

客户名称		机器型号	
机器编号		WBS(组件)	灌装机关键部位

检查项目	参考值	实际值	执行人	过程检
图5 转盘安装完后检查面板跳动，面板跳动≤0.5MM，径向跳动≤0.15MM	≤0.5MM ≤0.15MM			
图6 转盘与拼接板间隙均一致，应≤2MM 拼接板略高于转盘0.1-0.2MM	≤2MM 0.1-0.2MM			
图7				

2 / 9

TFL/RD7.5-01-22A-LF

Tofflon 灌装机装配检查表

客户名称		机器型号	
机器编号		WBS(组件)	灌装机关键部位

检查项目	参考值	实际值	执行人	过程检
图8 小转盘与进瓶星轮导轨间隙≤1.5MM，不可摩擦转盘；2.转盘略高于同带0.1-0.2MM	≤1.5MM 0.1-0.2MM			N/A
图9 加固，转盘星轮与梅花星轮转动良好，三相之间无干涉碰撞现象，各星轮轴径向跳动与轴向跳动，应≤0.05MM	≤0.05MM			

3 / 9

Manufacturing Quality Control

IPQC-Electrical Installation

TFL/RD7.5-01-022A-LT.

Tofflon 电器柜装配自检记录表

客户名称		机型	
项目编号			

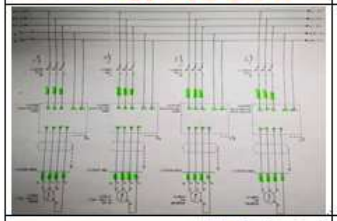
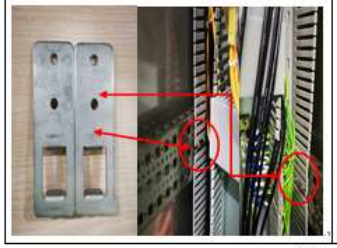
检查项目	检查项	结果	执行人	复检员
	检查Y90伺服驱动器是否与发热铜排，大线可靠套管（独立电源）T/F			
	接地是接发热体，一个独脚不允许有三个以上的接地线T/F			
	检查布线是否强弱电分开，按照强电在左，弱电在右区分T/F			

4 / 6

TFL/RD7.5-01-022A-LT.

Tofflon 电器柜装配自检记录表

客户名称		机型	
项目编号			

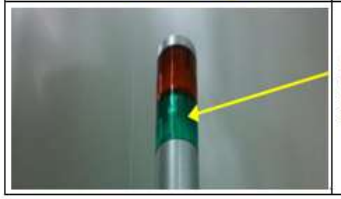
检查项目	检查项	结果	执行人	复检员
	检查SINOTION双轴驱动对应端口标签与伺服电机线上标签一致T/F			
	复检人员检验确认后，在测纸上用安全笔做标记T/F			
	配套接线检验结束后，安装电器柜，确认电器柜与原理接文字是否牢固T/F			

5 / 6

TFL/RD7.5-01-022A-LT.

Tofflon 电器柜装配自检记录表

客户名称		机型	
项目编号			

检查项目	检查项	结果	执行人	复检员
	检查欧美项目是否出现两标签面（外强电源）T/F			
	欧美项目急停开关必须带外壳T/F			
	检查欧美项目三色灯是否有指示标记T/F			

设备总负责人：
设备完成时间：

6 / 6

Manufacturing Quality Control

FQC-Test Protocols

S.N.	FQC Check Lists of Washing Machine
01	Preparation before starting up
02	Alarm Test
03	IO Test
04	P&ID Drawing Verification
05	Qualification of Safety Equipment
06	Check HMI Screen
07	Motors Verification
08	Welding Verification
09	Check of Control System
10	Layout Arrangement Verification
11	Qualification of Washing Process
12	System Access
13	System Operational Test
14	Noise Permitted Test

S.N.	FQC Check Lists of Tunnel
01	Preparation before starting up
02	Alarm Test
03	IO Test
04	P&ID Drawing Verification
05	Qualification of Safety Equipment
06	Check HMI Screen
07	Fan Verification
08	Check of Control System
09	Layout Arrangement Verification
10	System Access
11	Belt Speed Test
12	Empty Chamber Temperature Distribution Test
13	Full Load Temperature Penetration Test
14	Surface Temperature Test
15	System Operational Test
16	Noise Permitted Test

S.N.	FQC Check Lists of Filling Machine
01	Preparation before starting up
02	Alarm Test
03	IO Test
04	P&ID Drawing Verification
05	Qualification of Safety Equipment
06	Check HMI Screen
07	Motors Verification
08	Welding Verification
09	Check of Control System
10	Layout Arrangement Verification
11	System Access
12	Filling Accuracy Test
13	System Operational Test
14	Counting Test
15	Noise Permitted Test

Manufacturing Quality Control

FQC-Test Protocols

Tofflon	Filling Accuracy Test 灌装精度测试	Doc. No. 文件编号	SOP-053
		Version 版本号	V1.0
Shanghai Tofflon Science & Technology Co., Ltd. 上海东富龙科技股份有限公司	Filling and Stoppering Machine 灌装压塞机	Page 页码	3 of 7
		Issued Date 颁布日期	2019.04.30

Filling Accuracy Test
灌装精度测试

Test result / 测试结果			
The filling pump filling accuracy is in the range of ±1%. 灌装泵灌装精度在±1%之内。			Yes ( ) / No ( )
The surrouding test condtions / 测试条件			
Starting time 测试开始时间	T1 T2 T3	Ending time 测试结束时间	T1 T2 T3
Containers size 容器规格		Room temperature (℃) / humidity (%) 房间温湿度	
Filling system 灌装系统	☐ Piston pump 柱塞泵灌装系统 ☐ Peristaltic pump 蠕动泵灌装系统 ☐ Auger dosing 螺杆计量(粉末) ☐ Others 其他_____		
Filling product 灌装产品		Volume of piston pumps 柱塞泵体积	
Density 密度		Ø tube inside of peristaltic pump 蠕动泵的管内径 Ø	
Production speed 生产速度		Filling needle inside (Ø) 灌装针内径(Ø)	
Ids of pumps (Only for piston pump)/ 泵编号（柱塞泵适用）			
Pump 1/泵 1		Pump 2/泵 2	
Pump 3/泵 3		Pump 4/泵 4	
Pump 5/泵 5		Pump 6/泵 6	
Pump 7/泵 7		Pump8/泵 8	
Pump 9/泵 9		Pump10/泵 10	
Pump 11/泵 11		Pump12/泵 12	

Tofflon	Filling Accuracy Test 灌装精度测试	Doc. No. 文件编号	SOP-053
		Version 版本号	V1.0
Shanghai Tofflon Science & Technology Co., Ltd. 上海东富龙科技股份有限公司	Filling and Stoppering Machine 灌装压塞机	Page 页码	4 of 7
		Issued Date 颁布日期	2019.04.30

Test 1/测试 1

No. 泵号 / Weight 装量 / Time 取样时间	Pump 1 1号泵	Pump 2 2号泵	Pump 3 3号泵	Pump 4 4号泵	Pump 5 5号泵	Pump 6 6号泵	Pump 7 7号泵	Pump 8 8号泵	Pump 9 9号泵	Pump 10 10号泵	Pump 11 11号泵	Pump 12 12号泵
Maximum Value 最大值												
Minimum Value 最小值												
Yes/No 是否符合要求	Yes( ) No( )	Yes( ) No( )	Yes( ) No( )	Yes( ) No( )	Yes( ) No( )	Yes( ) No( )	Yes( ) No( )	Yes( ) No( )	Yes( ) No( )	Yes( ) No( )	Yes( ) No( )	Yes( ) No( )
Acceptance Value 接受标准	Filling Set Value 设定装量：_____ml		Filling Accuracy 灌装精度：_____%			Filling Water Acceptability Limit 即装量合格范围：_____ml						

If necessary, this page can be copied. 如有需要，此页可复制

Tofflon	Alarm Test 报警测试	Doc. No. 文件编号	
		Model 型号	
Shanghai Tofflon Science&Technology Co.,Ltd. 上海东富龙科技股份有限公司	Filling and Stoppering Machine 灌装压塞机	Version 版本号	V 3.4
		Page 页码	3

Alarm Test
报警测试

Test Description 测试描述	Test Procedure 测试方式	Expected result 预期结果	Yes/No 是否符合要求
Emergency stop alarm 急停报警	Press the relevant emergency stop button 按下相应急停按钮	The lamp is on, the horn beeps, and the machine stop, display the alarm information. 报警灯亮，蜂鸣器响，机器停止运行，显示报警信息	Yes ( ) No ( )
Vacuum low pressure 真空低压报警	Disconnect vacuum 断开进口真空	The lamp is on, the horn beeps, and the machine stop, display the alarm information. 报警灯亮，蜂鸣器响，机器停止运行，显示报警信息	Yes ( ) No ( )
CA low Pressure 压缩空气低压报警(如有)	Disconnect CA 断开进口压缩空气	The lamp is on, the horn beeps, and the machine stop, display the alarm information. 报警灯亮，蜂鸣器响，机器停止运行，显示报警信息	Yes ( ) No ( )
Vials infeed belt minimum load 进瓶侧缺瓶报警	During production, prevent vials into the machine manually 在生产过程中，人为的阻止瓶子进入	The lamp is on, the horn beeps, and the machine stop, display the alarm information. 报警灯亮，蜂鸣器响，机器停止，显示报警信息	Yes ( ) No ( )
Outfeed vials blocking alarm 出瓶堵塞报警	During production, manually vials are filled on outfeed belt 在生产过程中，人为将出瓶通道布满瓶子	The lamp is on, the horn beeps, and the machine stop, display the alarm information. 报警灯亮，蜂鸣器响，机器停止，显示报警信息	Yes ( ) No ( )
Reject system is full 剔废满瓶报警	During production, manually block the sensor 在生产过程中，用手挡住相应传感器	The lamp is on, the horn beeps, and the machine stop, display the alarm information. 报警灯亮，蜂鸣器响，机器停止，显示报警信息	Yes ( ) No ( )
Stopper feed channel minimum load 胶塞通道缺塞报警	During production, manually prevent stoppers into the feed channel 在生产过程中，人为阻止胶塞进入胶塞通道	The lamp is on, the horn beeps, and the machine stop, display the alarm information. 报警灯亮，蜂鸣器响，机器停止，显示报警信息	Yes ( ) No ( )

Manufacturing Quality Control

Test Instruments List

- Alloy analyzer: Innov system, U.S. brand
- Ultrasonic thickness inspector: imported from Japan
- Roughness inspector: imported from Japan
- Three-coordinate Detector: imported from France
- Video Measuring System: TaiShuo
- Temperature validation system: imported from UK
- Temperature calibrator: imported from UK
- Pressure calibrator: imported from UK
- Temperature validation system: GE KAYE, U.S. brand
- Temperature calibrator: GE KAYE, U.S. brand
- Signal generator: VICTOR
- Standard resistance box: ZX25a type
- Electron microscope: UK brand
- Endoscope detector: Olympus

Tofflon Vision:

Smart Pharma Factory Builder