



TRUKING Technology Limited



因为执着 所以卓越

We strive to achieve excellence through persistence

01

Company profile

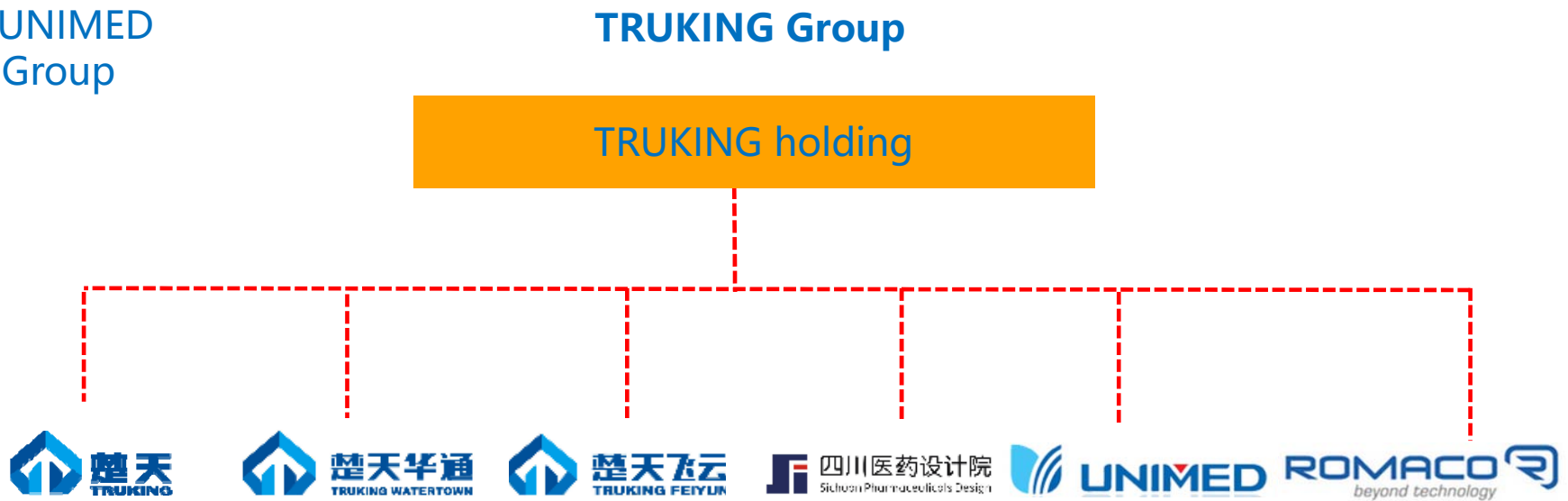
Company information

History & Milestone:



Company information

- TRUKING
- TRUKING WATERTOWN
- TRUKING FEIYUN
- TRUKING SICHUAN DESIGNING
- TRUKING UNIMED
- ROMACO Group



Company information

TRUKING

- *Headquarter*
- *Major Manufacture base(Filling, FD, ALUS, Isolator etc.)*
- *National standard R&D center*



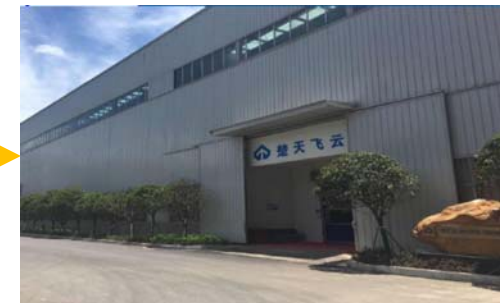
TRUKING Water Town

- *Water treatment*



TRUKING Sichuan Designing

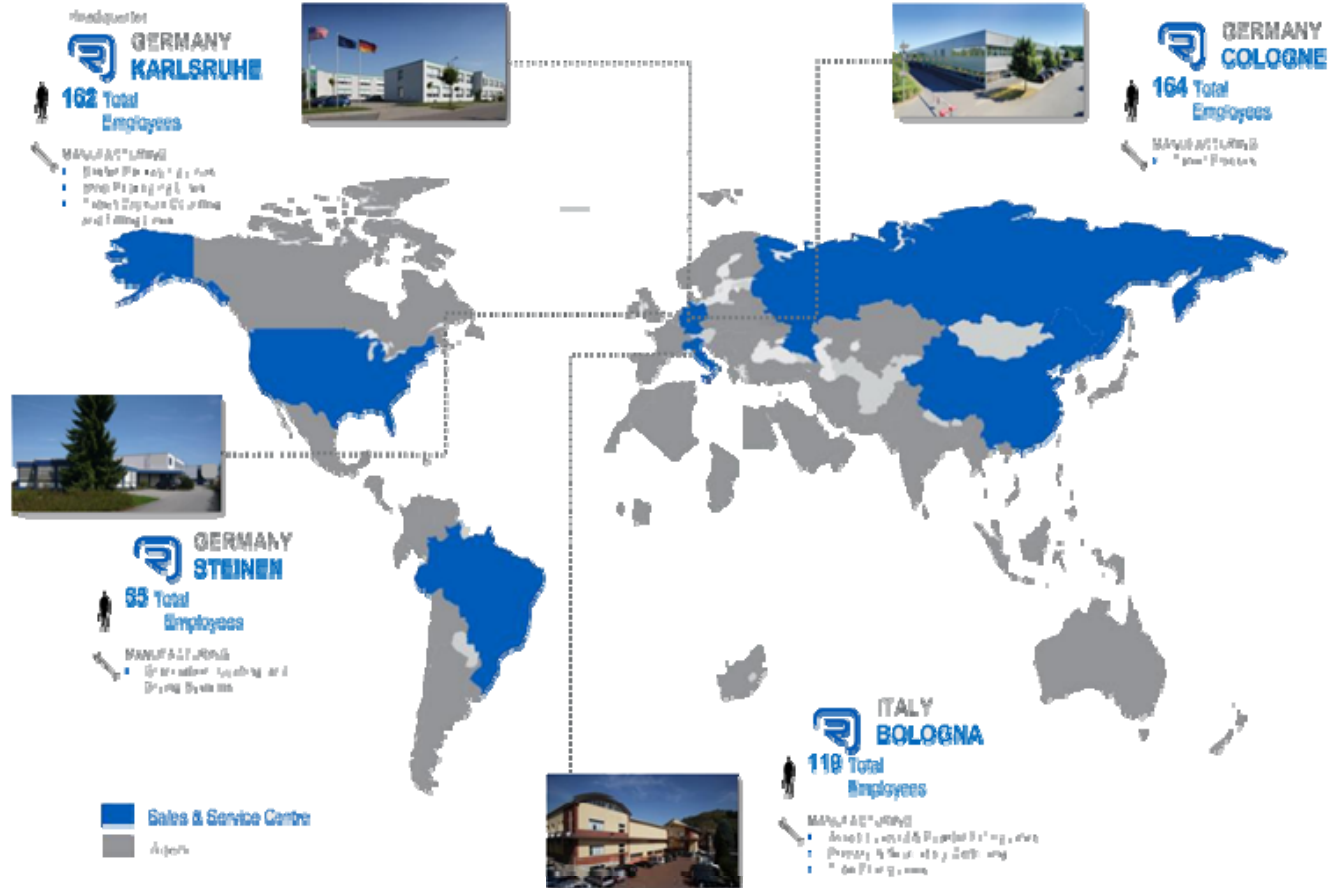
- *Concept and detail design*



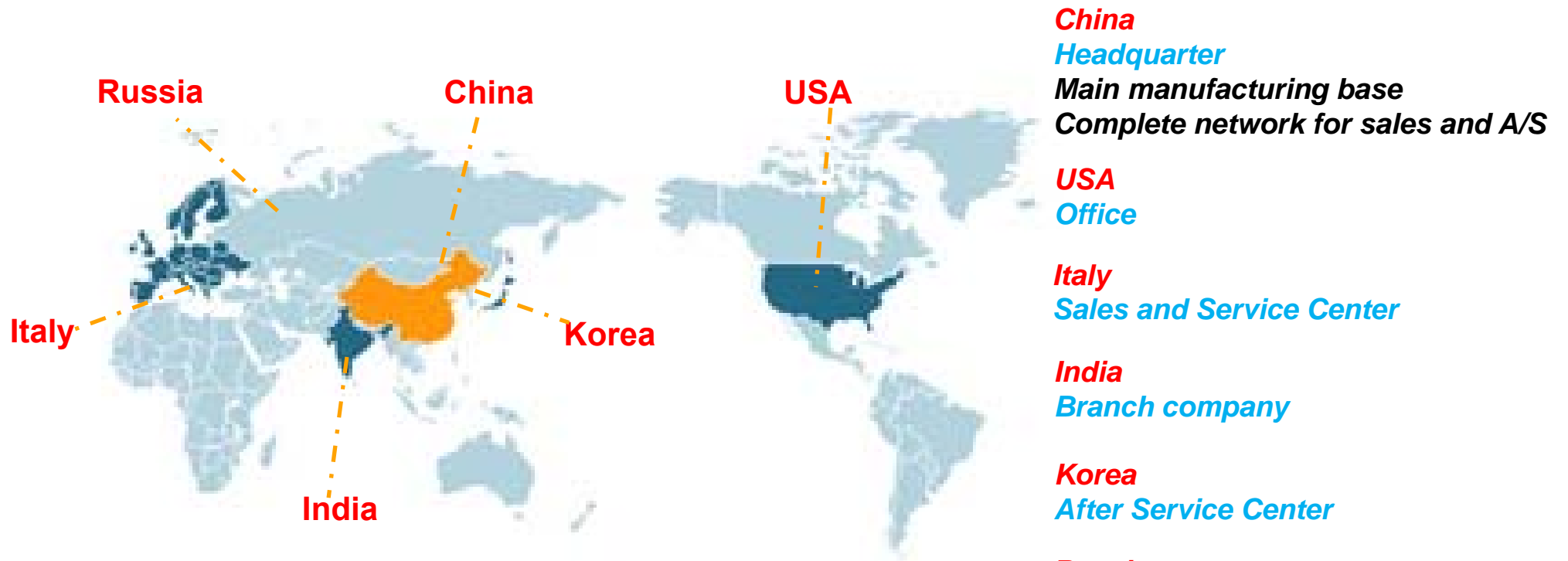
TRUKING FEIYUN

- *Capsule filling*

Company information



TRUKING Global Sales and Service Network



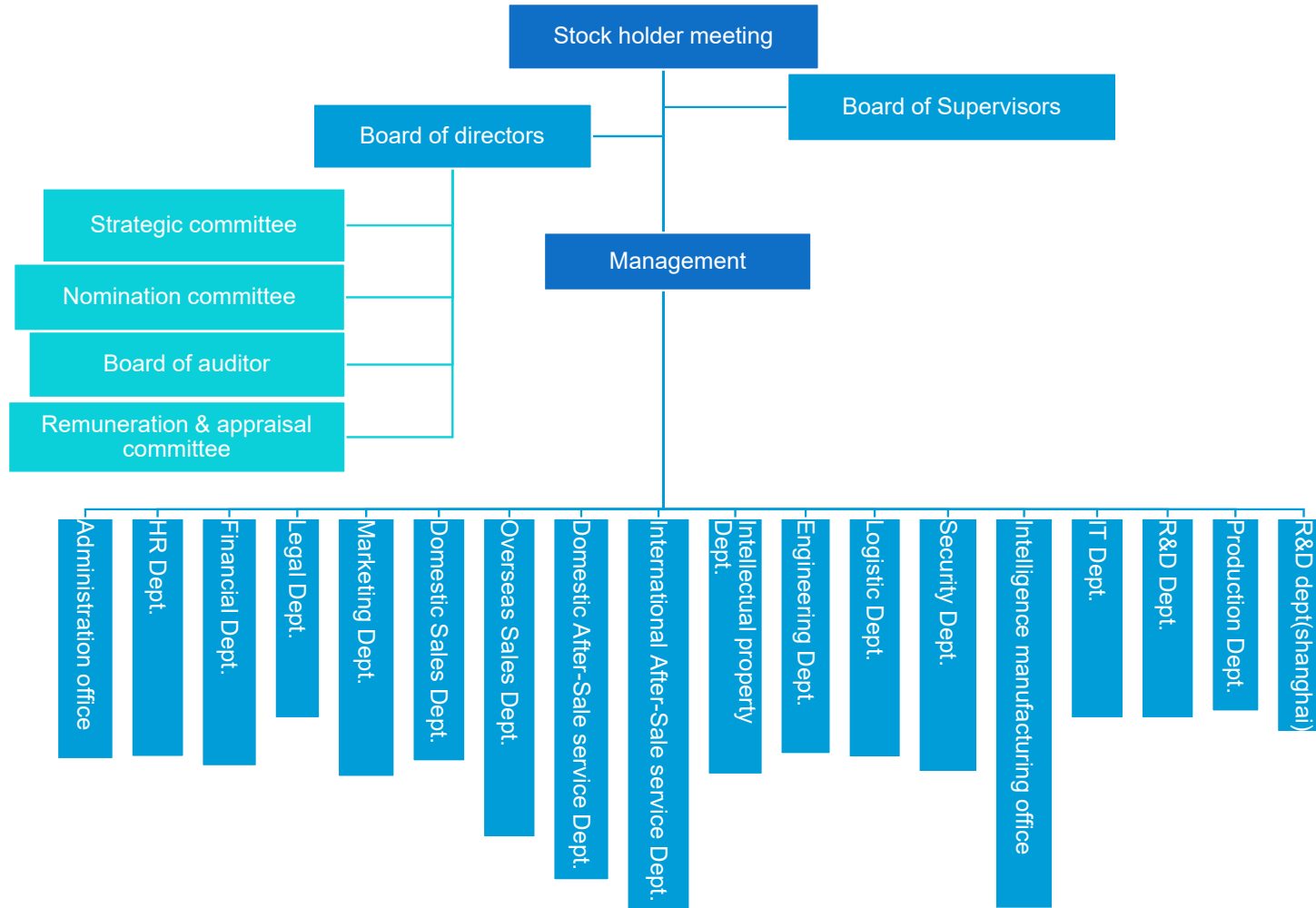
More are coming...

Russia
Office

Dubai
Office

Company structure

TRUKING Technology Ltd., Organization Structure chart



Company information

TRUKING Present

- Total asset 200+ million USD @ China
- Turnover 500+ million @ TRUKING + ROMACO
- Team 3000+ employee @ Global
500+ R&D engineers @ Global
100+ Oversea service engineer @ Global
- End user 3000+ @ Global / not including ROMACO
- Running machines 4000+ @ Global / not including ROMACO

TRUKING Products



Injectable & Sterile



Solid & Non-sterile



EPC project

TRUKING Products



Total Solution Provider for Sterile Production

TRUKING Products



Over all solution for lyophilization products



Freeze dryer system with Isolator



Freeze Dryer and RGV system

TRUKING Products



Glass Ampoule Filling Line



Glass Vial Filling Line



Cartridge filling lines



L shape Vial Filling Line



PFS Filling Line



Vial Dry Powder Filling Line

TRUKING Products



Pre-treatment for PW

RO & EDI for PW




Preparation system, CIP/SIP system



WFI Generator



Pure Steam Generator



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02



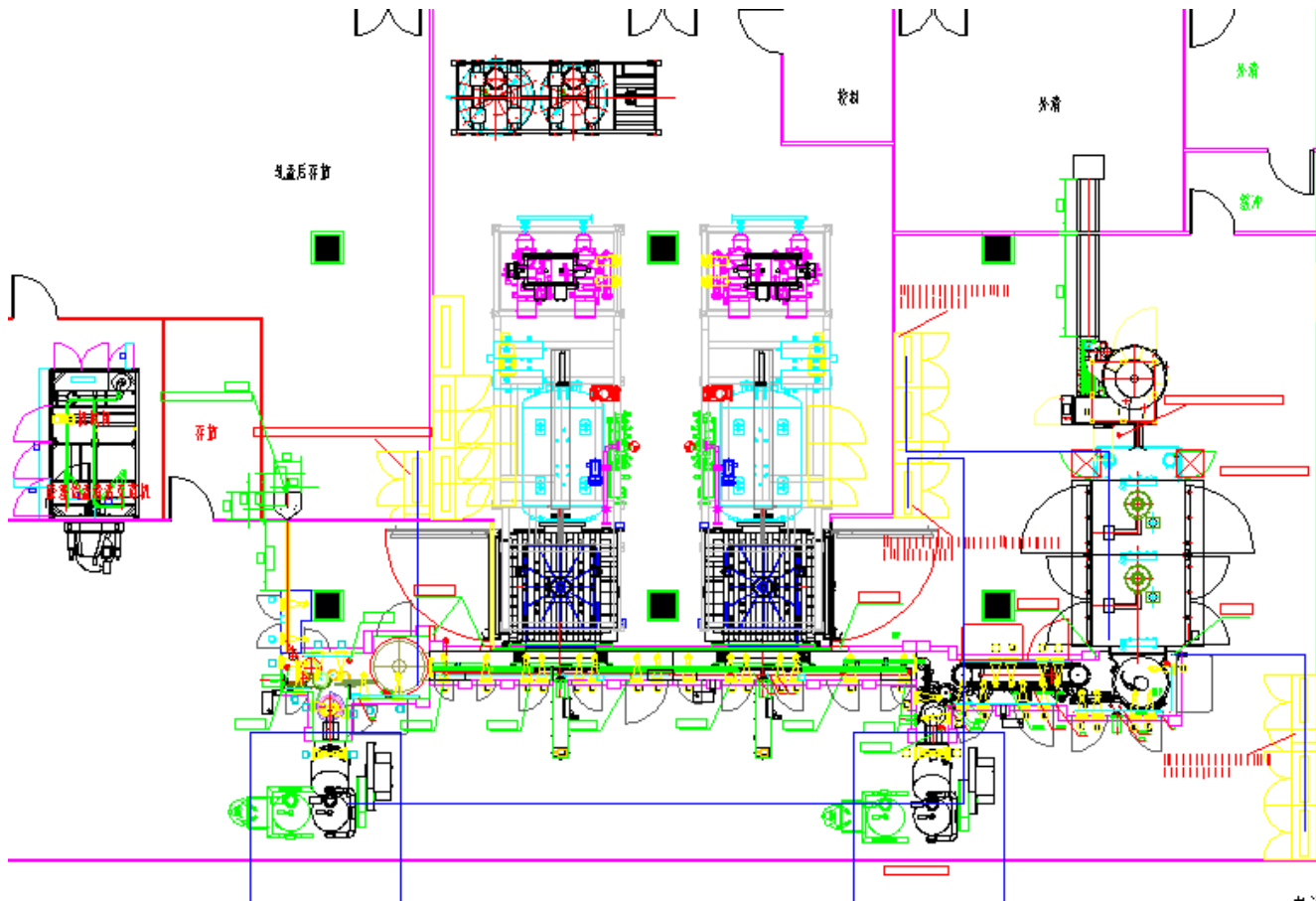
Projects in Experience

Overall solution for sterile injectable lyophilization production





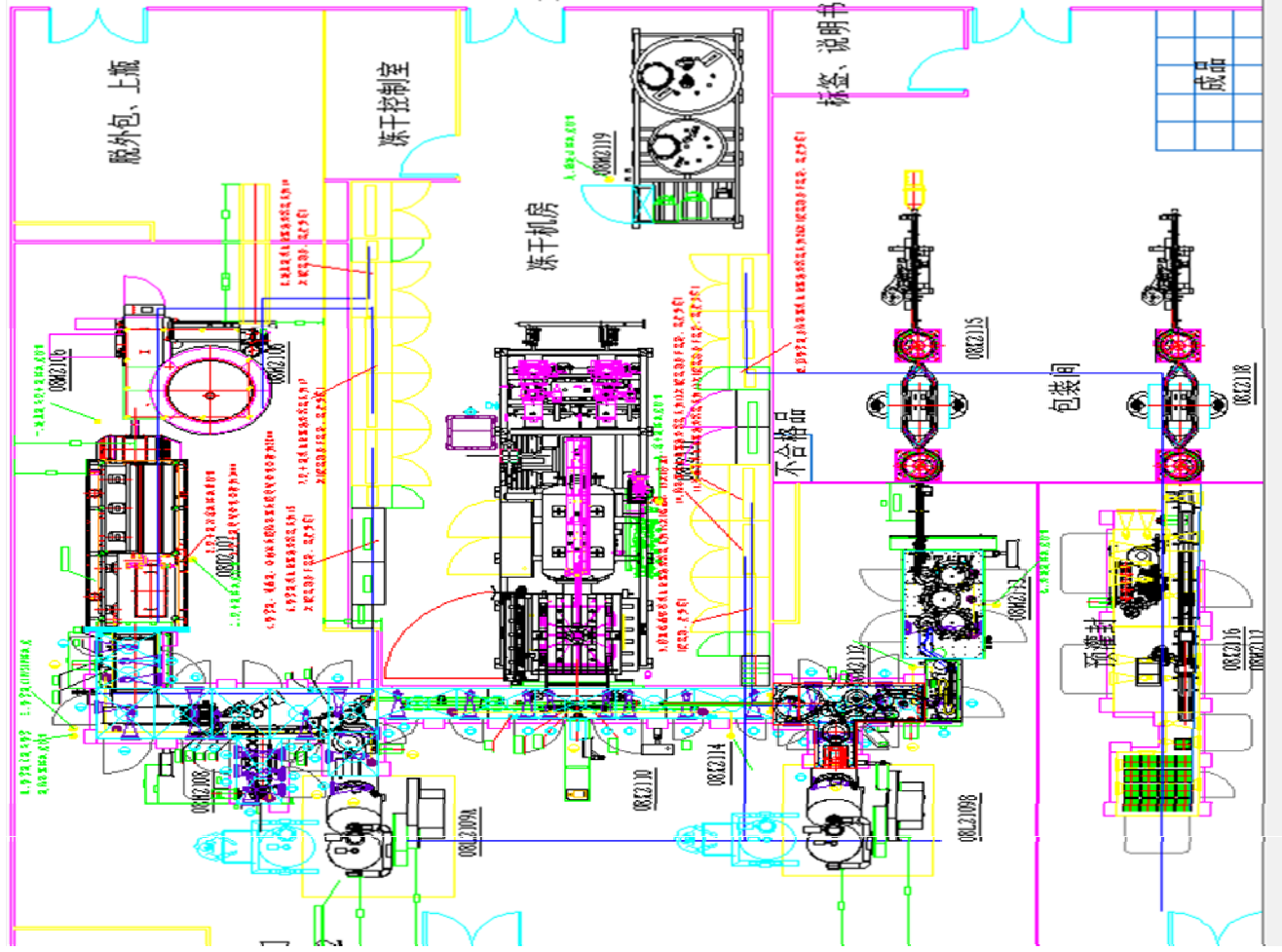
General information & principle for Isolator



OEB5 high patent Lyophilized production overall solution with isolator



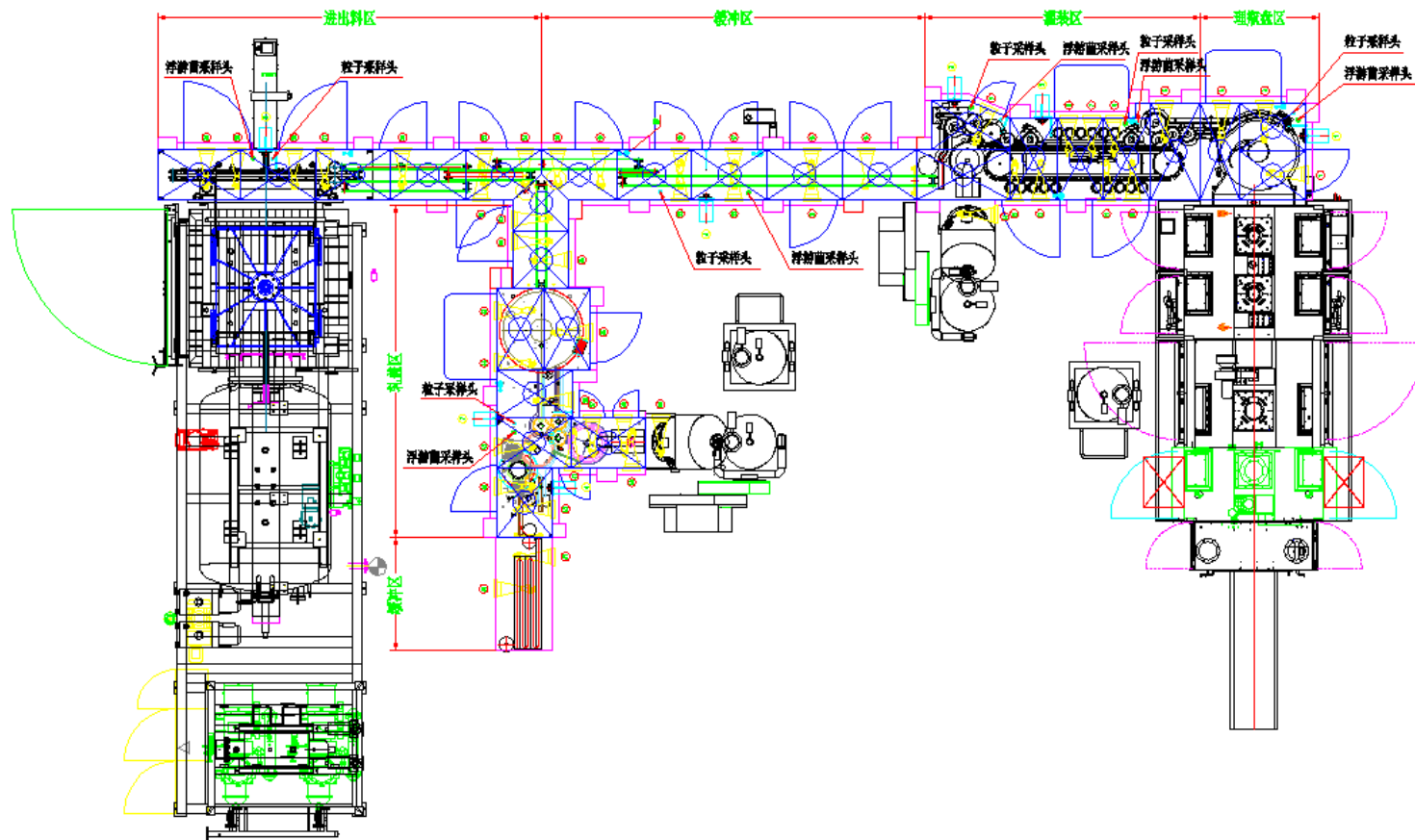
OEB5 high patent Lyophilized production overall solution with isolator



Intelligent robot filling machine with isolator



Intelligent robot filling machine



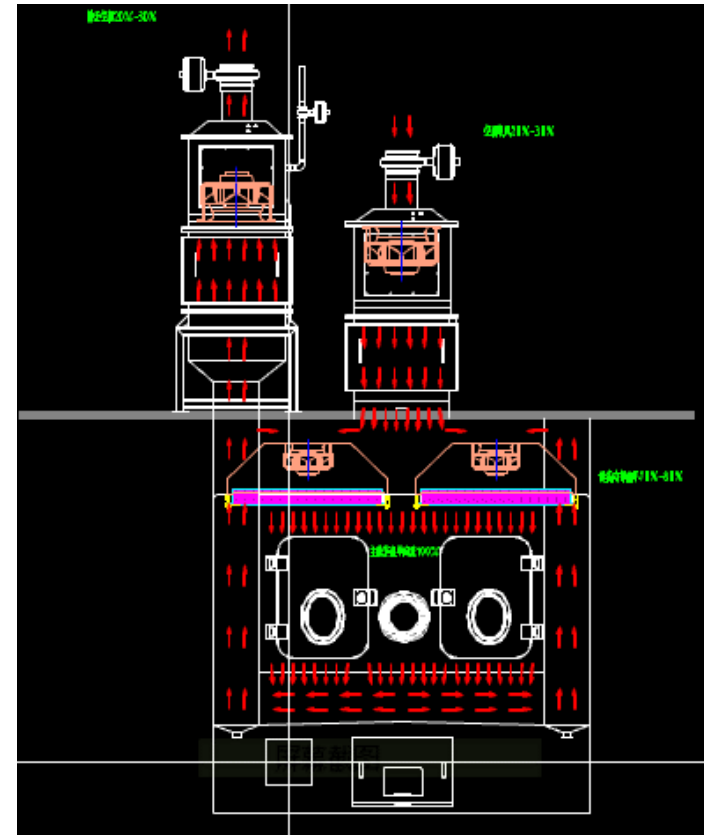
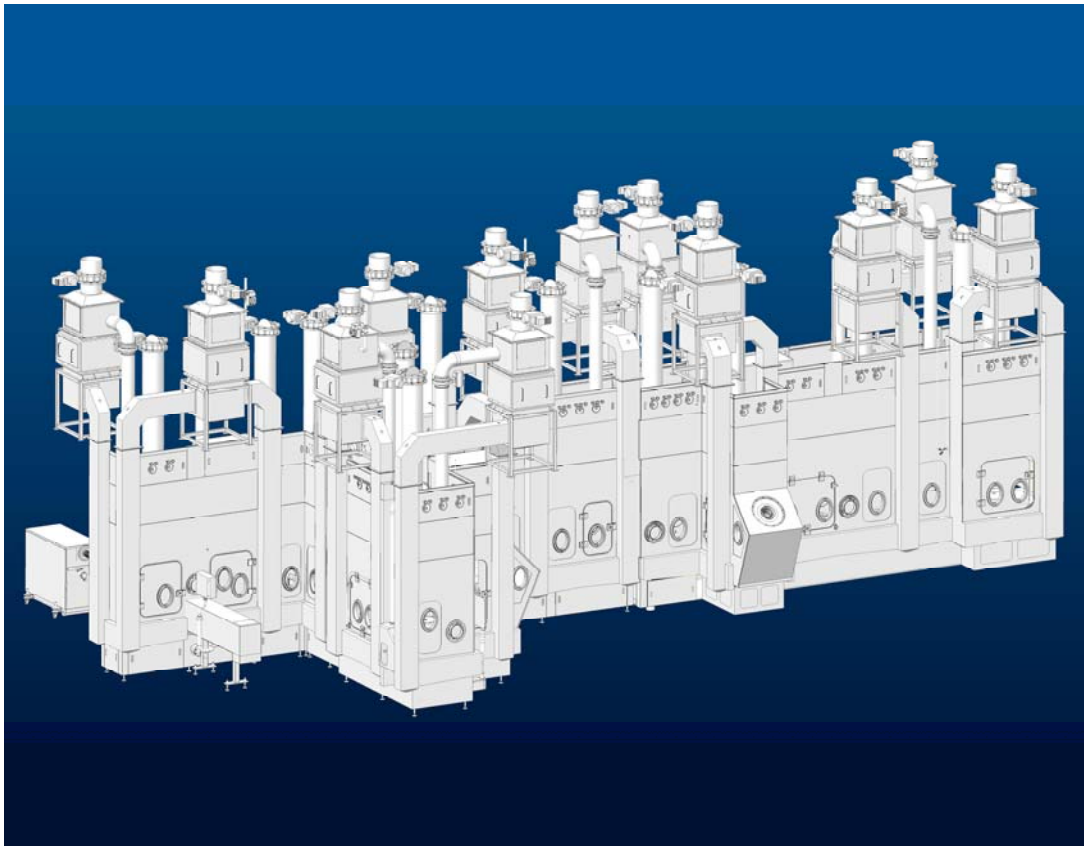
Solution for both liquid and lyophilized product

Technical solution



Mock up study

Technical solution



3D design, Air flow study



Amneal India

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Overall solution from TRUKING:

- Vial compact line * 1set
- Lyotk15 * 1set
- ALULS * 1set
- Isolator * 1set

Finish qualification 2017,
Pass FDA

Re-buy from TRUKING in
2017

Emcure India

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Overall solution from
TRUKING:

- Vial compact line * 1set
- Lyotk12 * 1set
- ALULS * 1set
- Isolator * 1set

Finish qualification 2017,
Pass FDA

United Pharma, Korea

Overall solution from
TRUKING:

- Vial compact line * 1set
- Lyotk12 * 1set
- Lyotk7 * 1set
- ALULS * 2set
- Isolator * 1set
- Water treatment * 1set
- Preparation * 1set
- Inspection machine * 1set

Finish qualification 2019



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Nativita, Belarus.



Overall solution from
TRUKING:

- Vial compact line * 1set
- Lyotk10 * 1set
- ALULS * 1set
- Isolator * 1set

Finish qualification 2018,



Wuxi Apptec, China (Pfizer partner)

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Overall solution from TRUKING:

Production line

- Vial compact line * 1set
- Lyotk5 * 1set
- ALULS * 1set
- Isolator * 1set
- Stopper washing machine

Finished qualification 2018.

Pilot line:

- Pilot filling & capping with isolator

Already in use 4 years.

Whiteson Pharma, China



Pilot filling with isolator:

- Pilot filling & capping * 1set
 - Lab LYO * 1set
 - Isolator * 1set
- (product with lower temperature control)

In use for 3 year;

Powder filling with Isolator:

- Powder filling with Isolator* 2set

Qualification in 2018



正大天晴药业
CHIA TAI TIANQING PHARMACEUTICAL

CTTQ, China



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Total 5 sets of overall solution with isolator from TRUKING in different factory:

Production line

- Vial compact line
- Lyotk5
- ALULS
- Isolator

Pilot line etc.

First one finished qualification in 2016.



科伦集团
KELUN GROUP

Kelun group, China

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Overall solution from TRUKING:

Production line

- Vial compact line * 1set
- Lyotk8 * 1set
- ALULS * 1set
- Isolator * 1set
- Stopper washing machine
- Preparation system

Finished qualification 2017.

Kindos FDA oncology workshop, China



Overall solution from TRUKING:

Production line

- Vial compact line * 1set
- Lyotk40 * 2set
- ALULS * 2set
- Isolator * 1set
- Stopper washing machine
- Preparation system

Now under IQ phase.

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Customer reference



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Customer reference



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Customer reference



Part of Isolator overall solution customer:

Emcure
SUCCESS THROUGH INNOVATION

OBiO 和元上海

amneal
PHARMACEUTICALS

HETERO

正大天晴药业
CHIA TAI TIANGING PHARMACEUTICAL

Canton Biologics
汉腾生物

普南

上海东蕴
药明康德
WuXi AppTec

景峰制药

KINDOS
KINDOS PHARMA CO
健进制药有限公司

汇宇制药
HUIYU PHARMACEUTICAL

东曜药业
TOT BIOPHARM COMPANY LIMITED

惠盾生物

金宇集团

普利药业
POLY POLY PHARM

科伦集团
KELUN GROUP

WuXi Biologics
Global Solution Provider

惠迪森药业
WHITESON PHARMA

For the Best Global Pharmaceutical Company
KOREA UNITED PHARM. INC.

VACMICRO
苏州微超生物科技有限公司

方盛制药
FANGSHENG PHARMACEUTICAL





03

Qualification



Key points as concern:

- 01 **Company quality management system**
- 02 **Product quality management system**
- 03 **Pressure vessel control**
- 04 **CE compliance**
- 05 **Other qualification**

Company quality management system

Strictly follow and meet the ISO9001 quality management requirements. Already pass and get QMS, EMS, OHSMS etc. certificate.

Now apply the latest ISO9001 2015 since March, 2018

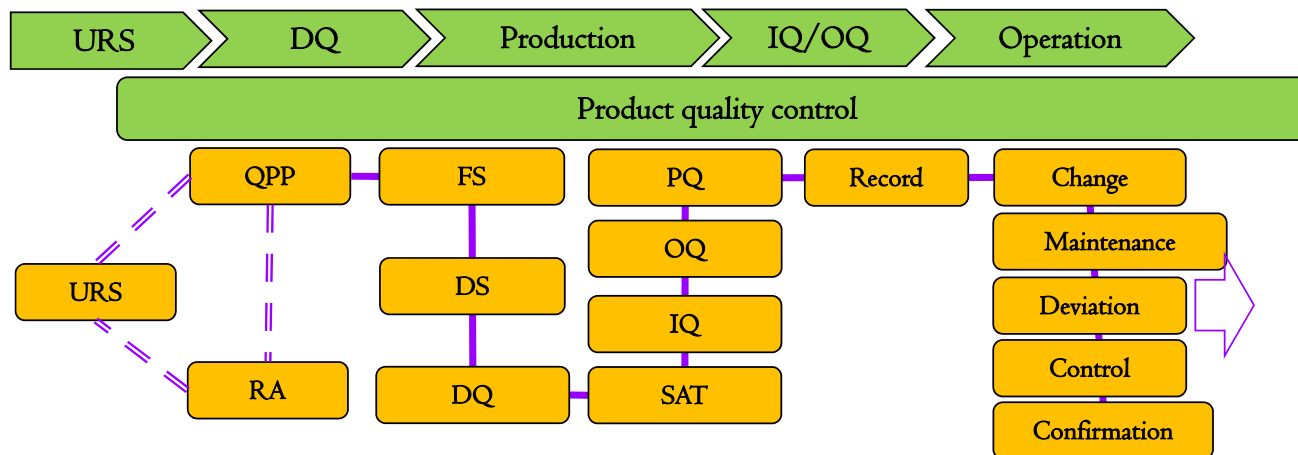


Product quality management system

To meet GMP requirements, start from the URS and product design requirement. The project will run as project management and go through DQ, IQ, OQ and PQ to strictly control every step the quality. Also VIT, FAT and SAT will carry out to ensure the system are well qualified.

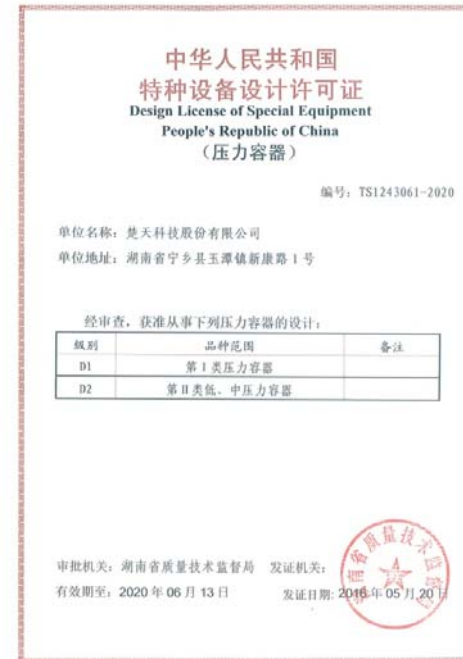
During production, strictly control the material, key components, key process, testing instrument etc. with data and reports to ensure the final quality.

Quality control process



Pressure vessel control

Start from 2010 we are qualified with pressure vessel design, manufacturing qualification. It is China pressure vessel standard GM150



Pressure vessel certificate for GB150

Pressure vessel control

From 2015, we are qualified and start apply PED and ASME for pressure vessel. PED nondestructive testing, PED welding certificate, PED process qualification and PED certification etc.

Bureau Veritas Italia S.p.A. s.r.l. Notified Body under the number 1379

BUREAU VERITAS

APPROVAZIONE PER ESECUZIONE DI PROVE NON DISTRUTTIVE
APPROVAL FOR NON DESTRUCTIVE TEST EXECUTION
 secondo l'Allegato I paragrafo 3.1.3 della direttiva attrezzature a pressione 2014/68/UE
 as per Annex I paragraph 3.1.3 of pressure equipment directive 2014/68/UE

CE-PED-NDT-TTL003-18-BVI

Bureau Veritas Italia, entità terza competente ai sensi della direttiva 2014/68/UE, approva il signor Bureau Veritas Italia, third-party organization in the frame of directive 2014/68/UE, approve Mr.

Cognome / Surname	HU	Nome / First Name	Minglang
Divisa License State / N.A.	N.A.	Il / Date of Birth	October 28, 1989
Società / Company	TRUKING TECHNOLOGY LIMITED		
Indirizzo / Address	No.1 XinKang Road , Yutan Town , Ningxiang , Changsha , Hunan 410600, China		

per l'esecuzione dei seguenti controlli non distruttivi:
 for the execution of the following non destructive test:

Metodo / Method	Livello / Level	Tipologia di giunto / Joint type (1)	Materiale / Material (2)	Spessore / Thickness	In base al documento n° / Based on the document n°	Emesso da / Issued by	Scadenza / Expiry date
RT	2	B	A-D	NA	SNT-TC-1A ed. 2006	TRUKING TECHNOLOGY	March 26, 2023
PT	2	B-T-C	A-D	NA	SNT-TC-1A ed. 2006	TRUKING TECHNOLOGY	March 26, 2023

(1) B = testa testa / butt joint; T = giunto a T / T joint; C = connessioni / branch connections
 (2) F = ferritici / ferritic; A = acciai / steels; U = duplex / duplex; E = giunti eterogenei / heterogeneous joints

Questa approvazione è da ritenersi valida fino alla scadenza di ciascuna qualifica, purché la continuità applicativa possa essere dimostrata su richiesta e non subentrino cambiamenti organizzativi che possano influire la validità.
 The present approval is valid until the expiry date of each qualification, provided that the continuity of application can be demonstrated upon request and except changes in the organization that can challenge its validity.

Emesso a / Issued at	Il / On	Firmato da / Signed by	Firma / Signature
Milan	May 25, 2018	Niko Caputo	

Codice di registrazione / Registration code: CND-061-18

Contratto BVI / BVI contract: Zig # 70185M Chr. S208M18NChe

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Bureau Veritas Italia S.p.A. s.r.l. Notified Body under the number 1379

BUREAU VERITAS

APPROVAZIONE PER ESECUZIONE DI PROVE NON DISTRUTTIVE
APPROVAL FOR NON DESTRUCTIVE TEST EXECUTION
 secondo l'Allegato I paragrafo 3.1.3 della direttiva attrezzature a pressione 2014/68/UE
 as per Annex I paragraph 3.1.3 of pressure equipment directive 2014/68/UE

CE-PED-NDT-TTL002-18-BVI

Bureau Veritas Italia, entità terza competente ai sensi della direttiva 2014/68/UE, approva il signor Bureau Veritas Italia, third-party organization in the frame of directive 2014/68/UE, approve Mr.

Cognome / Surname	HUANG	Nome / First Name	Jianqing
Divisa License State / N.A.	N.A.	Il / Date of Birth	June 21, 1985
Società / Company	TRUKING TECHNOLOGY LIMITED		
Indirizzo / Address	No.1 XinKang Road , Yutan Town , Ningxiang , Changsha , Hunan 410600, China		

per l'esecuzione dei seguenti controlli non distruttivi:
 for the execution of the following non destructive test:

Metodo / Method	Livello / Level	Tipologia di giunto / Joint type (1)	Materiale / Material (2)	Spessore / Thickness	In base al documento n° / Based on the document n°	Emesso da / Issued by	Scadenza / Expiry date
RT	2	B	A-D	NA	SNT-TC-1A ed. 2006	TRUKING TECHNOLOGY	March 26, 2023
PT	2	B-T-C	A-D	NA	SNT-TC-1A ed. 2006	TRUKING TECHNOLOGY	March 26, 2023

(1) B = testa testa / butt joint; T = giunto a T / T joint; C = connessioni / branch connections
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Questa approvazione è da ritenersi valida fino alla scadenza di ciascuna qualifica, purché la continuità applicativa possa essere dimostrata su richiesta e non subentrino cambiamenti organizzativi che possano influire la validità.
 The present approval is valid until the expiry date of each qualification, provided that the continuity of application can be demonstrated upon request and except changes in the organization that can challenge its validity.

Emesso a / Issued at	Il / On	Firmato da / Signed by	Firma / Signature
Milan	May 25, 2018	Niko Caputo	

Codice di registrazione / Registration code: CND-069-18

Contratto BVI / BVI contract: Zig # 70185M Chr. S208M18NChe

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Bureau Veritas Italia S.p.A. s.r.l. Notified Body under the number 1379

BUREAU VERITAS

APPROVAZIONE PER ESECUZIONE DI PROVE NON DISTRUTTIVE
APPROVAL FOR NON DESTRUCTIVE TEST EXECUTION
 secondo l'Allegato I paragrafo 3.1.3 della direttiva attrezzature a pressione 2014/68/UE
 as per Annex I paragraph 3.1.3 of pressure equipment directive 2014/68/UE

CE-PED-NDT-TTL001-18-BVI

Bureau Veritas Italia, entità terza competente ai sensi della direttiva 2014/68/UE, approva il signor Bureau Veritas Italia, third-party organization in the frame of directive 2014/68/UE, approve Mr.

Cognome / Surname	YANG	Nome / First Name	Ruxian
Divisa License State / N.A.	N.A.	Il / Date of Birth	June 10, 1982
Società / Company	TRUKING TECHNOLOGY LIMITED		
Indirizzo / Address	No.1 XinKang Road , Yutan Town , Ningxiang , Changsha , Hunan 410600, China		

per l'esecuzione dei seguenti controlli non distruttivi:
 for the execution of the following non destructive test:

Metodo / Method	Livello / Level	Tipologia di giunto / Joint type (1)	Materiale / Material (2)	Spessore / Thickness	In base al documento n° / Based on the document n°	Emesso da / Issued by	Scadenza / Expiry date
RT	3	B	A-D	NA	SNT-TC-1A ed. 2006	TRUKING TECHNOLOGY	March 26, 2023
PT	3	B-T-C	A-D	NA	SNT-TC-1A ed. 2006	TRUKING TECHNOLOGY	March 26, 2023

(1) B = testa testa / butt joint; T = giunto a T / T joint; C = connessioni / branch connections
 (2) F = ferritici / ferritic; A = acciai / steels; U = duplex / duplex; E = giunti eterogenei / heterogeneous joints

Questa approvazione è da ritenersi valida fino alla scadenza di ciascuna qualifica, purché la continuità applicativa possa essere dimostrata su richiesta e non subentrino cambiamenti organizzativi che possano influire la validità.
 The present approval is valid until the expiry date of each qualification, provided that the continuity of application can be demonstrated upon request and except changes in the organization that can challenge its validity.

Emesso a / Issued at	Il / On	Firmato da / Signed by	Firma / Signature
Milan	May 25, 2018	Niko Caputo	

Codice di registrazione / Registration code: CND-068-18

Contratto BVI / BVI contract: Zig # 70185M Chr. S208M18NChe

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PED nondestructive testing certificate

Pressure vessel control

From 2015, we are qualified and start apply PED and ASME for pressure vessel. PED nondestructive testing, PED welding certificate, PED process qualification and PED certification etc.

Shanghai 28042015

Welder: **Chen Li**

4352127511133014

27042017

12092015

Pressure vessel control

Shanghai 28042015

Welder: **Chen Li**

4352127511133014

27042017

12092015

Pressure vessel control

Shanghai 28042015

Welder: **Chen Li**

4352127511133014

27042017

12092015

Pressure vessel control

PED welder welding certificate

Pressure vessel control

From 2015, we are qualified and start apply PED and ASME for pressure vessel. PED nondestructive testing, PED welding certificate, PED process qualification and PED certification etc.



PROCES-VERBAL DE QUALIFICATION DE MODE OPERATOIRE DE SOUDAGE
WELDING PROCEDURE QUALIFICATION RECORD

N°SGI 15B 0299

Fabricant / Manufacturer : TRUKING TECHNOLOGY LIMITED

Lieu du soudage / Place of welding : TRUKING TECHNOLOGY LIMITED, Workshop

Date de soudage / Date of welding : 2015.4.28

DMOS - P / DMOS No. : HGP-ENG03

Norme de référence / Reference standard : EN ISO15614-1: Edition 2004+A1/2008+A2/2012

Complétée par / Supplemented by : /

Essai réalisé en présence de / Test performed in the presence of : Chris LI N° de poinçon / Stamp No. BV272

BUREAU VERITAS
3/F No 1288, Waian Road, Huangpu District, Shanghai 200011, China

certifie que les assemblages de qualification ont été préparés, soudés et contrôlés de façon satisfaisante conformément aux exigences des documents référencés ci-dessus.
certifies that test pieces were prepared, welded and tested satisfactorily in accordance with the requirements of the documents indicated above.

Procès-verbal établi le / Record issued on : 2015.5.12

ORGANISME D'EXAMEN / Examining body	FABRICANT / Manufacturer
Représentant autorisé / Authorized representative : Chris LI Signature / Visa :  Cachet de l'organisme / Stamp of the examining body : 	Représenté par / Represented by : Zhao Xiaoyan Signature / Visa :  Cachet du fabricant (éventuellement) / Stamp of the manufacturer (optional)

Autre identification (si besoin) / Other identification (as necessary) : R6-S-02-15/068

MBE14 au 01 Copyright BV 11/2012



PROCES-VERBAL DE QUALIFICATION DE MODE OPERATOIRE DE SOUDAGE
WELDING PROCEDURE QUALIFICATION RECORD

N°SGI 15B 0295

Fabricant / Manufacturer : TRUKING TECHNOLOGY LIMITED

Lieu du soudage / Place of welding : TRUKING TECHNOLOGY LIMITED, Workshop

Date de soudage / Date of welding : 2015.4.28

DMOS - P / DMOS No. : HGP-ENG02

Norme de référence / Reference standard : EN ISO15614-1: Edition 2004+A1/2008+A2/2012

Complétée par / Supplemented by : /

Essai réalisé en présence de / Test performed in the presence of : Chris LI N° de poinçon / Stamp No. BV272

BUREAU VERITAS
3/F No 1288, Waian Road, Huangpu District, Shanghai 200011, China

certifie que les assemblages de qualification ont été préparés, soudés et contrôlés de façon satisfaisante conformément aux exigences des documents référencés ci-dessus.
certifies that test pieces were prepared, welded and tested satisfactorily in accordance with the requirements of the documents indicated above.

Procès-verbal établi le / Record issued on : 2015.5.12

ORGANISME D'EXAMEN / Examining body	FABRICANT / Manufacturer
Représentant autorisé / Authorized representative : Chris LI Signature / Visa :  Cachet de l'organisme / Stamp of the examining body : 	Représenté par / Represented by : Zhao Xiaoyan Signature / Visa :  Cachet du fabricant (éventuellement) / Stamp of the manufacturer (optional)

Autre identification (si besoin) / Other identification (as necessary) : R6-S-02-15/068

MBE14 au 01 Copyright BV 11/2012



PROCES-VERBAL DE QUALIFICATION DE MODE OPERATOIRE DE SOUDAGE
WELDING PROCEDURE QUALIFICATION RECORD

N°SGI 15B 0300

Fabricant / Manufacturer : TRUKING TECHNOLOGY LIMITED

Lieu du soudage / Place of welding : TRUKING TECHNOLOGY LIMITED, Workshop

Date de soudage / Date of welding : 2015.4.28

DMOS - P / DMOS No. : HGP-ENG02

Norme de référence / Reference standard : EN ISO15614-1: Edition 2004+A1/2008+A2/2012

Complétée par / Supplemented by : /

Essai réalisé en présence de / Test performed in the presence of : Chris LI N° de poinçon / Stamp No. BV272

BUREAU VERITAS
3/F No 1288, Waian Road, Huangpu District, Shanghai 200011, China

certifie que les assemblages de qualification ont été préparés, soudés et contrôlés de façon satisfaisante conformément aux exigences des documents référencés ci-dessus.
certifies that test pieces were prepared, welded and tested satisfactorily in accordance with the requirements of the documents indicated above.

Procès-verbal établi le / Record issued on : 2015.5.12

ORGANISME D'EXAMEN / Examining body	FABRICANT / Manufacturer
Représentant autorisé / Authorized representative : Chris LI Signature / Visa :  Cachet de l'organisme / Stamp of the examining body : 	Représenté par / Represented by : Zhao Xiaoyan Signature / Visa :  Cachet du fabricant (éventuellement) / Stamp of the manufacturer (optional)

Autre identification (si besoin) / Other identification (as necessary) : R6-S-02-15/068

MBE14 au 01 Copyright BV 11/2012

PED process qualification certificate

Pressure vessel control

From 2015, we are qualified and start apply PED and ASME for pressure vessel. PED nondestructive testing, PED welding certificate, PED process qualification and PED certification etc.

Bureau Veritas SA is a Notified Body under the number 0002

CERTIFICAT DE CONFORMITE
CERTIFICATE OF CONFORMITY
 selon Module G de la directive équipements sous pression 2014/68/UE
 as per Module G of pressure equipment directive 2014/68/UE

N° CE-0062-PED-G-TTL 002-16-CHN

Bureau Veritas SA, agissant dans le cadre de sa notification (numéro d'organisme notifié 0002), certifie que l'équipement sous pression identifié ci-après a été conçu, fabriqué et testé de façon satisfaisante selon les prescriptions du module G de l'annexe III de la directive "Équipements sous pression" N° 2014/68/UE.
 Bureau Veritas SA, acting within the scope of its notification (Notified Body number 0002) for module G according to annex III of the Pressure Equipment Directive 2014/68/UE, certifies that the design and manufacturing examination and the tests have been carried out on the equipment below identified, with satisfactory result.

Fabricant (Nom) / Manufacturer (Name): Truking Technology Limited
 Adresse / Address: No.1 Xinkang Road, Ningqiang 410001, Changsha City, China

EQUIPEMENT / EQUIPMENT
 Nom / Name: 20x2 Q44 Tank
 Description de l'équipement / Equipment description: 20x2 Q44 Tank

INFORMATIONS / INFORMATION
 Identification du fabricant / Identification of the manufacturer: Truking Technology Limited
 Identification du mandataire / Identification of the authorized representative: Truking Technology Limited
 Marquage / Marking: CE 0062 (numéro d'organisme notifié du fabricant) / Manufacturer number (Bureau Veritas SA)
 Année de fabrication / Year of manufacture: 2016
 Numéro de série / Serial number: D018042 D0018 08150-2011
 Pour la réalisation de la présente mission et l'émission du certificat, Bureau Veritas SA a pu se référer au dossier technique completant.
 For the activity carried out for the issuance of the present certificate, Bureau Veritas SA has been able to reference the following manufacturer's technical file.

Existence d'une annexe au certificat de conformité / Existence of an annex to the certificate

Limites essentielles maximales/minimales admissibles / Essential limits (maximal/minimal admissible):
 Shell side: Pmax = 16.0 MPa (160 Bar) / Tmax = 150°C
 Tube side: Pmax = 18.2 MPa (182 Bar) / Tmax = 175/130°C

ESSAIS EFFECTUES PAR LE FABRIQUANT / TESTS CARRIED OUT BY MANUFACTURER
 Liste des essais / List of tests: Hydrostatic pressure test
 Remarques - Liste des pièces jointes / Remarks - Attachments: Test report HT-D018042-D0018

© Bureau Veritas SA File n°: INS-S-02-161722 Chr: www.bureauveritas.fr Page 1 of 2

Bureau Veritas SA is a Notified Body under the number 0002

CERTIFICAT DE CONFORMITE
CERTIFICATE OF CONFORMITY
 selon Module G de la directive équipements sous pression 2014/68/UE
 as per Module G of pressure equipment directive 2014/68/UE

N° CE-0062-PED-G-TTL 002-16-CHN

Bureau Veritas SA, agissant dans le cadre de sa notification (numéro d'organisme notifié 0002), certifie que l'équipement sous pression identifié ci-après a été conçu, fabriqué et testé de façon satisfaisante selon les prescriptions du module G de l'annexe III de la directive "Équipements sous pression" N° 2014/68/UE.
 Bureau Veritas SA, acting within the scope of its notification (Notified Body number 0002) for module G according to annex III of the Pressure Equipment Directive 2014/68/UE, certifies that the design and manufacturing examination and the tests have been carried out on the equipment below identified, with satisfactory result.

Fabricant (Nom) / Manufacturer (Name): Truking Technology Limited
 Adresse / Address: No.1 Xinkang Road, Ningqiang 410001, Changsha City, China

EQUIPEMENT / EQUIPMENT
 Nom / Name: 20x2 Q44 Tank
 Description de l'équipement / Equipment description: 20x2 Q44 Tank

INFORMATIONS / INFORMATION
 Identification du fabricant / Identification of the manufacturer: Truking Technology Limited
 Identification du mandataire / Identification of the authorized representative: Truking Technology Limited
 Marquage / Marking: CE 0062 (numéro d'organisme notifié du fabricant) / Manufacturer number (Bureau Veritas SA)
 Année de fabrication / Year of manufacture: 2016
 Numéro de série / Serial number: D018042 D0018 08150-2011
 Pour la réalisation de la présente mission et l'émission du certificat, Bureau Veritas SA a pu se référer au dossier technique completant.
 For the activity carried out for the issuance of the present certificate, Bureau Veritas SA has been able to reference the following manufacturer's technical file.

Existence d'une annexe au certificat de conformité / Existence of an annex to the certificate

Limites essentielles maximales/minimales admissibles / Essential limits (maximal/minimal admissible):
 Shell side: Pmax = 16.0 MPa (160 Bar) / Tmax = 150°C
 Tube side: Pmax = 18.2 MPa (182 Bar) / Tmax = 175/130°C

ESSAIS EFFECTUES PAR LE FABRIQUANT / TESTS CARRIED OUT BY MANUFACTURER
 Liste des essais / List of tests: Hydrostatic pressure test
 Remarques - Liste des pièces jointes / Remarks - Attachments: Test report HT-D018042-D0018

© Bureau Veritas SA File n°: INS-S-02-161722 Chr: www.bureauveritas.fr Page 1 of 2

PED certificate

Bureau Veritas SA is a Notified Body under the number 0002

CERTIFICAT DE CONFORMITE
CERTIFICATE OF CONFORMITY
 selon Module G de la directive Équipements sous pression 2014/68/UE
 as per Module G of pressure equipment directive 2014/68/UE

N° CE-0062-PED-G-TTL 001-17-CHN

Bureau Veritas SA, agissant dans le cadre de sa notification (numéro d'organisme notifié 0002), certifie que l'équipement sous pression identifié ci-après a été conçu, fabriqué et testé de façon satisfaisante selon les prescriptions du module G de l'annexe III de la directive "Équipements sous pression" N° 2014/68/UE.
 Bureau Veritas SA, acting within the scope of its notification (Notified Body number 0002) for module G according to annex III of the Pressure Equipment Directive 2014/68/UE, certifies that the design and manufacturing examination and the tests have been carried out on the equipment below identified, with satisfactory result.

Fabricant (Nom) / Manufacturer (Name): Truking Technology Co., Ltd.
 Adresse / Address: No.1 Xinkang Road, Ningqiang 410002, Hunan, China

Mandataire (Nom) / Authorized representative (Name): Truking Technology Co., Ltd.
 Adresse / Address: No.1 Xinkang Road, Ningqiang 410002, Hunan, China

EQUIPEMENT / EQUIPMENT
 Nom / Name: D012038-1401
 Description de l'équipement / Equipment description: 27x30 Chamber of Self-heating Water Identifier

INFORMATIONS / INFORMATION
 Marque commerciale / Trademark: Truking - Mark
 Marquage / Marking: CE 0062 (numéro d'organisme notifié du fabricant) / Manufacturer number (Bureau Veritas SA)
 Année de fabrication / Year of manufacture: 2017
 Numéro de série / Serial number: D012038-1401
 Date de la mise en service / Date of installation: 2017-02-01
 Le présent document a été établi en conformité de la norme EN ISO 9001:2015 par l'organisme notifié 0002.
 The present document has been established in conformity with the standard EN ISO 9001:2015 by the notified body 0002.
 Le présent document a été établi en conformité de la norme EN ISO 9001:2015 par l'organisme notifié 0002.
 The present document has been established in conformity with the standard EN ISO 9001:2015 by the notified body 0002.

Shanghai 301020017

Code d'engagement / Registration Code: 20170518012-0002-PED

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Pressure vessel control

PED Pressure vessel qualification folder:

- 1-Application Form
- 2-General Description of equipment
- 3-ESR and Harzards Analysis
- 4-Design
- 5-PMA design
- 6-Permanent Joining Procedure
- 7-Marking
- 8-Operation manual
- 9-Inspection during manufacture
- 10-Permanent Joining welder and Operator
- 11-NDE and DE
- 12-Material
- 13-Technical Files
- 14-Visual Inspection Report
- 15-Proof Test report

Pressure vessel control

Pressure vessel certification for ASME:



CERTIFICATE OF AUTHORIZATION

The named company is authorized by the American Society of Mechanical Engineers (ASME) for the scope of activity shown below in accordance with the applicable rules of the ASME Boiler and Pressure Vessel Code. The use of the certification mark and the authority granted by this Certificate of Authorization are subject to the provisions of the agreement set forth in the application. Any construction stamped with this certification mark shall have been built strictly in accordance with the provisions of the ASME Boiler and Pressure Vessel Code.

COMPANY:
Truking Technology Limited
No. 1 Xinkang Road
Yutan Town
Ningsiang
Changsha, Hunan 410500
People's Republic of China


SCOPE:
Manufacture of pressure vessels at the above location only

AUTHORIZED: August 29, 2018
EXPIRES: September 30, 2021
CERTIFICATE NUMBER: 51,789

Richard Robinson
Board Chair, Conformity Assessment

Joseph ...
Managing Director, Conformity Assessment

The American Society of Mechanical Engineers



Pressure vessel machines have been sold to Korea, India, Vietnam, Pakistan, Russia, Greece, Turkey, Brazil etc. more than 20 countries.

CE compliance

All TRUKING main products like filling lines, freeze dryer, auto loading/unloading system, isolator, water treatment system, packaging line have pass CE and get CE certificate.

Industry & Facilities Division

INSPECTION CERTIFICATE

VOLUNTARY VERIFICATION OF CONFORMITY TO MACHINERY DIRECTIVE 2006/42/EC AND LOW VOLTAGE DIRECTIVE 2014/35/EU

BY Job No: **INS/HH-18/220-01**

PROJECT: VERIFICATION OF CONFORMITY TO MD 2006/42/EC AND LVD 2014/35/EU
 BV Client: **TRUKING TECHNOLOGY LIMITED**
 Manufacturer: **TRUKING TECHNOLOGY LIMITED**
 Inspection requested by: **TRUKING TECHNOLOGY LIMITED**

Ref: **INS/HH-18/220**
 P/O No: **INS/HH-P18/230 Rev.0**
 P/O No: **N/A**
 (Refer to Manufacturer)

DESCRIPTION OF MACHINE SUBJECT OF INSPECTION
 Vertical Ultrasonic Washing Machine / KQCL2003

ITEM / TAG Nr QTY
 14474 1

Scope of inspection:
 - Reference documents used for conformity verification:
 2006/42/EC, KQCL2003 / TCF REV0
 Risk assessment (EN 60204-1)
 Operation manual (Rev.0)
 Declaration of conformity (2018.12.18)
 - Place of inspection & date of report of conformity verification:
 Place: No.1, Xinkang Road, Yutan Town, Ningxiang, Changsha, Hunan Province, P. R. China, Zip: 410600
 Date: Dec, 2018
 - Marking and stamping:
 N/A
 - Annexes to this certificate:
 Safety File 01 Vertical Ultrasonic Washing Machine / KQCL2003 (Total 18 pages)

The undersigned, inspector to Bureau Veritas, certifies that the here above mentioned machinery was inspected in conformity with applicable requirements of Machinery Directive and Low Voltage Directive, the contractual requirements governing this mission attached to Bureau Veritas at the date and conditions reported in the Inspection Report Safety File 01 Vertical Ultrasonic Washing Machine / KQCL2003, without any remarks.

Special Conditions: Special conditions applicable to the issue of this certificate are given in the attached appendices:
 Appendix 1: Restrictions

This certificate delivered by Bureau Veritas China becomes null and void in case of any changes in design.

Inspected by:
 Name: Youguo Wang
 Signature:

Checked by:
 Name: Peter SUN
 Signature:

Date of issue: December 18th, 2018
 Inspection centre: BV Shanghai
 Distribution: CLIENT MANUFACTURER

CE Product Manager:

OM MD 003 IR 002 1/2 Copyright Bureau Veritas 03/2011

Industry & Facilities Division

INSPECTION CERTIFICATE

VOLUNTARY VERIFICATION OF CONFORMITY TO MACHINERY DIRECTIVE 2006/42/EC AND LOW VOLTAGE DIRECTIVE 2014/35/EU

Job No: **INS/S-GZ-16/123-12**

PROJECT: VERIFICATION OF CONFORMITY TO MD 2006/42/EC AND LVD 2014/35/EU
 BV Client: **TRUKING TECHNOLOGY LIMITED**
 Manufacturer: **TRUKING TECHNOLOGY LIMITED**
 Inspection requested by: **TRUKING TECHNOLOGY LIMITED**

Ref: **INS/S-GZ-16/123-12**
 P/O No: **INS/S-GZ-P16/030 Rev.1**
 P/O No: **N/A**
 (Refer to Manufacturer)

DESCRIPTION OF MACHINE SUBJECT OF INSPECTION
 Filling and Stoppering Machine / ISAB, KGSABF, KGSAB4, KGSAB4F, KGSAB2, KGSAB2F

ITEM / TAG Nr QTY
 1 1

Scope of inspection:
 - Reference documents used for conformity verification:
 2006/42/EC, KGSAB, KGSABF, KGSAB4, KGSAB4F, KGSAB2, KGSAB2F, TCF REV0
 Risk assessment (EN 60204-1)
 Operation manual (Rev.0)
 Declaration of conformity (2018.03.16)
 - Place of inspection & date of report of conformity verification:
 Place: No.1, Xinkang Road, Yutan Town, Ningxiang, Changsha, Hunan Province, P. R. China, Zip: 410600
 Date: Mar, 2018
 - Marking and stamping:
 N/A
 - Annexes to this certificate:
 Safety File 01 Filling and Stoppering Machine ISAB, KGSABF, KGSAB4, KGSAB4F, KGSAB2, KGSAB2F (Total 18 pages)

The undersigned, inspector to Bureau Veritas, certifies that the here above mentioned machinery was inspected in conformity with applicable requirements of Machinery Directive and Low Voltage Directive, the contractual requirements governing this mission attached to Bureau Veritas at the date and conditions reported in the Inspection Report Safety File 01 Filling and Stoppering Machine / KGSABF, KGSAB4, KGSAB4F, KGSAB2, KGSAB2F, without any remarks.

Special Conditions: Special conditions applicable to the issue of this certificate are given in the attached appendices:
 Appendix 1: Restrictions

This certificate delivered by Bureau Veritas China becomes null and void in case of any changes in design.

Inspected by:
 Name: Youguo Wang
 Signature:

Checked by:
 Name: Peter SUN
 Signature:

Date of issue: Mar 16th, 2018
 Inspection centre: BV Shanghai
 Distribution: CLIENT MANUFACTURER

CE Product Manager:

MD 003 IR 000 1/2 Copyright Bureau Veritas 03/2011

BUREAU VERITAS

CERTIFICATE OF COMPLIANCE
 EC-INSIS-GZ-16/123-06

Requested By:
 Manufacturer: **TRUKING TECHNOLOGY LIMITED**
 Address: **No.1, Xinkang Road, Yutan Town, Ningxiang, Changsha, Hunan Province, P. R. China, Zip: 410600**

Description of Product:
 Model / type: **Freeze Dryer / LYTK(X-3, 5, 7, 10, 15, 20, 25, 30, 35, 40)**
 Serial Number: /
 Location (inspection item): **No.1, Xinkang Road, Yutan Town, Ningxiang, Changsha, Hunan Province, P. R. China, Zip: 410600**

Conclusions of examination:
 Based on the technical construction file and test result review, the FREEZE DRYER specified above has been examined and found to comply with the essential safety requirements specified in the EC Machinery Directive 2006/42/EC and Low Voltage Directive 2014/35/EU. The EC declaration of conformity for the FREEZE DRYER can be established by the manufacturer.

Harmonized standards: **EN IEC 12100:2010, EN 60204-1:2009 / AC:2010**

Special Conditions:
 Special conditions applicable to the issue of this certificate are given in the attached appendices:
 Appendix 1: Restrictions

This certificate delivered by Bureau Veritas China becomes null and void in case of any changes in design.

Inspected by:
 Name: Allan Zhong
 Signature:

Bureau Veritas Greater China, Industry and Facilities Division
 Date: 31st Oct, 2016

This certificate is subject to the terms of Bureau Veritas General Conditions of Service attached to the agreement signed by the client. This document contains results related only to the items assessed; it does not imply the conformity of the whole production to the assessed items.

1828-3F, No.1285, Wei Ma Road, Huangpu District, Shanghai, 200011, P.R. China
 +86 21 2319 0001/2319 0002, 2319 0003 Fax: +86 21 68804121

CERTIFICATE
 of Conformity
 Low Voltage Directive 2014/35/EU

Registration No.: **AN 50350370 0003**
 Report No.: **16073707 001**

TRUKING TECHNOLOGY LIMITED
 No.1 Xinkang Road, Yutan Town
 Ningxiang
 Changsha 410600
 P.R. China

Projecting Machine
 (Flat Caping Machine)

Nr.	Type Designation	Serial No.	Type Designation	Serial No.
01	20-F-18	11918	20-F-P2-18	11918
	20-F-18	11919	20-F-P2-18	11919
	20-F-18	11940	20-F-P2-18	11940
	20-F-18	11941	20-F-P4-18	11941

TradeMark: TRUKING (Large)

Remarks: Refer to test report 16073707 001 for details.

If conformity is based on an evaluation of a sample of the above mentioned product, and documentation are at the License Holder's disposal. This is to certify that the is in conformity with Annex I of Council Directive 2014/35/EU, referred to as the Low V. This certificate does not imply assessment of the series production of the product with the use of a TVD thousand mark of conformity. The holder of this certificate is this certificate in connection with the EC declaration of conformity according to Directive.

Certification Body:

 Allan Zhong

018

and LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

marking may be used if all relevant and effective EC Directives are complied with.

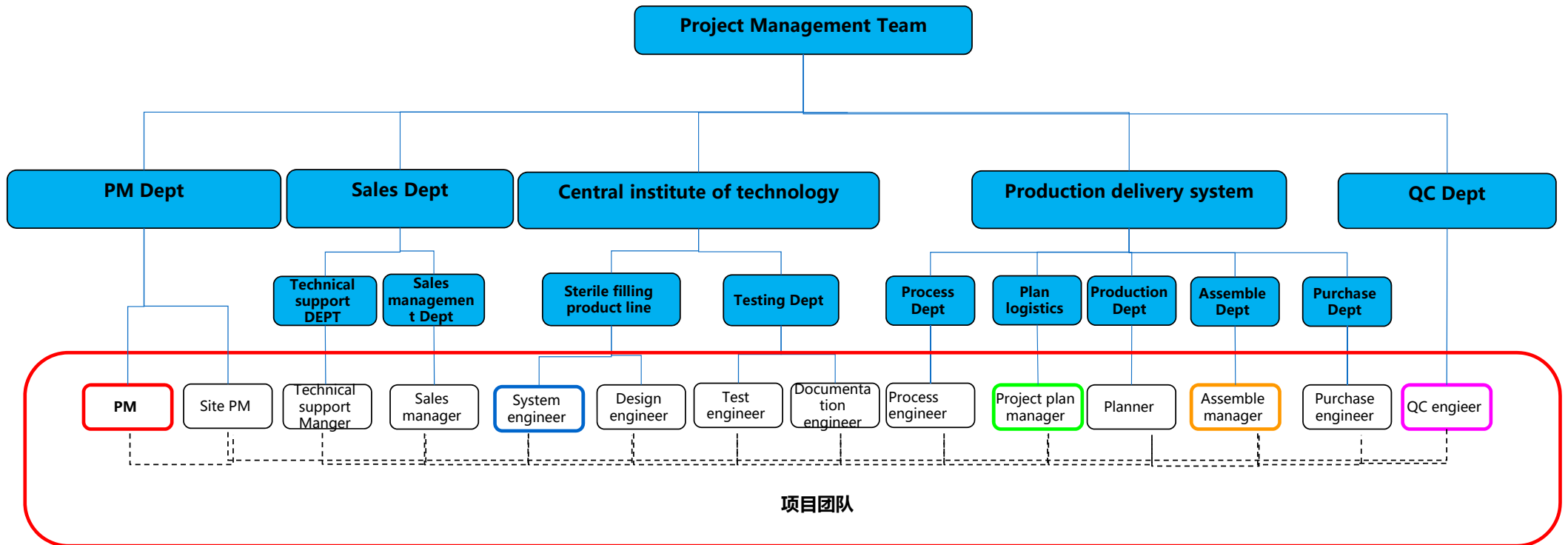
因为执着 所以卓越

We strive to achieve excellence through persistence

04

Project Management

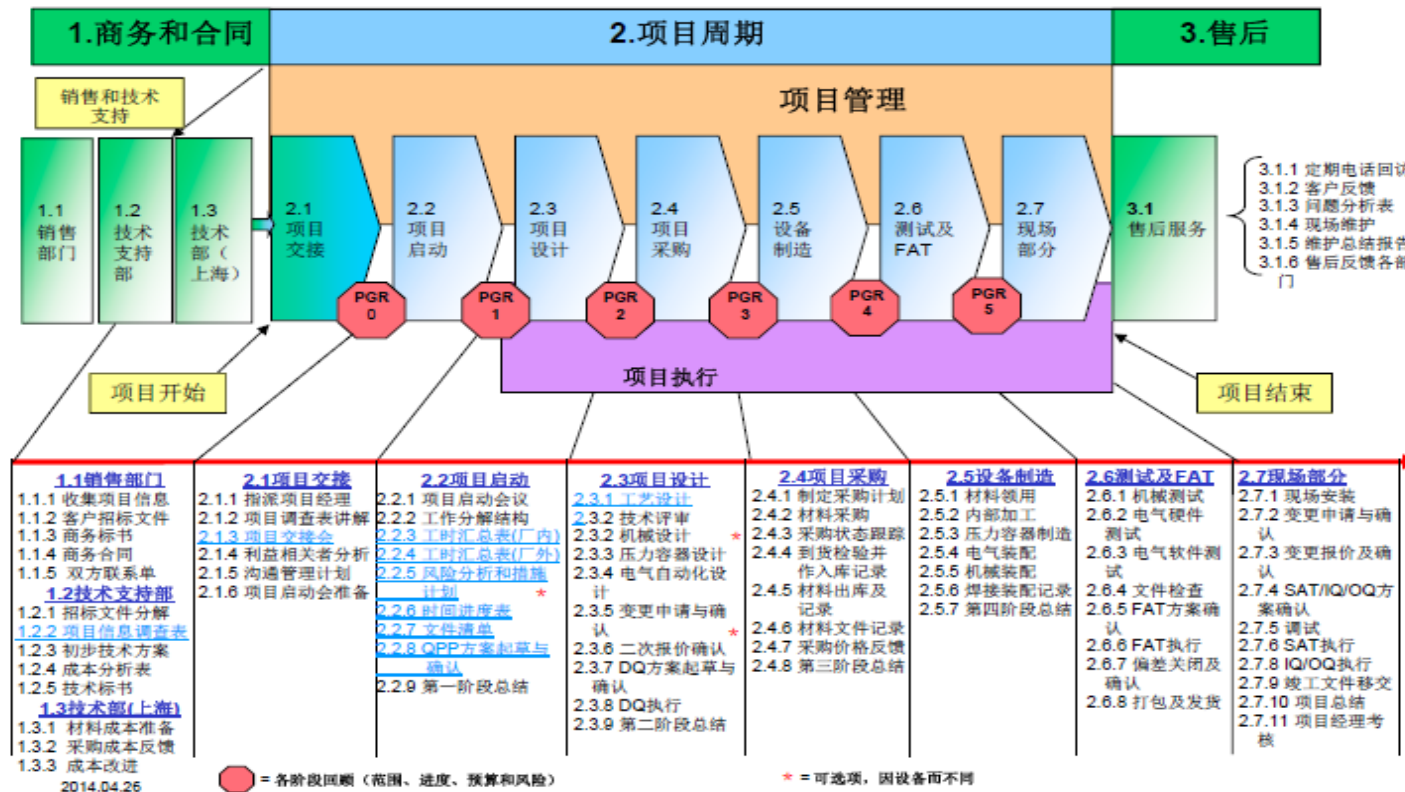
Project management team



Project Management chart flow



项目执行流程

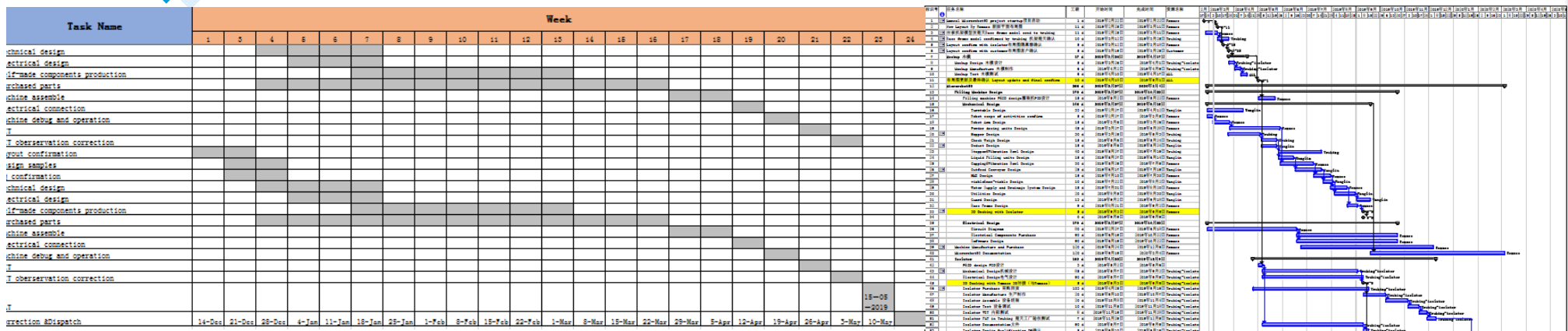


Hand over->Project kick off->Design-> Procurement-> Manufacture-> VIT & FAT -> SAT/IQ/OQ

Professional Project Management

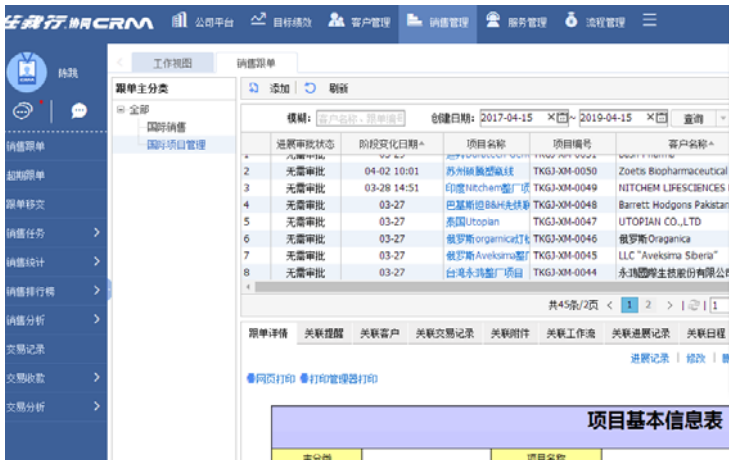
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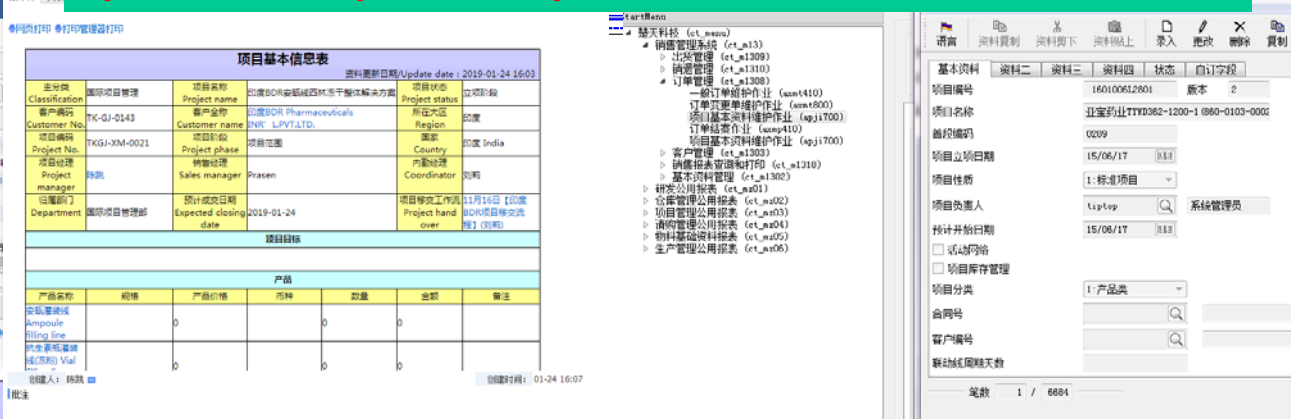


Project timeline/schedule/Gantt Chart

Multiple tools/software for project management. (ERP system, CRM system, Project software).



CRM system



ERP system

Professional Project Management

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Customer Site:

- URS questions
- Utility request
- Machines questions
- Project Status
- Documents support
- SOP support



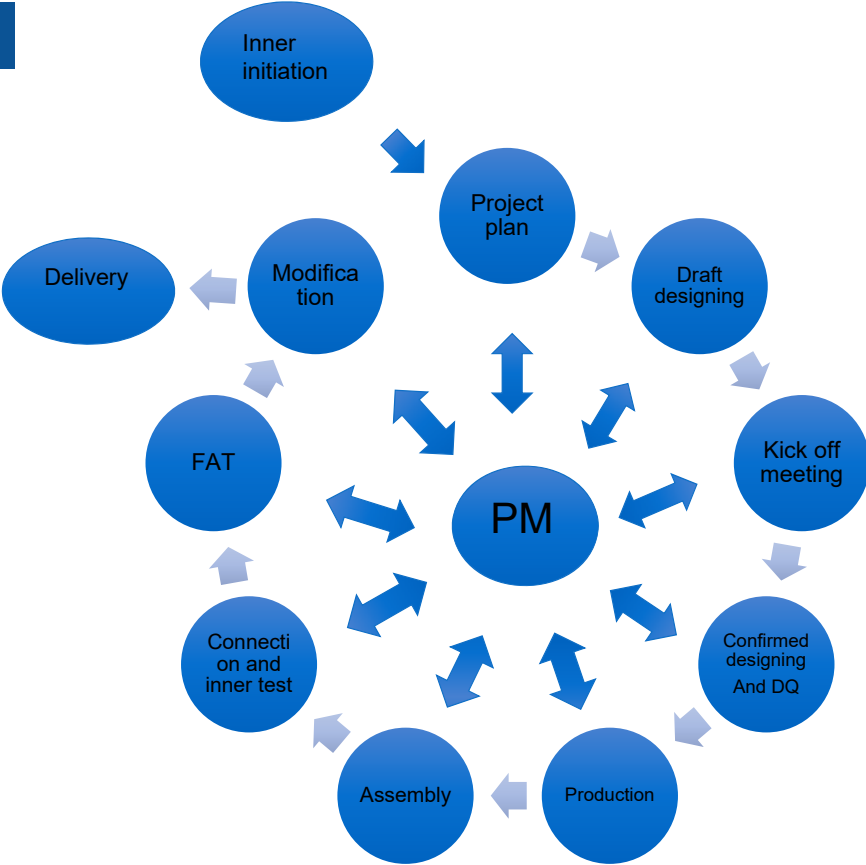
Single contactor for project status track/project hand-over/FAT activities arrangement etc.

TRUKING Site:

- Project Schedule
- DQ confirmation
- Main Production Plan
- Component purchase plan
- Component manufacturing plan
- SIT(Internal Test)
- FAT activities
- Project handover

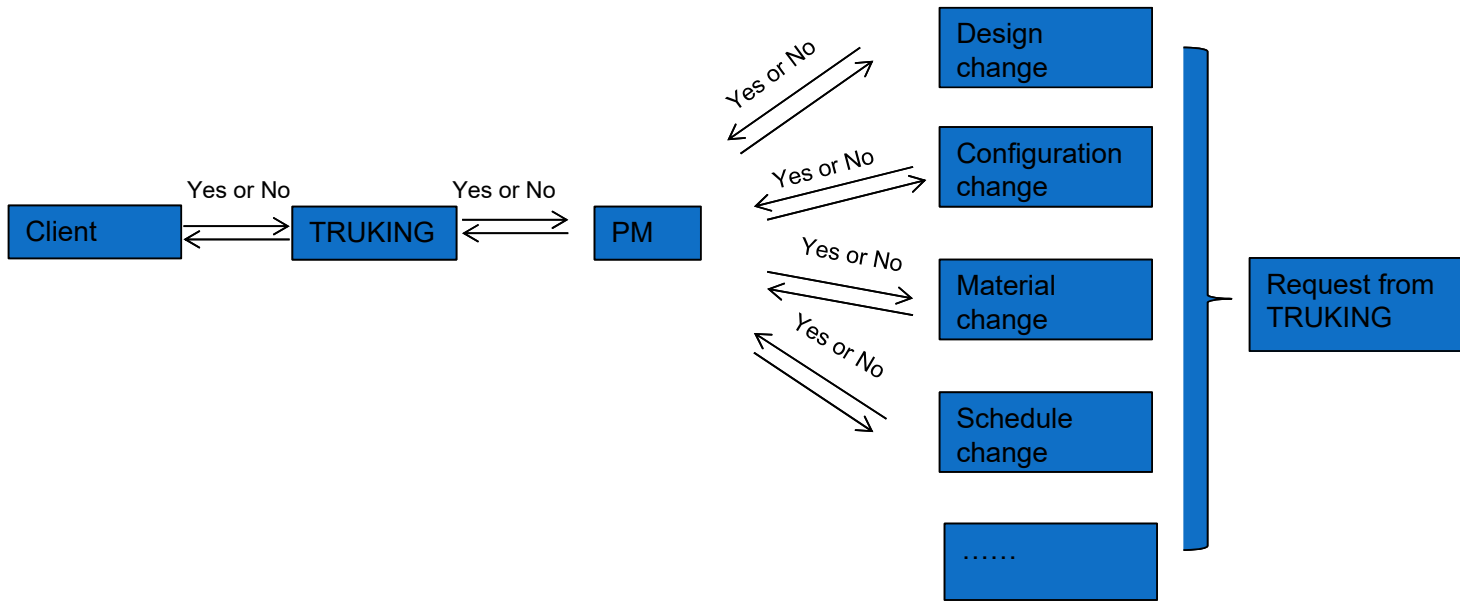
Project Management

Issue management



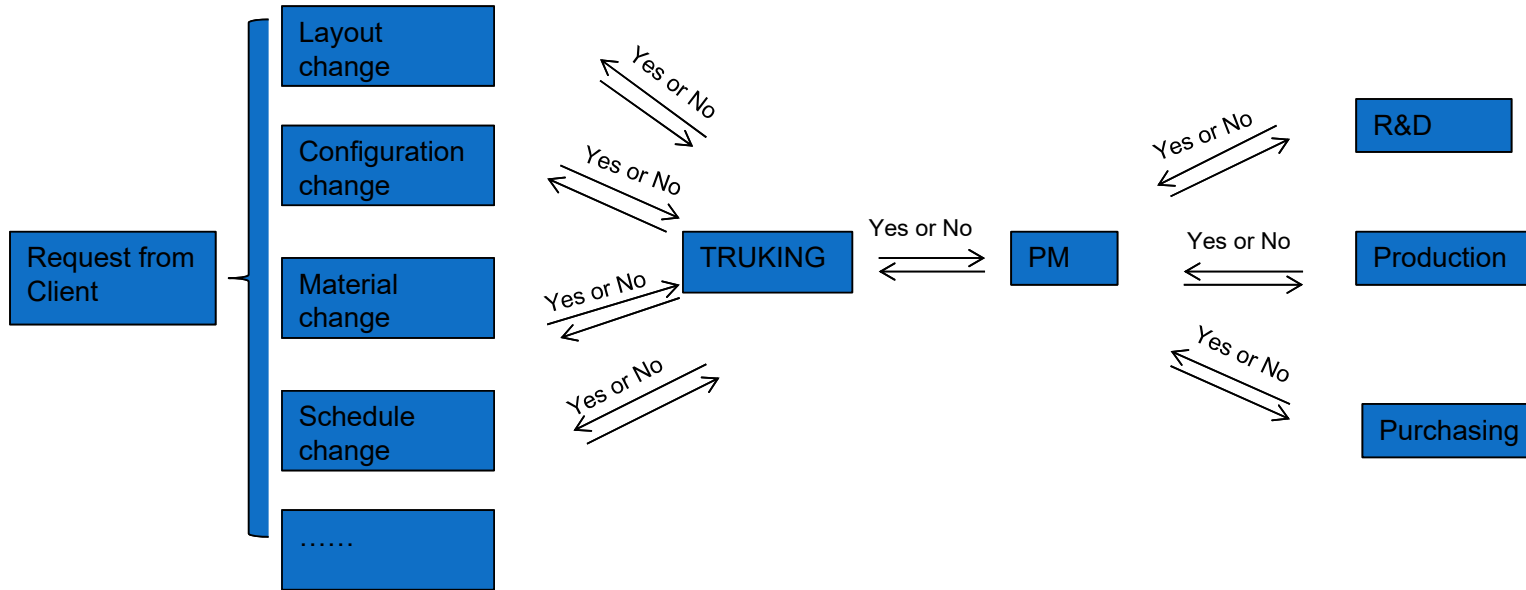
Project Management

Change control



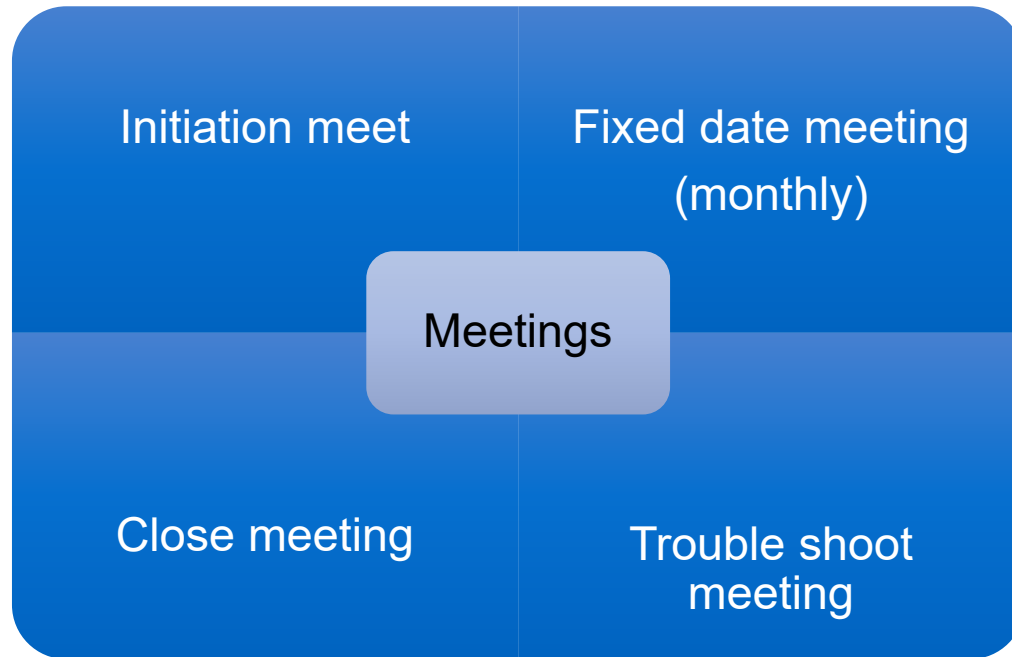
Project Management

Change control



Project Management

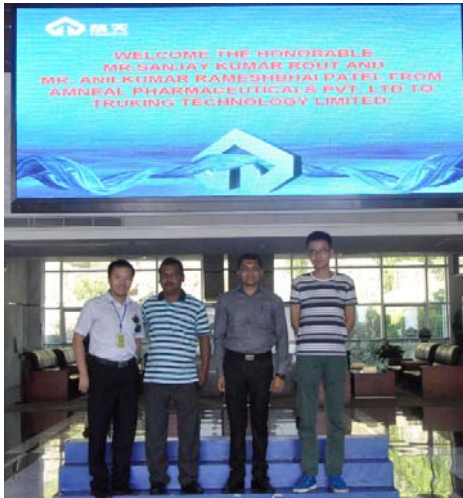
Meetings



Professional Project Management

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Documentation

3 levels documentation:

- Level1 : Standard basic documents
 - Level2 : Standard basic documents + Validation documents package (optional)
 - Level3: Standard basic documents + Validation documents package + GAMP 5 (optional)
-



Documentation

Level 1 Standard basic documents, documentation supplied with the equipment includes:

- General Arrangement drawing (as built)
- Pipework & Instrumentation drawings (as built)
- Electrical Schematics (as built)
- Lifting Drawings
- Component Listing (as built)
- Manufacturers Certificates of Conformance for main components fitted

Note: Hard and soft copies of all documentation generated by Truking are provided in English and Chinese dual language, using the metric system (dual units for USA)



Documentation

- Original Manufacturers Instructions for main components (in their original language)
- Material Certificates for necessary items
- Critical Instrument Calibration Certificates
- Installation Manual (inc. Unpacking and utility connections)
- Operating Manual
- Maintenance Manual
- Safety manual
- Spare part list
- One set of hardcopy documents will be provided, together with one set of soft-copies

Note: Hard and soft copies of all documentation generated by Truking are provided in English and Chinese dual language, using the metric system (dual units for USA)



Documentation

Level 2 , except documents in Level 1, documentation supplied with the equipment includes:

- *FS – Functional Specification*
- *HDS – Hardware Design Specification*
- *SDS – Software Design Specification*
- *SIT – Supplier Internal Testing*
- *FAT – Factory Acceptance Testing*
- *SAT- Site Acceptance Testing*
- *IQ/OQ/PQ*

Note: Hard and soft copies of all documentation generated by Truking are provided in English and Chinese dual language, using the metric system (dual units for USA)



Documentation

Level 3, GAMP 5 documentation

- *URS – User requirement specification (TruKing format)*
- *TM – Traceability Matrix (GAMP)*
- *GMP Risk Review (GAMP)*

Note: Hard and soft copies of all documentation generated by TruKing are provided in English and Chinese dual language, using the metric system (dual units for USA)

Training and handover

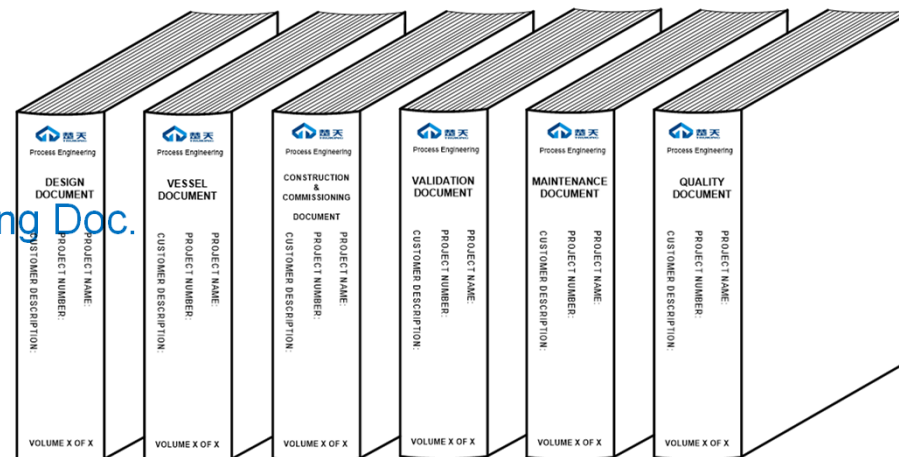
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- Training
 - Training table
 - Training record
 - Training content

From	To	Day 1 (Monday)		Day 2 (Tuesday)	
		Pitt	By	Pitt	By
9:00	9:45	P&I diagrams Production	Truking Control engineer	Electric and instrumentation (electrical drawing)	Truking Control engineer
9:45	10:00	Coffee Break		Coffee Break	
10:00	11:30	P&I diagrams CIP	Truking Control engineer	Electric and instrumentation (special instruments, equipment list)	Truking Control engineer
11:30	13:30	Lunch		Lunch	
13:30	14:45	P&I diagrams SIP	Truking Control engineer	Electric and instrumentation (Motor list, VFD list)	Truking Control engineer
14:45	15:00	Coffee Break		Coffee Break	
15:00	16:00	Plant walk-through relating to Control system architecture	Truking Control engineer	Electric and instrumentation (Variable Frequency Drive)	Truking Control engineer

- Document handover
 - Design document
 - Pressure vessel Doc.
 - Manufacturing & Commissioning Doc.
 - Verification Doc.
 - Quality Doc.
 - Maintenance Doc.





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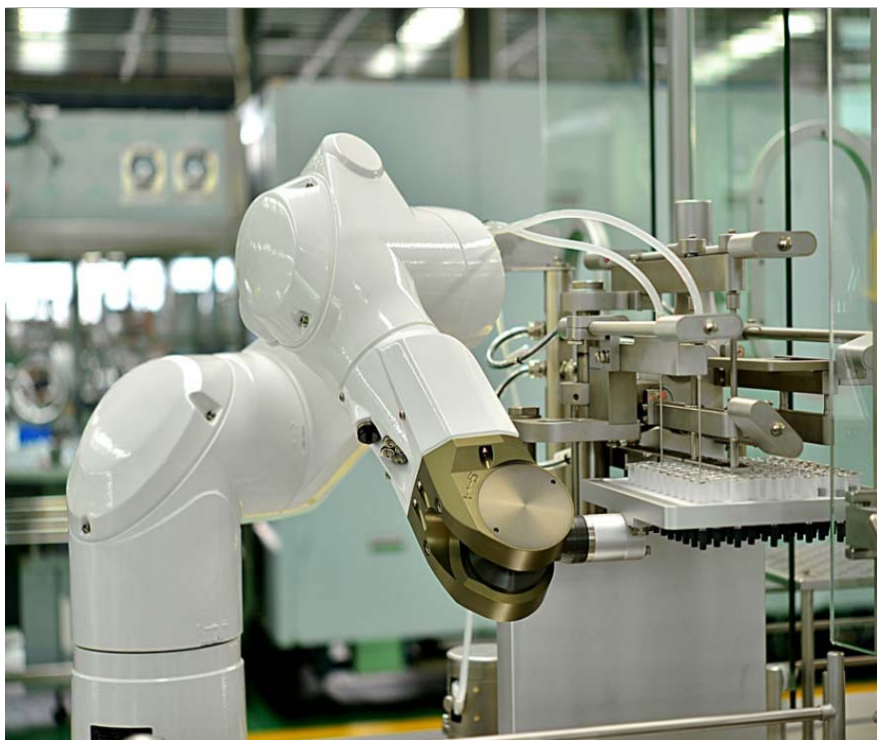


05

Technical points



Robotic filling & stoppering machine



Robotic filling & stoppering machine

- **Stability**
- **Contamination risk control**
- **Easy change over**
- **Data integrity**



Robotic filling & stoppering machine: stability

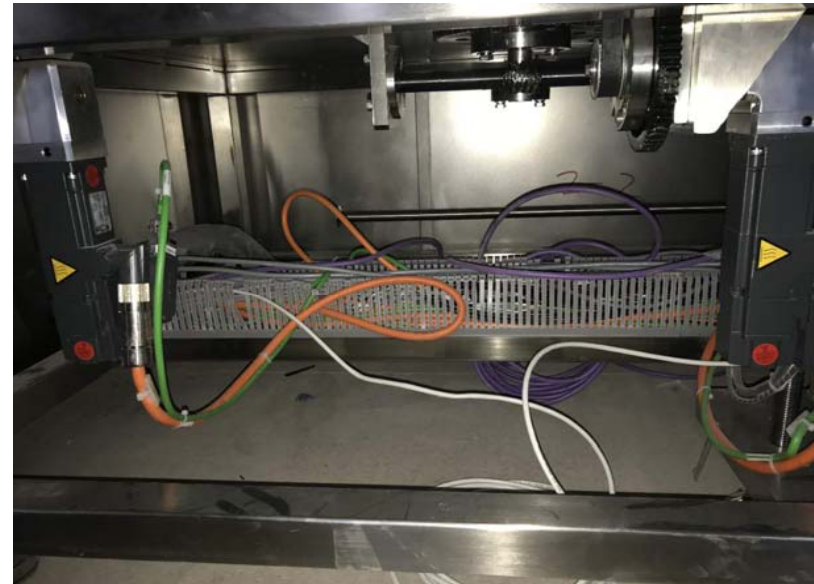
All servo control and direct drive to ensure stability.

Easy for maintenance and avoid cross contamination

Share using of servo to two infeed screws and stoppering output and rejection star-wheels with multi-chains to drive makes more abrasion and malfunctions. (5servo motors in total)



VS



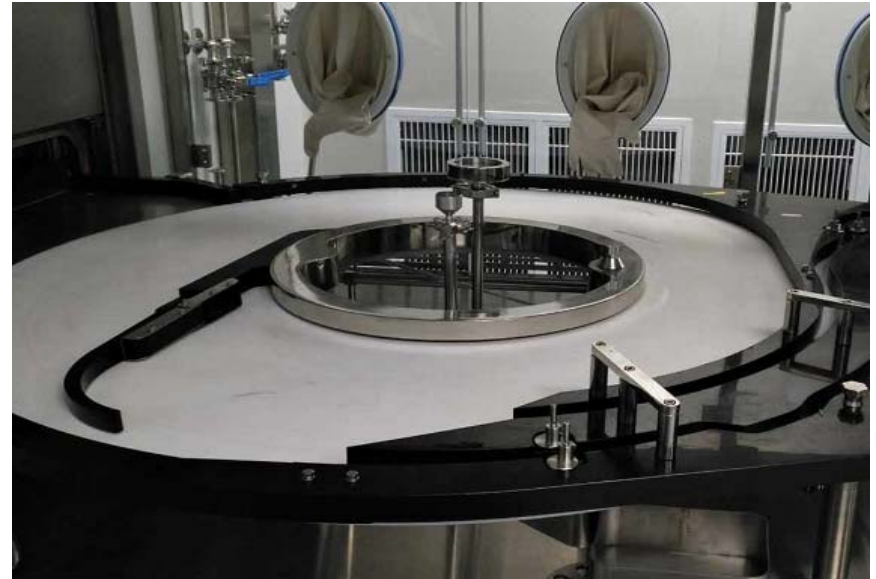
Robotic filling & stoppering machine: stability

Conveyor belt: multi channel for bottle infeed, small friction with the belt. After the bottle in position, the belt will stop and reduce the risk of contamination.



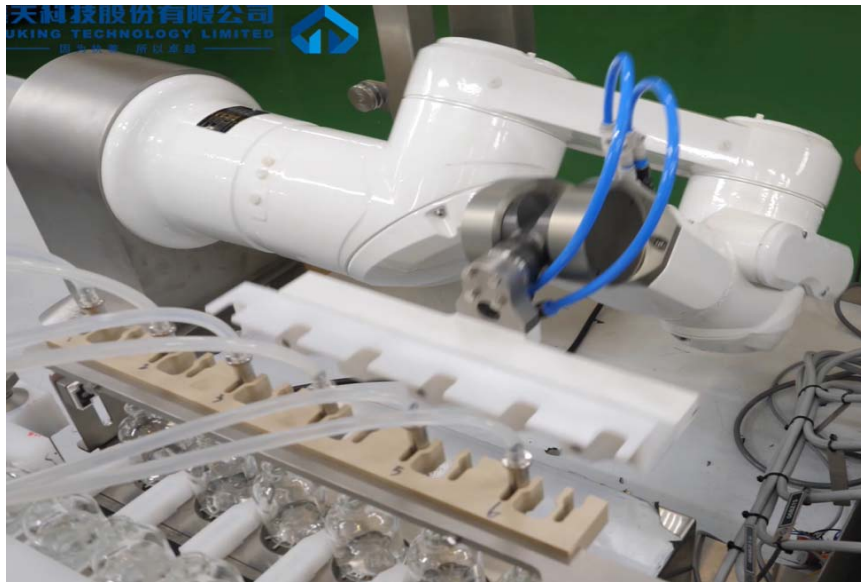
VS

Turntable: made by aluminum alloy and covered by Stainless steel. The material is easy to be corroded by VHP, and table easy to be deformed.



Robotic filling & stoppering machine: stability

In-feed, filling area both adopt robot arm. Simple structure with high level sterile guarantee. Largely reduce the risk in the core area.



Star wheel and screw conveyor for infeed, single line in-feed, bigger risk of friction and bottle broken, risk of contamination for the core area.



VS

Robotic filling & stoppering machine: stability

Filling system: FLEXICON PD12 Peristaltic pump with its' origin MC100 driver to ensure accuracy and stability of filling.



Filling System: Watson-Marlow peristaltic with domestic made driver. Can not ensure filling accuracy and stability.



VS

Robotic filling & stoppering machine: stability

Bottom rail: made by UPE, with better performance of wear proof. Installation of star-wheels based on same reference to ensure stability of vial delivery



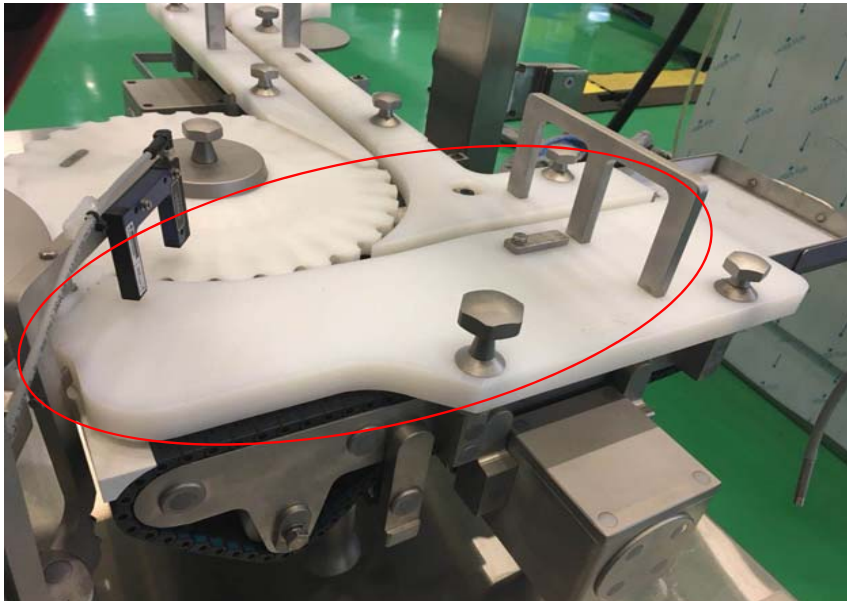
Bottom rail: Star-wheels are installed based on different references. Vials are easy to be stuck and broken



VS

Robotic filling & stoppering machine: stability

Sampling/rejection: Star-wheel and belt cooperation to avoid stuck of vials.



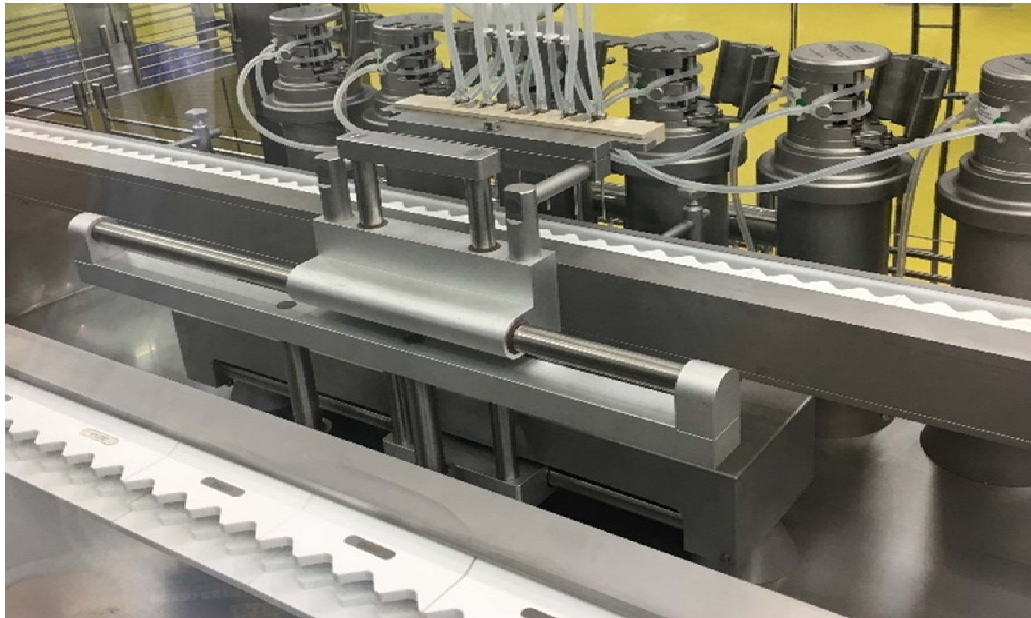
VS

Sampling/rejection: Star-wheel and fixed bottom rail cooperation, vial is easy to be stuck and broken.



Robotic filling & stoppering machine: stability

Filling tracing: Double guide rods for filling up/down unit to minimize the shaking of filling frame.



Filling tracing: Single guide rod will increase the shaking of filling frame.

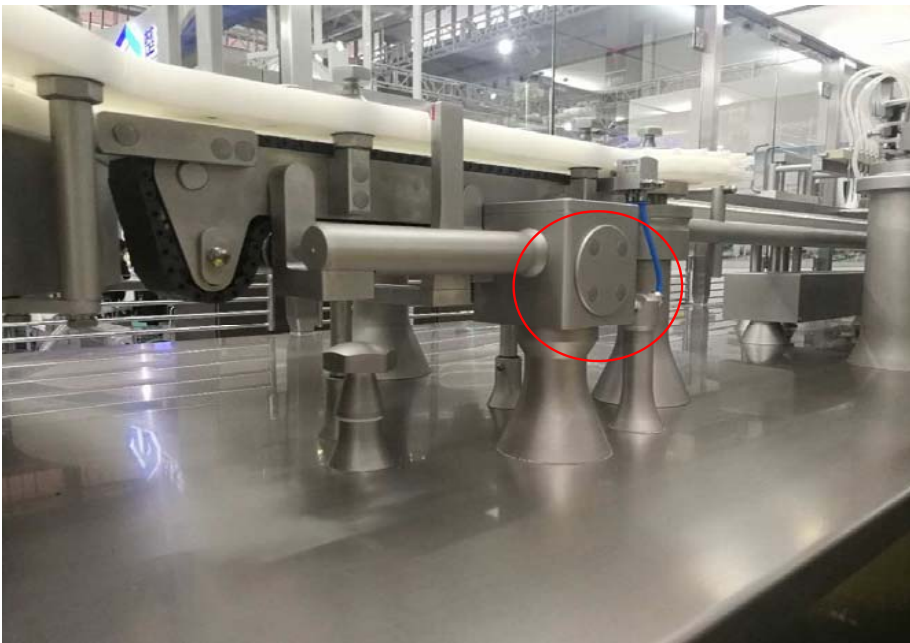


VS

Robotic filling & stoppering machine: risk control

Chamfer head screws be used at necessary place to avoid cleaning dead space.

Using of normal screws will create cleaning dead space.

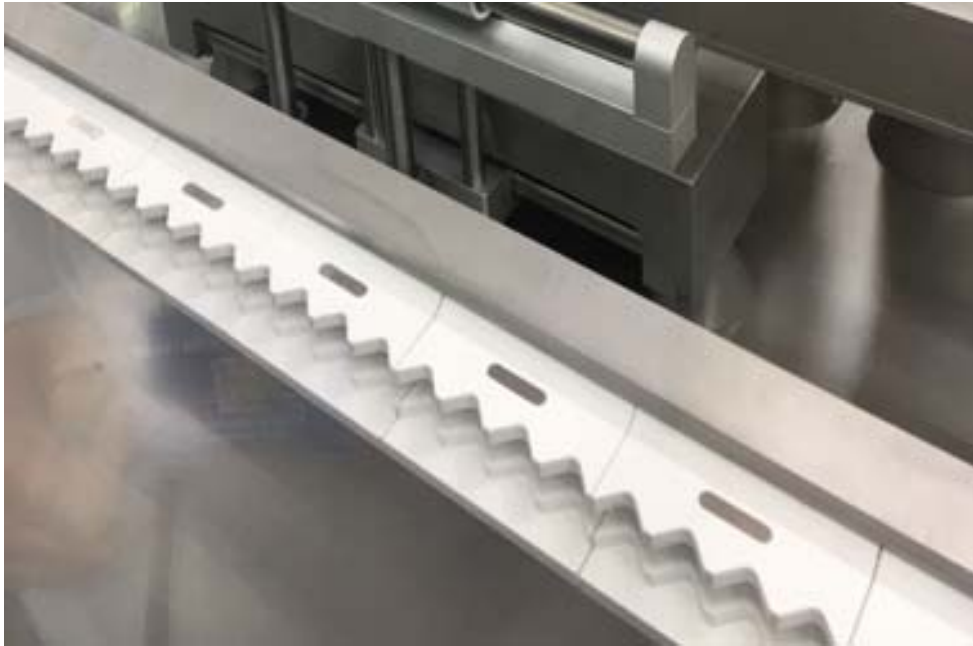


VS



Robotic filling & stoppering machine: Easy changover

Conveyor: V-shaped block design for applicability from 2-50ml.



Circular shaped blocks have to be replaced all when change over.



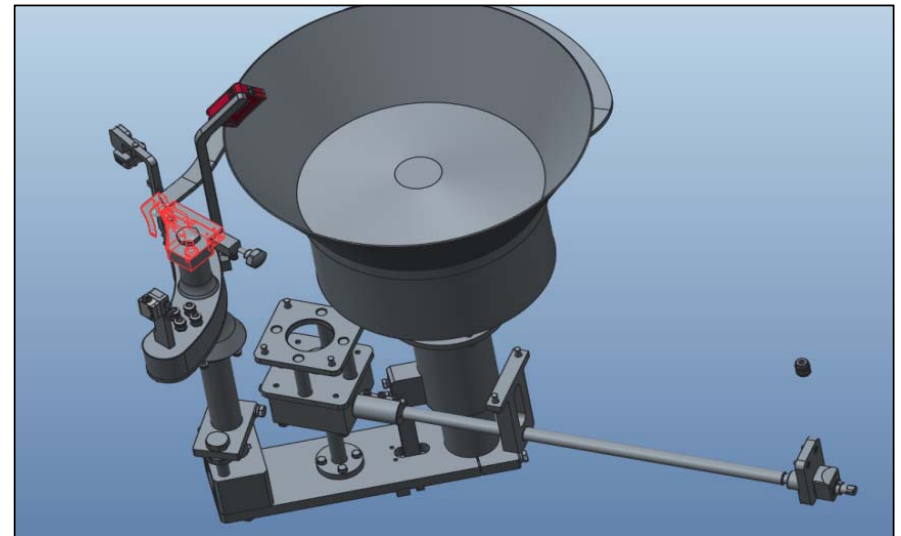
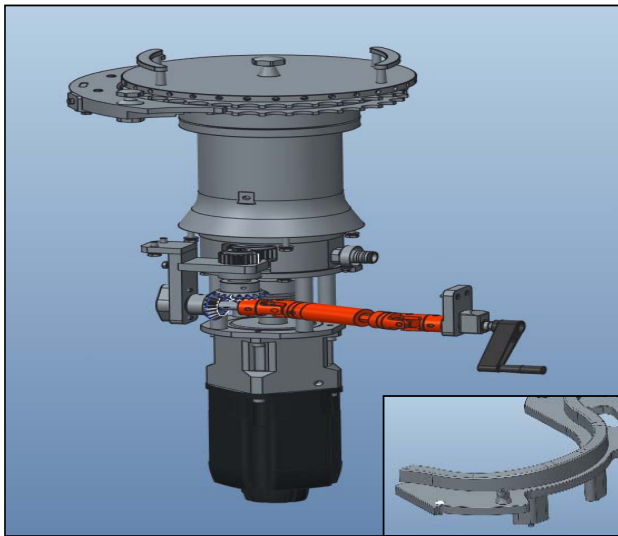
VS

Robotic filling & stoppering machine: Easy change over



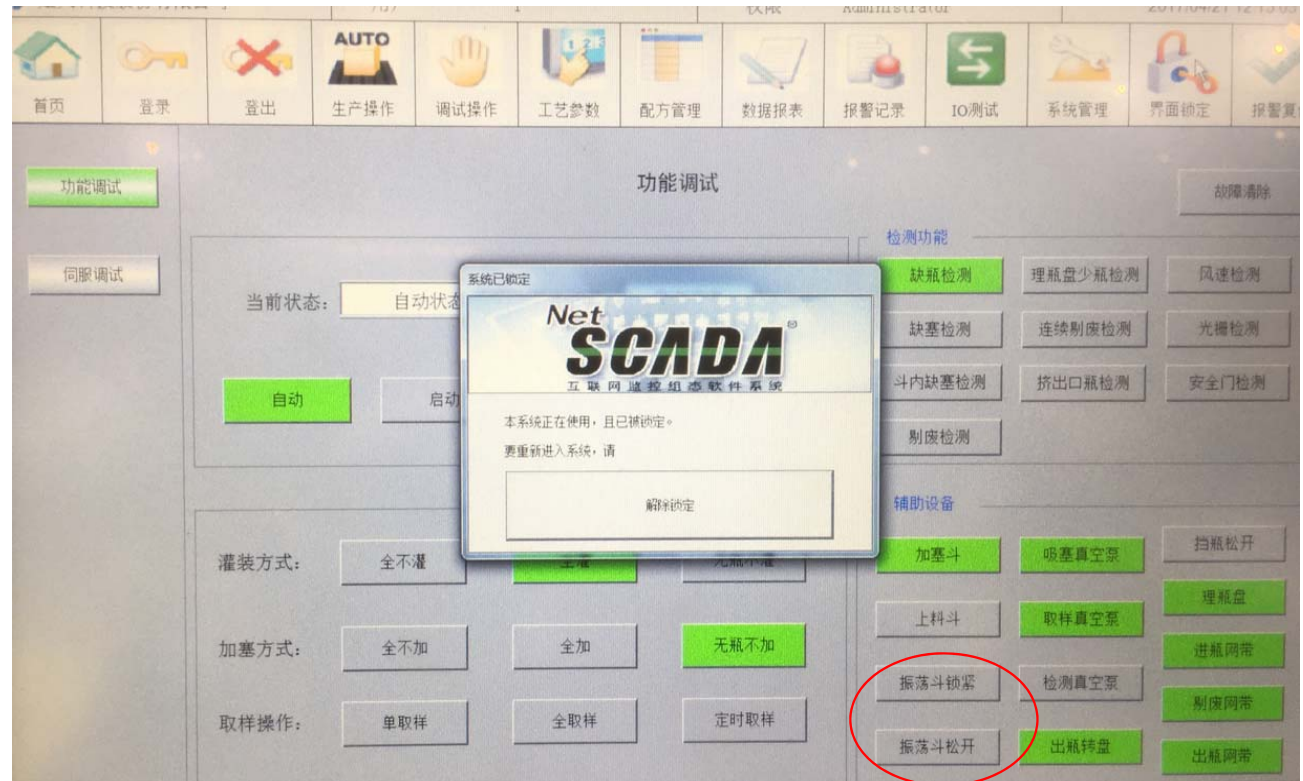
Improvement of stoppering structure:

- Height adjustment of suction plate is visible via a displayer.
- Flexible design of bottom rail to increase performance of stoppering.
- Integrated design of stopper hopper and infeed rail for easy change over and adjustment.



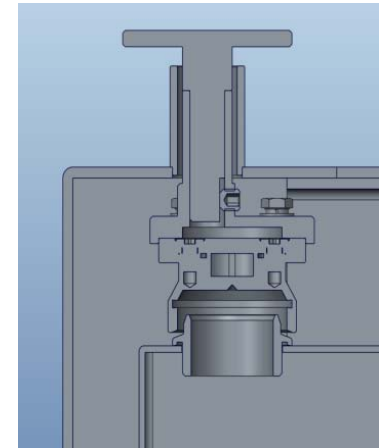
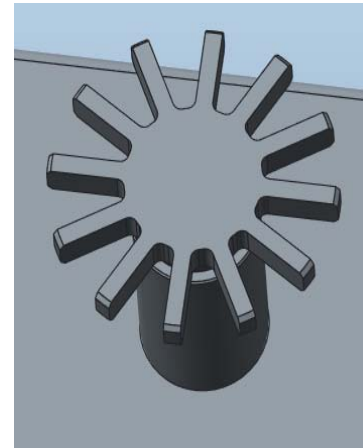
Robotic filling & stoppering machine: easy change over

The lock and release of vibration hopper are controlled via HMI



Robotic filling & stoppering machine: data integrity

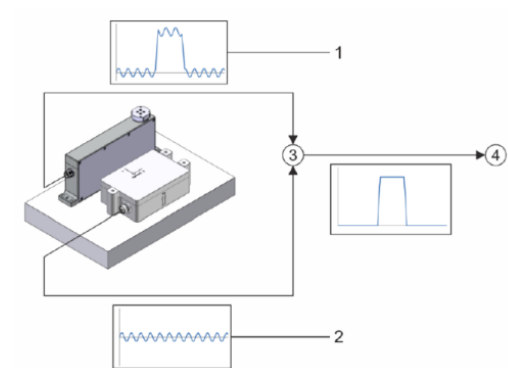
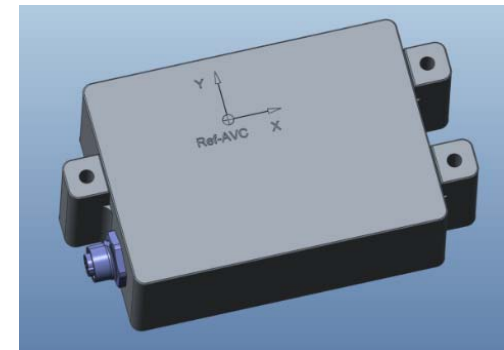
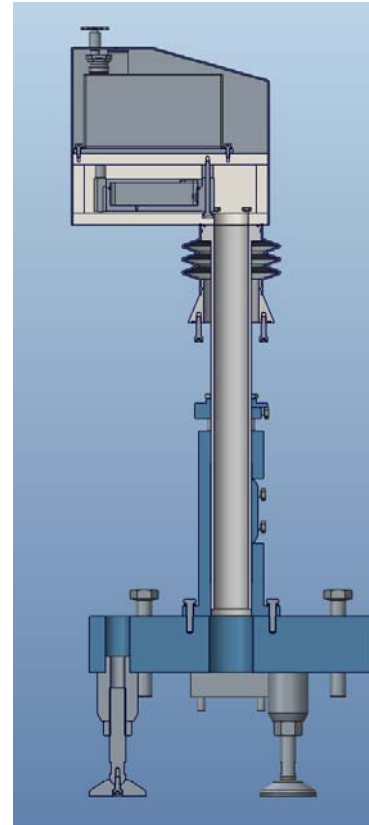
Online weighing system: TruKing has much more experience of online weighing system and improved it with Romaco team. The influence of static electricity, LAF and vibration have been minimized.



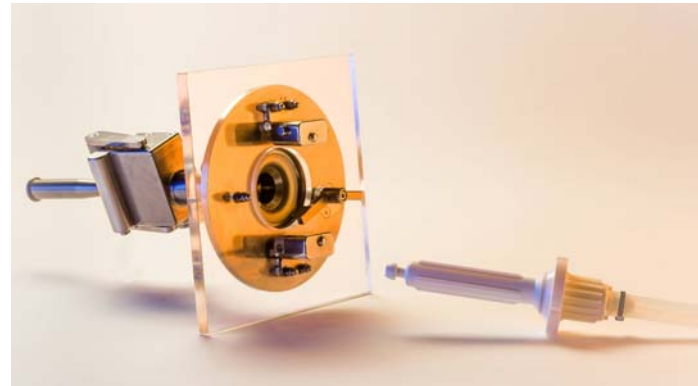
Robotic filling & stoppering machine: data integrity

The influence of vibration to weighing system be avoid by:

- Individual designed support section
- AVC sensor (Optional)



Sterile transfer in isolator

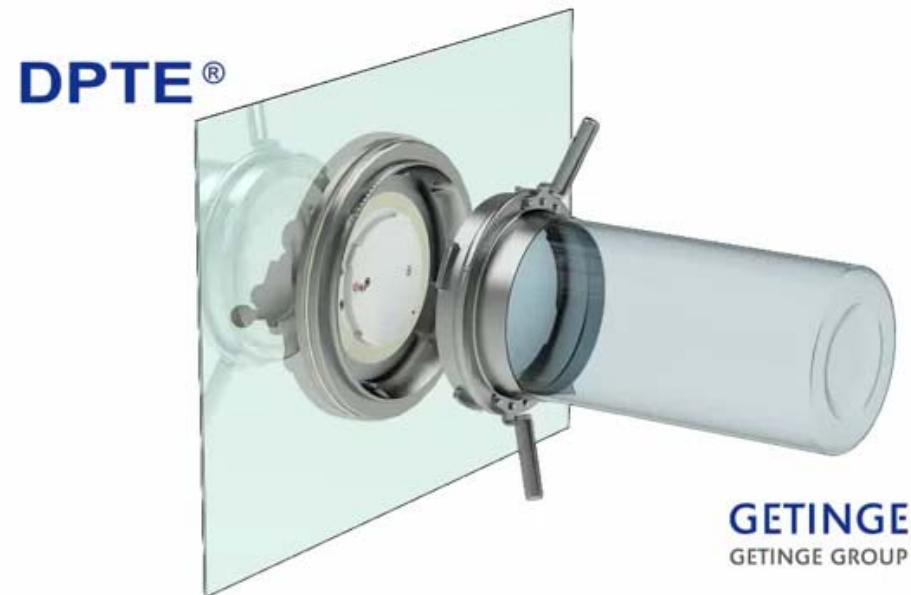


因为执着 所以卓越

We strive to achieve excellence through persistence

Sterile transfer in Isolator

- With RTP system to achieve sterile transfer for the isolating system.
- For stopper, cap, environmental monitoring device, tools etc.



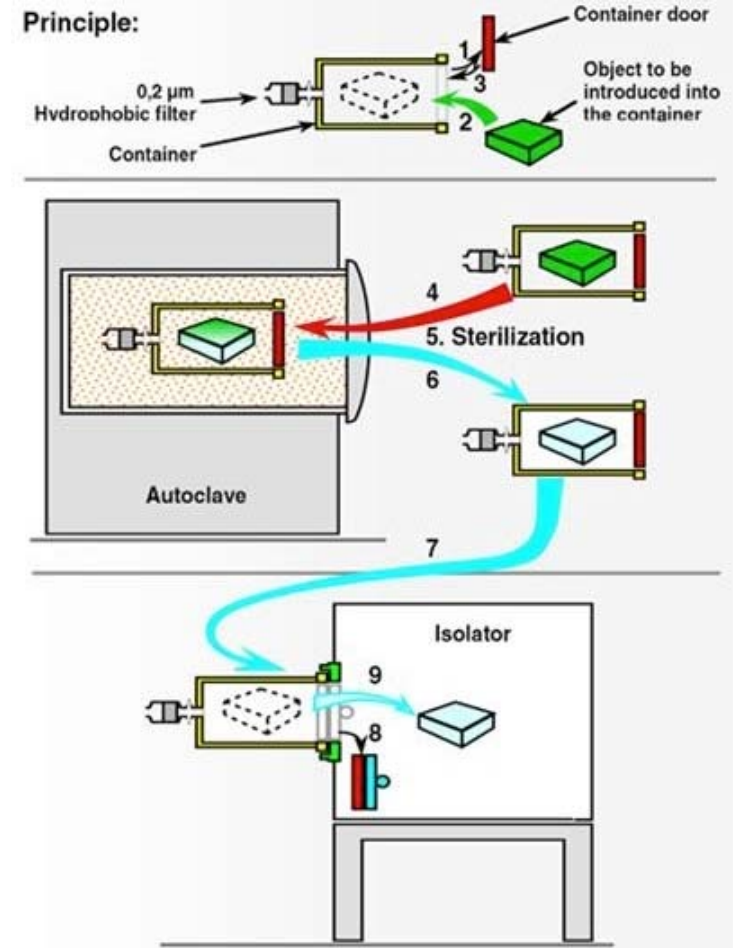
因为执着 所以卓越

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Sterile transfer in Isolator



RTP tank



因为执着 所以卓越

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Sterile transfer in Isolator



Sterile transfer for stopper and cap.

Pre-washed stopper or cap after sterilizing can transfer to the isolator via RTP tank

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Sterile transfer in Isolator



Big batch size stopper in-feed by special RTP

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Sterile transfer in Isolator



Single use sterile bag, pre-washed/pre-sterilized

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Sterile transfer in Isolator

DPTE-BetaBag®

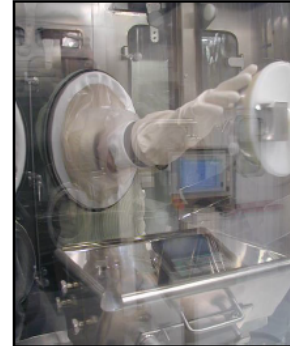
TRANSFER STEPS 使用步骤

GETTING GROUP

1. A sterile DPTE-BetaBag® is connected onto the DPTE® alpha part of the enclosure 连接



2. Operator opens the DPTE® door via glove ports 打开双门



3. Operator unrolls the inner chute of the DPTE-BetaBag® 内部衬袋打开



4. DPTE-BetaBag® is lifted by the operator to unload the bag into the hopper of the machine 将袋子内胶塞倒入胶塞震荡盘



因为执着 所以卓越

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Sterile transfer in Isolator



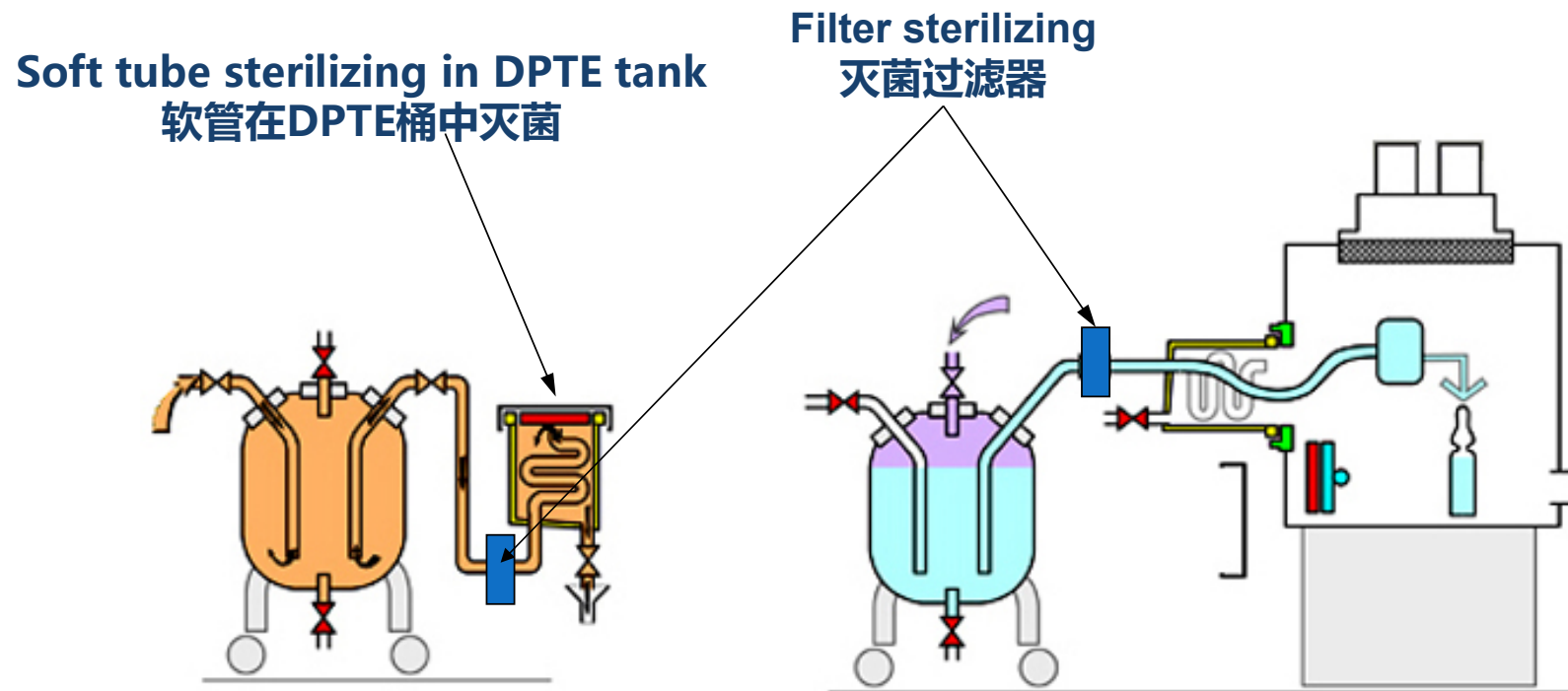
RTP leak detector: integrity test for different size of RTP (pressure decrease method)

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Sterile transfer for solution

DPTE® Used for solution sterile transfer用于药液无菌传输

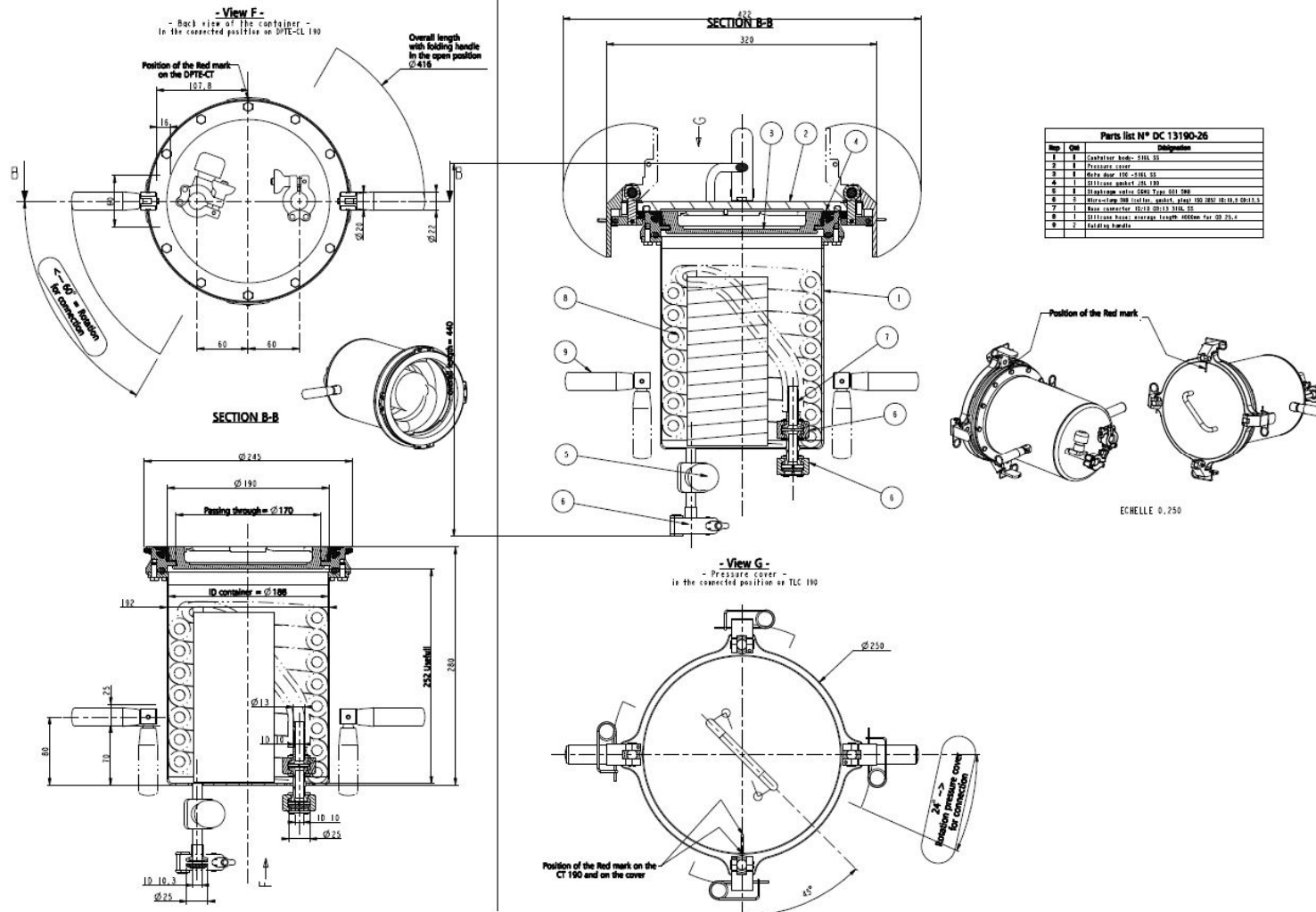


DPTE tank and preparation tank together SIP
桶与配液罐一起SIP

因为执着 所以卓越

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Sterile transfer for solution

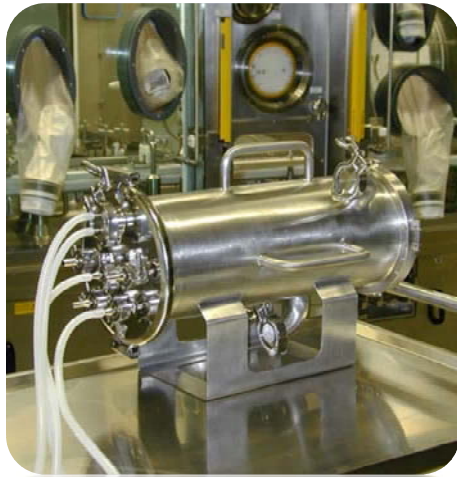


因为执着 所以卓越

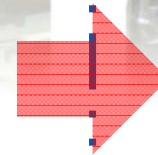
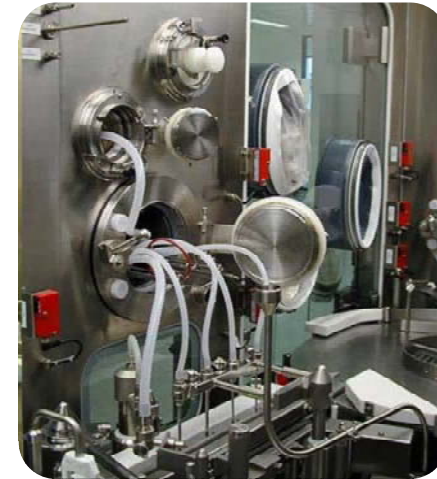
We strive to achieve excellence through persistence

Sterile transfer for solution

DPTE® Beta AUT CT
(View outside isolator)



DPTE® Beta AUT CT
(View Inside isolator)



因为执着 所以卓越

We strive to achieve excellence through persistence

Sterile transfer for solution



- The SART System™ is designed to allow aseptic liquid transfer between two areas with different containment classifications :
- from a clean room into a protected environment (Isolator, Restricted Access Barrier System|RABS).
 - from a Class C/ISO 7 clean room into a class A/ISO 5 clean room

因为执着 所以卓越

We strive to achieve excellence through persistence

Sterile transfer for solution



Sartorius: SART system for sterile transfer

因为执着 所以卓越

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Sterile transfer for solution



Hard pipe connecting, directly transfer from preparation tank to the buffer tank inside isolator. CIP/SIP with the preparation system.

Thank you!

