



International OSD Project Finding

外资固体制剂项目经验简析



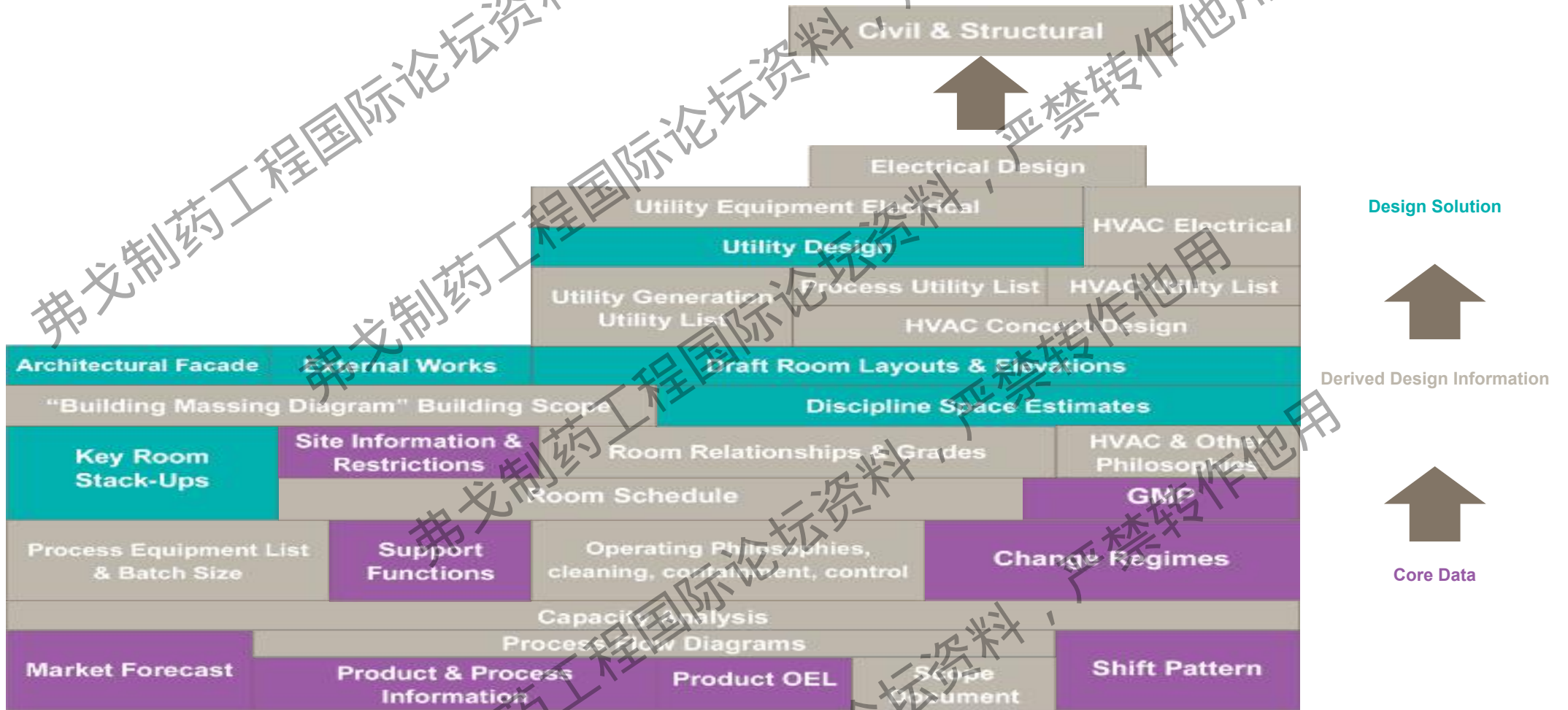
design.

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Design Execution Approach

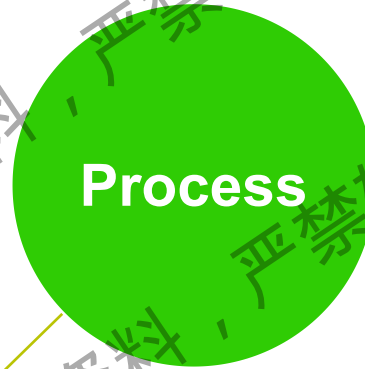


Design Execution Approach

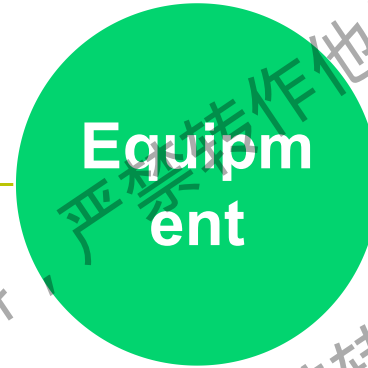


Key Delivery of Process Design

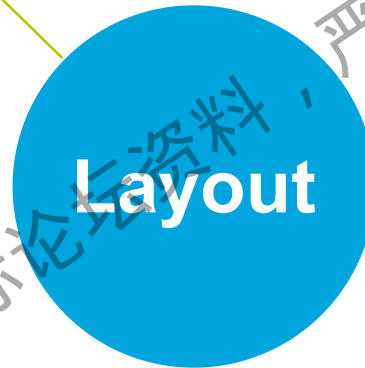
REDUCE
THE
COST



- **Quality + Production**



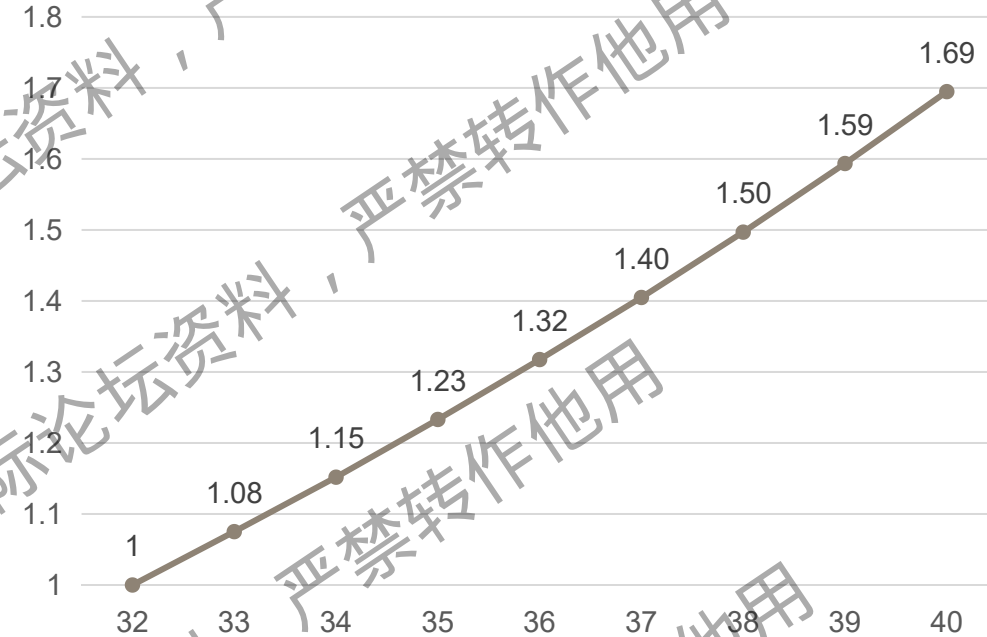
- **Quality + Cost**



- **Operation**
- **Maintenance**
- **Cleanable**
- **Safety**

Coater AHU

Air Properties	CDB, RH (Coater)	CDB, RH (Environment)	CDB, RH (Environment)
°CDB	10.0	32.0	36.0
°CWB	10.0	29.0	32.8
g/kg	7.7	24.4	30.8
RH	100%	80%	80%
Pressure (kPa)	101.3	101.3	101.3
Dewpoint (°C)	10.0	28.1	32.0
Enthalpy (kJ/kg)	29.3	94.5	115.2



1. 32° C @ 80% RH was used in design which referred from HVAC design. In this case there may be approx. 50h (extremely weather condition) every year which can't be cover.
2. In coater URS, it should be confirmed with end user do we need to add any margin in or not?
3. Such as 36° C @ 80% may cause 32% capacity more add on coater AHU.

Case Study - Post Hoist Vs Walkie Stacker

Expensive	Cheaper
Difficult to move and dock	Operation friendly
Heavy for entire floor	Partly reinforced
Safety issue – battery charging	No such issue
No interlock with SBV	Interlock with SBV – much safer



Case Study - Maintenance Clean Accessible



1. The air distributor in clean stair is too high which not easy for maintenance
2. Maintenance platform on press top
3. Coater mechanical space need light
4. DFB maintenance space in tech area



Case Analysis – Cleanable Design

Equipment cleaning

- Dead corner - Beam
- Gap between wall
- Dead corner - Beam



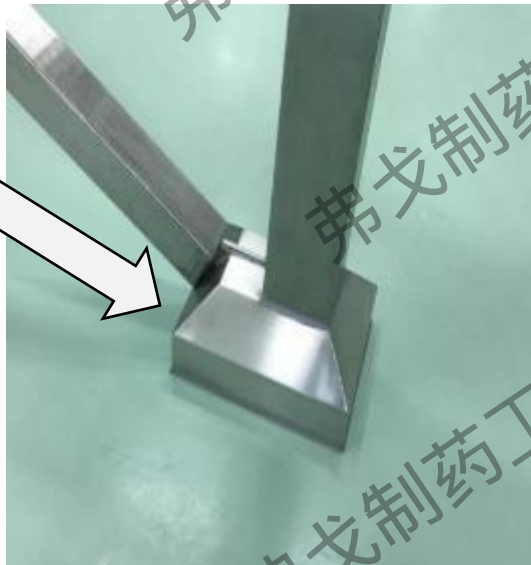
Article 71. Manufacturing equipment should be **designed**, selected, **installed**, reconstructed and maintained to suit its intended purpose, and maximally prevent from the risk of contamination, cross-contamination, confusion and errors; also should be easily operated, **cleaned**, maintained and permitted disinfection and sterilization when necessary.

Case Analysis – Cleanable Design

Beam Sealed by partition



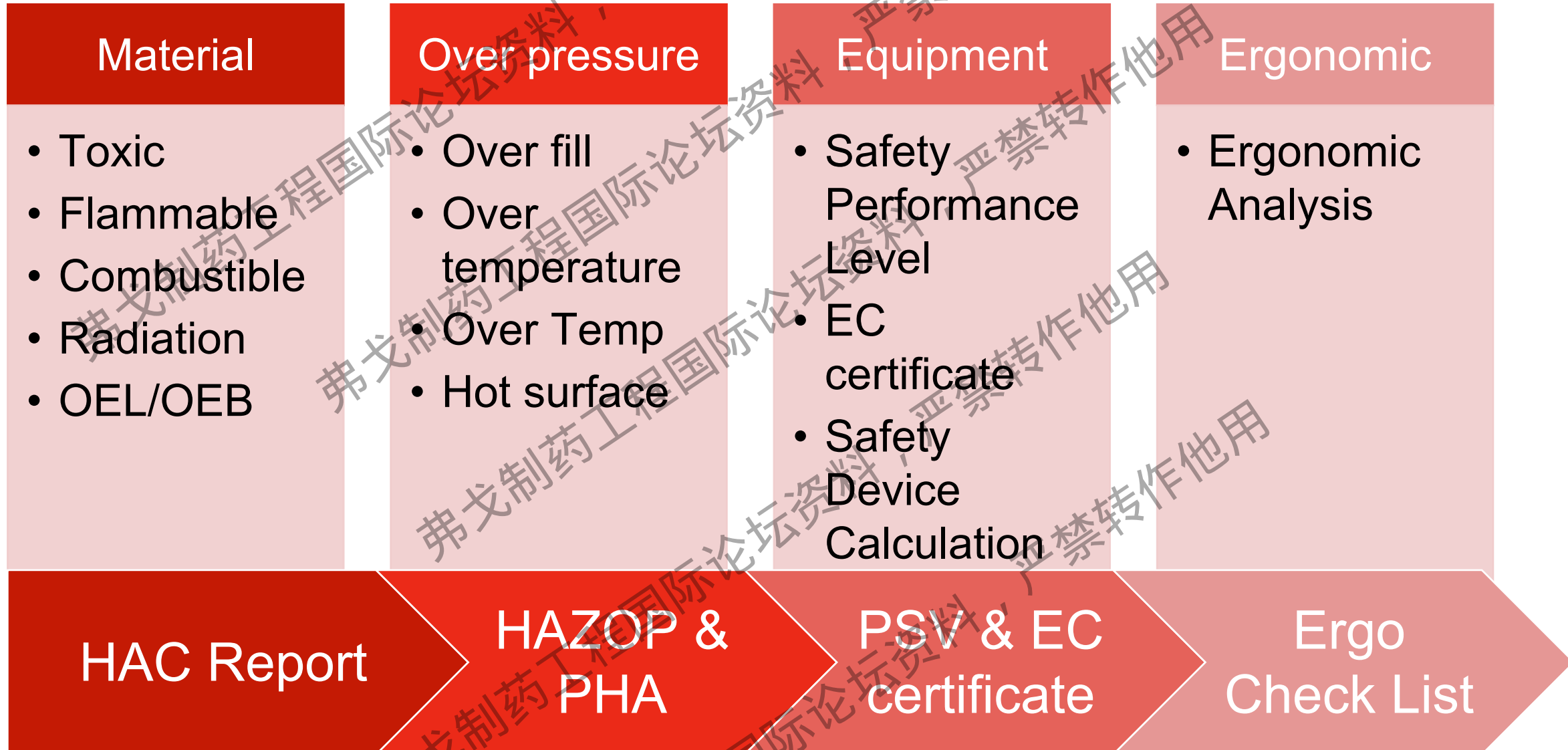
Well sealed foot



Column Sealed by partition



More Focus on Safety



Coater & Suspension Tank

1. Anti-falling Design

- Gravity center (Empty & Full)
- Ergonomics (handler height, force to push)
- Angle of hand rail
- Proper Calculation

抗倾覆受力分析说明如下:

配液罐空载与满载时的重心位置如上图所示 (通过三维建模分析所得)。

$$T_{\text{抗倾覆力矩}} = G \times L + F_{\text{推}} \times h \quad (F_{\text{推}} \text{取} 300\text{N})$$

$$T_{\text{倾覆力矩}} = F_{\text{阻}} \times H \quad (F_{\text{阻}} \text{取} 300\text{N})$$

满载: $M=430\text{kg}, L=271\text{mm}$

$$T_{\text{抗倾覆力矩}} = 4300 \times 0.271 + 300 \times 0.711 = 1378.6 \text{ N}\cdot\text{m}$$

$$T_{\text{倾覆力矩}} = 300 \times 1.063 = 318.9 \text{ N}\cdot\text{m}$$

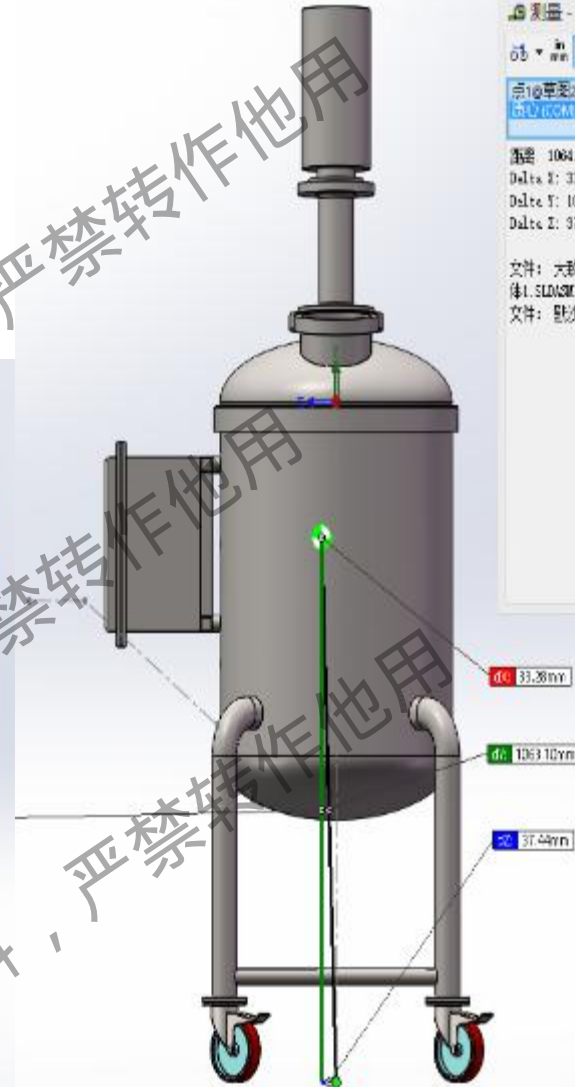
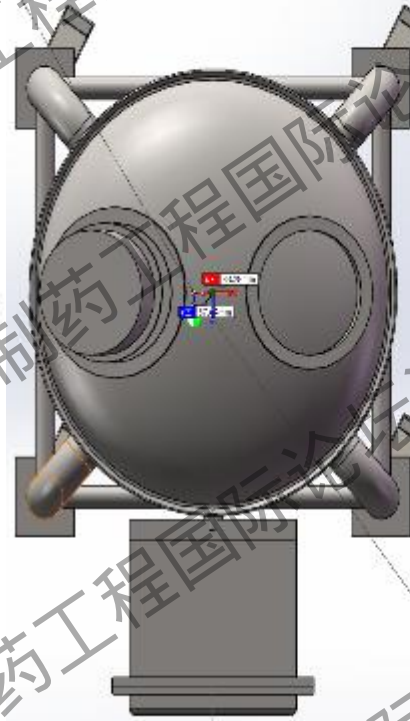
则 $T_{\text{抗倾覆力矩}} > T_{\text{倾覆力矩}}$, 故满载时配液罐不会产生倾覆。

空载: $M=230\text{kg}, L=241\text{mm}$

$$T_{\text{抗倾覆力矩}} = 2300 \times 0.271 + 300 \times 0.711 = 836.6 \text{ N}\cdot\text{m}$$

$$T_{\text{倾覆力矩}} = 300 \times 1.2 = 360 \text{ N}\cdot\text{m}$$

则 $T_{\text{抗倾覆力矩}} > T_{\text{倾覆力矩}}$, 故空载时配液罐不会产生倾覆。



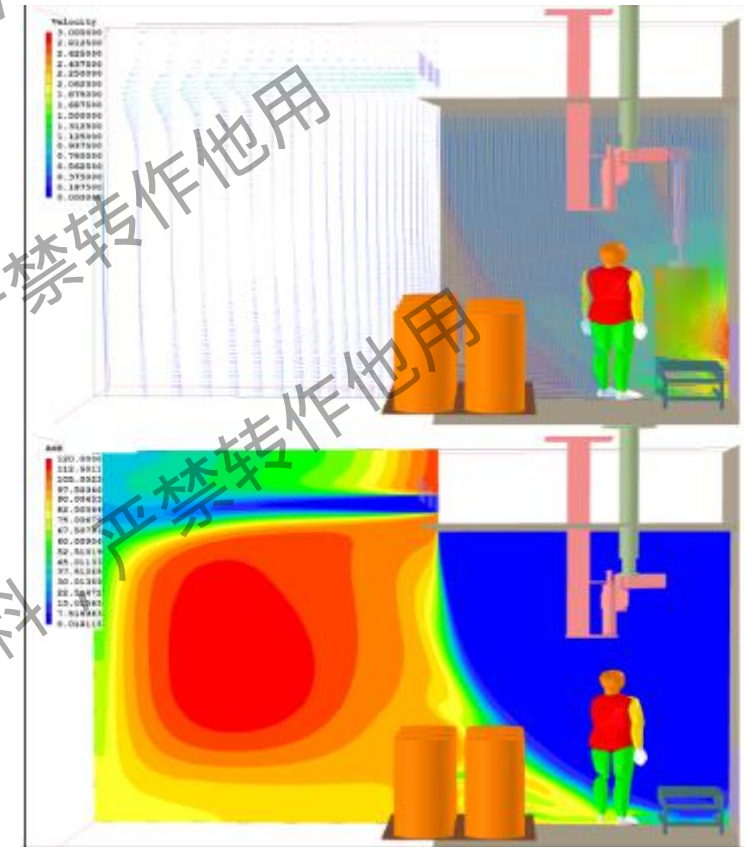
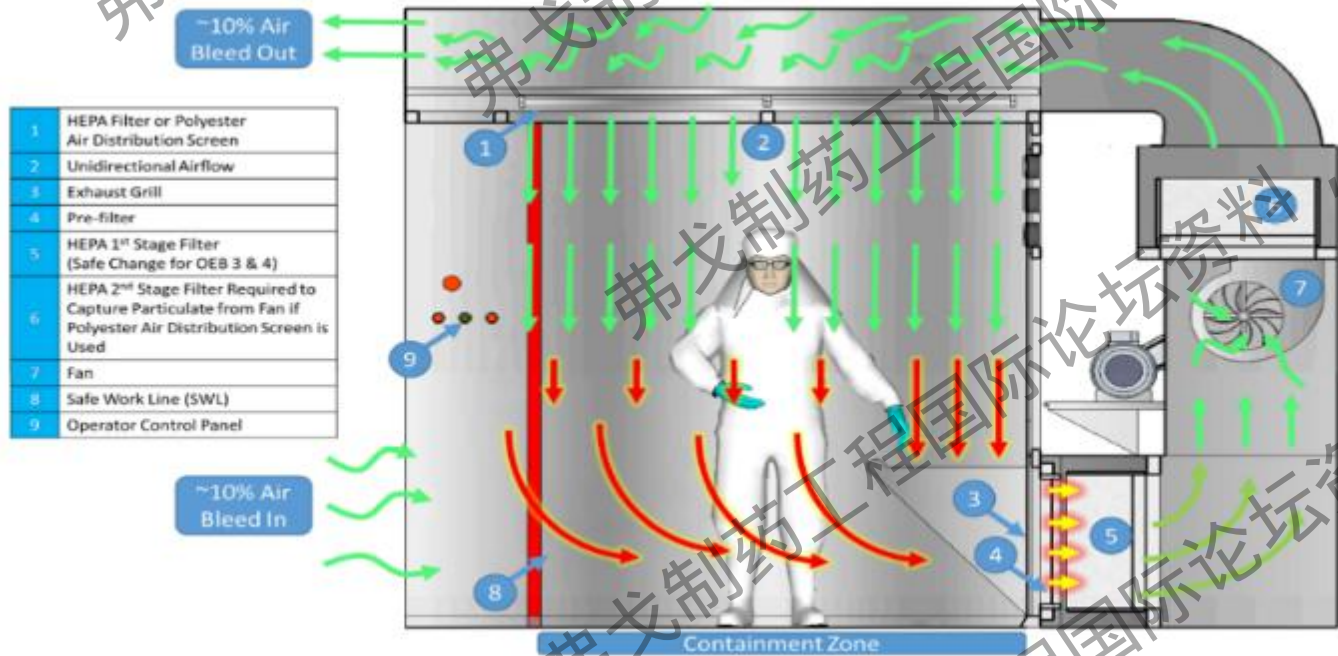
DFB – Dust and Noise Control

Noise

- HEPA filter installed at downstream of fan is preferred
- Sound-proof sponge is only efficacious when installed in the internal surface of duct behind fan
- Need to identify the noise level in FAT, considering ~ 3 dBA increasing when DFB is installed at site.

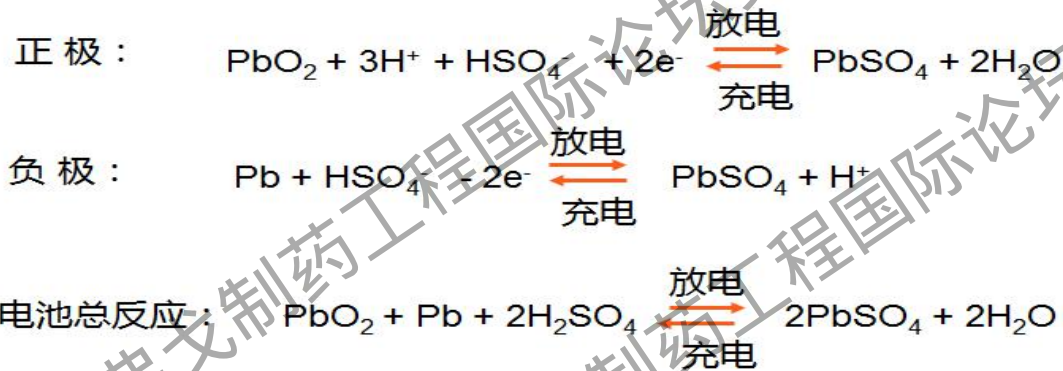
CFD (Computational Fluid Dynamics)

- This report describes a CFD analysis of the proposed ventilation system for a pharmaceutical powder processing down flow booth.



UPS Battery Selection

1. Water proof Vs heating & H2 emission for UPS (lead-acid cell)

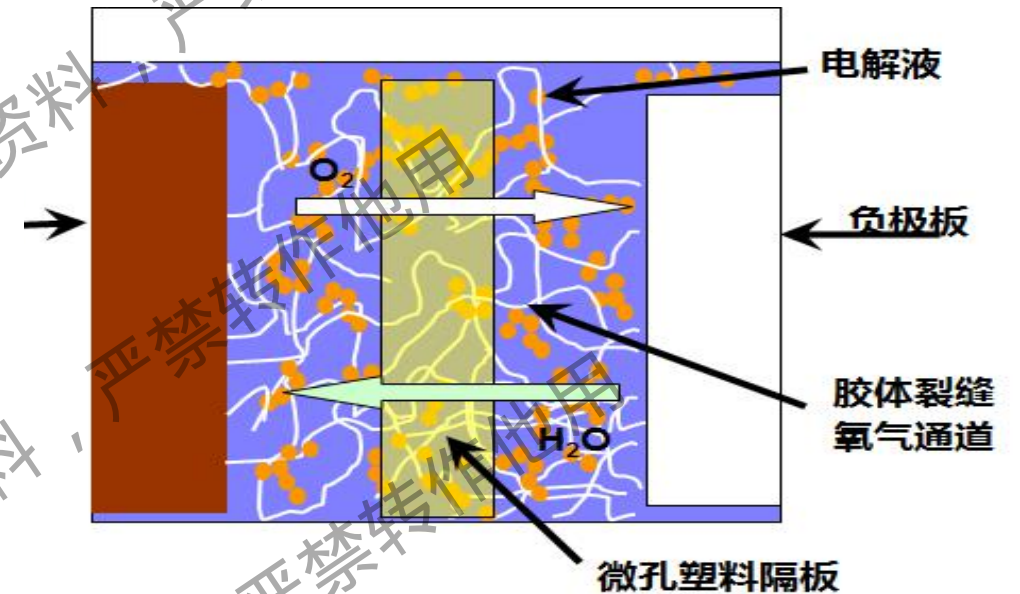


正常情况下，电化学反应的氢和氧会再次复合成水。

如果电池环境突然快速温升，或者发生短路时，电池剧烈放电，里面氢气产生的速度会大于复合成水的速度时，压力快速上升，密封阀会进行压力释放，释放出氢气。

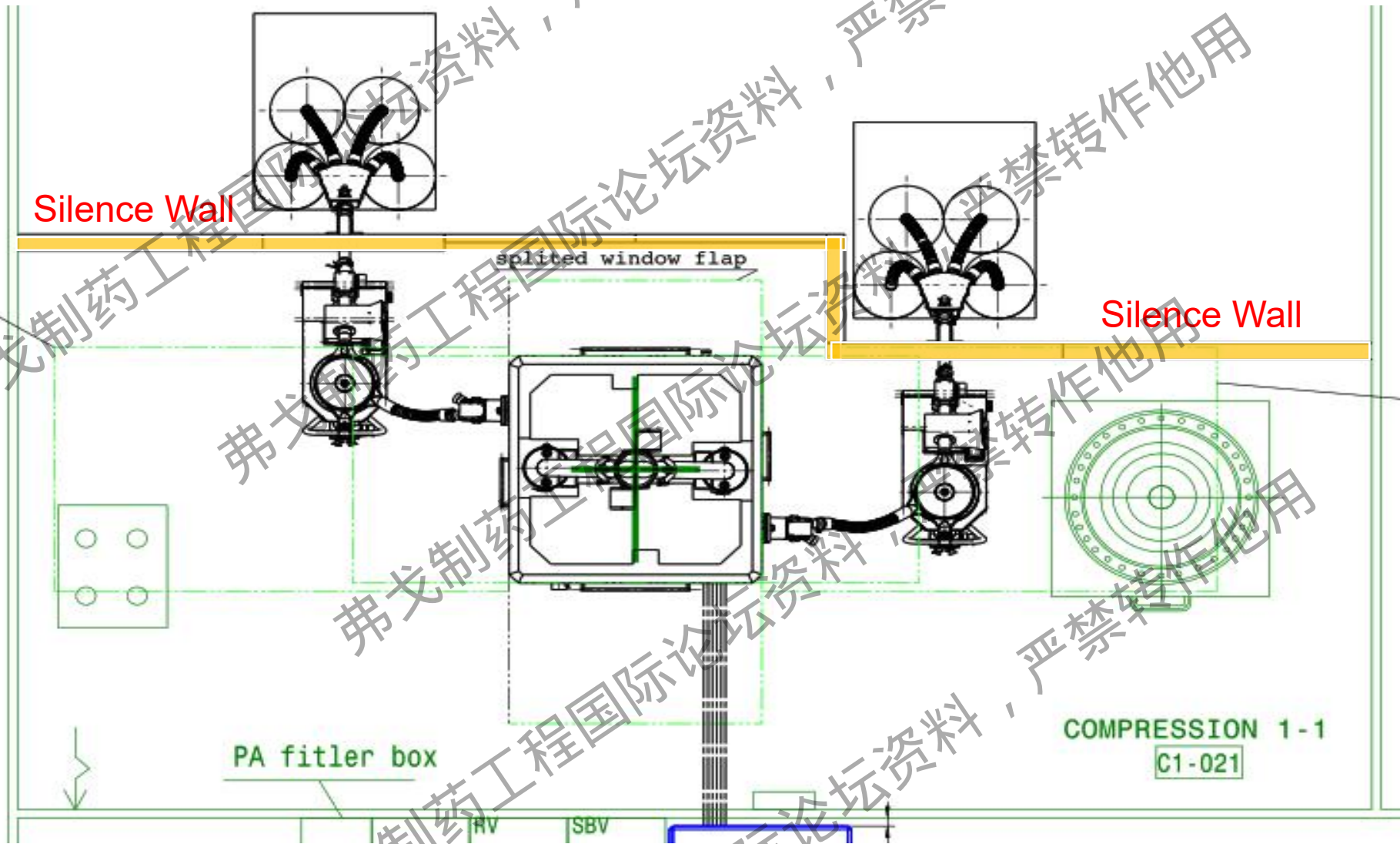
胶体电池稳定性是所有密封电池里最好的，如果不出现特殊情况，是不会大量排出氢气的。

定期开柜通风可以将偶尔溢出的氢气稀释掉



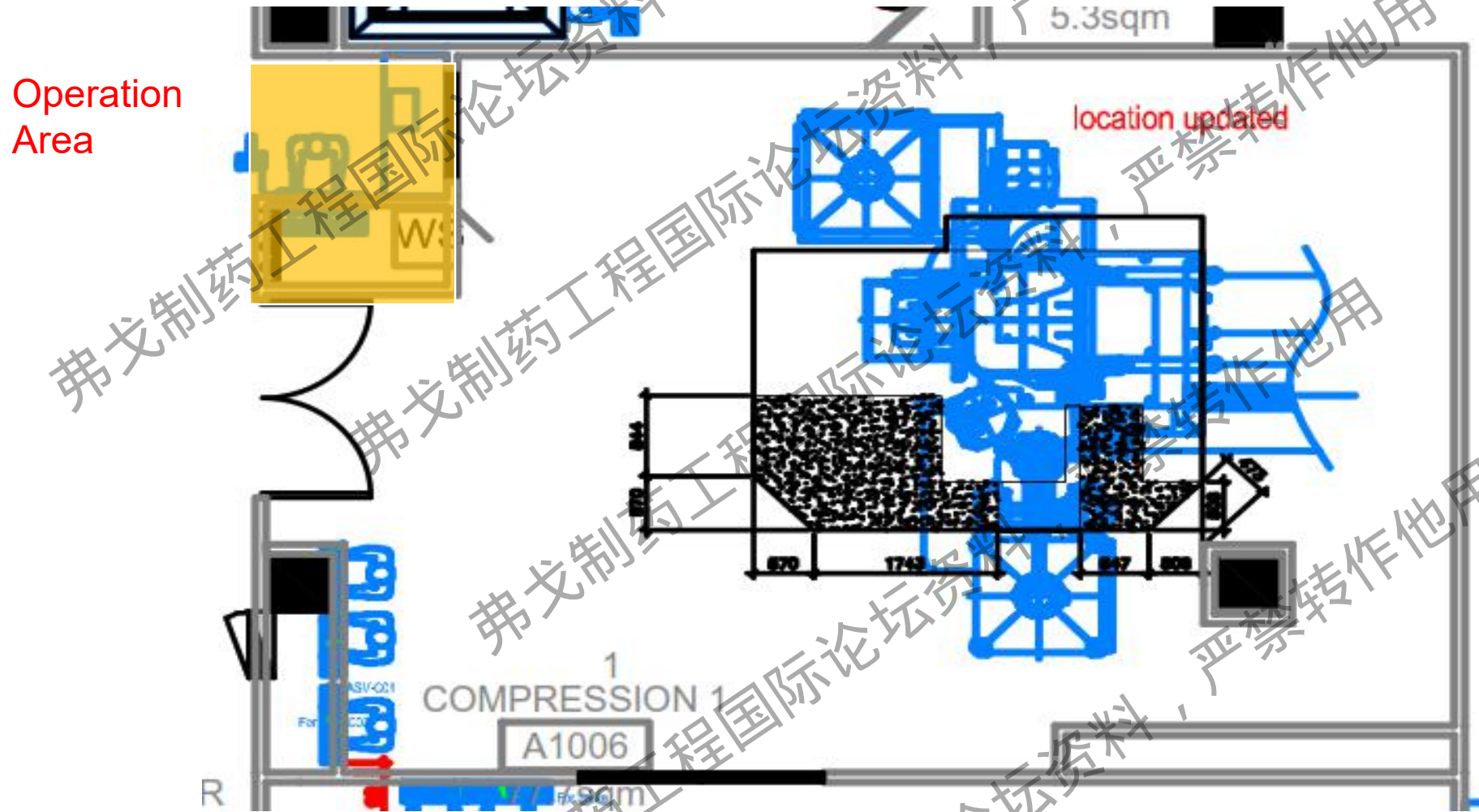
<https://baike.baidu.com/item/%E9%93%85%E9%85%B8%E7%94%B5%E6%B1%A0/7007612?fr=aladdin>

Press – Noise Protect



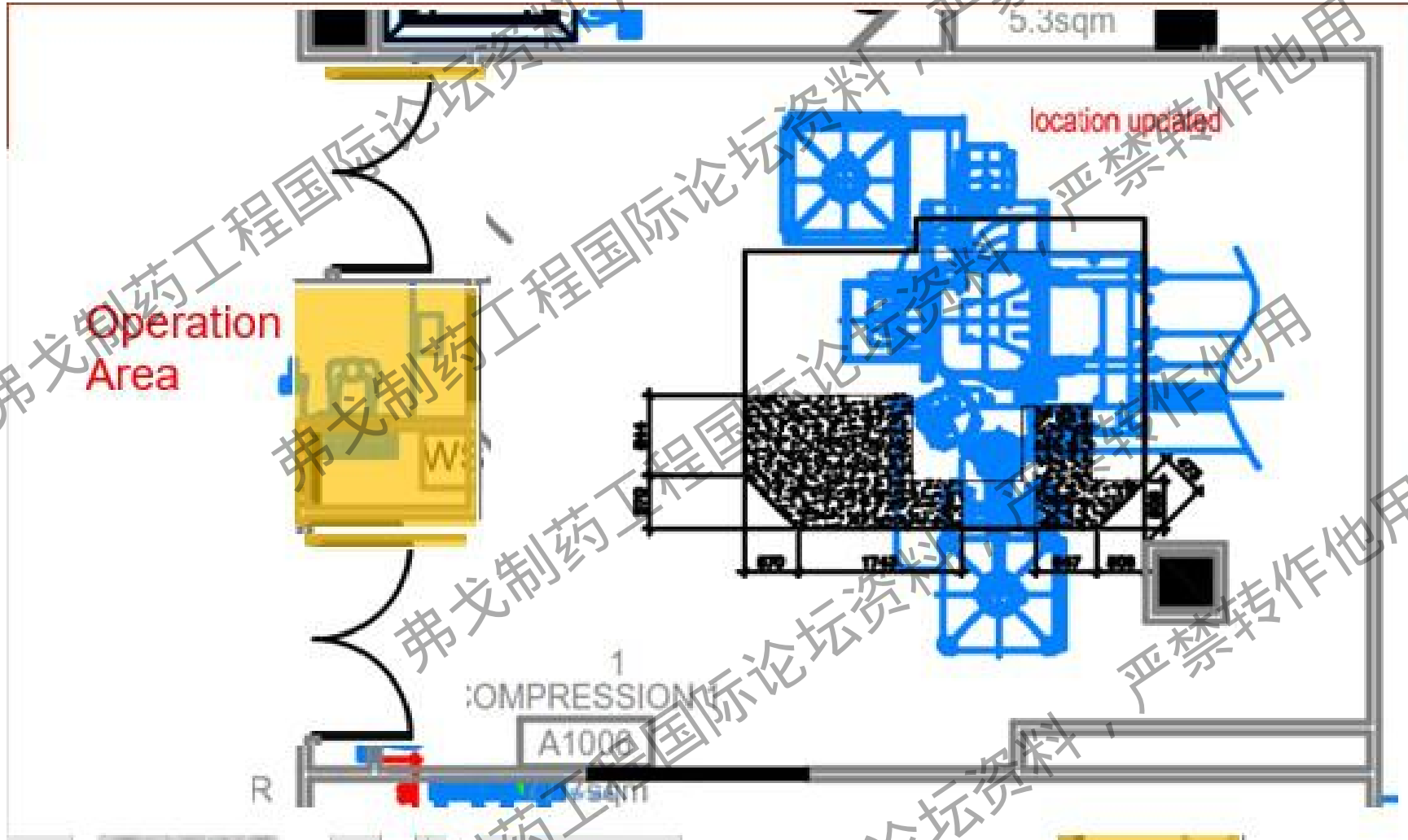
Keep noise in small room by silence wall

Press – Noise Protect



Keep operator away from noise

Press – Noise Protect



Case Analysis - Design

- Clear requirement/condition
- Consider about operation, maintenance, but don't forget cleaning.
- Communication / Design meeting
- Cross Checking is Quite Important
- Don't rely on too much site change
- Remove over design requirement
- Visit and photo good example



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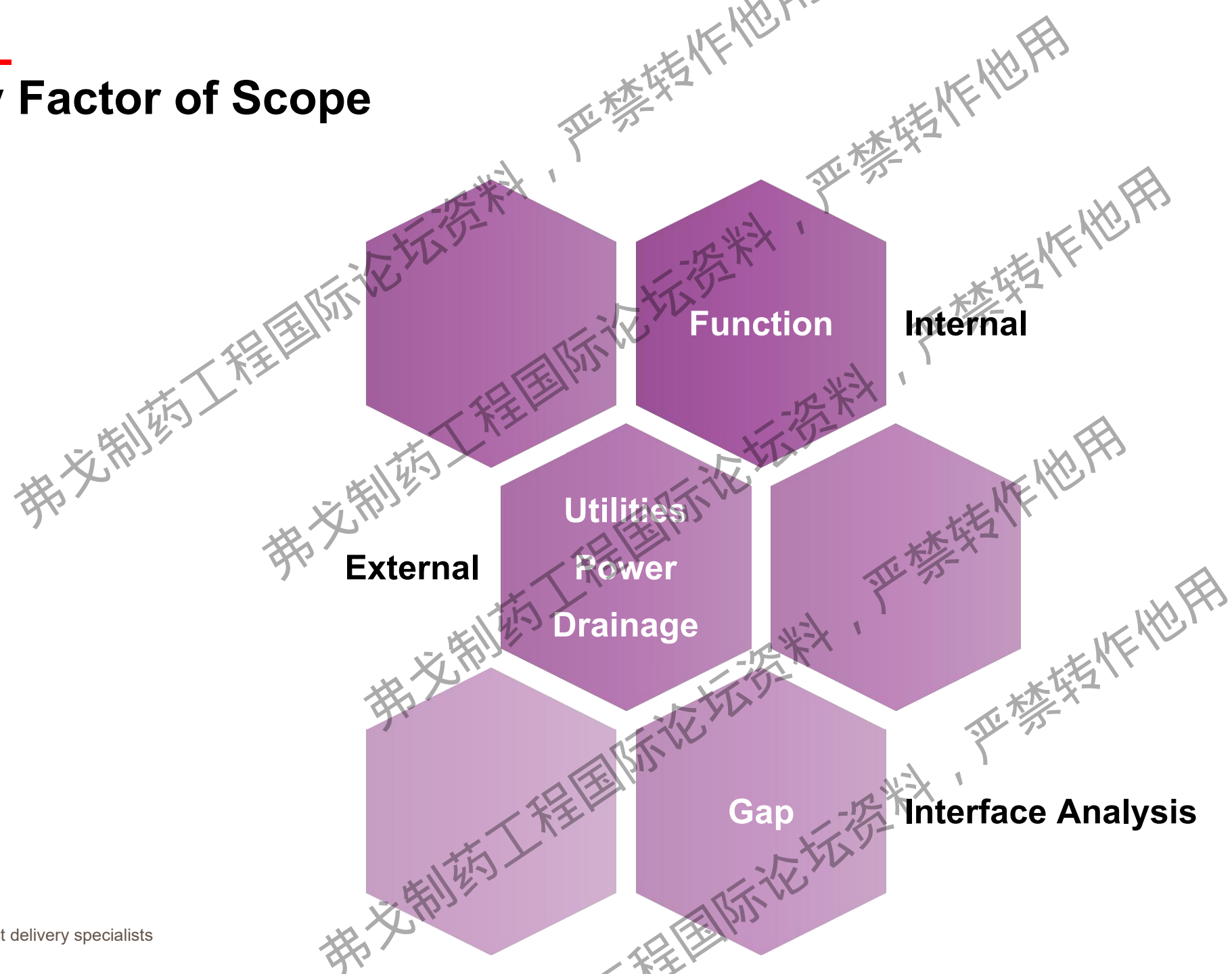
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Procurement

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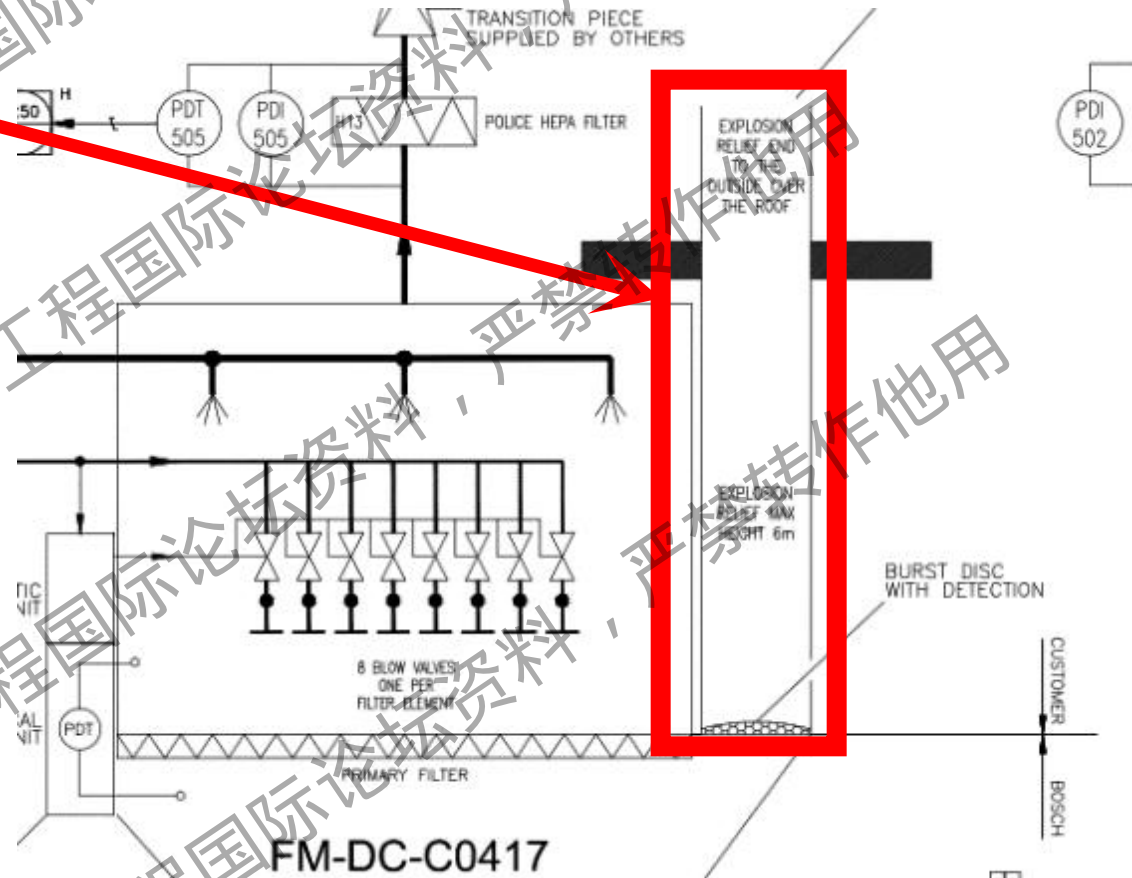
Key Factor of Scope



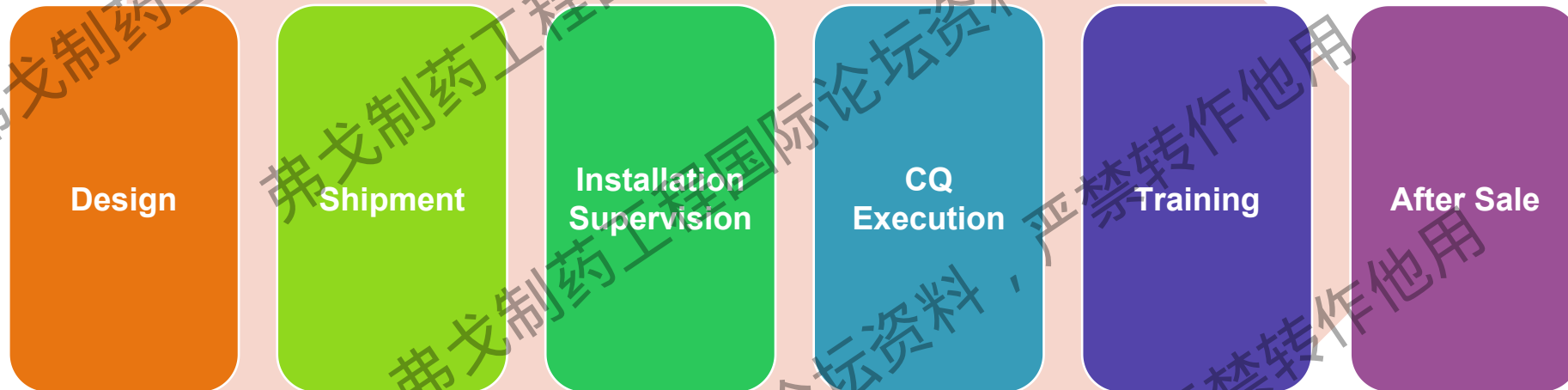
Case Study - Coater



Dust collector explosion vent duct should be a standard component from dust collector supplier.



Key Factor of Service By Vendor



Vendor Management

Items	Local	Foreign	Hybrid
Quality		✓	✓
Price			
Documents	✓	✓	✓
Schedule	✓		
Response			✓
Change order	✓		✓
Reliable		✓	✓
Acceptable		✓	✓

Summary

- ✓ For key equipment Hybrid is preferred
- ✓ Local vendor (Hybrid) must have strong capability of local service or meaningless
- ✓ Local vendor team (Hybrid) should be involved early
- ✓ As 3rd party we have lower bargaining power, raise up to management team to push foreign vendor.
- ✓ Confirm before execution
- ✓ More and more purely local vendor grow up and get stronger

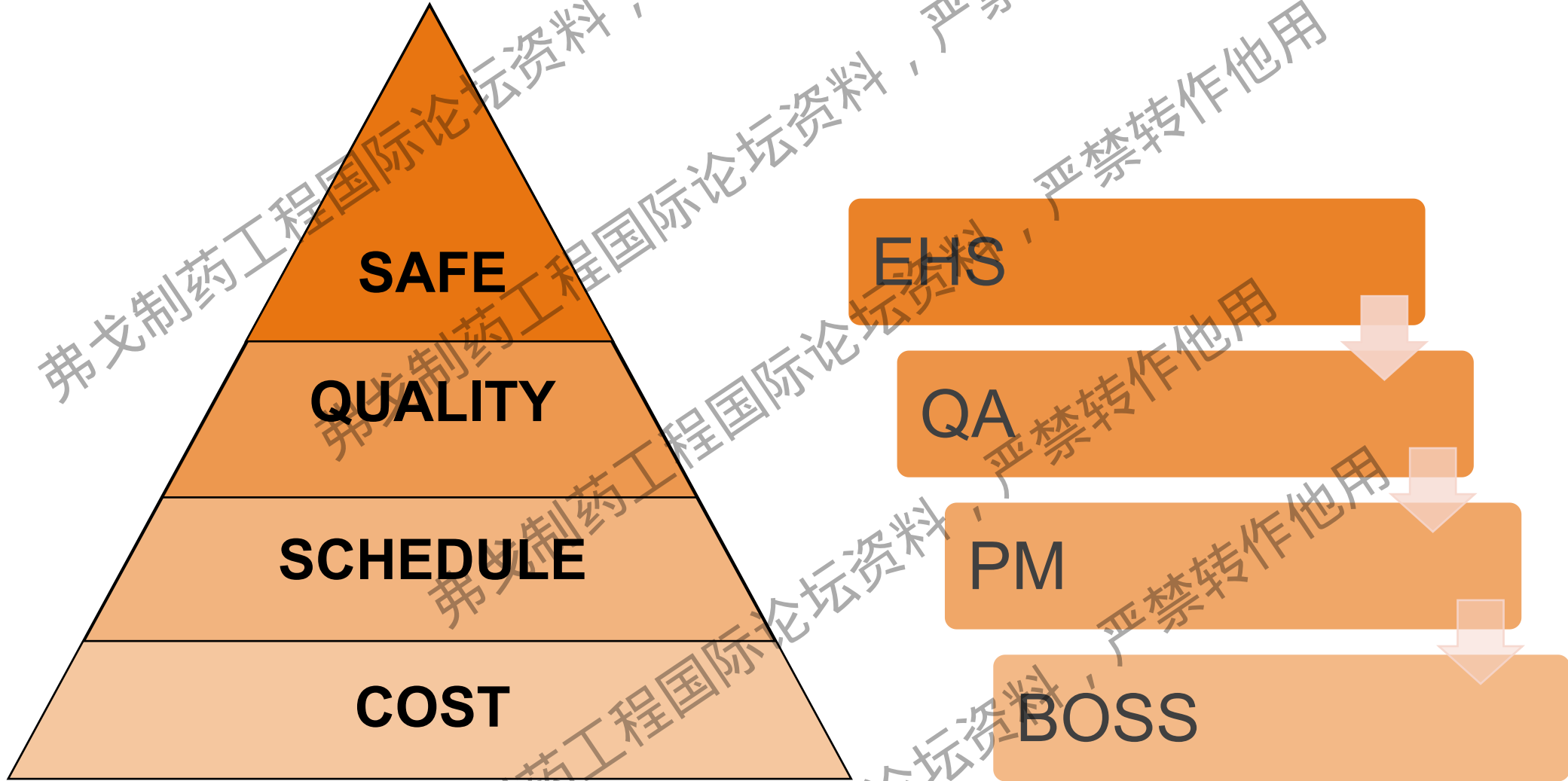




Construction

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Construction Management



SAFETY ALWAYS THE FIRST PRIORITY !!!

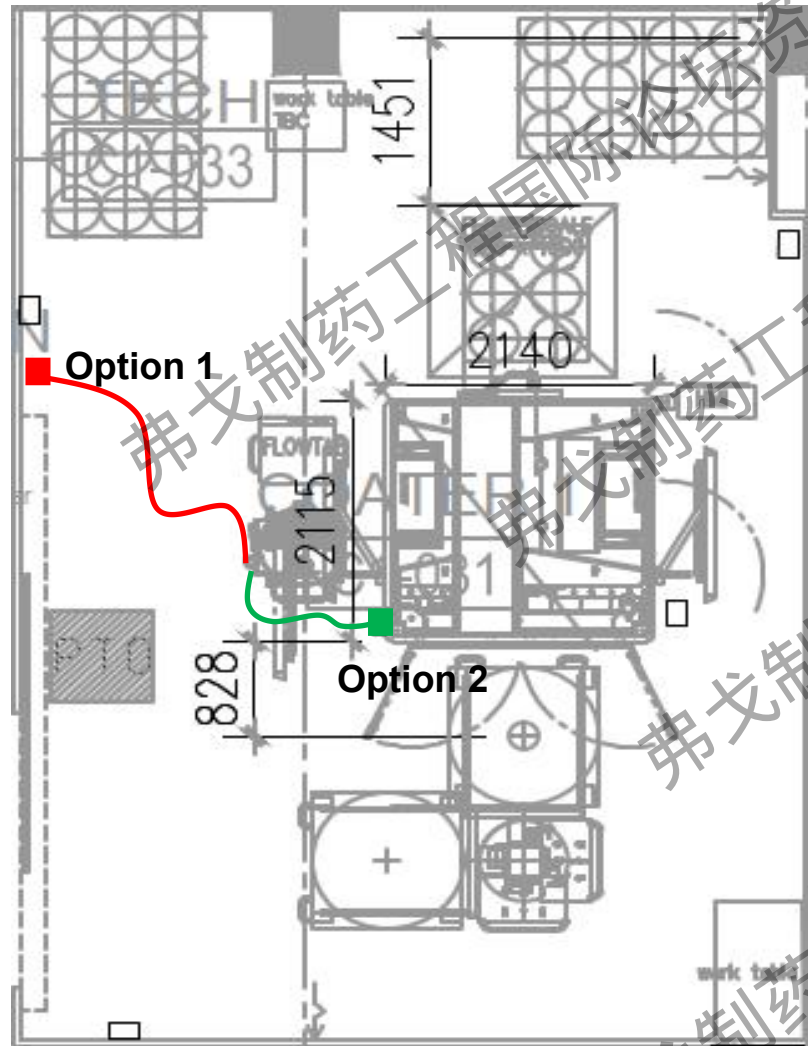
Unsafety Finding From MC Walk Down



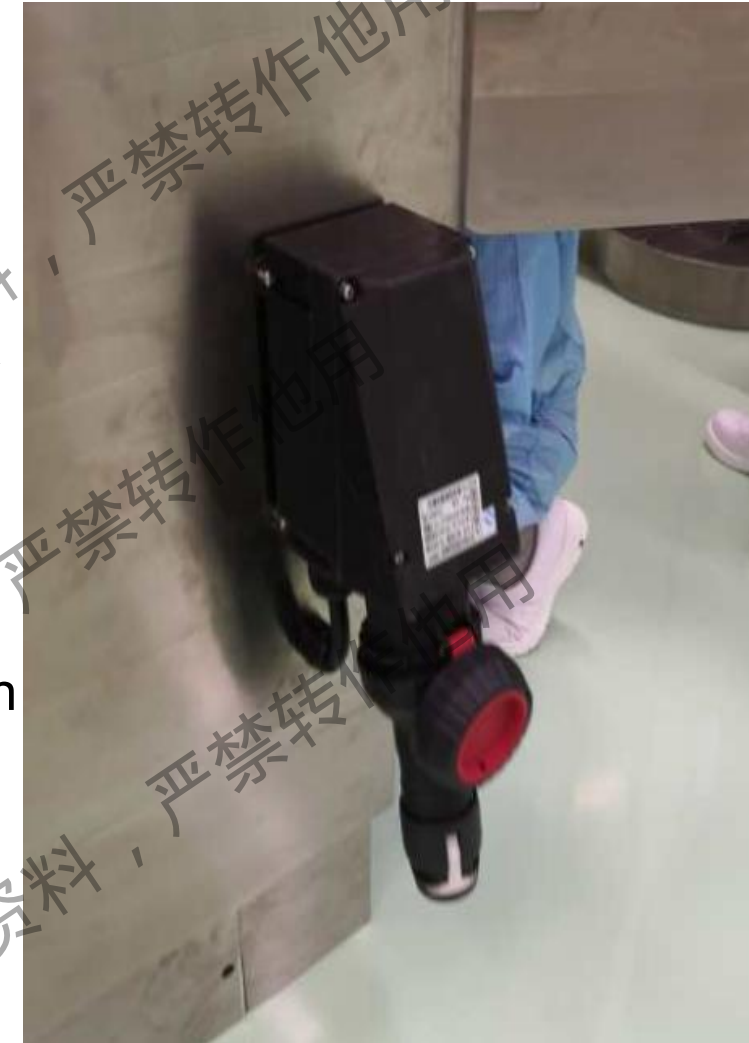
**POOR
INSTALLATION
QUALITY BRING
POTENTIAL
SAFETY RISK**



Maintenance – Socket for Coating Tank



1. Option 1 socket on clean partition.
2. Option 2 socket on coater body
3. Confirm with vendor
4. Risk analysis
5. Based on our understanding on machine
6. Based on installation condition

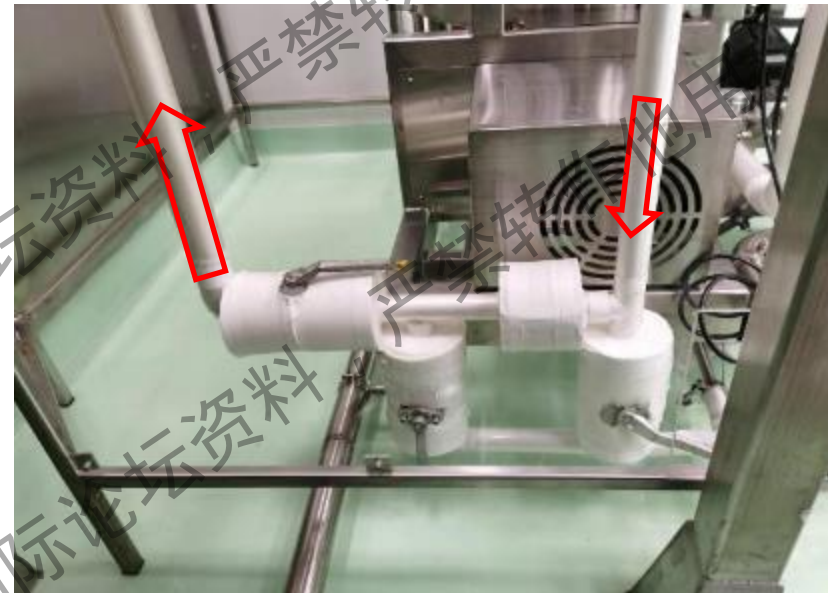
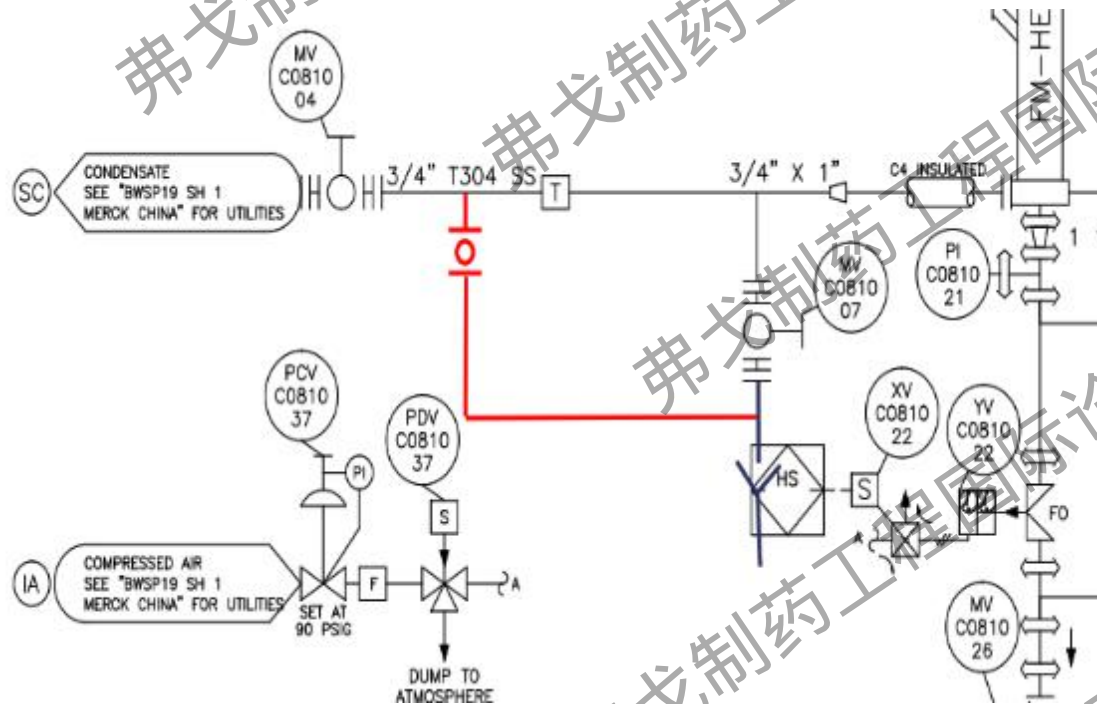


Operational & New Material Application

1. Steam condensate return to up floor is not recommended
2. Max 50% back up pressure from thermodynamic steam trap which can't guarantee the return of condensate

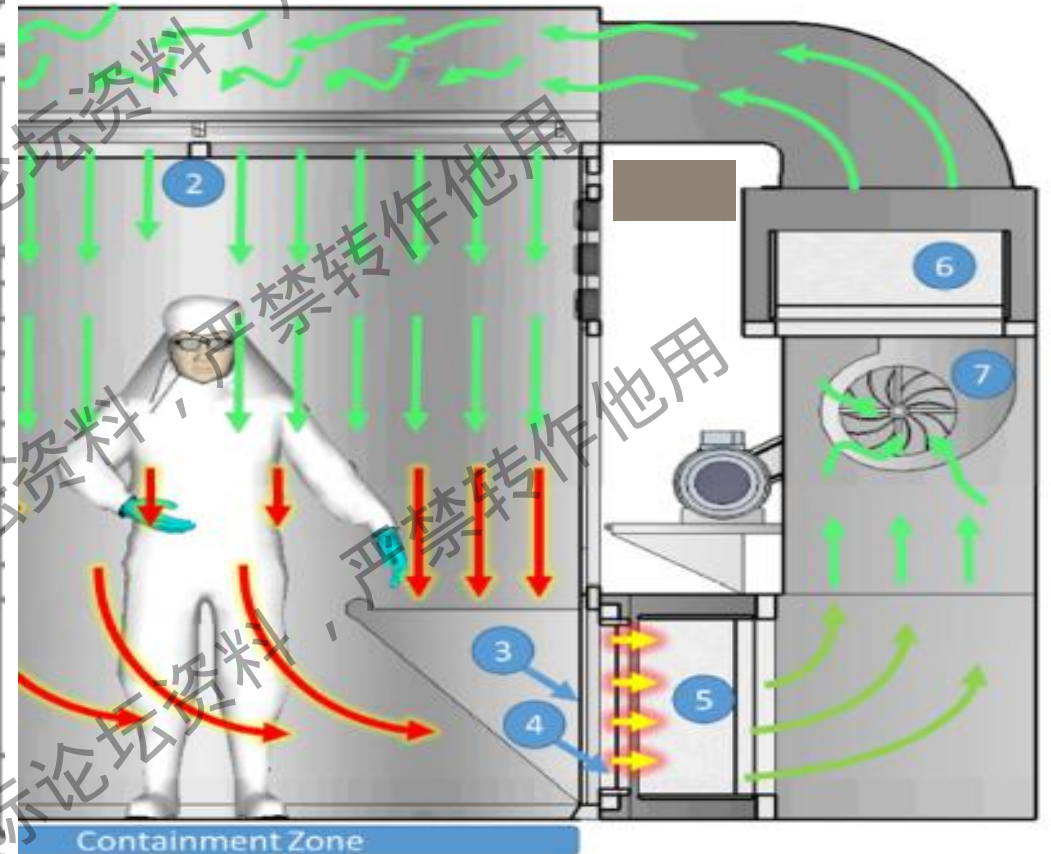
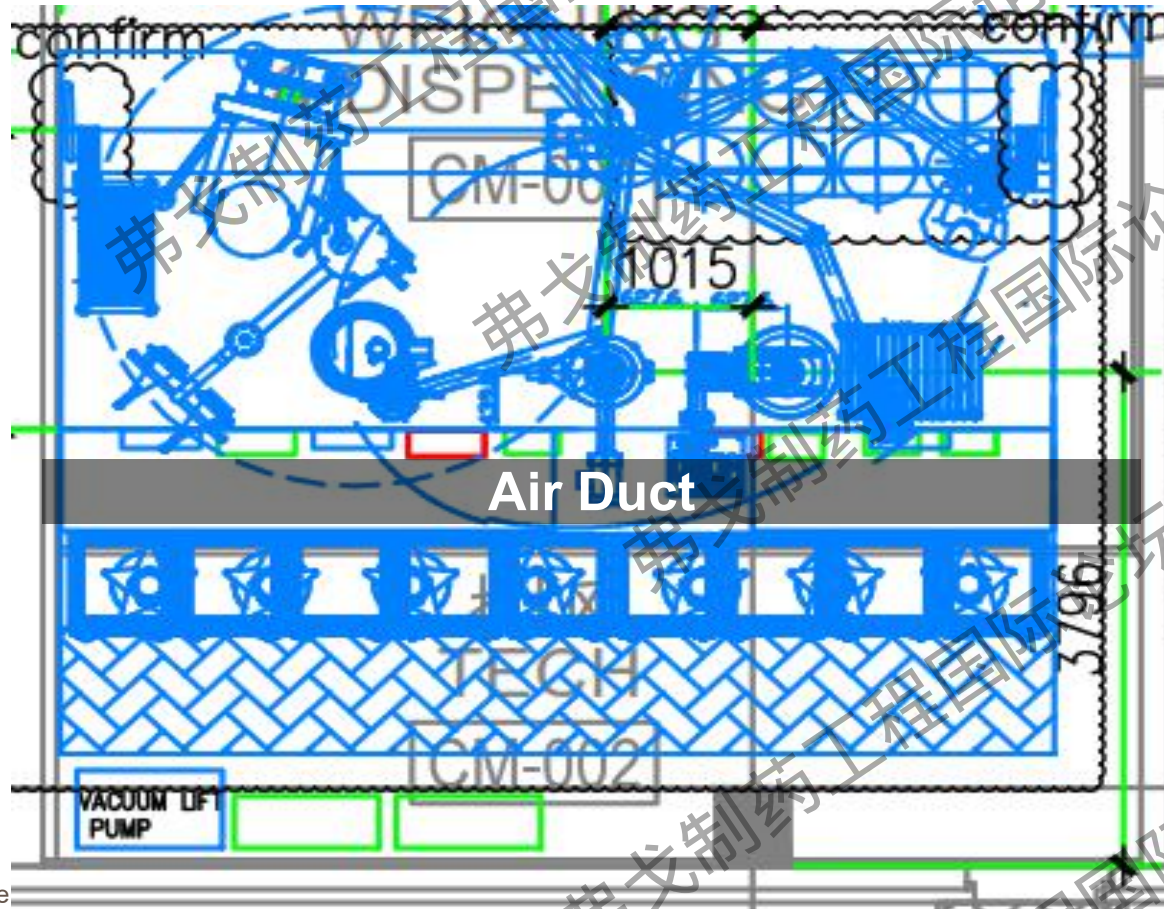
1. New insulation material

Pro	Con
Thin	Easy broken
Easy Installation	Expensive
Design for clean room	
Flexible	
Nice out looking	



Site Space Adjusting

DFB installation need to be considered together with clean room and relevant system installation, floor must be level.
DFB maintenance space need to be reserved in design.



Utility Panel



Corner



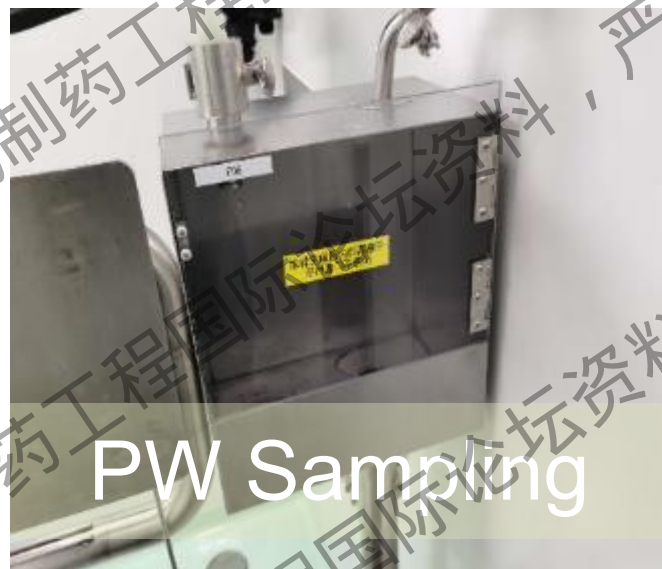
Corridor



Coater



Pit Scale



PW Sampling



PA Filter

Key Point - Construction

- Safety first
- Good Plan And Strategy
- Involve team of EHS + End User + Qualification
- Early Analysis Find The Problem And Fix It Early
- Good Relationship With Supplier
- Rely On Supplier But Never Trust
- Keep The Supplier To Solve All The Critical Problem On Site

C&Q

Commissioning

- A well planned, documented, and managed engineering approach to the start-up and turnover of facilities and systems, and equipment to the End-User that results in a safe and functional environment that meets established design requirements and stakeholder expectations

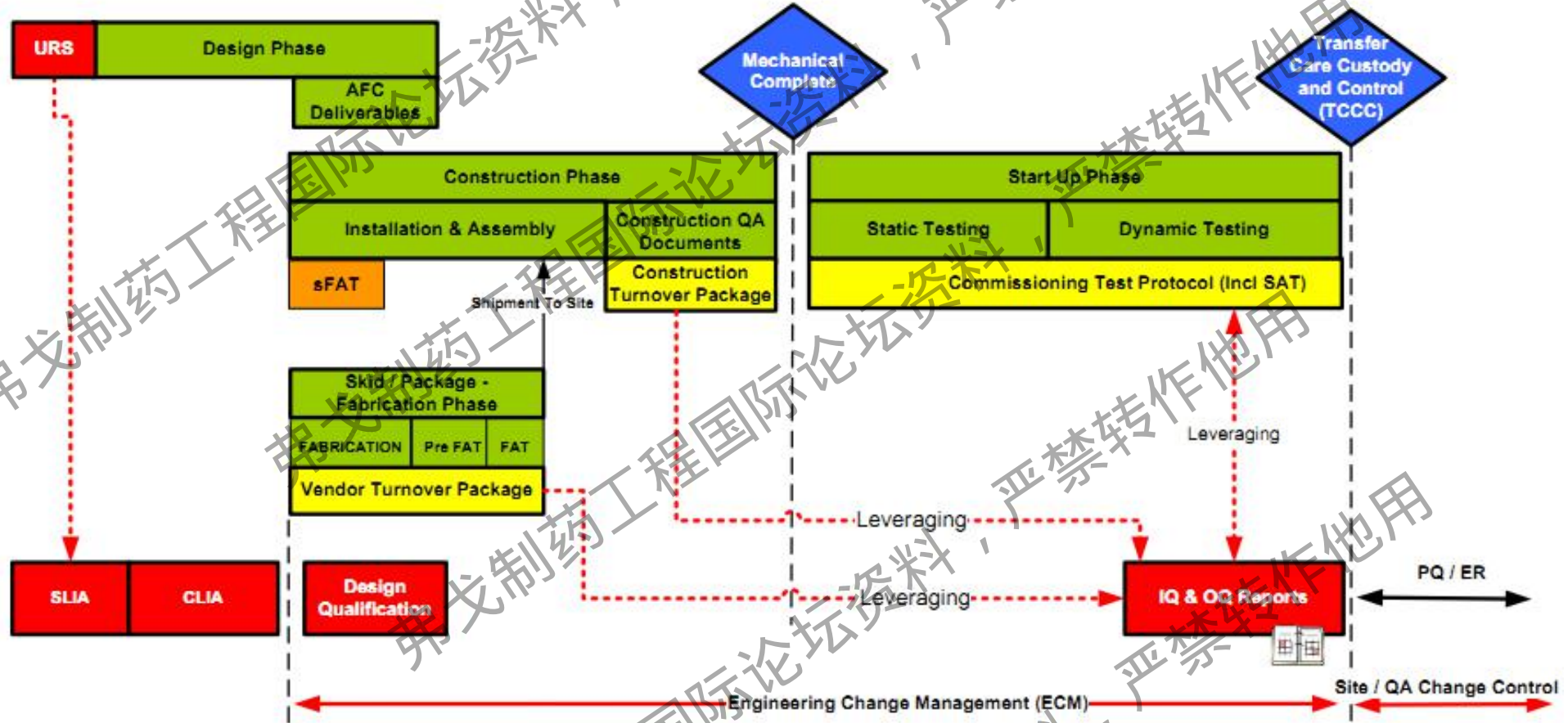
Publication Source: [ISPE Baseline® Guide, Commissioning](#)

Qualification

- (ICH Q7) Action of proving and documenting that equipment or ancillary systems are properly installed, work correctly, and actually lead to the expected results.

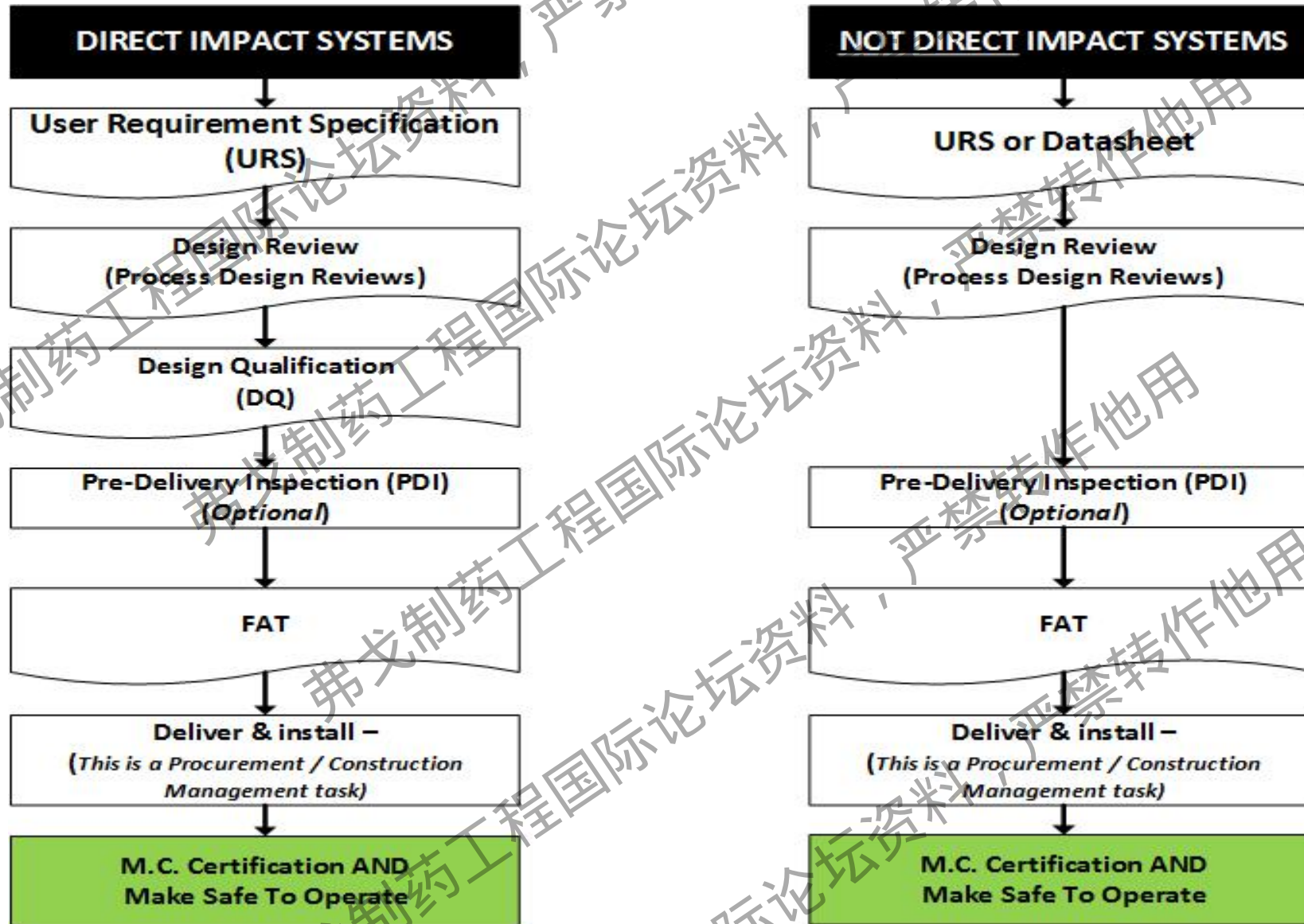
Publication Source: [ISPE Baseline® Guide, Vol. 6: Biopharmaceutical Manufacturing Facilities](#)

C&Q

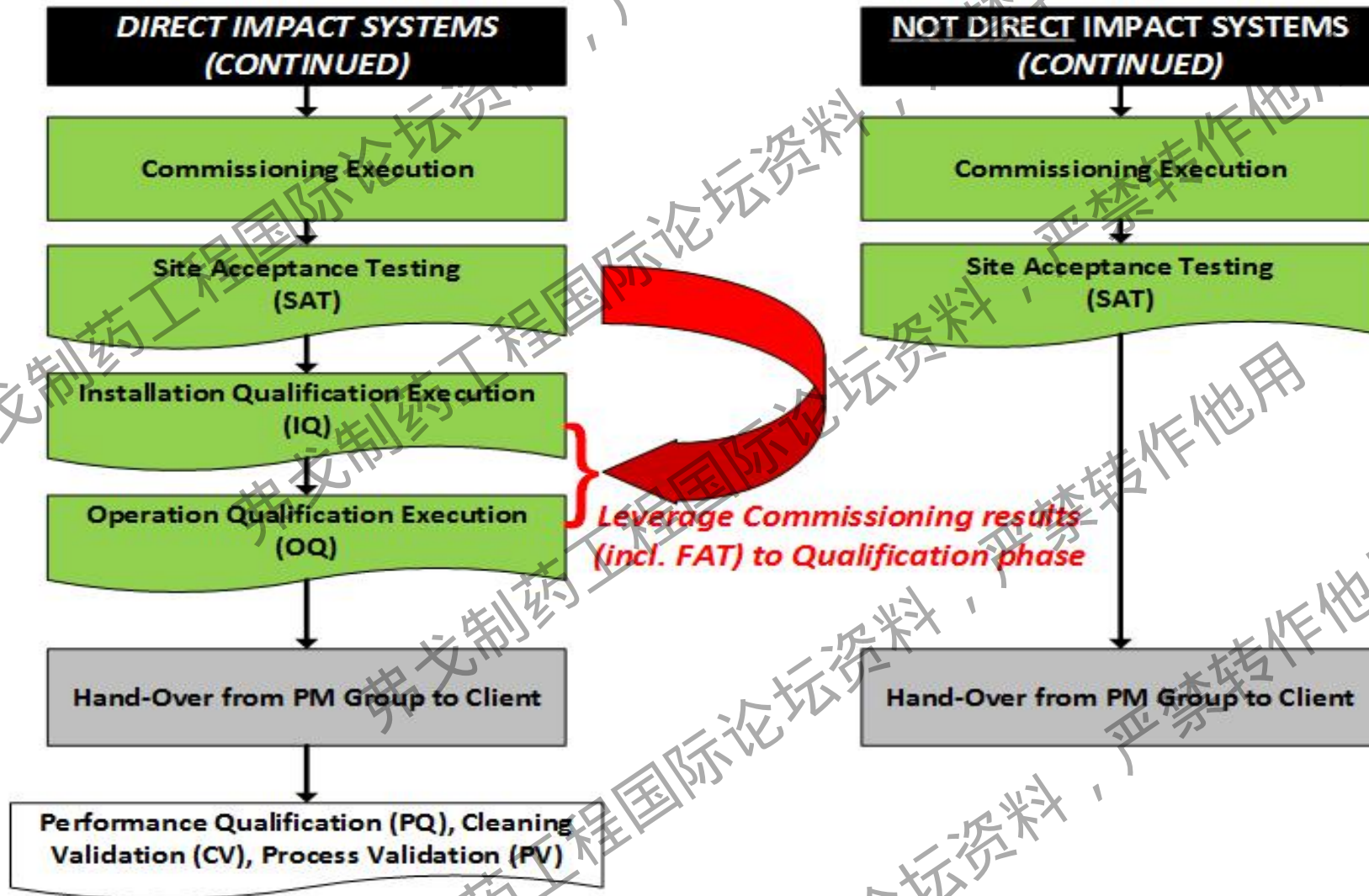


- Construction & Commissioning Activities
- Test Documentation
- QA Approved Documentation

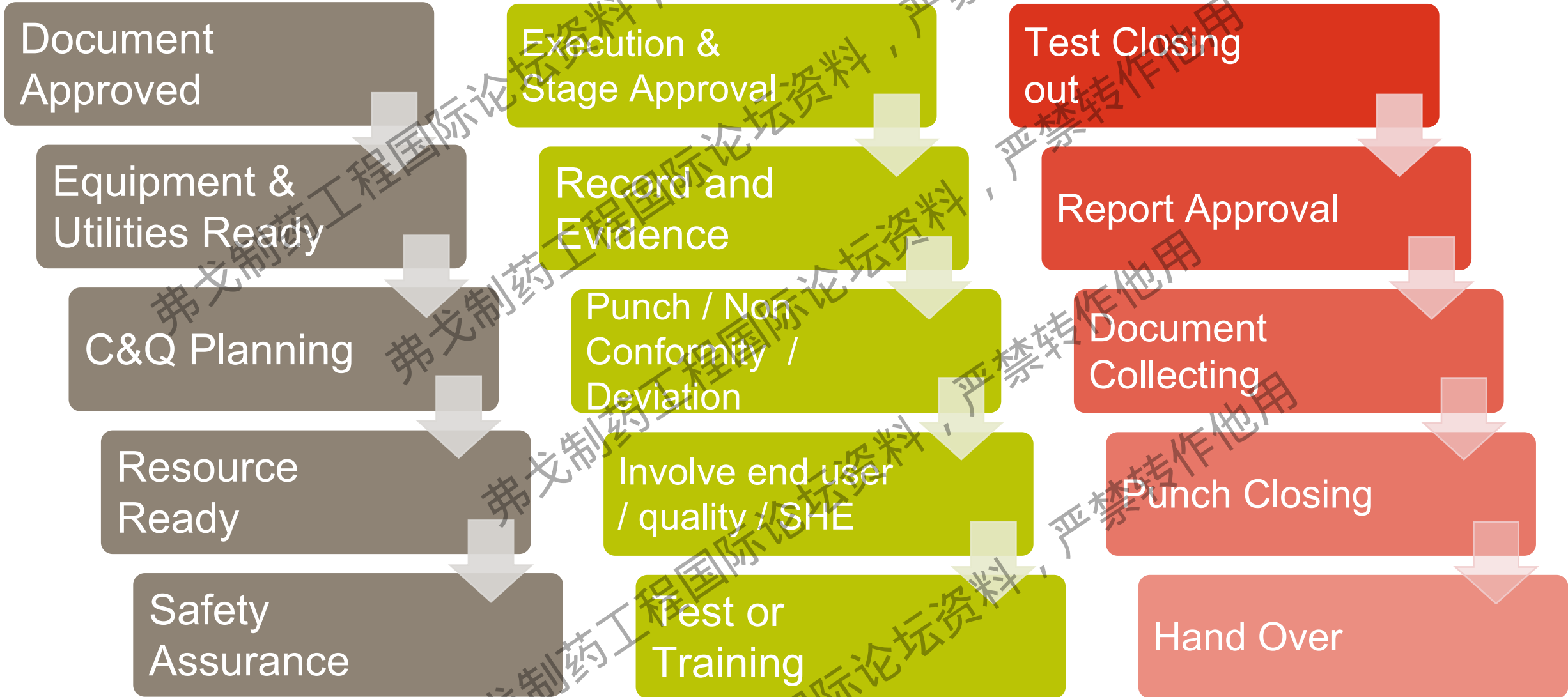
C&Q



C&Q



Site C&Q Main Actions

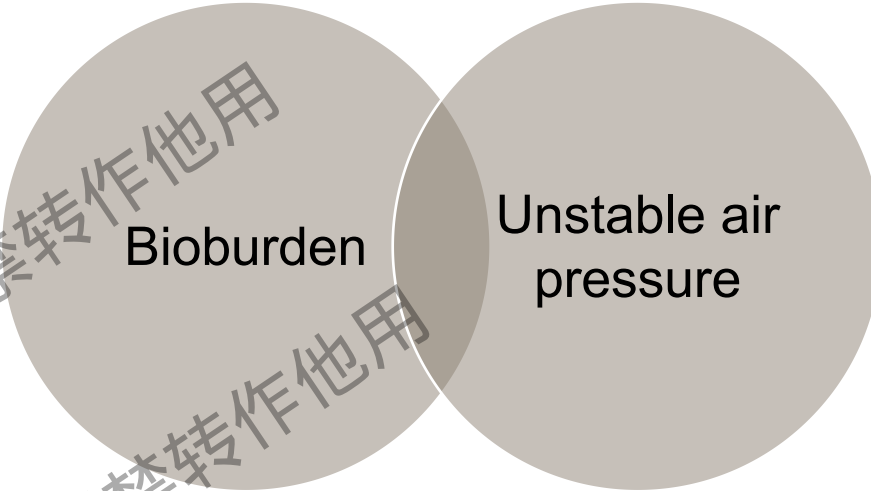
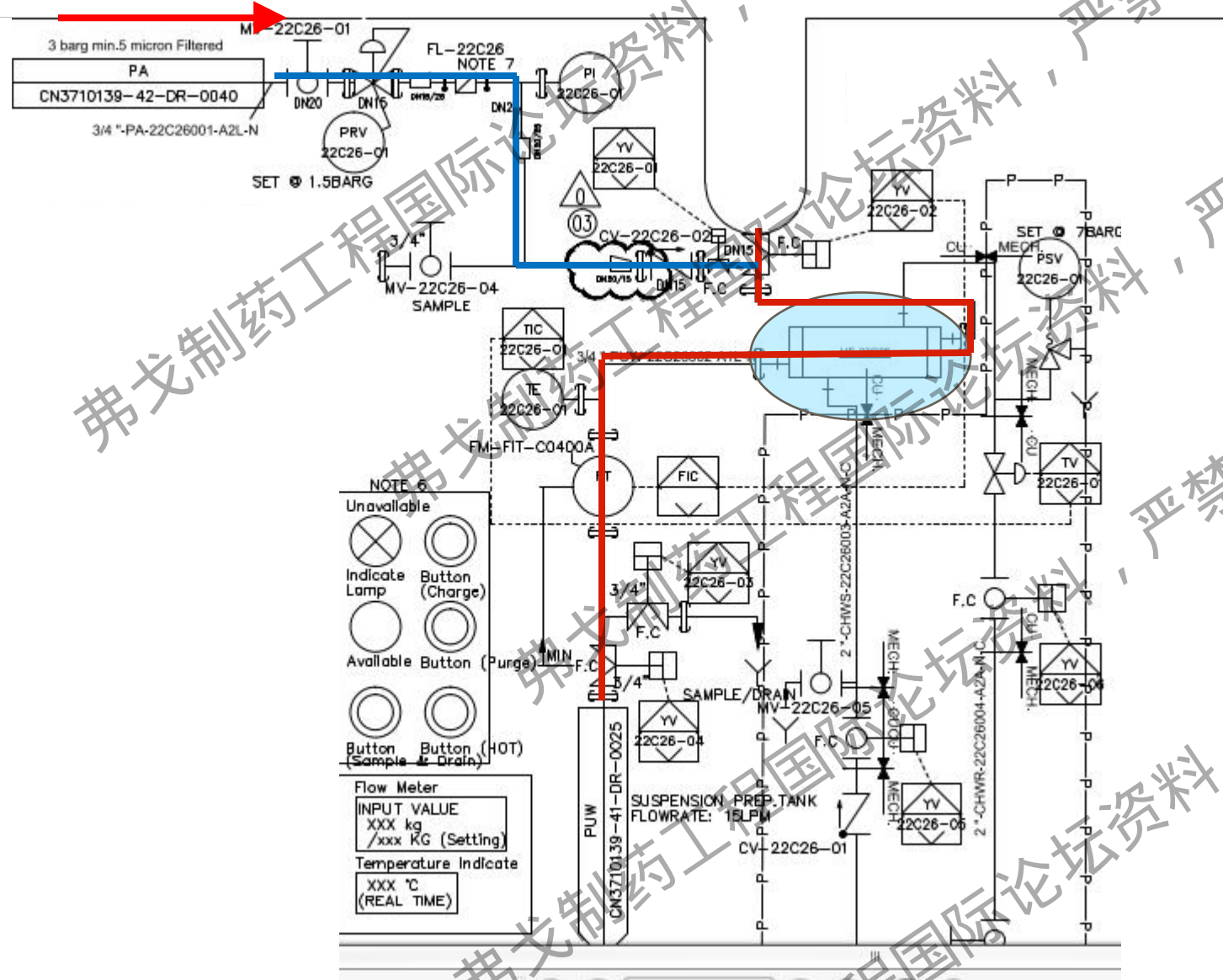


C&Q Critical Success Factors



PW & PA

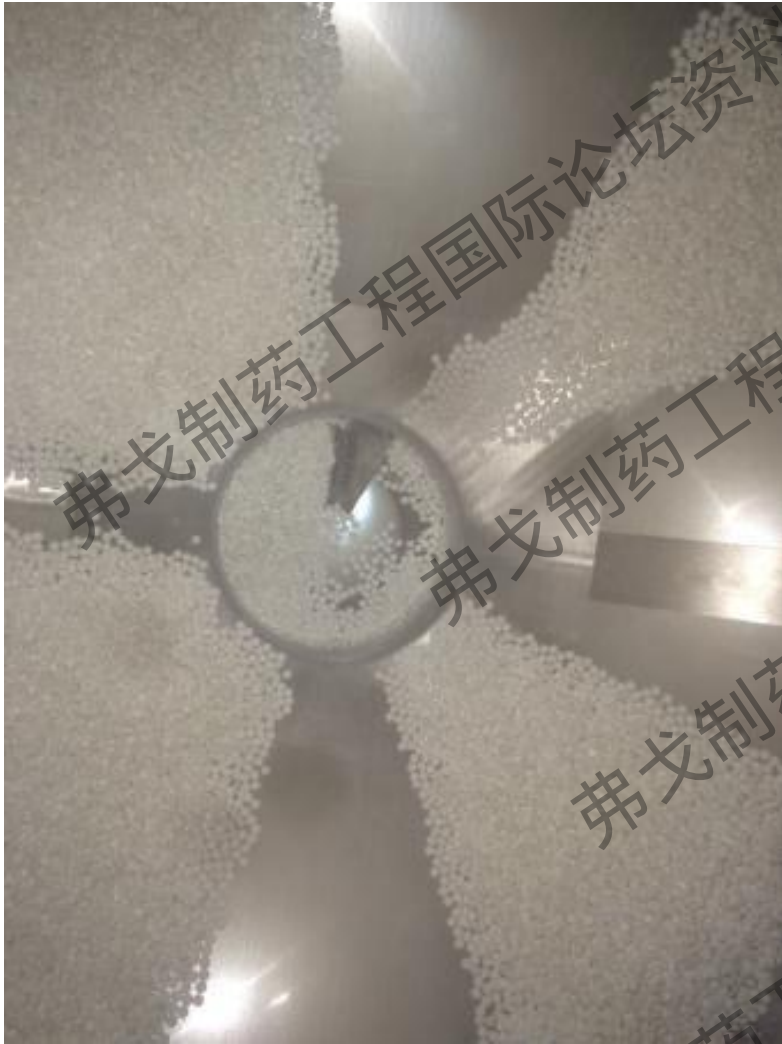
85dC



PW & PA



Case Analysis – C&Q



Tablet remain in IBC

- ❑ The angle followed the original design from client
- ❑ Large amount of tablet remained in the square IBC
- ❑ Flowability: Large > Small
- ❑ Vibration device can not solve problem but bring noise issue

Key function must be tested in FAT



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Thank You

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