

PM Group

固体制剂工艺设计经验分享



细节决定成败

- Peter Peng

PM Group

固体制剂工艺设计经验分享

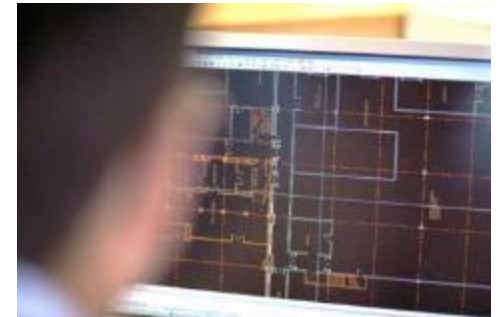
□ 工艺设计

□ 工程采购

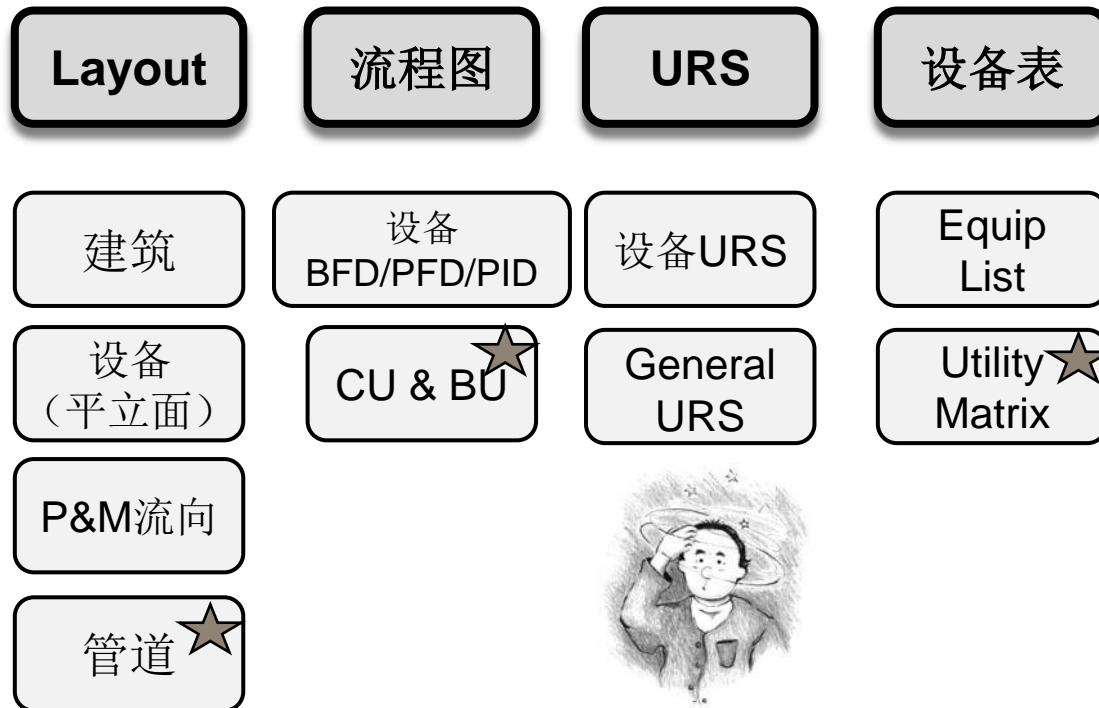
□ 公司简介

➤ 工艺设计

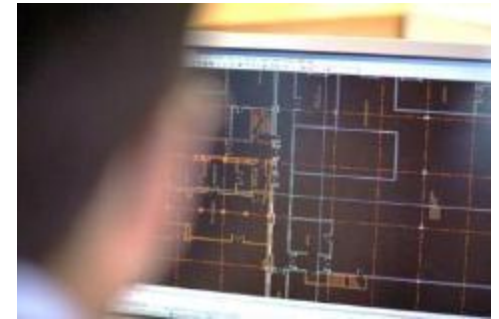
- 文件编制 - **Layout**, 流程图, **URS**, 设备表
- 工艺计算 - 物料衡算, 生产模型
- 文件更新 - 牵一发动全身
- 设备选择 - 设备互相关联互相牵制



文件编制

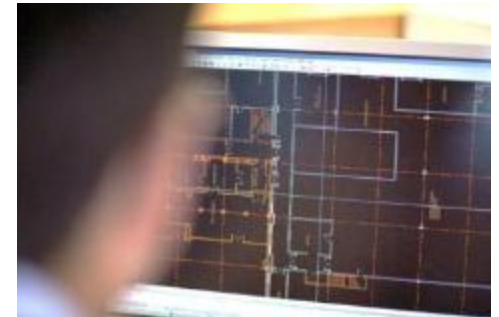


分析类 Analysis Document



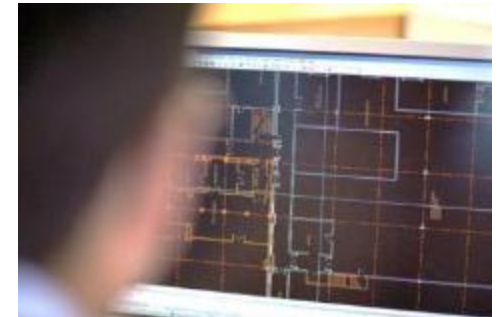
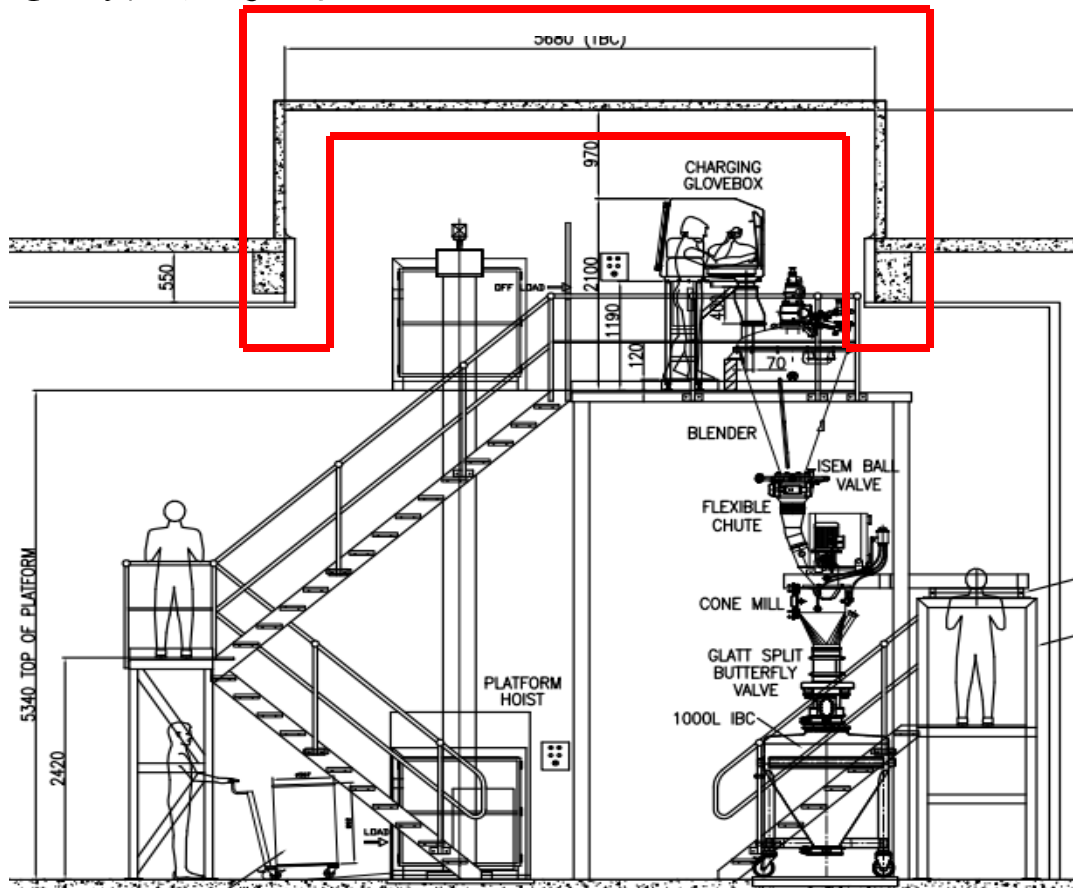
平面图

- ❖ **重点讨论建筑平面，一旦敲定不能轻易变动，所以需要各方参与讨论。**
- ❖ **建筑平面不但要考虑工艺布局满足GMP，还需要考虑洁净室安装，设备进场，设备安装，改扩建等。**
- ❖ **不但要考虑平面布局还要考虑立面布局。**



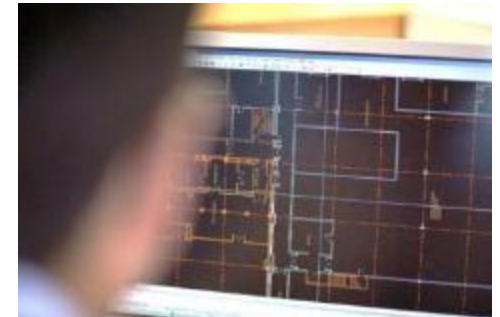
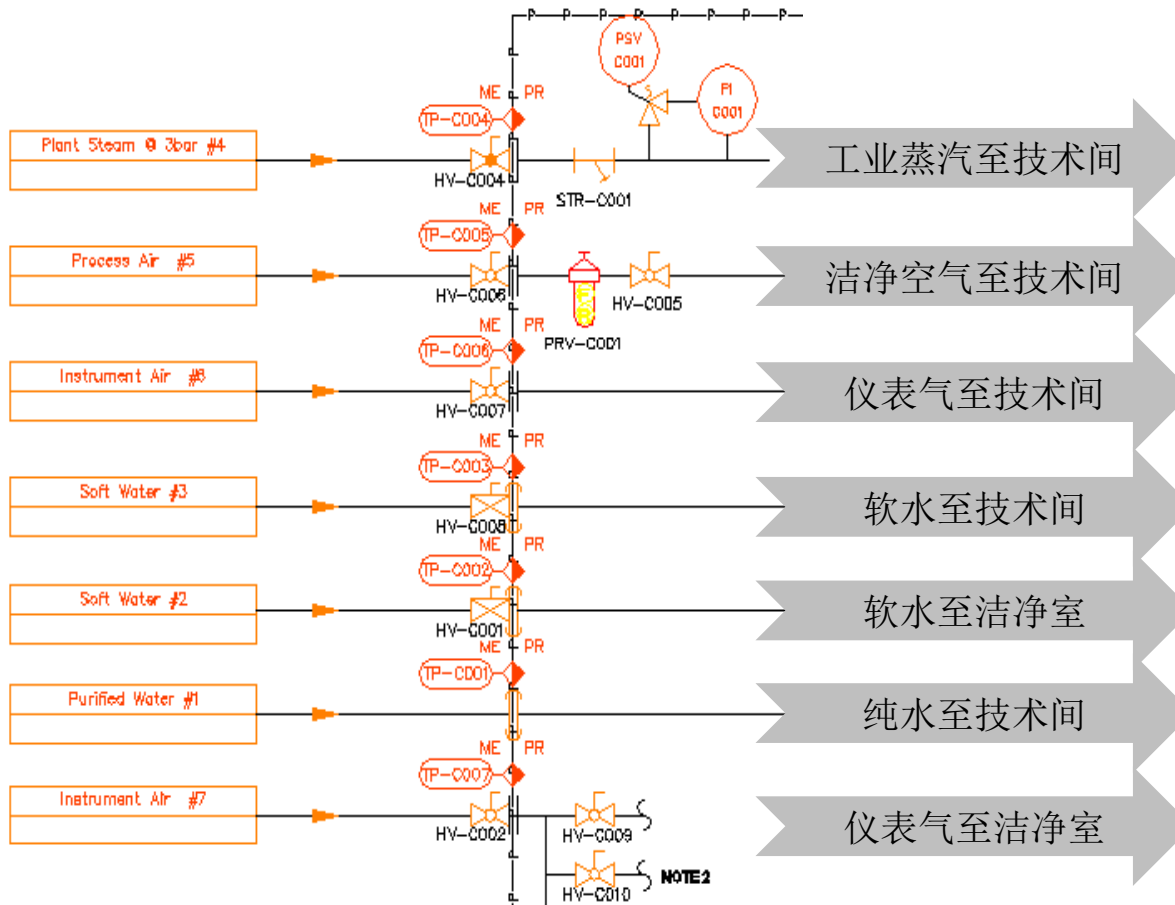
平面图

❖ 案例分析 – 现有厂房改造项目预混系统太高导致楼板穿孔



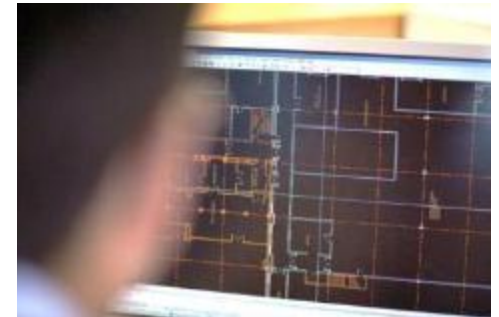
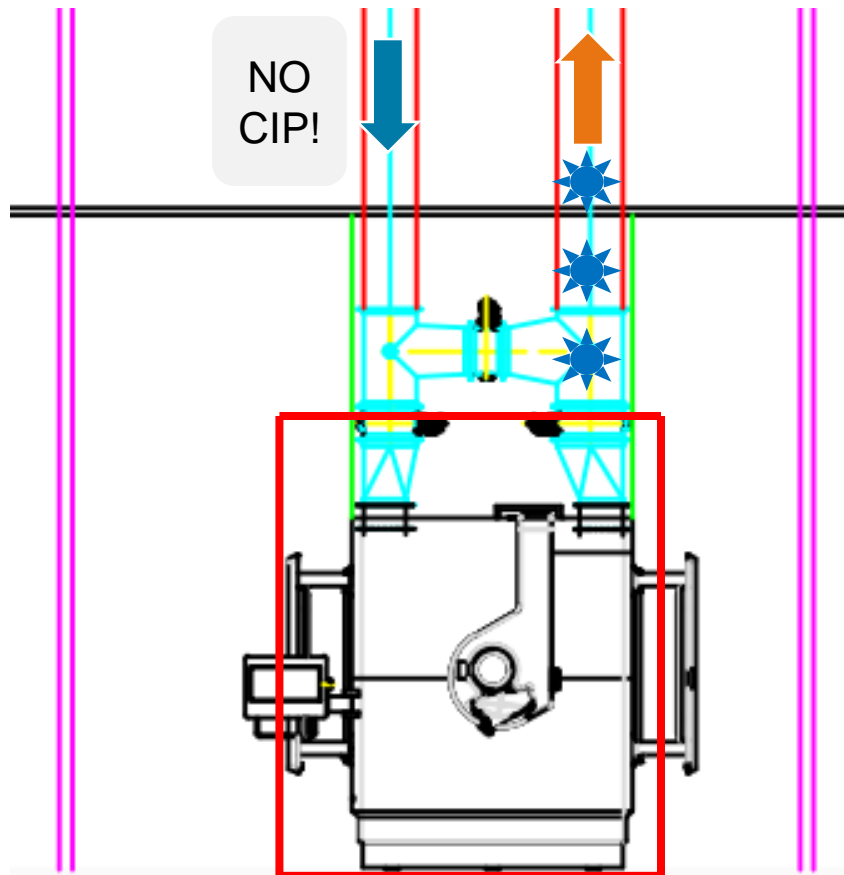
流程图

❖ 案例分析 – 界面清晰 流程图



URS

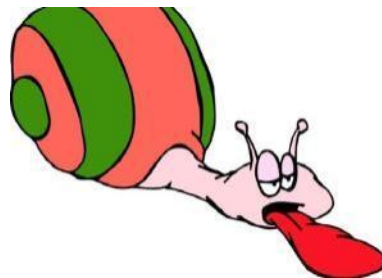
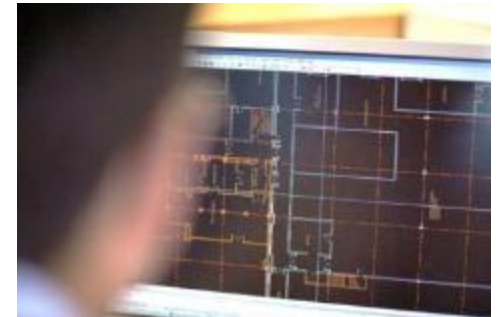
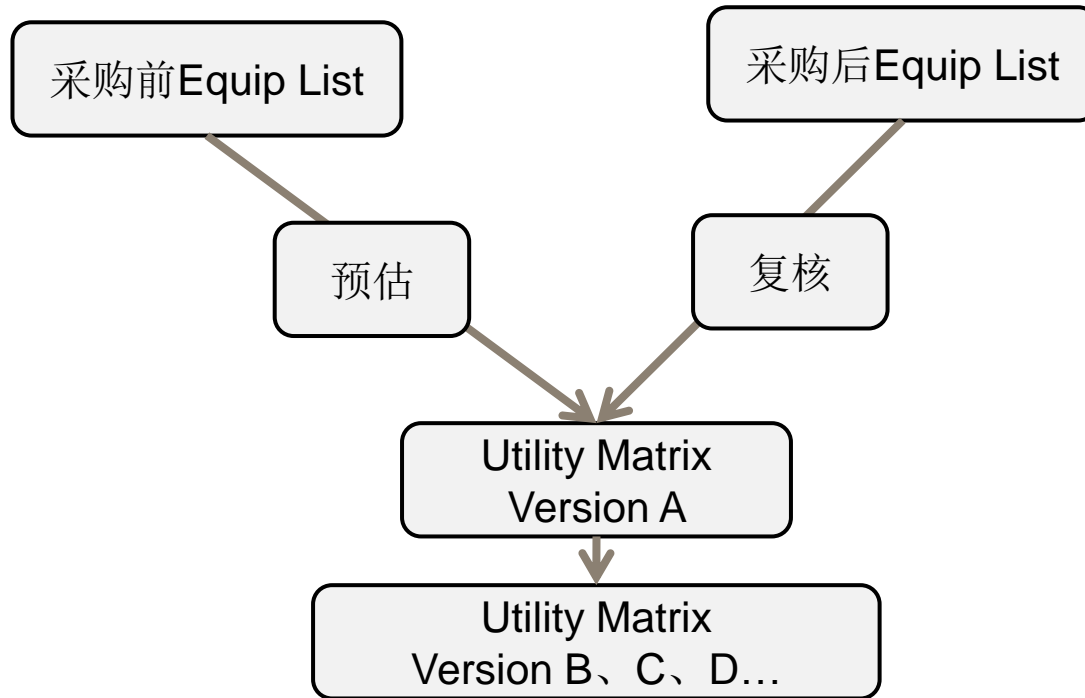
❖ 案例分析 – 包衣机送回风管道清洗方案



清洗范围
Clean Scope?

细节决定成败 – 工艺设计

设备表



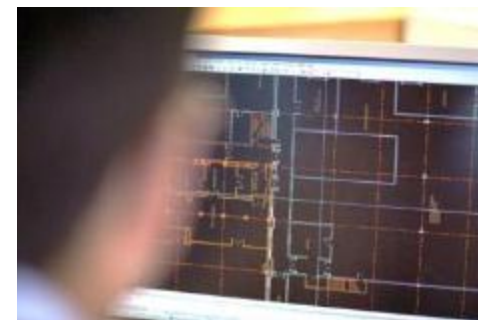
➤ 工艺计算

物料衡算 Mass Balance

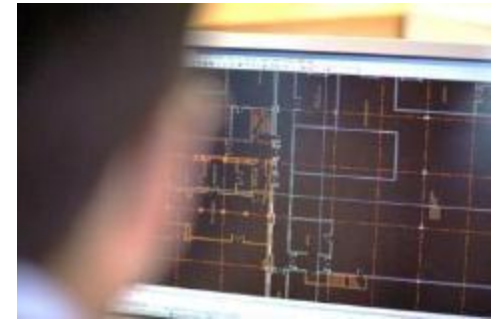
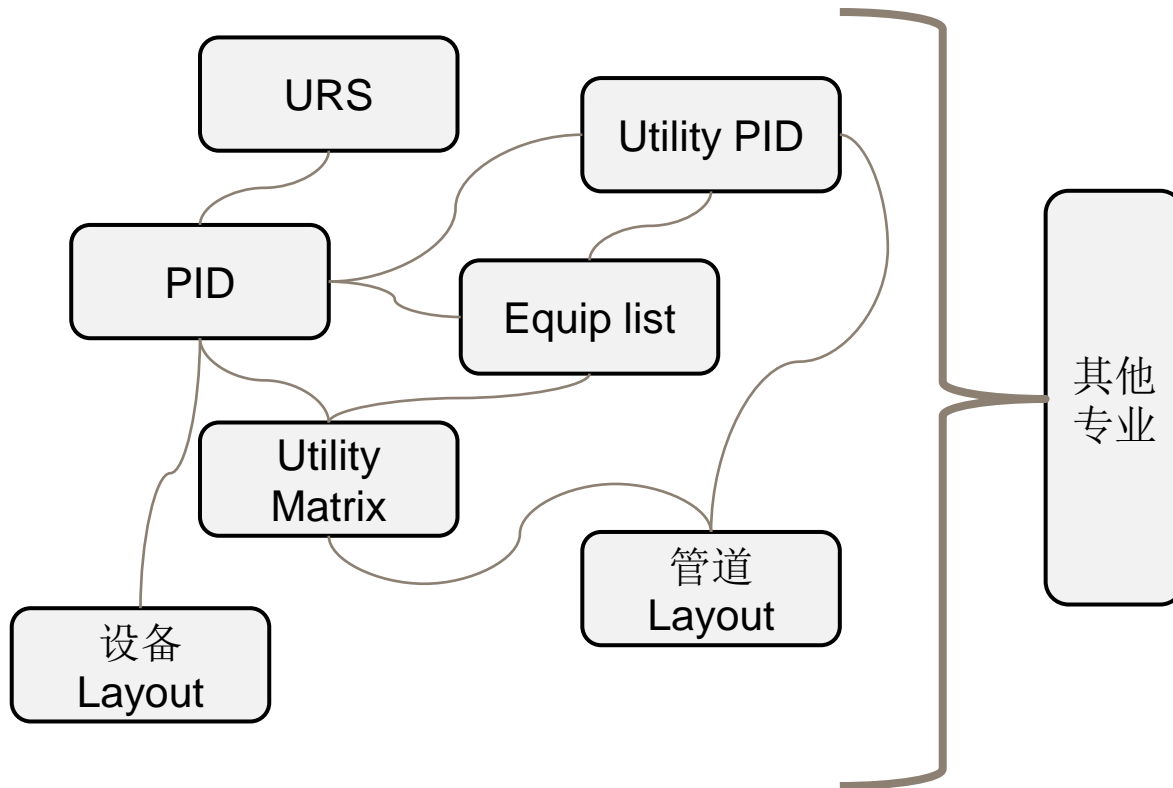
- ❖ 清晰的公式算法
- ❖ 合理的损耗
- ❖ 每班工作时间
- ❖ 班次
- ❖ 年工作时间
- ❖ 适当的余量
- ❖ 改扩建能力

生产模型 Production Module

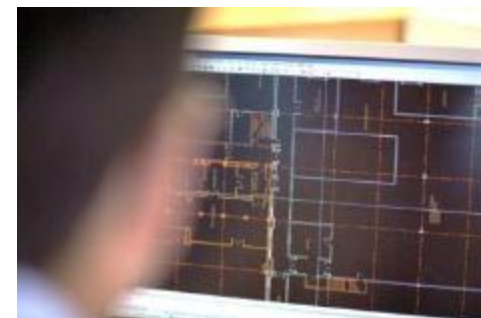
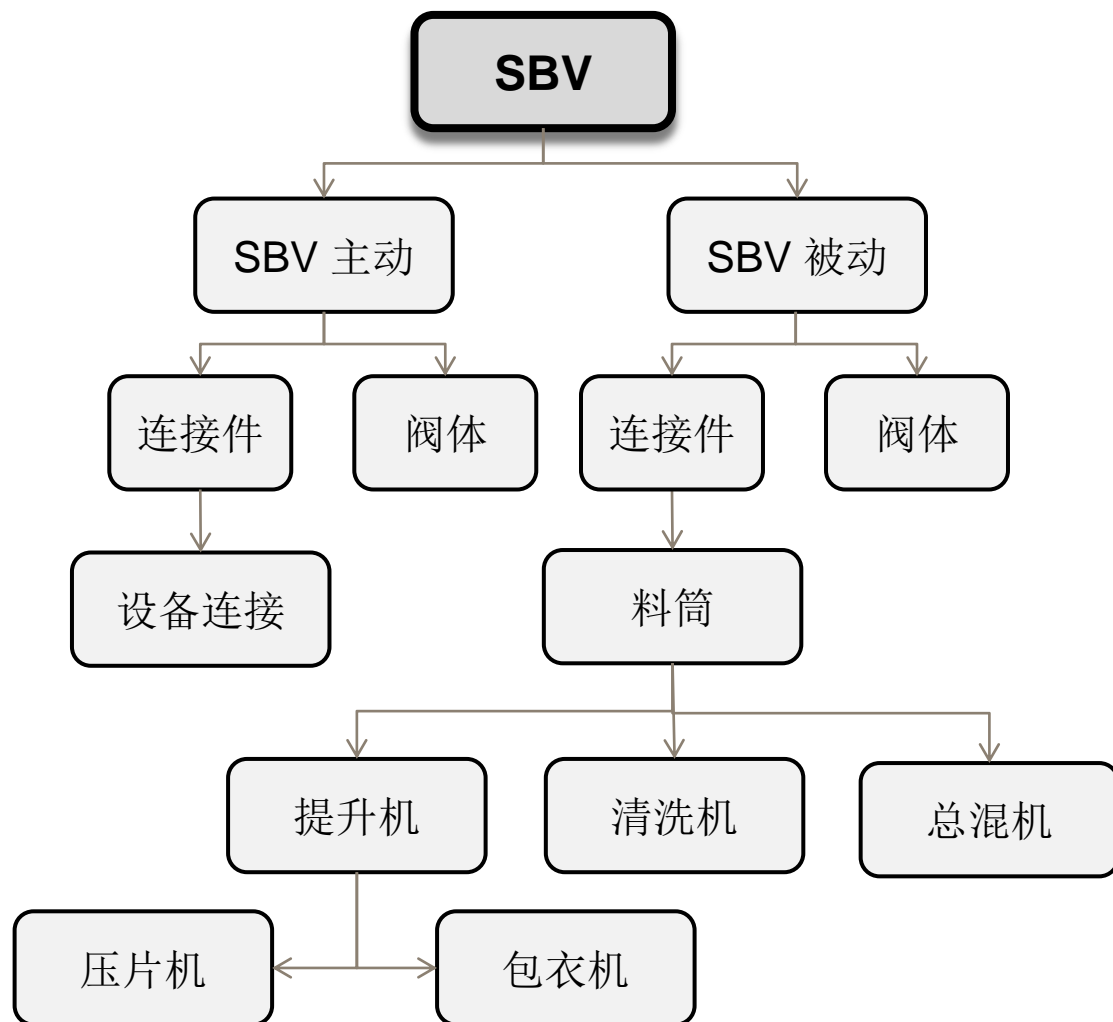
- ❖ 涵盖所有工序
- ❖ 涵盖所有设备
- ❖ 合理操作时间
- ❖ 合理工作间隙
- ❖ 自动和人工



➤ 文件更新



➤ 设备选择



➤ 工程采购之 供应商审核

如何敲定正确的供应商名录!

是否有类似产品



是否有类似工程经验



是否业主钟意名牌



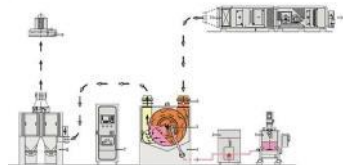
是否有类似愿意参与此次项目



➤ 预澄清

更明确的设备需求!

对于复杂工艺设备系统



是否经济可行



确保供应商合理报价



➤ 进度管理 Schedule

点



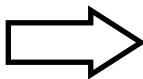
每个单项的时间跨度是否合理-够不够

线



单个设备进度安排是否合理-顺序对不对

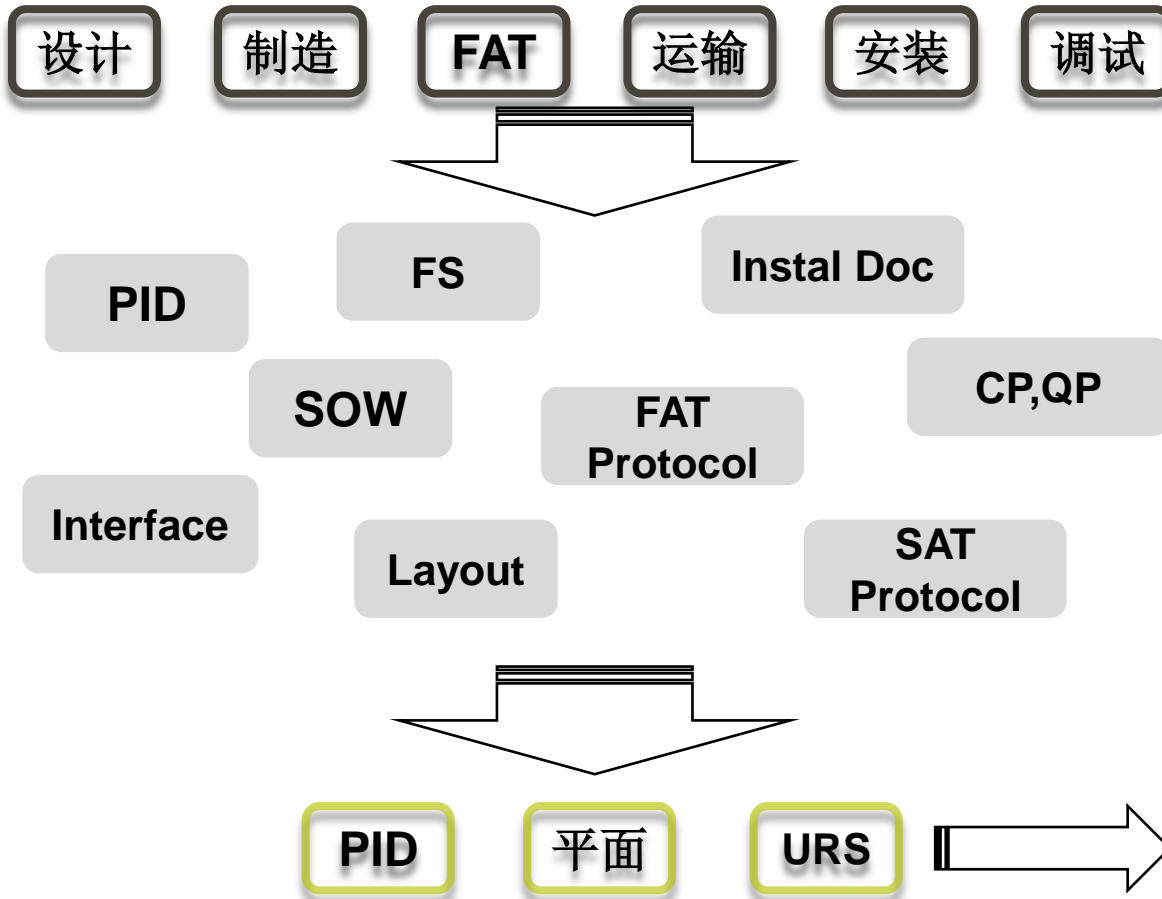
面



设备之间配合度-设计条件、进场先后



设备文件审核



➤ 设备递送 – 进口设备

❖ SOW工作范围 – DAP

❖ 清关

❖ 分批运送

❖ 打包设备与合同相符

❖ SCHEDULE



PM Group China Overview



Capability in China



A Full Service Company



Programme & Project Management

Consulting

Architecture & Master Planning

Engineering Design

Permitting & Regulatory Services

Procurement

Cost Management & Schedule Control

Construction Management

C&Q

Field Management

The Project Delivery Specialists



You can rely on our team of 2,100 people to deliver your project successfully

- An integrated A&E design and project management firm
- Proven track record since 1973
- An employee-owned company
- Revenue of over €200 million
- 20 offices worldwide and projects in over 50 countries
- World class expertise



A World Leader in Pharmaceutical Engineering



ENR ranks
PM Group
**#2 Pharma
Engineering
Firm Worldwide**



(ENR Global Sourcebook)

Pharma Clients include...



China: Office Details



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**Country General
Manager**
Niall O'Loughlin



谢谢!

Thank You!

The project delivery specialists