Biotech Process Module Design, Construction and Testing
生物制药设施模块的设计，建设和测试

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May 2016

Agenda议程

- 项目设计和计划（我们的合作伙伴BCD）
- 建设与测试

Case Study 项目案例研究

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BCD TEAM 团队

40	ENGINEERING 工程
6	PROCUREMENT 采购
4	OPERATIONS MANAGEMENT 运营管理
5	ADMINISTRATIVE 行政
141	FITTERS / WELDERS 钳工/焊工
4	QUALITY & COMPLIANCE 质量与合规
5	SAFETY 安全

TOTAL 205 EMPLOYEES
总计205名员工

PRODUCTS & SERVICES产品与服务

Modular Process Systems

- Bio-effluent Treatment Systems
  配料系统，无菌过滤，CIP，SIP，生物模块：培养基制备，缓冲液制备，收获模块，污水与生物污水处理系统
- Utility Skids – Heating & Cooling, Dosing etc.
  设备模块–加热和冷却，加药等。
- Detailed Design
  详细设计
  - ASME BPE, 31.3, GAMP, etc.
  - Inventor 3D, Electrical & Automation
  - PED, ATEX
- Fabrication
  制造
  - Skid Modules, Superskids
    标准模块，大模块。
  - High Alloy (AL6XN, C22, SMO, Duplex, Super Duplex)
    高合金（AL6XN，C22，SMO，双相，超级双相）

模块化系统

- Product Formulation, Sterile Filtration, CIP, SIP, Bioprocess Modules: Media Prep, Buffer Prep, Harvest Skids, Effluent and

Integrated Testing
集成测试

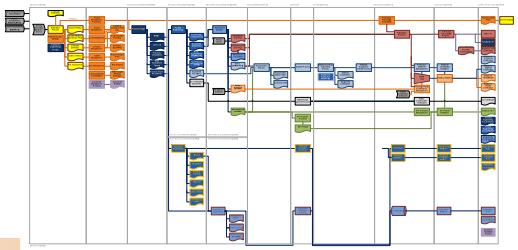
- Mechanical and electrical verification
  机械和电气的验证
- Riboflavin sprayball coverage
  核黄素喷淋覆盖
- SIP / Thermal mapping
  SIP /热分布
- Integrated functional testing
  集成功能测试
- IV / OV / ASTM E2500

Product Realisation Process产品实现过程

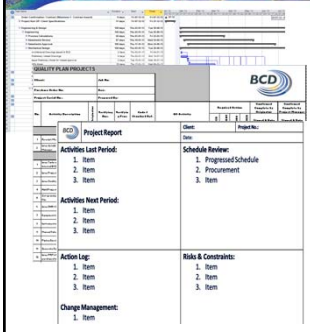
Product Realisation Process is fully documented in the Quality Management System (QMS).

产品实现过程完全记录在质量管理系统中（QMS）。

Definition Phase 定义阶段 → Planning Phase 计划阶段 → Design Phase 设计阶段 → Procurement Phase 采购阶段 → Fabrication Phase 制备阶段 → Verification Phase 验证或确认



Project Management: Definition & Planning Phases项目管理：定义及方案阶段



- Quality Plan describes how the requirements of the contract will be met throughout the project lifecycle.

  质量计划描述了怎样通过项目周期来满足合同要求。
- Schedule Development in MS Project

  Ms Project格式的进度计划
- Project Meetings (Internal & Client).

  项目会议（与内部或与客户）
- Action Log.

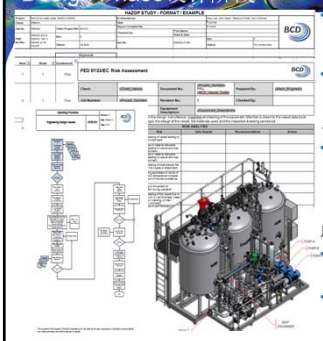
  操作记录
- Constraint & Risk Review.

  约束条件与风险回顾
- Change Management

  变更管理
- Project Reporting.

  项目报告

Design Phase设计阶段



- Procedures are in place to define the design process

  定义设计过程的程序已落实
- Where in BCD scope, HAZOP's are executed.

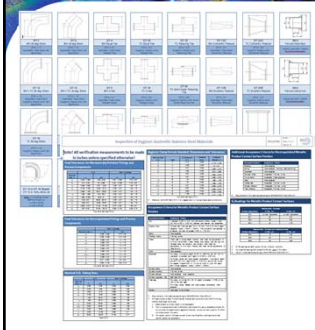
  在BCD范围内，已经执行HAZOP分析。
- Design risk assessments are completed for pressure equipment, machinery and ATEX risks, where applicable.

  设计风险评估在压力设备、机器以及适用的防爆风险中已经是完善的。
- Design is subject to peer review.

  设计是经过内部审核的
- Internal & client design review meetings and model reviews are conducted.

  会进行内部及客户设计审查会议和模块审查。

Procurement Phase采购阶段



- Supplier & Subcontractor assessment and management processes.

  评估和管理供应商及分包商。
- Material & Equipment Inspection is in accordance with OP120-004 and to ASME BPE.

  根据标准OP120-004 和ASME BPE检查材料。
- Visual and Physical Inspection.

  外观和物理检查
- Calibrated inspection equipment include: Micrometers, Profilometers, Ferrite Scope, Digital Protractors, Positive Material Identification (PMI).

  校准检测设备包括:千分尺、轮廓仪、铁素体检测仪,数显角度仪,[illegible]分析仪(PMI)。
- The material traceability and certification lifecycles are in accordance with OP100-18 Material Certification Review.

  材料的可追溯性和认证周期符合OP100-18材料认证审核。

Fabrication Phase制造阶段

BCD has a comprehensive welding and welder qualification system:

BCD有完善的焊接和焊工资格审核系统

- Library of Procedure Qualification Records (PQR's).

  工艺评定记录的程序库
- Library of Welding Procedure Specifications (WPS's).

  焊接工艺评定的程序库
- Notified Body Approved.

  公告机构批准
- Dual Qualified (EN/ASME).

  双部准（EN/ASME）
- Stainless Steel, Higher Alloys, Titanium, Carbon.

  不锈钢、高合金、钛、碳
- Manual & Semi-Automatic Welding.

  手动焊及半自动焊
- Low Ferrite Welding.

  低铁素体焊接
- Range of Processes.

  广阔的工艺范围

Welding Implementation焊接实施

Welding Equipment Includes焊接设备:

- Calibrated Orbital Welders标准轨道自动焊机
- Calibrated Purge Monitors标准吹扫检测仪
- Magnahelic Gauges 气压表
- High Purity Purge Gas高纯度气体

Welding Documentation Includes焊接文件:

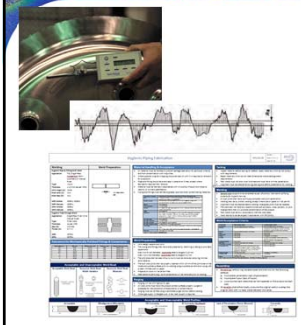
- Weld Maps焊接图
- Weld Logs焊接日志
- Weld Coupon Logs焊样日志

Welding Inspection To Approved Procedures By焊接检验批准程序:

- Qualified BCD Personnel BCD相关资格人员
- Independent Third-Party NDT Contractors

  独立第三方无损检测承包商

Inspection & Testing Phase检查及测试阶段



In-Process inspection is conducted in accordance with defined procedures按既定程序的过程检查.

Subsidiary procedures define specific test requirements including辅助程序定义具体测试要求:

- Visual Examination of Welds焊缝目测检查
- NDT无损探伤
- Surface Finish表面抛光度
- Drainability排水能力
- Piping Slope Tests管道坡度测试

Pre-FAT & FAT are executed in accordance with pre-approved protocols.

符合预先批准协议的预FAT及FAT。

SAT, Commissioning & Qualification services are provided.

提供SAT、调试及认证服务。

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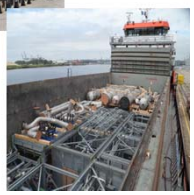
Test Facilities测试设施

Test Facilities Include:

测试设施包括：

- RO Water
  RO水
- Plant Steam
  工厂蒸汽
- Clean Steam
  洁净蒸汽
- Clean Dry Air
  清洁干燥空气
- Vessel Test Bay
  容器试验台
- Sprayball testing
  喷淋测试
- Calibrated inspection equipment includes: Micrometers, Profilometers, Ferritescope, Digital Protractors, Positive Material Identification (PMI).
  校准检测设备包括：千分尺，表面粗糙度仪，铁离子检测仪，数显角度仪，材料检测仪（PMI）。

Shipping Phase运输阶段



Experienced in delivering large scale projects throughout the globe.

有交付全球大规模项目的丰富经验。

All aspects of logistics.

全方位物流

Buffer Hold Area
缓冲液暂存区

Media Preparation Skid

Buffer Preparation Skid

WORKSHOP TEMPORARY PLATFORM

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WORKSHOP TEMPORARY BUFFER SKID

建造和测试

预制间及仓库

配管及预制间

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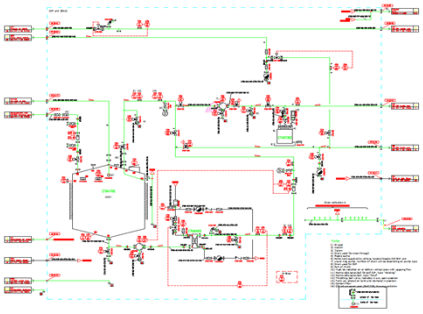
cGMP Perspectives

cGMP Perspectives

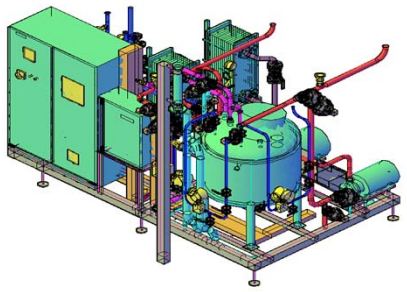
For single line
- Material
- Deadleg
- Drainability
- Welding
- Calibration
- Marking & Labeling
- Insulation
- Pickling & Passivation
- Decontamination
- Valve Angles
- Air Break
- Filter Integrity
- Etc.

For System
- Surface Finish test
- Sprayball Coverage Test
- GAMP5 & Part 11
- Minimum Flow Rate
- Wiring Test
- System Alarm
- Interlock
- P&ID Verification
- Critical Process Parameter
- Critical Quality Attributes
- Etc.

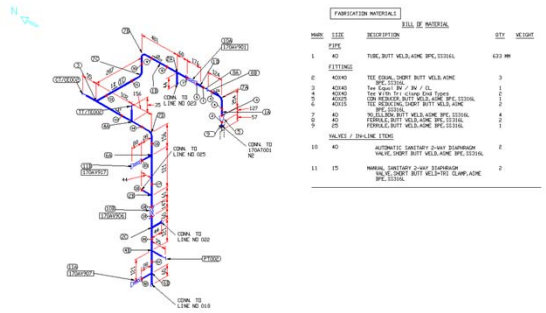
设计图1 PID



设计图2 三维模型



设计图3 轴测图



Material Inspection

Qualified Materials

Sample Installation

- Material Certificate
- Surface Finish Report
- Random Check
- 3rd Party Check

Materials Quality Control 材料质量控制

- 必要货物的第三方取样检查
- 到货货物的外观及文件资料检查
- 货物分区域归类集中存放及储存环境控制

Welding Inspection

Qualified Welding

3rd Party Inspection

- WPS & Welder Qualificarion
- Purging Gas Quality
- Boroescope
- Welding Log &Map

Welding Quality Control 焊接质量控制

焊接前确认及焊接

焊接工艺评定（WPS）确认

↓

焊工资质，焊工现场考核，编号及业主确认

↓

焊样拉伸试验（第三方）

↓

预制车间环境控制

↓

焊接

↓

自检及第三方内窥镜检测

↓

每焊20道焊缝后，进行焊样测试

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Welding Quality Control 焊接质量控制

文件记录

- 焊点图及焊点编号
- 每日焊样记录
- 每日焊接记录
- 内窥镜记录
- 第三方抽检记录

Welding Quality Control 焊接质量控制

- 预制配管及准备
- 焊接前确认及焊接
- 文件记录

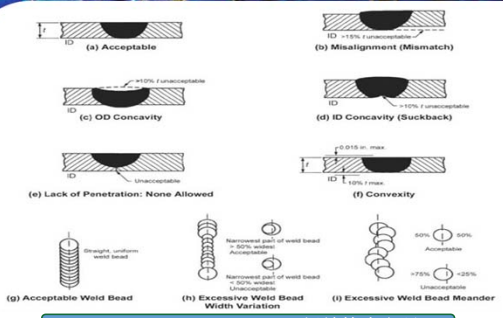
Welding Quality Control 焊接质量控制

预制配管及准备

- 被批准的轴测图
- 管道切割及切口平口
- 合资高纯氩气及PTFE焊接气管
- 焊接管对口及三点式点焊

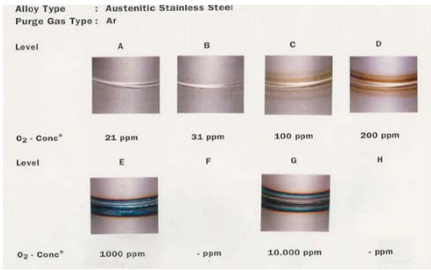
Welding Quality Control 焊接质量控制

Welding Quality Control 焊接质量控制



Weld inspection reference焊缝检查参照

Welding Quality Control 焊接质量控制



Oxidation check reference standard氧化检查参照的标准

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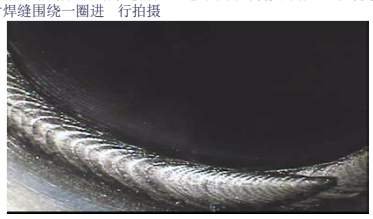
Welding Quality Control 焊接质量控制

内窥镜检查程序及录像

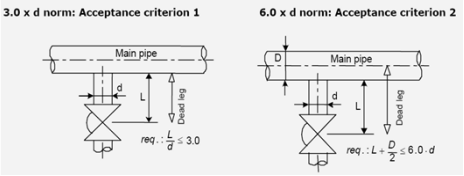
对内窥镜检测结果进行拍照，每张照片/视频根据实际焊口编号对照片/视频进行标识

在拍摄时 根据现场的焊缝情况，选用不同的镜头 例如 全视镜 侧视镜等需要对焊缝围绕一圈进 行拍摄



Quality Control 质量控制

- D.坡度死角检查程序与报告----确认相关坡度死角符合设计要求Deadleg and slope inspection and report--- Be sure deadleg and slope comply with the design requirements

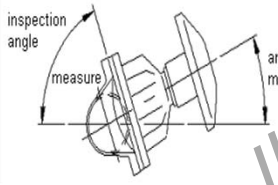


3D检查示意图：
Picture for instruction of 3d inspection

Quality Control 质量控制

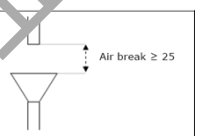
- E阀门安装角度检查Installation valve and angle inspection

在水平管路上安装的隔膜阀，生产商必须明确需要安装的角度（如果不能以其他方式排水）。测量的误差不需考虑



Validation系统验证

F 空气隔断的检查Air break inspection



Our Client
我们的客户

Questions? Thank You!

More information please contact
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