

LISTEN.  
THINK.  
SOLVE.®

# 制药行业MES

Manufacturing Execution System – 制造执行系统

张可

Rockwell Automation 制药行业技术顾问



Allen-Bradley • Rockwell Software

**Rockwell**  
**Automation**

# Rockwell Automation 在制药行业的总体能力

Rockwell  
Automation

## 信息与分析



- 和ERP及其他系统的集成
- 多层实时历史数据库
- 将数据转化为信息，综合分析和展现
- 整体序列化解决方案(serialization)
- 云、虚拟化技术的运用

## 合规与验证



- 提供包含预验证模块的自动化、信息化产品
- 符合FDA 21CFR Part11
- 符合GAMP5的实施和咨询服务
- 前端工程设计FEED

## 原料药



- 多种柔性批量(Batch)解决方案，符合S88
- 完整、强大的PLC/DCS控制平台
- 工业以太网，信息共享与透明

## 制剂



- 条码化物料管理，电子称配系统，防错防混淆，物料跟踪，产品谱系
- 电子批记录(EBR)规范现场作业，落实SOP和新版GMP要求
- 工单执行、进度、生产实绩

## 公用工程

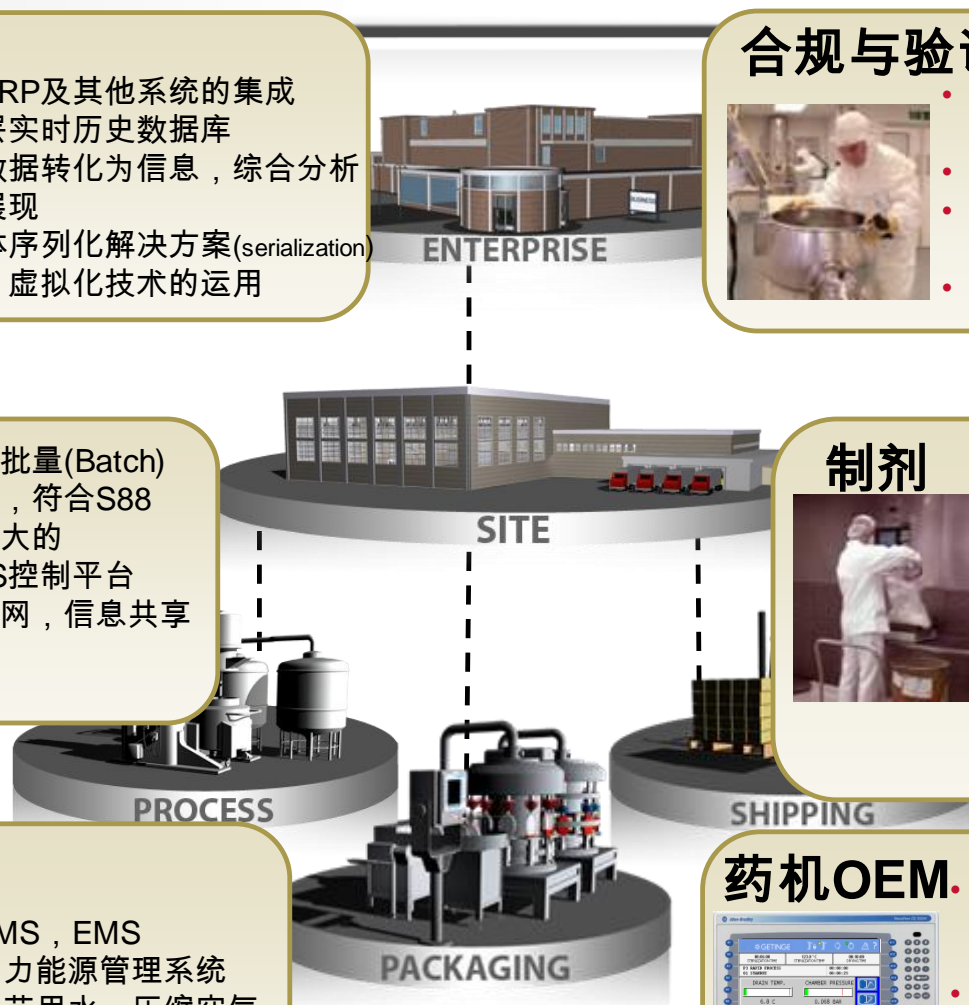


- BMS, EMS
- 动力能源管理系统
- 工艺用水、压缩空气
- 工厂设施和设备的统一监控

## 药机OEM



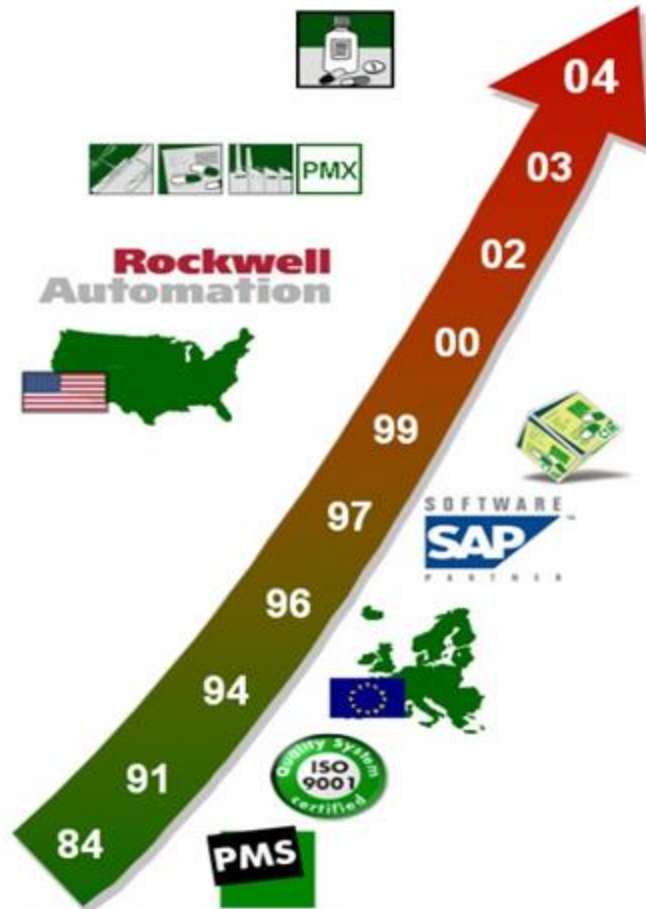
- PLC、操作面板、变频器用于：净化水、CIP/SIP、压片机、灭菌柜、灌装机等
- 帮助药机商符合法规，缩短验证时间
- 支持工业标准OPC协议的数采软件
- RAPID (包装线效率统计)



# PharmaSuite®



# Rockwell Automation 30余年制药MES经验

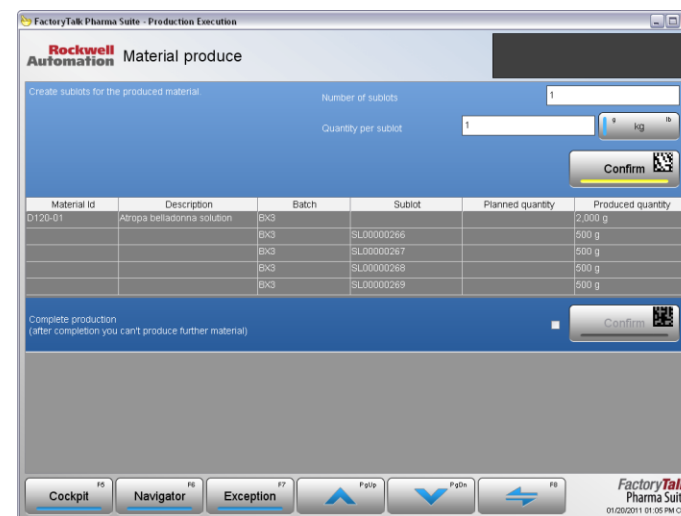
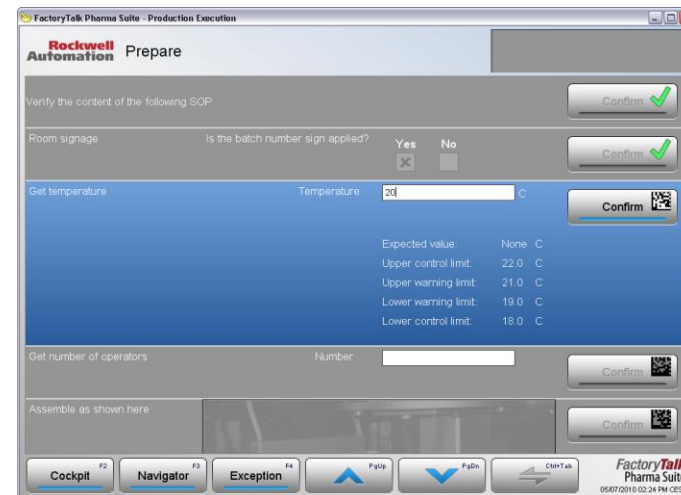


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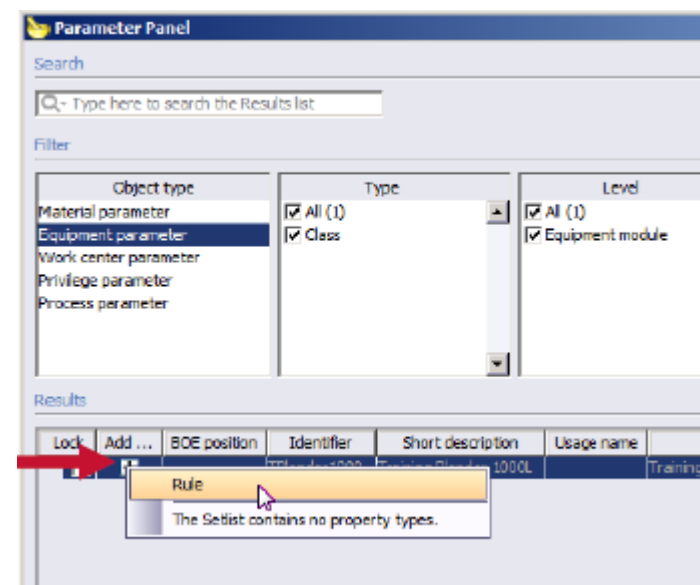
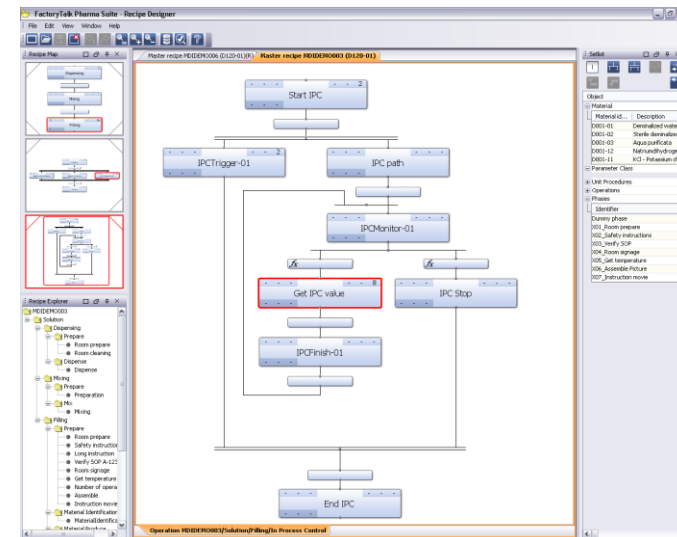
- 2004** Leading EPM brand for the Life Sciences Industry
- 2003** Introduction of the new integrated product suites
- 2002** Propack Data - A Rockwell Automation Business
- 2000** Expansion in the USA
- 1999** 1<sup>st</sup> Propack Data PMX CTM™ solution
- 1997** Certified SAP Software Partner
- 1996** Expansion in Europe
- 1994** Propack Data passes ISO 9001 certification
- 1991** 1<sup>st</sup> Propack Data PMX MES™ solution
- 1984** Foundation of Propack Data



- MES的工作方式
  - 在MES看到当前班次的生产工单
  - 在MES浏览操作指导(视频/图像/文档)
  - 在MES浏览房间/设备/容器的清洁状态
  - 生产时依照MES提示的操作流程，产生偏差时MES有报警，必要时需领导授权
  - 在MES的关键操作都有日志记录
  - MES从设备自动化系统自动采集数据
- MES带来的效益：与传统方式比较
  - 显著减少生产记录的手工劳动
  - 降低了人员操作带来的质量风险
  - 提高了数据记录的准确性、实时性

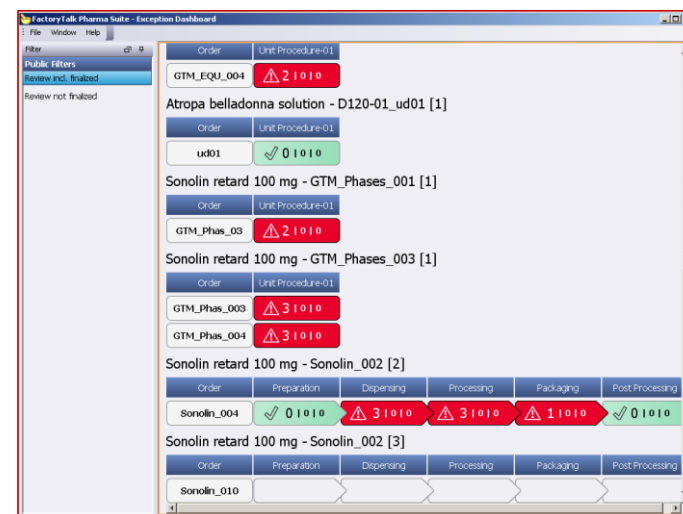
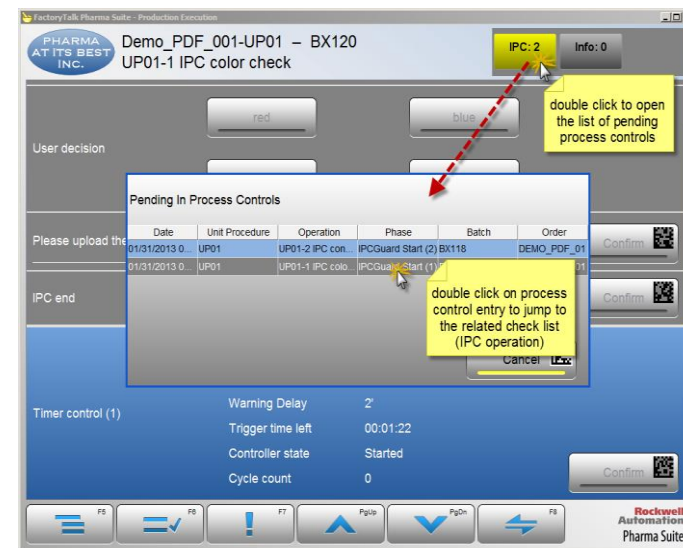


- MES的工作方式
  - 在MES创建流程化模块化的“电子配方”
  - 在MES设置各个工序的物料投入/产出
  - 在MES设置各个工序的关键参数
  - 在MES严格控制配方的访问权限
  - 在MES管理配方的版本，升级新版本，归档老版本
  - 在MES修改配方要电子签名、日志记录
- MES带来的效益：与传统方式比较
  - 电子配方的设计、维护更加便捷，减少了手工劳动
  - 电子配方与生产批次MES自动绑定和防错，提高了生产安全性
  - 电子配方的安全性更高



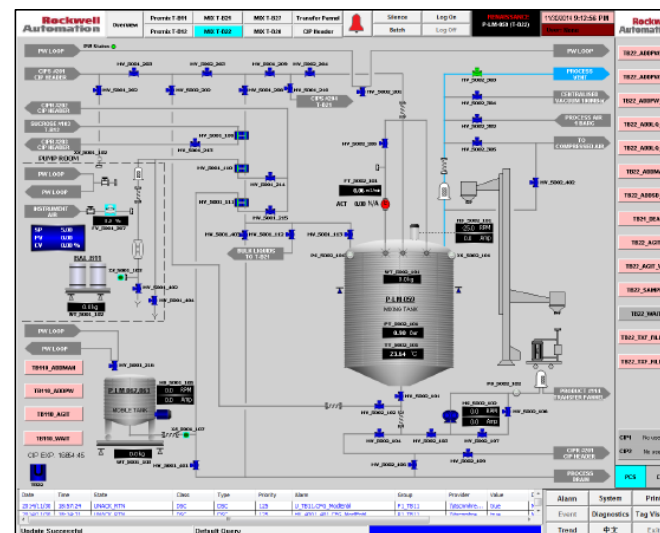


- MES的工作方式
  - 在MES自动启动过程质量检查任务，自动获取自控系统数据或是提示手工录入数据
  - 在MES实时监控质量管控参数，如有异常MES自动报警
  - 在MES查看偏差，处理偏差，提供电子签名、日志记录
  - 在MES浏览电子批记录，执行批次放行
- MES带来的效益：与传统方式比较
  - 显著减少了生产批记录的人工审核时间，减少了手工劳动
  - 显著提升了对质量问题的反应和处理速度，提高了质量合格率



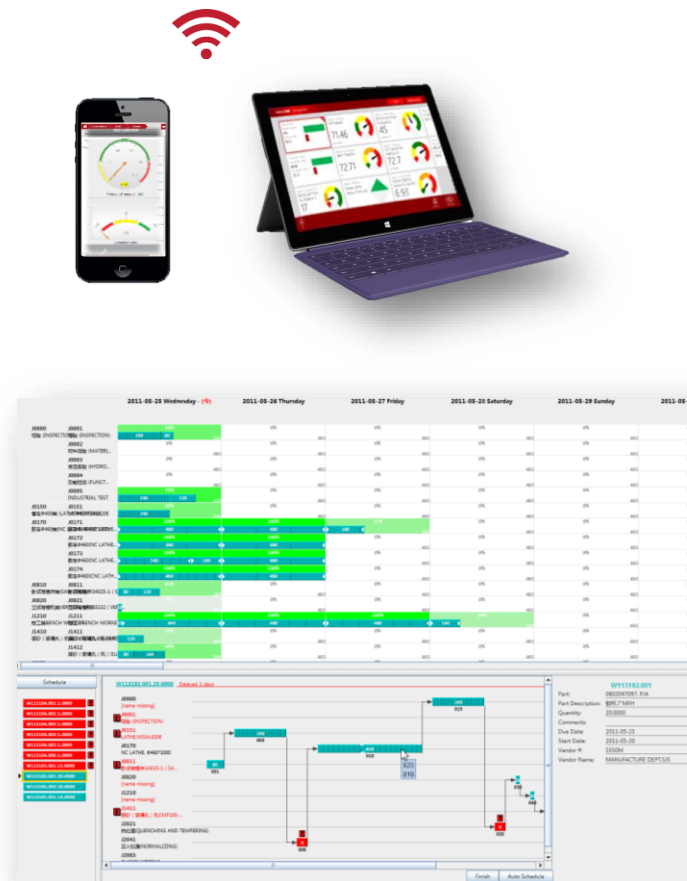
- MES的工作方式
  - 在MES查看日生产计划、下发生产工单
  - 在MES查看各类报警：设备、质量等，处理异常情况
  - 在MES浏览生产工单的实时进度和状态
  - 在MES浏览生产设备的实时状态
  - 在MES浏览电子版生产批记录
- MES带来的效益：与传统方式比较
  - 提高了生产过程的可视化程度
  - 提高了对生产过程掌控的及时性、准确性和完整性

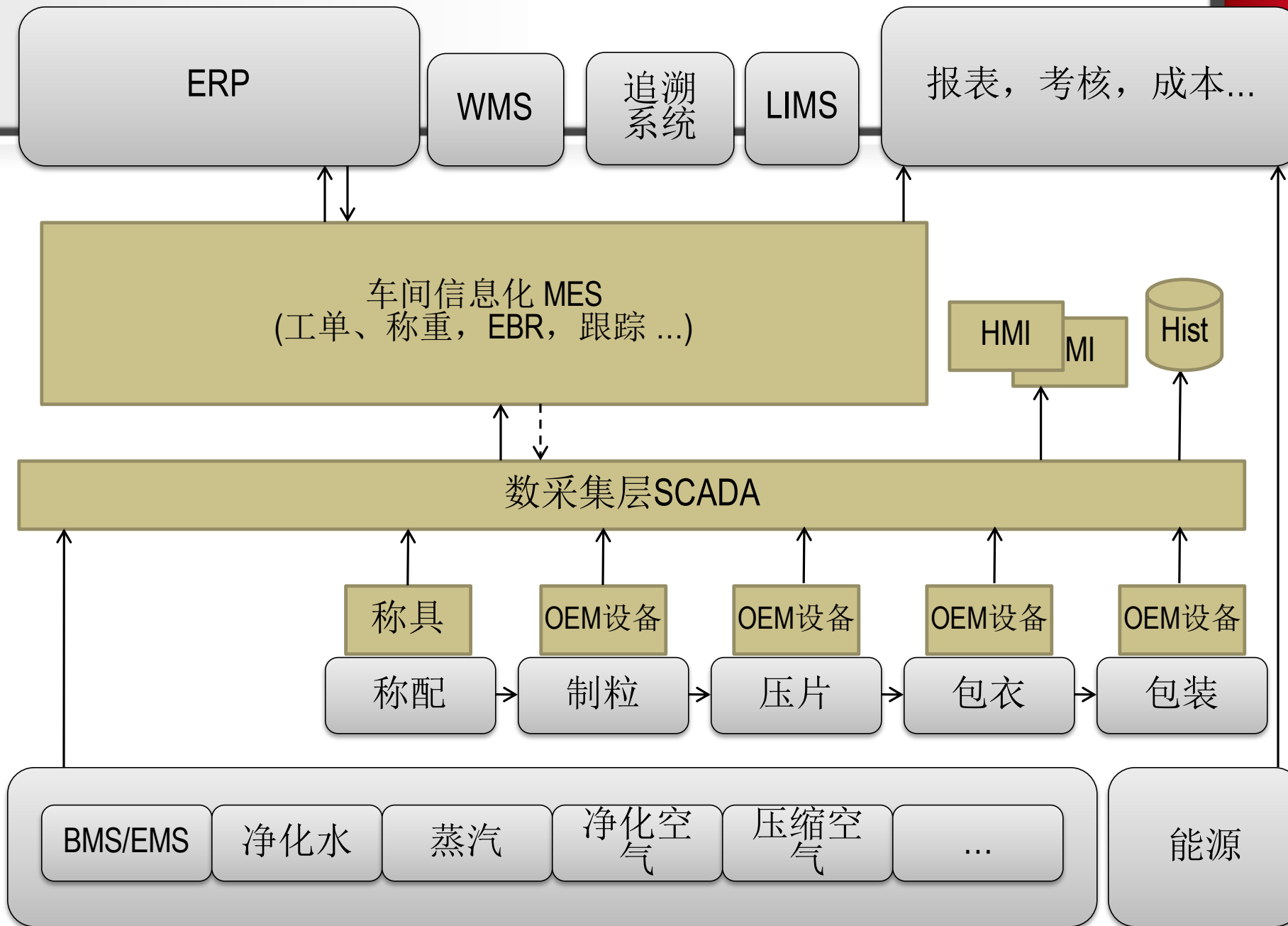
工单单号	工单状态	计划数量	物料代码	物料名称	生产物料名称	备注
070P	已确定	24,000 0.001	11001	甘氨酸		
MES-0001	已取消	24,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES-0002	已取消	24,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES-003	已取消	36,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES-004	已取消	36,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES-004-01	已取消	24,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES-005	已取消	24,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES-006	已取消	24,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES-007	已取消	24,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES-008	已取消	24,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES0009	已取消	24,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES010	已取消	24,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES01036	已取消	24,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES011	已取消	24,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES012	已取消	24,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES013	已取消	24,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES014	已取消	24,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES015	已取消	24,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES016	已取消	24,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES017	已取消	36,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES018	已取消	36,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES019	进行中	36,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES020	进行中	36,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES021	进行中	36,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES022	进行中	24,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
MES023	已确定	24,000 瓶	010100020	0.9%氯化钠注射液	0.9%氯化钠注射液	
CPC	进行中	100 kg	11007	原料药	CPC	





- MES的工作方式
  - 在MES查看日生产计划和生产工单
  - 在MES浏览每天每个班次的生产报表（厂内或远程）、质量报表
  - 在MES查看有无生产异常情况
- MES带来的效益：与传统方式比较
  - 提高了生产过程的可视化程度
  - 提高了对生产过程掌控的及时性、准确性和完整性





# 制剂工厂普遍现状



- 先进的自动化设备
  - 制粒机、包装机
  - 自动配料系统
  - HVAC系统
  - 公用系统
  - CIP/SIP系统
  - IBC清洗站
- 数据“孤岛”和“断层”现象严重
  - 生产过程是断离的；物料的转运和存放，质量监控模式人工为主
  - 大量的表格要填写，易错、难辩；不同的表格上多次填写相同的内容，一式多联的表格要传递到各个部门，信息传送不及时
  - 工艺参数、环境参数手工记录
  - 已填写的表格数量多，管理难度大，查找困难，历史资料不能充分运用



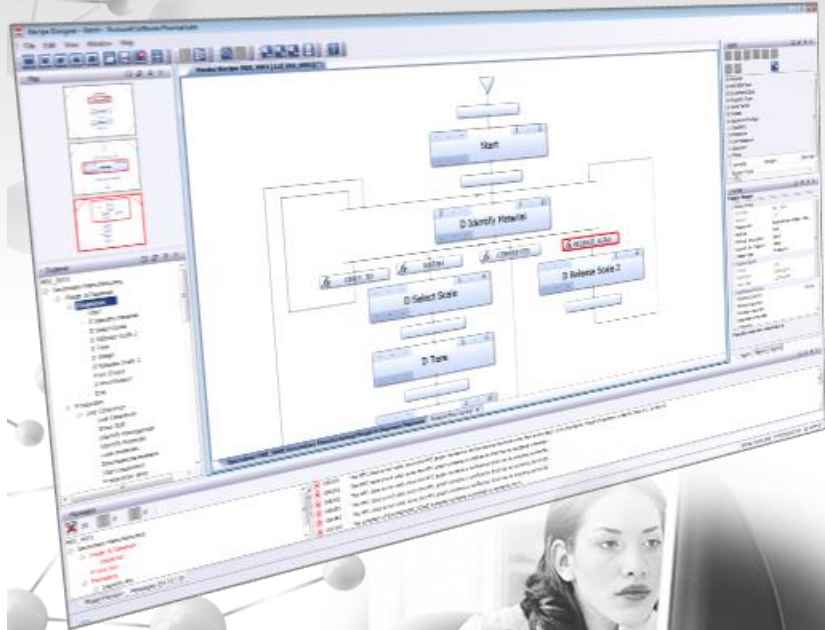
# 现代化制剂工厂车间信息化实施目标

- 建立生产信息化流程管理平台，涉及生产设备、物料、人员、配方、计划，将药品生产过程的各个环节联系、管控起来，维持高度标准化的系统运行状态。
- 物料
  - 利用条码标签、RFID实现物料跟踪
  - 物料有效性(状态，有效期)
  - 称量配料
  - 投料复核、物料平衡
- 生产过程
  - EBR电子批记录
  - 工艺一致性
  - 设备有效性(房间，设备，器具)
  - 避免人为因素造成的错误操作
  - 偏差管理，及时响应与处理
  - 生产车间的在线实时数据采集





# PharmaSuite®



# PharmaSuite 模块化架构

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Automation

## Phase Packages功能包

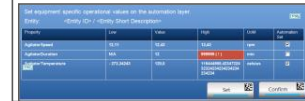
### EBR Basic Phases 电子批记录



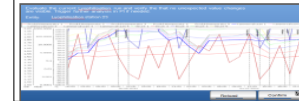
### Dispense Phases 称量配料



### Equipment Tracking 设备追踪



### Equipment Automation 设备自动化集成

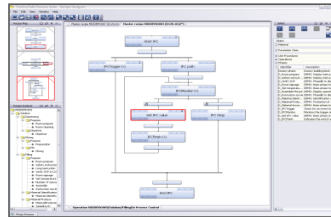


### IPC Phases 中控检查

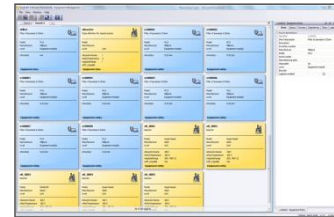


## Design Framework设计框架

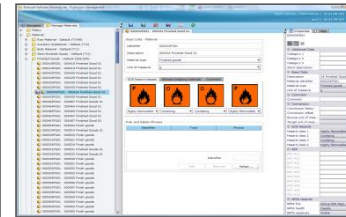
### Recipe & Workflow Designer 配方管理



### Data Manager (Equipment) 设备基础定义

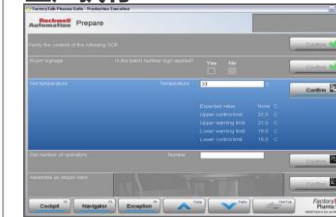


### Production Management 生产配置管理



## Execution Framework执行框架

### Production Execution 生产执行



### Production Review 偏差审核



## ProductionCentre MES平台

## Enterprise Integration Gateway 集成平台

## Upgrade Engine 升级引擎

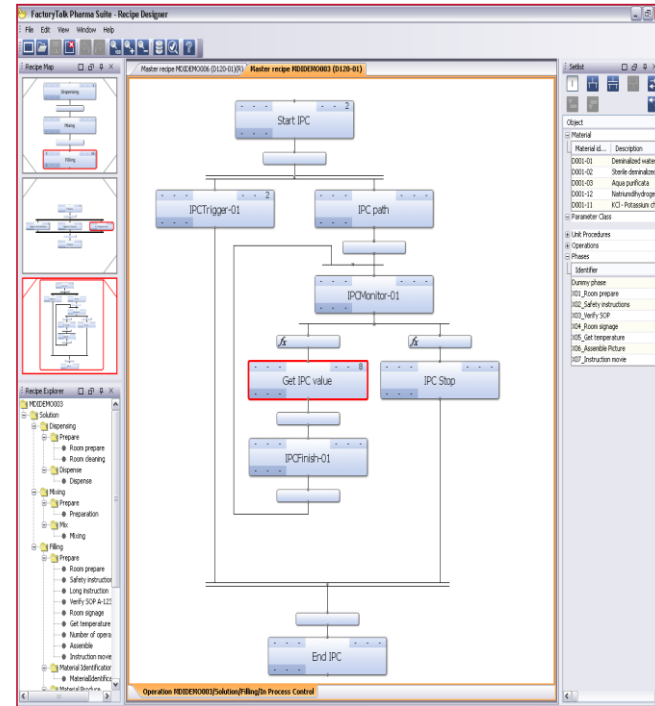




## 工艺规程

## 操作规程

## 空白批记录



# 配方设计

Recipe Designer - Batch - Rockwell Software PharmaSuite

Master Recipe: MDI\_9001 [1.2] (RA\_9001)\*

Unit Procedure: MDI\_9001/Secondary Manufacturing/Packaging

Messages

- MDI\_9001
- Secondary Manufacturing
  - Packaging
    - IPC Summary
      - IPC Values Summary
    - SPC Graph
      - SPC Graph
    - IPC Operation
    - Attachment

Phase Preview Messages (6 | 0 | 0)

- 0012RS The operation has no outgoing link. (Identify Mix)
- 0019RS The components cannot be reached from the start step.
- 0036RS The attribute's expression contains a reference error. (phase: IPC Values Summary, parameter: De
- 0036RS The attribute's expression contains a reference error. (phase: SPC Graph, parameter: Definition, a
- 0097RS The Trigger-enabled capability contains a trigger that specifies an unavailable trigger phase. (opera
- 0036RS The attribute's expression contains reference errors. (phase: Process Duration, parameter: Instruc

FactoryTalk Pharma Suite - Production Execution

Prepare

Verify the content of the following SOP

Confirm

FactoryTalk Pharma Suite	SOP	PMX_SOP_1010
	Prevention of cross-contamination in production	Page 1 of X Version: 01 Valid from: 01.05.2004

Contents

- 1 PURPOSE ..... 2
- 2 SCOPE ..... 2
  - 2.1 IN SCOPE ..... 2
  - 2.2 OUT OF SCOPE ..... 2
- 3 PROCEDURE ..... 3
  - 3.1 MEASURES ..... 3
  - 3.2 PERIODS OF CHECKS ..... 3

Cockpit Navigator Exception

PHARMA AT ITS BEST INC.

DWO-002-Production - BX27

IPC: 0 Info: 0

Filtration

ChangeFilterClip Change the filter according to the video: Confirm

Carefully remove o-ring with wrench

Rockwell Software PharmaSuite™



# 生产的组织安排

FactoryTalk Pharma Suite - Production Execution

Start Order Step

Order step	Status	Material ID	Material descr.	Quantity	Target batch	ERP start	ERP
EXT_01-Filling	Generated	D120-01	Atropa beladonna solution	2,000 g BK2			

选工单

FactoryTalk Pharma Suite - Production Execution

Operation-01

000399RM01 Marathon raw mat... 300 g  
MDIB001 SL00000310

Net weighing MDI1

Tare 64.9 g

277.1 g

称量



FactoryTalk Pharma Suite - Production Execution

Mixing

Set mixing recipe R00978  
Recipe name R00978

Fill mixer with all necessary materials

Confirm start of

Record room temperature in °C

Record mixer speed rpm

lower limit 190

Measure and record the pH value

Exception

pH value has to be adjusted.  
upper limit : 7.1  
Actual value: 8

配液



# 备料领料

领料  
出库单明细

Alt+T F1 Ctrl+F4

出库单号  车间代码  出库时间

出库状态  领料完成时间  确认人

物料编码	物料名称	批次	出库数量	单位	领料数量

F5 F11 F12



# 典型的称量间

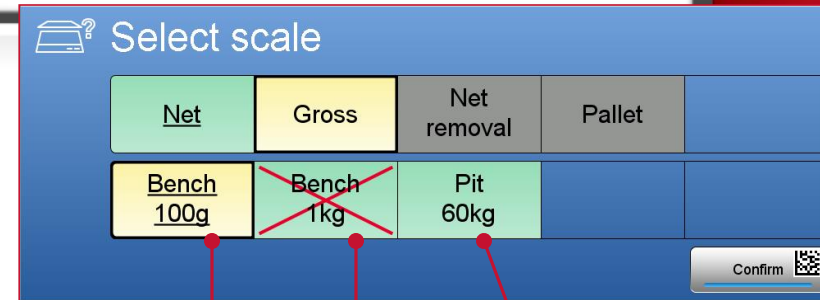
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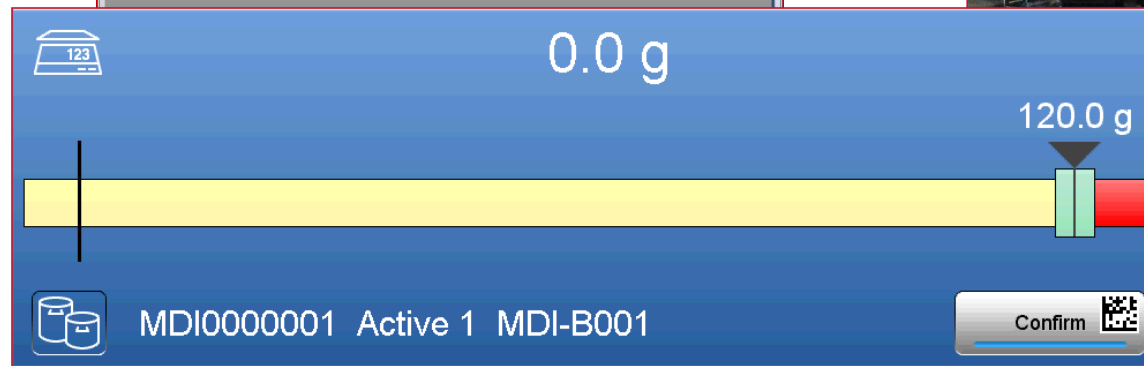
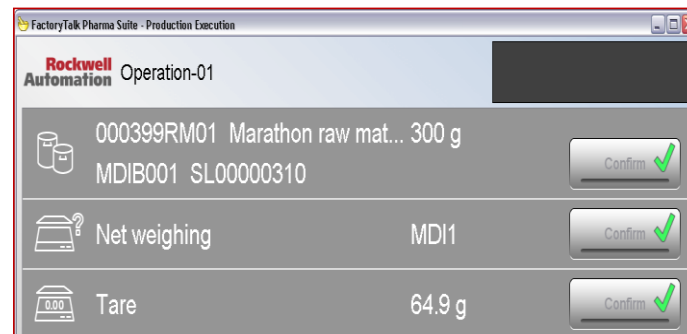


# 称量

- 自动预选量程上下限和精度匹配的称
- 监督称的标定、测试状态、通讯状态
- 允许切换称具（扫描设备编号）
- 如果称通讯失败，允许切换手工操作继续业务（电子签名，必要时强制双签名）



Select weighing method and scale





# 各个车间、岗位电子化的操作指导和记录

The image displays a series of overlapping screenshots from the Rockwell Automation FactoryTalk Pharma Suite software, illustrating the production execution process. The screenshots are as follows:

- Start Order Step:** Shows a table with columns: Order step, Status, Material ID, Material descr., Quantity, Target batch, ERP start, ERP end.
- D-WC001:** Shows a sidebar with 'Production' and 'Inventory' sections, and a 'Running Workflows' area.
- Line preparation:** Shows instructions like 'Assemble equipment as shown.' and a QR code.
- Fill:** Shows a 'pH-value' input field with the value '7.5' and a 'Confirm' button.
- Material produce:** Shows a 'Material produce' screen with a table of produced material sublots.

Material Id	Description	Batch	Sublot	Planned quantity	Produced quantity
D120-01	Atropa belladonna solution	BX3		2,000 g	
		BX3	SL00000266	500 g	
		BX3	SL00000267	500 g	
		BX3	SL00000268	500 g	
		BX3	SL00000269	500 g	

At the bottom of the 'Material produce' screenshot, there is a 'Complete production' section with a 'Confirm' button and a QR code. The bottom navigation bar includes buttons for 'Cockpit', 'Navigator', 'Exception', 'PgUp', 'PgDn', and 'F8'. The bottom right corner shows the text 'FactoryTalk Pharma Suite 01/20/2011 01:05 PM CET'.



FactoryTalk Pharma Suite - Production Execution

PHARMA AT ITS BEST INC. Demo\_PDF\_001-UP01 – BX120  
UP01-1 IPC color check

IPC: 2 Info: 0

User decision: red, blue

Please upload the...

IPC end

Timer control (1)

Warning Delay	2'
Trigger time left	00:01:22
Controller state	Started
Cycle count	0

Pending In Process Controls

Date	Unit Procedure	Operation	Phase	Batch	Order
01/31/2013 0...	UP01	UP01-2 IPC con...	IPCGuard Start (2)	BX118	DEMO_PDF_01
01/31/2013 0...	UP01	UP01-1 IPC colo...	IPCGuard Start (1)		01

double click to open the list of pending process controls

double click on process control entry to jump to the related check list (IPC operation)

Rockwell Automation Pharma Suite

FactoryTalk Pharma Suite - Production Execution

PHARMA AT ITS BEST INC. DWO-002-Production – DemoBA-021  
pH check

20/05/2013 06:08:08 HHH Alarm: Intervention  
20/05/2013 06:08:25 HHH Alarm: Intervention

pH value check Select "Confirm" to start this workflow.

Please, enter pH value: 4

Upper limit: 8

Lower limit: 6

pH too low

Adjust according to SOP 110

Please, enter pH value:

Upper limit: 8

Rockwell Automation Pharma Suite



FactoryTalk Pharma Suite - Production Execution

**Rockwell Automation** Sonolin\_1027-Production - BX24  
Production

Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Pro
D130-01	Sonolin 100 mg premix	BX25			
		BX25	SL00000082		

Account Materials

Refresh

Material ID	Material short description	Batch ID	Sublot ID	Identified	Consumed	Wasted	Sampled
D001-03	Aqua purificata			200.00 g			
		BX2					
			SL00000079	200.00 g			
D003-04	Ethanol 96 %			300.00 g			
		BX4					
			SL00000081	300.00 g			
D080-30	Sonolin			500.00 g			
		BX8					
			SL00000080	500.00 g			

Account

Identified  t g kg  
 Consumed  t g kg  
 Wasted  t g kg  
 Sampled  t g kg  
 Returned  t g kg

Account Cancel

Cockpit F5 Navigator F6 Exception F7 PgUp PgDn F8 Confirm

FactoryTalk Pharma Suite  
02/20/2012 01:24 PM GMT+...

Start Services FactoryTalk ProductionC... order\_labelsAndReports FactoryTalk Pharma ... Untitled - Notepad 1:24 PM



# 物料迁移，暂存间

Rockwell  
Automation

FactoryTalk Pharma Suite - 生产执行

PHARMA AT ITS BEST INC. admin

启动 workflow 运行 workflow

生产

工序执行

库存

领料

物料迁移

库存调整

库存查询

物料销毁

清洁

房间清场

系统

Rockwell Software PharmaSuite™

| Dispense1 | nullnull Dispense1 | 01:28 下午 CST

物料迁移  
物料迁移

源位置 Active\_02\_L1

目标位置 Active\_02\_L2 迁移子批次

子批次号	物料编码	物料名称	数量	批次编码	质量状态	存储位置	存储区域
SL00000175	D120-01	Atropa belladonna solution	400 g	BX8	待检	Active_02_L1	Active_02

Production Location: Rockwell Software PharmaSuite

WO-001-Packaging - BX72

Identify Mix

Identify IBC

Required class	Additional requirements	Actual entity	Status
IBC / IBC	Take off / IBC must be the same class during "Production"	IBC0000001 / IBC	EQ_Cleaning / White


Scan IBC Seal: WRKS2857Q

Identify MIX (autoconsume: ON)

Material ID	Material short description	Batch ID	Sublot ID	Planned quantity	Identified quantity
RA_1101	Active substance	BX76	SL00000145	100 g	0 g

Change IBC status Entity: Property: EQ\_Cleaning

Rockwell Software PharmaSuite™ 04/14/2016 14:21 PM CST



Rockwell Software PharmaSuite - Data Manager

File View Window Help

Search 1 +

Class ✓ Entity ✓ Property type ✓ Q- Type your search term

**Blender\_Small\_RQ**

A blender is a laboratory appliance used to mix, puree, or emulsify subs...

Equipment class

**Compressing\_Ma...**

Press for manufacturing of tablets. A mechanical device that compre...

Equipment class

**Drum**

Laboratory Drum (Container); drum for corrosives, class B pois...

Equipment class

**Hopper**

Silo discharge unit. Used for in-plant handling of powders and granules.

Equipment class

**Outlet**

Part of the hopper.

Equipment class

**Printer**

Generic class for label printer.

Equipment class

**Reactor\_Small\_G...**

Class to group reactors of Type small

Equipment class

**Reactor\_Small\_RQ**

Class for reactor of Type small

Equipment class

**Room**

Generic class for rooms.

Equipment class

**Scale**

Generic class for scales.

Equipment class

**Scanner**

Generic class for scanner.

Equipment class

**Blender\_003**

Laboratory mixer (Section 003)

Equipment entity

**Compressing\_Ma...**

Press for manufacturing of tablets (Section 003)

Equipment entity

**Drum\_003**

Laboratory Drum (Container) (Section 003)

Equipment entity

**Hopper\_003**

Silo discharge unit (Section 003)

Equipment entity

**Outlet\_003**

Part of the hopper (Section 003).

Equipment entity

**Printer\_003**

Label printer #003

Equipment entity

**Dispense\_Room\_...**

Dispense room #003

Equipment entity

**Manufacturing\_0...**

Manufacturing room #001

Equipment entity

**Manufacturing\_0...**

Manufacturing room #002

Equipment entity

**Manufacturing\_0...**

Manufacturing room #003

Equipment entity

**Lab\_Scale\_003**

Scale #003

Equipment entity

**Barcode\_Scane...**

Barcode scanner #003

Equipment entity

70 of 70 objects

Blender\_003 - Entity

Basic Specification Process Engineering Class Logbook Change History

Asset Attributes

Identifier	Blender_003
Short description	Laboratory mixer (Section 003)
Description	GTM
Inventory number	R_2013_0984321
Manufacturer	Rockwell Automation
Model	model GTM
Serial number	91112392
Manufacturing date	01/07/2013
Disposable	<input type="checkbox"/>
Level	Equipment module
Barcode	Blender_003
Logbook enabled	<input checked="" type="checkbox"/>

Automation Attributes

Automation Integration server name (de...	AutomationIntegrationServer1
Automation Integration server name	
Live Data Area path (default)	RNA://\$Global/PharmaSuite/APIProduction
Live Data Area path	

Live Data Test Client C:\AR\ProductLine001-OPC(selection).xml

File Group Data View Help

Item ID	Current Value	Current Quality	Updat...	Run Avg.
ProductLine001.RecipeHom	<none>	Good	2 (0)	0.002
ProductLine001.StartFlag	Off	Good	1 (0)	0.001
ProductLine001.Temperature	18	Good	2 (0)	0.002

Ready | Fid: 2932 | Elapsed: 0:00:19:44





# 设备状态的检查

FactoryTalk Pharma Suite - Production Execution

PHARMA AT ITS BEST INC. DWO-002-Production - DemoBA-021  
Line check

Status: Clean Clean Confirm ✓

**Temperature check**  
(value read via OPC)

 18

Max temp: 24  
Min temp: 20 Confirm ✓

Check homogenizer status (status must be: False = OFF) False Confirm ✓

Check if the following components are properly settled

 Confirm

Pressure gauge  Confirm

Sight glass  Confirm

F5 F6 F7 PgUp PgDn F8

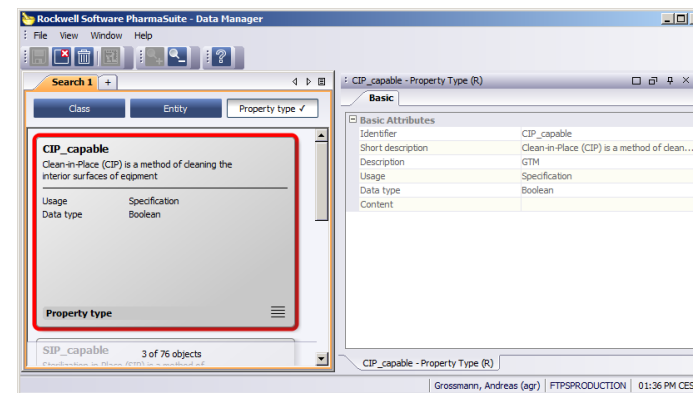
Rockwell Automation  
Pharma Suite





# IBC属性和状态管理

属性类型	属性定义
Boolean	CIP or SIP 标识
Integer	次数
Time	效期



**SIP\_capable**  
Sterilization-in-Place (SIP) is a method of sterilization the interior surfaces

---

Usage: Specification  
Data type: Boolean

Property type

**Stainless**  
Stainless

---

Usage: Specification  
Data type: Boolean

Property type



## ■ 工单绑定和释放，容器和物料的绑定

Rockwell Software PharmaSuite - Equipment Management

File View Window Help

Search 1

Search

Q- Type your search term

**000982ET0101**  
Equipment class 000982CL01  
Equipment entity

**000982ET0102**  
Equipment class 000982CL01  
Equipment entity

**000982ET0201**  
Equipment class 000982CL01  
Equipment entity

**000982ET0202**  
Equipment class 000982CL01  
Equipment entity

**000982ET0501**  
Equipment class 000982CL01  
Equipment entity

**000982ET0502**  
Equipment class 000982CL01  
Equipment entity

**000982ET0301**  
Equipment class 000982CL02  
Equipment entity

**000982ET0302**  
Equipment class 000982CL02  
Equipment entity

**000982ET0401**  
Equipment class 000982CL02  
Equipment entity

**000982ET0402**  
Equipment class 000982CL02  
Equipment entity

**000993ET0102**  
000993 EQUIPMENT ENTITY SHORT DESCRIPTION  
Equipment entity

**ablTestEntity**  
ablTest short description

237 of 237 objects

---

000982ET0202 - Equipment Entity

Basic Specification Process Engineering Class **Logbook** Change History

Between 01/17/2013 12:00:00 AM CET And 01/17/2013 11:59:59 PM CET

Timestamp	Category	Action	Old status	New status	Property type	Information	Workflow	Order	Product batch	Product material	Unit procedure	Operation	Phase	Work center	Station	User
01/17/2013 04:34:23 PM CET	Binding	release	Bound	Available				000982OR.10	BX28	000982FG0.1.1	UP01	OP01	PH03	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:34:23 PM CET	Manual					Manual text entered from the phase		000982OR.10	BX28	000982FG0.1.1	UP01	OP01	PH02	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:34:22 PM CET	FSM	Transition_2	State_2	State_1	000982PT01			000982OR.10	BX28	000982FG0.1.1	UP01	OP01	PH02	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:34:22 PM CET	FSM		State_3	State_2	000982PT01			000982OR.10	BX28	000982FG0.1.1	UP01	OP01	PH02	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:34:22 PM CET	FSM		State_2	State_3	000982PT01			000982OR.10	BX28	000982FG0.1.1	UP01	OP01	PH02	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:34:22 PM CET	FSM	Transition_1	State_1	State_2	000982PT01			000982OR.10	BX28	000982FG0.1.1	UP01	OP01	PH02	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:34:21 PM CET	Binding	bind	Identified	Bound				000982OR.10	BX28	000982FG0.1.1	UP01	OP01	PH01	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:34:20 PM CET	Binding	identify	Available	Identified				000982OR.10	BX28	000982FG0.1.1	UP01	OP01	PH01	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:34:20 PM CET	Binding	release	Identified	Available				000982OR.10	BX28	000982FG0.1.1	UP01	OP01	PH01	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:34:14 PM CET	Denial					Identification denied, equipment is identified elsewhere.	WF13000006				UP01	OP01	PH01	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:34:07 PM CET	Binding	identify	Available	Identified				000982OR.10	BX28	000982FG0.1.1	UP01	OP01	PH01	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:28:18 PM CET	Binding	release	Bound	Available				000982OR09	BX27	000982FG0.1.1	UP01	OP01	PH03	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:28:17 PM CET	Manual					Manual text entered from the phase		000982OR09	BX27	000982FG0.1.1	UP01	OP01	PH02	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:28:17 PM CET	FSM	Transition_2	State_3	State_1	000982PT01			000982OR09	BX27	000982FG0.1.1	UP01	OP01	PH02	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:28:17 PM CET	FSM		State_2	State_3	000982PT01			000982OR09	BX27	000982FG0.1.1	UP01	OP01	PH02	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:28:17 PM CET	FSM	Transition_1	State_1	State_2	000982PT01			000982OR09	BX27	000982FG0.1.1	UP01	OP01	PH02	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:28:16 PM CET	Binding	bind	Identified	Bound				000982OR09	BX27	000982FG0.1.1	UP01	OP01	PH01	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:28:16 PM CET	Binding	identify	Available	Identified				000982OR09	BX27	000982FG0.1.1	UP01	OP01	PH01	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:28:15 PM CET	Binding	release	Identified	Available				000982OR09	BX27	000982FG0.1.1	UP01	OP01	PH01	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:28:10 PM CET	Denial					Identification denied, equipment is identified elsewhere.	WF13000005				UP01	OP01	PH01	000982WC01	000982ST01	Marathon Red...
01/17/2013 04:28:03 PM CET	Binding	identify	Available	Identified				000982OR09	BX27	000982FG0.1.1	UP01	OP01	PH01	000982WC01	000982ST01	Marathon Red...

000982ET0102 - Equipment Entity | 000982ET0302 - Equipment Entity | 000982ET0402 - Equipment Entity | 000982ET0202 - Equipment Entity

Tester1, Marathon (mt1) | ev14 | 06:07 PM CET



# 设备报告上传

Rockwell  
Automation

Rockwell Software PharmaSuite - Production Execution

PHARMA AT ITS BEST INC. DWO-002-Production - BX27 Filtration IPC: 0 Info: 0

Attach report Select ... Confirm

C:\Users\Public\Documents\Recipe\_Test\_Data\IPC\Pressure ipc.pdf 02/25/2013 04:42:15 PM CET

Time	Temperature	Pressure
0:01:00	21.0	20.82730569
0:02:00	20.0	41.6184581
0:03:00	19.0	62.33736669
0:04:00	21.0	82.94806635
0:05:00	20.0	103.4147798
0:06:00	19.0	123.7019796
0:07:00	21.0	143.7744502
0:08:00	18.0	163.5973484
0:09:00	22.0	183.1362645
0:10:00	18.0	202.3572818
0:11:00	21.0	221.2270351
0:12:00	22.0	239.7127693
0:13:00	20.0	257.7823957
0:14:00	20.0	275.4045479
0:15:00	21.0	293.5486355

Pressure

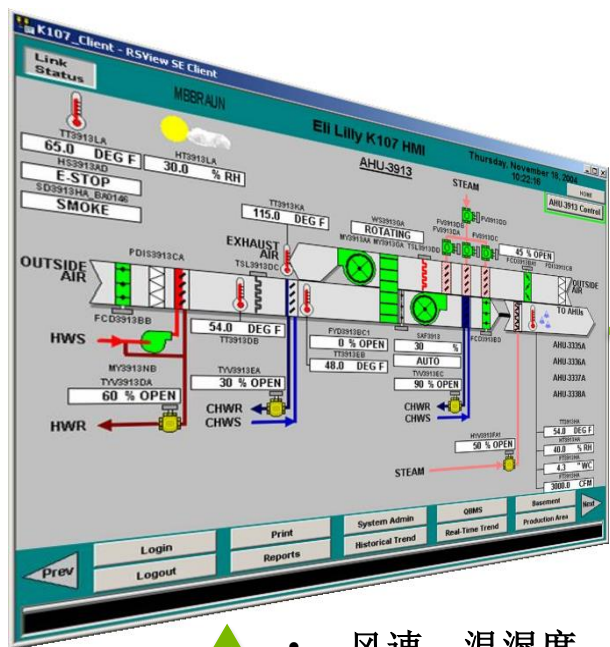
Page 1 of 1

F5 F6 F7 PgUp PgDn F8

Rockwell Software PharmaSuite™



# 集成BMS、EMS环境监控系统



**Rockwell Automation Room setup**

Room:	Check the cleaning status of the room.	
Mixing vessel:	Check the cleaning status of the mixing vessel.	
Dump valve:	Check if the dump valve is closed.	<input type="button" value="Confirm"/>
Room temperature:	Record value between 20 °C and 25 °C.	<input type="button" value="Confirm"/>
Room humidity:	Record value between 35 % and 40 %.	<input type="button" value="Confirm"/>

FactoryTalk Pharma Suite  
 29-04-2009 17:02 CET

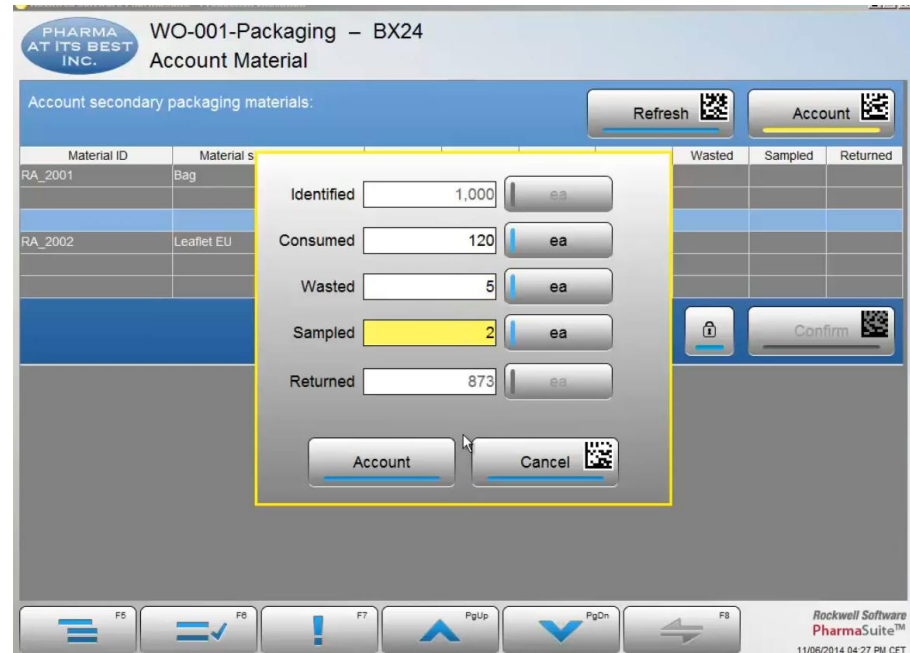
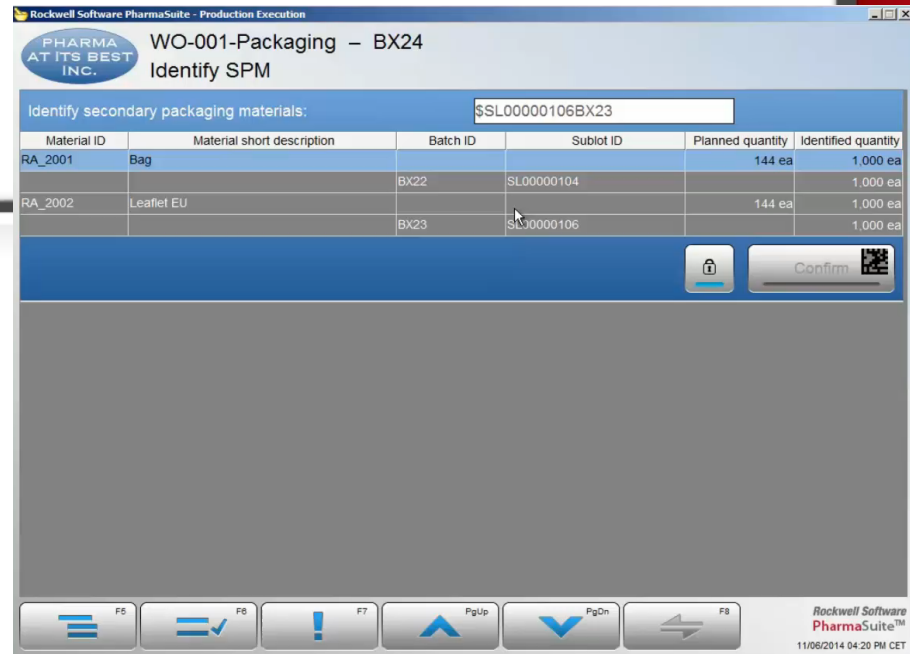
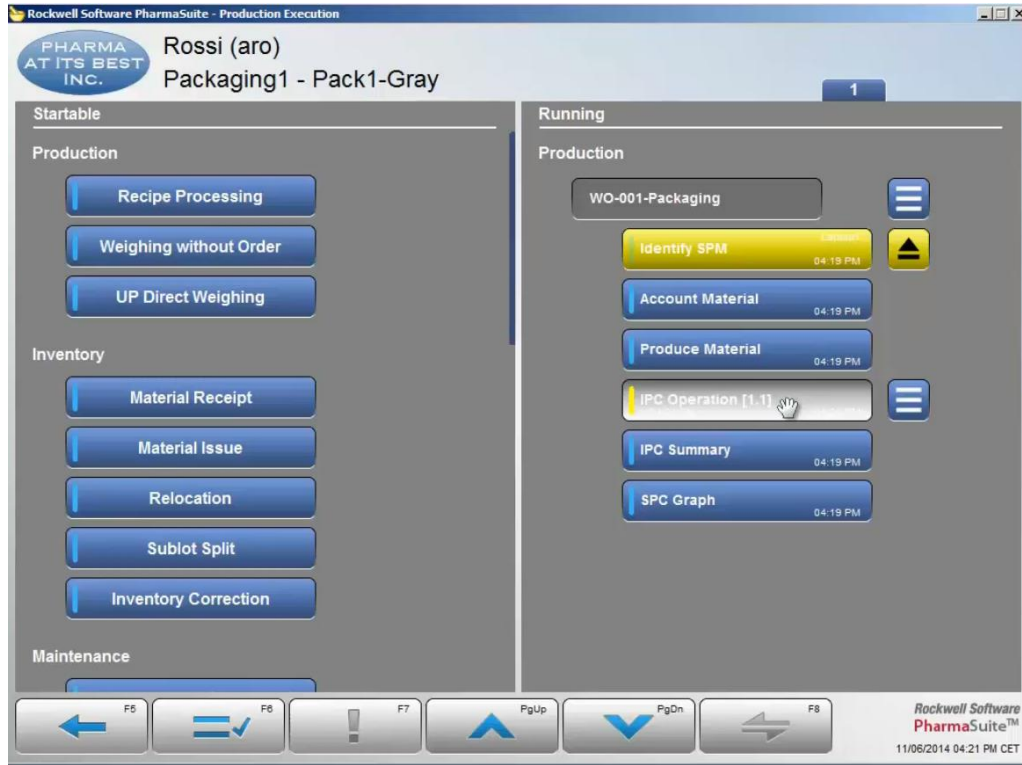
- 风速、温湿度、压差传感器
- 空气粒子传感器，计数器
- 浮游菌采样仪





# 包装线

- 包材投料; 废, 退, 取样
- IPC, 偏差处理, 产出,
- 启停时间, 上传图片、报告



# 生产进度, 偏差管理, 电子批报





## QA的工作模式的改变, 偏差审核 Review by Exception

The screenshot displays the 'FactoryTalk Pharma Suite - 异常仪表盘' (Exception Dashboard) for '钙片压片半成品 - PR08\_20141014002 [1]'. The dashboard shows a summary of exceptions for work orders UP-18, UP-19, and UP-20. The UP-19 work order has 2 exceptions, highlighted in red. A table below provides details for these exceptions, including their status, risk, and descriptions. An 'Exception Recording Panel' is visible at the bottom, allowing users to add new exceptions with fields for description, risk, status, result, CAPA ID, and reference.

标记	标识符	状态	异常 / 注释	目录	风险	引用
006	工单	关闭	已确认的子批次: SL00000246 单位工序	用户触发	无	UP-19 钙片: 制粒/OP-27 钙片: 制粒/PH-06 投料识别物料
006-01		关闭	1 之前的风险:High	---	无	
007		关闭	Operation (OP-27 钙片: 制粒) was detached by supervisor action.	用户触发	无	UP-19 钙片: 制粒/OP-27 钙片: 制粒/PH-12 物料称重产出
007-01		---	Operation has been restarted.	---	---	





- 合规的电子称量流程；管控和实时追踪物料；物料平衡计算
- 电子化工艺规程，工艺参数的检查复核，电子批记录
- 设备合规状态的检查和监控
- 集成BMS/EMS，自动获取实时环境参数
- 对人的操作行为进行指导、约束和取代
- 偏差的记录，追踪和处理
- 批次生产记录审核和放行；查询和归档



# 验证项目交付物

## Planning 计划

Risk Assessment (Template) 风险评估 (模板), Validation Master Plan 验证主计划, Quality Plan 质量计划, Test Plan 测试计划, Configuration Management Plan 组态管理计划

## Specification 说明规范

User Requirement Specification 用户需求说明, Functional/ Design Specification 功能/设计说明, Requirement Traceability Matrix (Template) 需求追踪矩阵 (模板)

## System Build 系统构建

Configuration/Coding Building 组态/编码建立, *Source Code Review* (Optional) 源代码审查 (可选), Internal Test 内部测试, Version Control 版本控制

## Verification 确认

Factory Acceptance Test 工厂验收测试, Site Acceptance Test 现场验收测试 (*HW/SW/21 CFR Part 11.....*), Installation Qualification 安装确认, Operational Qualification 运行确认, *Performance Qualification* (Optional) 性能确认 (可选)

## Reporting 报告

Validation Summary Report 验证总结报告, Documents Handover 交付文档, Risk Assessment integrated with the life cycle 生命周期集成风险评估, Requirement Traceability Matrix integrated with the life cycle 生命周期集成需求追踪矩阵

