

Emerson MES方案介绍与工业 4.0案例分享

生命科学行业负责人

赵洪



艾默生数字化智能工厂建议



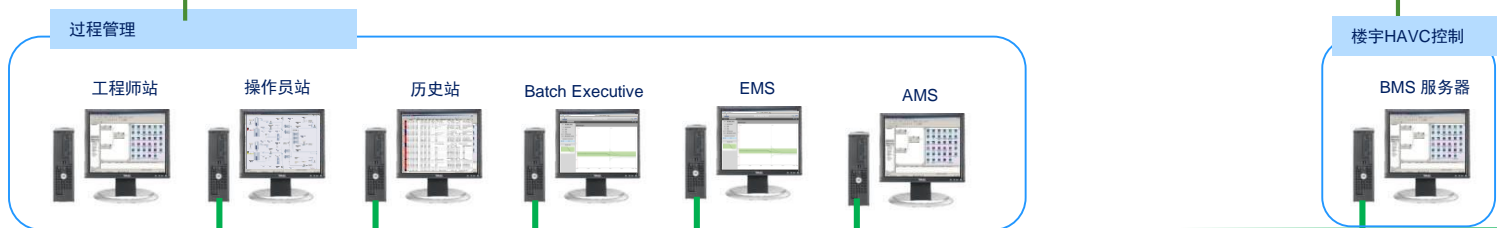
4 层



3 层



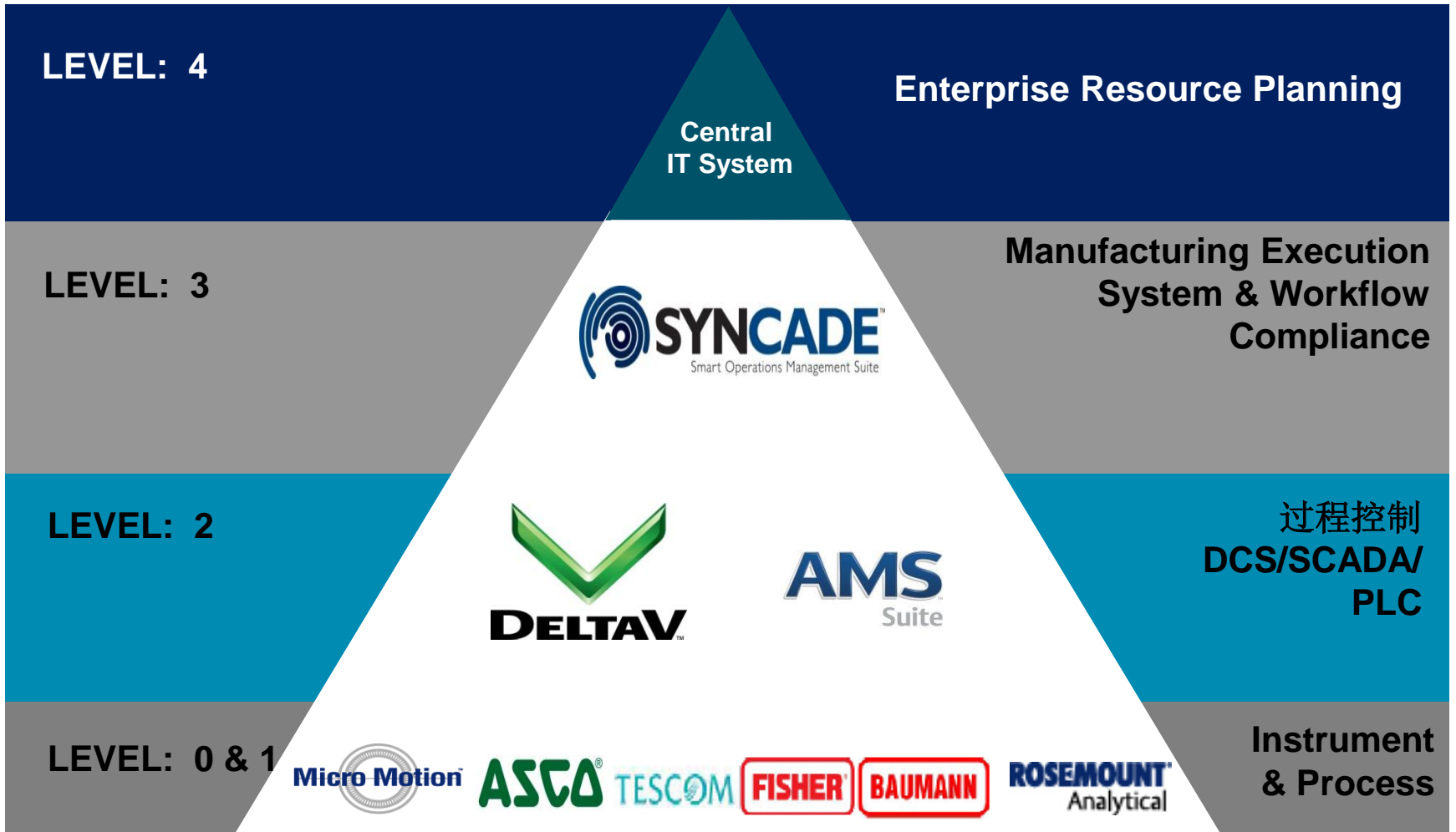
2 层



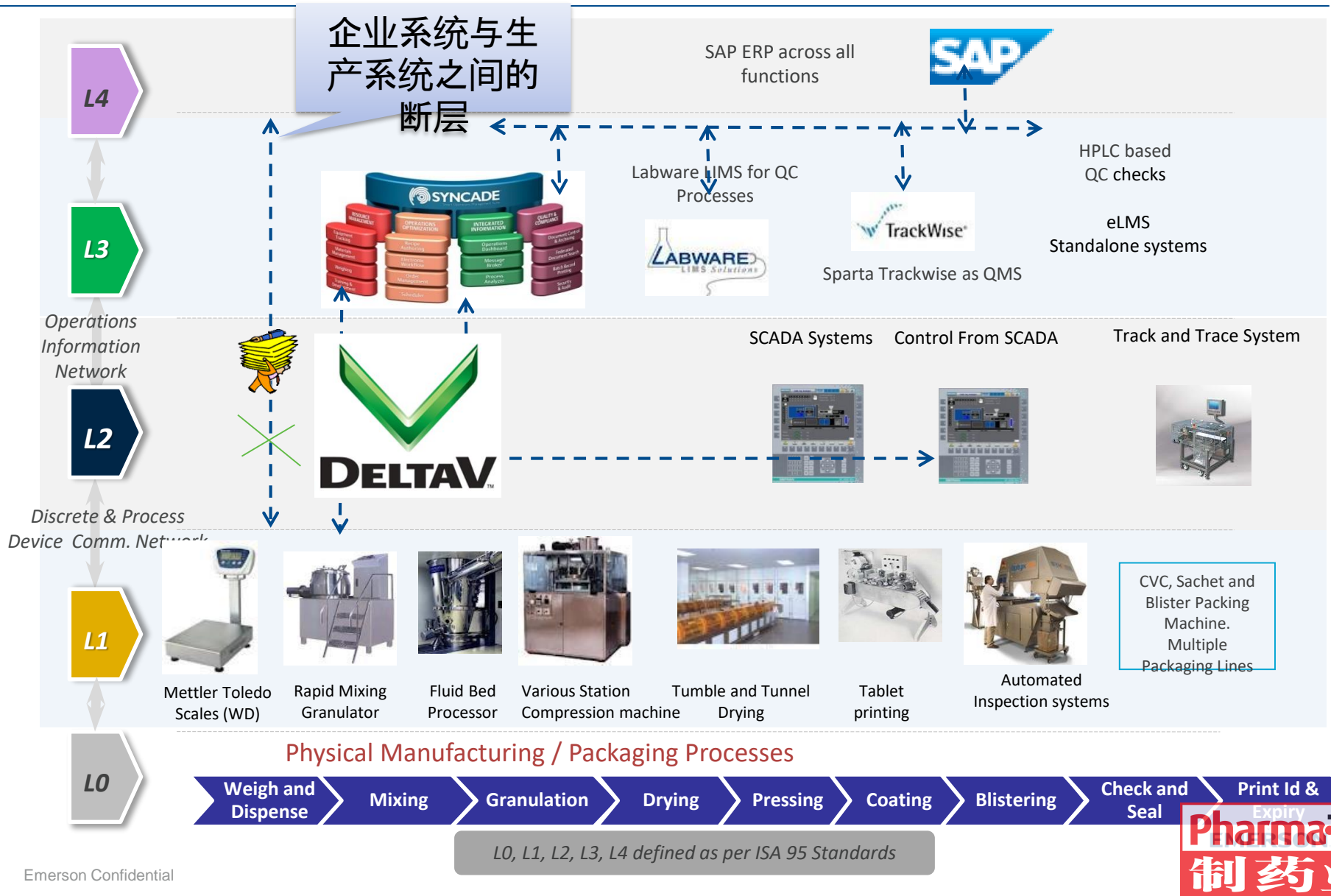
1 层



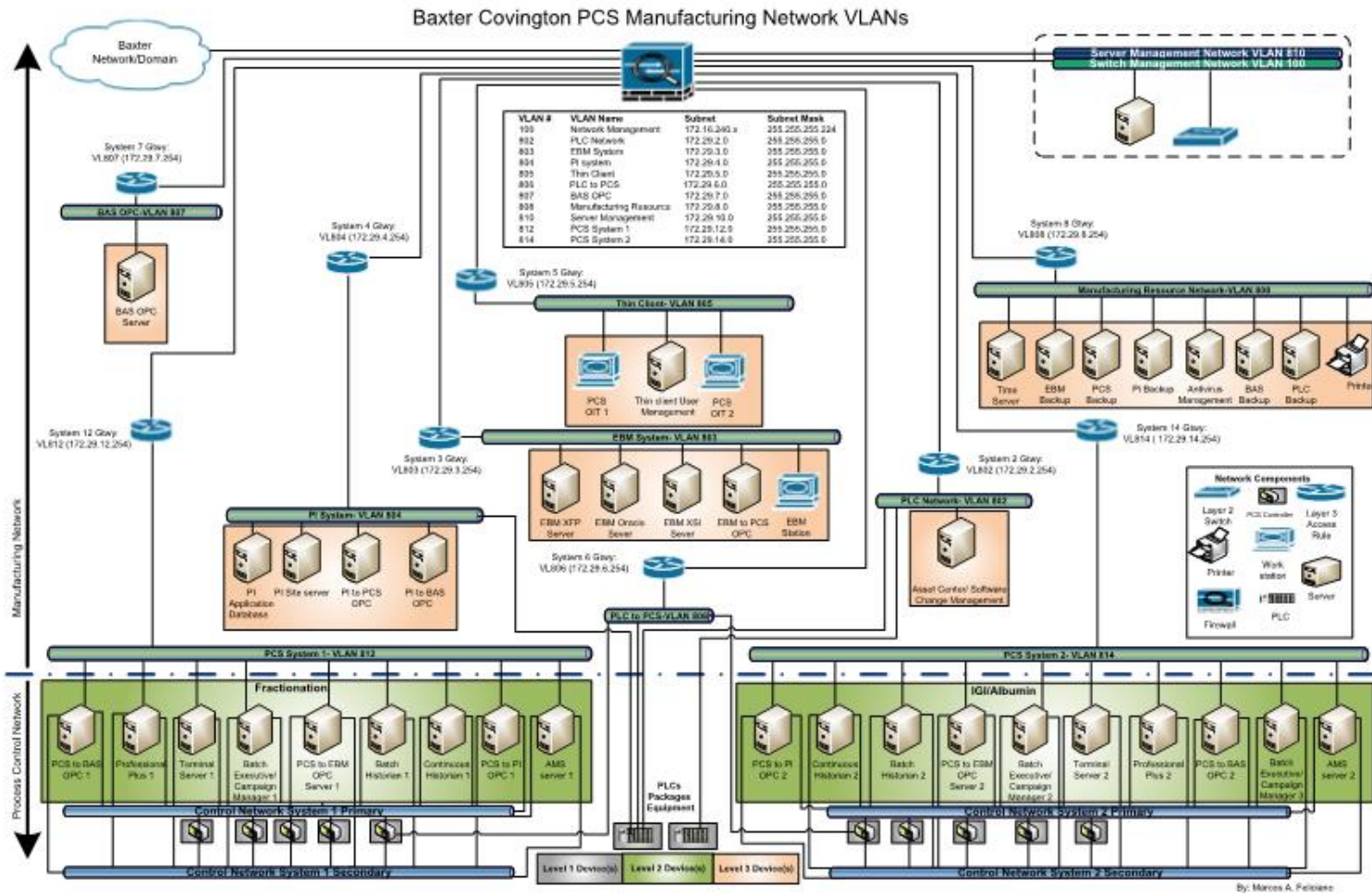
ISA S95 企业自动化模型



艾默生平台的解决方案



国际上流行的企业系统架构



By: Marcos A. Pelegrini

Syncade Smart Operations Management Suite





智能化生产管理解决方案

目前在制药行业的挑战

- 制药的生产必须确保
 - 生产流程正确
 - 物料正确
 - 设备正确
 - 操作人员正确
 - 可追溯

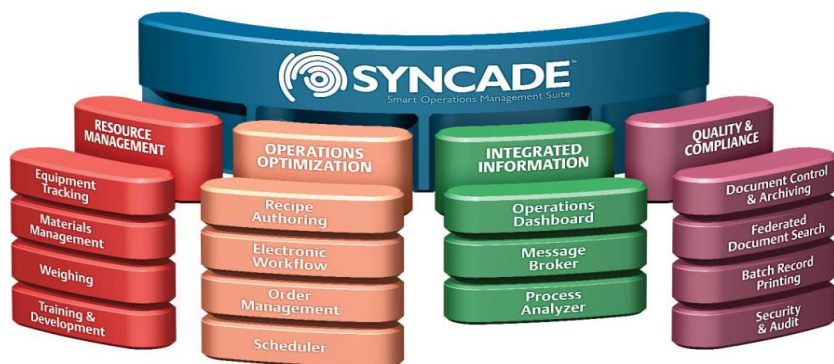


Printed on: January 31, 2008

CONFIDENTIAL

ACME Pharma	MANUFACTURING PROCEDURE			
TITLE Aspirin, Preparation	PROCEDURE NO. BA1000	PAGE 2 of 3		
Process Order ID SAP-080131	Batch ID BJC0131c			
Instruction	Parameter	Actual	Per'd By / Date	Ver'd By / Date
1 Preparation				
Equipment Verification Before Use				
1.1	Ensure the following equipment is ready for use per SOP 5000.	Mixing Tank T-1000		
		Reactor R-1000		
1.2	Label equipment with "In Use" label per SOP 5001			
Components				
	Item	Item #	Vessel	Theo. Amount

生产管理和合规的解决方案 - Syncade



- 专门为制药行业研发
- 符合 21CFR Part 11
- 模块化和可扩展
- 100% 可组态
- 基于网页的架构确保非常容易连接到整个企业其他系统

Resource	Solution
设备	Equipment Tracking (ET) Module
人员	Training Module
物料	Material Management (MM) Module and Weigh and Dispense (WD) Module
文档	Document Control and Archiving (DCA) Module
订单	Order Management (OM) Module
批记录	Workflow Module
配方	Recipe Authoring
所有	Security and Audit (SA) Module

LEVEL: 3



Manufacturing Execution System & Workflow Compliance

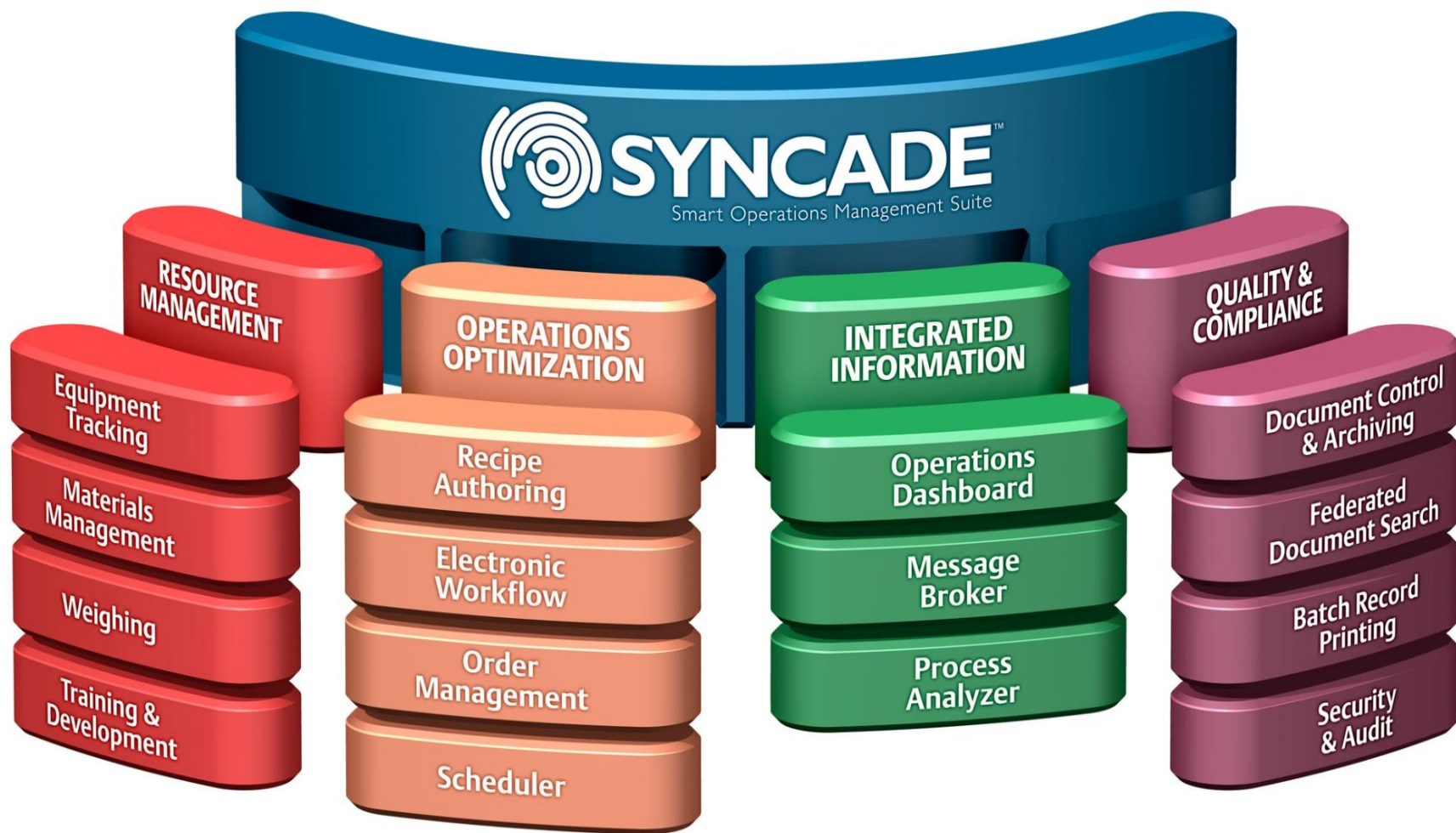
Syncade 模块

- Weigh and Dispense (WD) 称重模块
- Equipment Tracking (ET) 设备跟踪模块
- Document Control and Archiving (DCA) 文档管理模块
- Recipe Authoring (RA) 配方授权模块
- Electronic Batch Records (EBR) 电子批记录
- Material Management (MM) 物料管理模块
- Security and Audit (SA) 安全和审计
- Training and Development (TD) 培训和发展



Syncade

智能化生产管理方案





模块的详细介绍

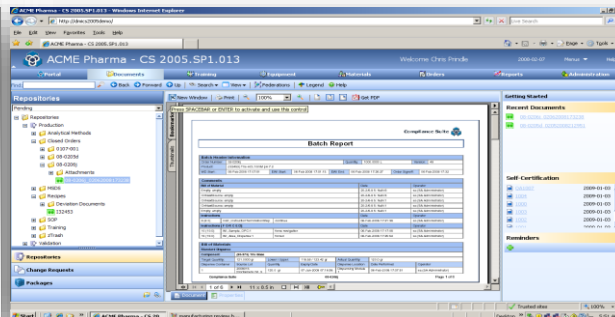
文档管理模块



电子文档管理解决方案

- 定义审阅 / 批准的流程
- 管理主配方, 电子批记录, and SOPs
- **Execute Change Requests** 执行变更需求
- **Users only access effective documents** 用户只能看到当前有效的文档

简化审阅和批准的流程有利于提高质量



ACME Pharma		MANUFACTURING PROCEDURE			
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1.2	Label equipment with "In Use" label per SOP 5001				
Components					
Item	Item #	Vessel	Theo. Amount		

DCA – 文档控制和存储

DOCUMENT NUMBER: SOP
REVISION NUMBER:
Author:
Author's Signature/Date:

SUPERSEDE DATE:	PAGE: 1 of 7
EFFECTIVE DATE:	

Standard Operating Procedure
P-K V-Blender Operation, Calibration, and Preventative Maintenance
FINAL APPROVAL SIGNATURES:

Approval:	Date:	Approval:	Date:
QA Approval:	Date (Issued):		

1.0 PURPOSE
The purpose of this Standard Operating Procedure (SOP) is to outline the operational and preventative maintenance procedures for the P-K V-Blender.

2.0 SCOPE
The following subsections describe the scope in terms of its purpose, organization, reporting, and applicable documents.

3.0 RESPONSIBILITY

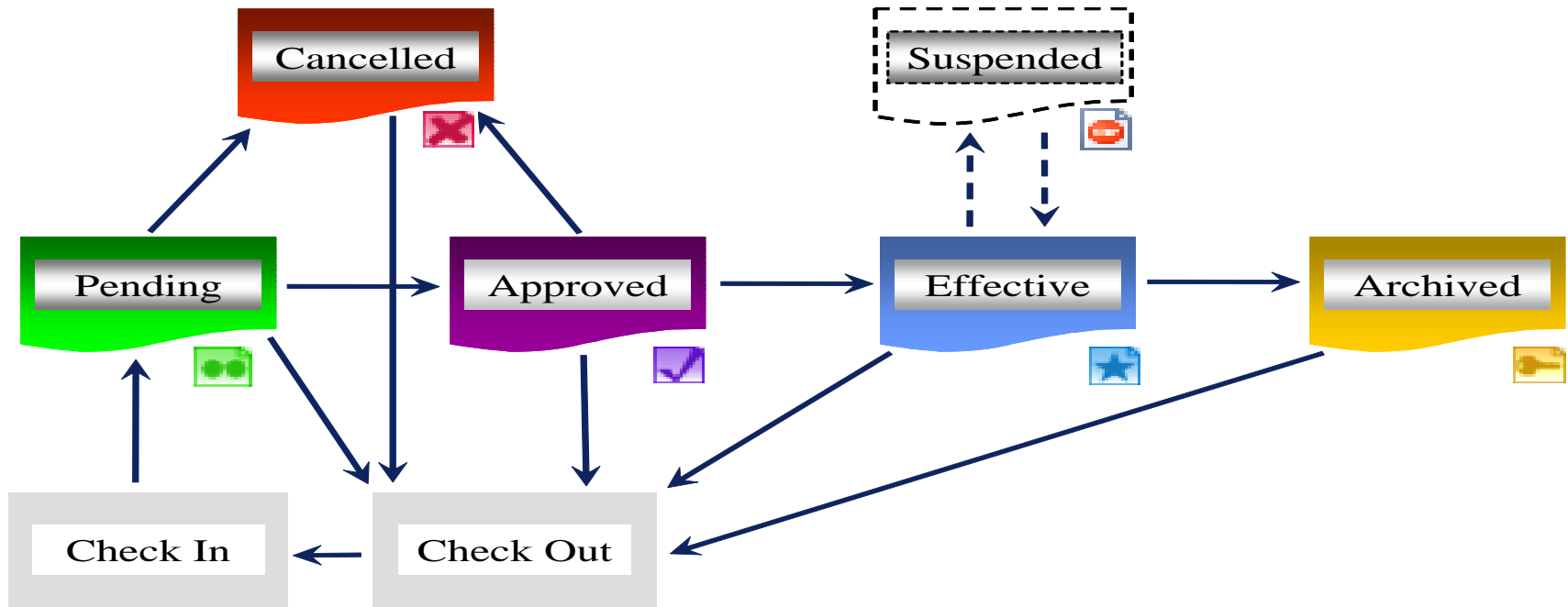
3.1 It is the responsibility of the **Senior Director, Manufacturing**, or his/her designee, to maintain all logs and files, and to update the operational portion of this SOP when deemed necessary.

3.2 It is the responsibility of the **Research Associate** to understand and adequately perform this procedure. Additionally, the Manufacturing Associate is responsible for promptly reporting any aberrant results and/or problems to the Supervisor,

Document Status is Pending as of 2008-04-17T09:02:19

- 存储主批记录和批报告
- 支持文档生命周期管理包括文档状态

内嵌的 Document 文档生命周期管理



- cGMP document life cycle / Electronic routing / Versions control
- Engineering practice and good documentation practice

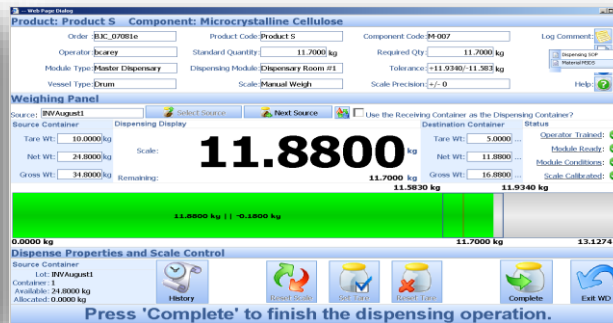
Material Management 物料管理



库存解决方案

- Define Material Masters
- Receive, Ship, and Manage Inventory
- Allocate, Weigh, and Dispense
- Track, and Provide Genealogy

预防失误
优化库存水平



物料管理 - MM

- **Material specification 物料说明书**
- **生产配料**
 - 先进先出，后进后出，过期时间
- **Quality Assurance disposition**
 - Expiration, retest dates, Quarantine status
- **库存管理功能 Inventory management functionality**
 - Receiving, shipping, ... 收货，发货
- **Track material genealogy 跟踪物料族谱**
- **Real-time update for Inventory Control 库存控制的实时更新**



物料管理 - MM

Syncade 2008 - Microsoft Internet Explorer

Welcome Oscar Operator 2008-02-20

Portal Documents Training Equipment **Materials** Orders Reports

Find: Actions Searches View Maximize Legend

Lot Genealogy

View the genealogy of this lot.

Lot Composition

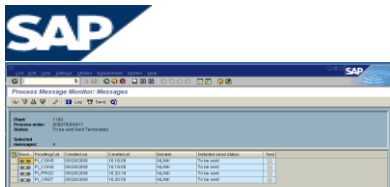
- LNAugust31-1
- LNAugust31-2
- LNAugust31-3
- 092704ott
- 01225
- INNMerch10

Properties

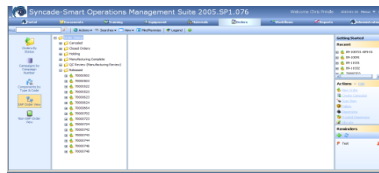
Current User: oscar

WD – 什么是 “Material Weighing” Procedure

订单的预创建



下订单到生产



选取物料



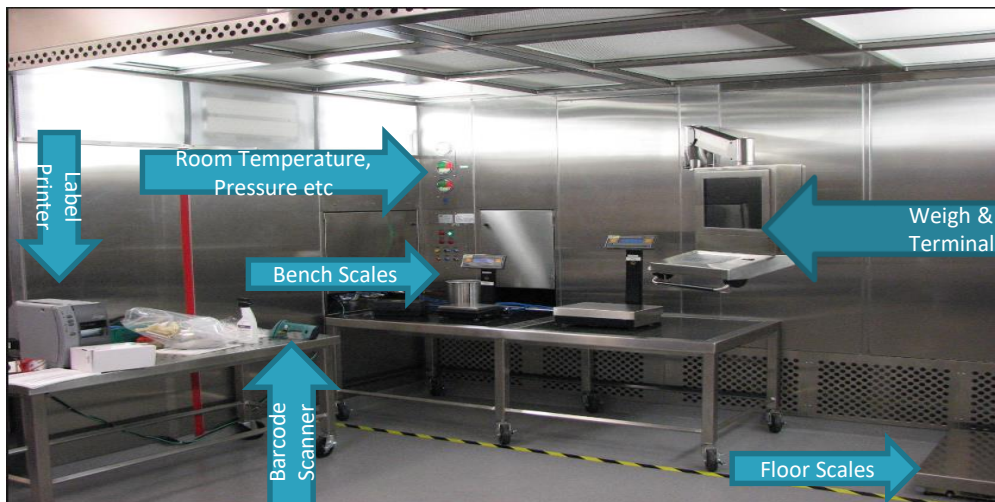
预称重设备检查



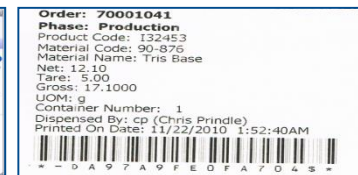
条形码扫描物料



Pre-weigh Checks

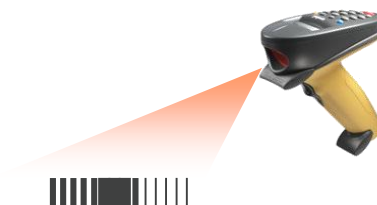
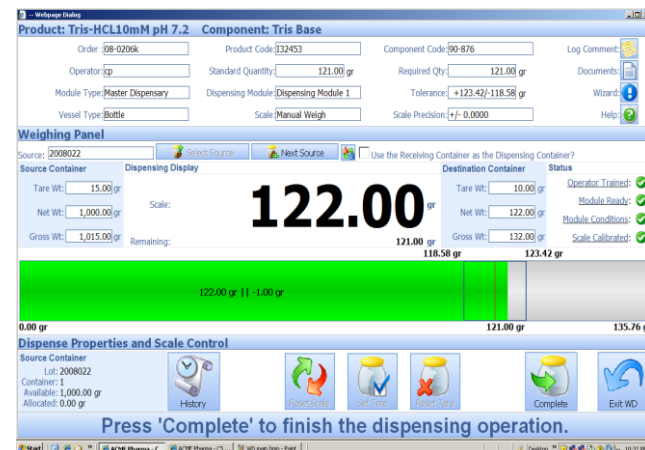


称重



称重 & 分配 - WD

- 配料的各种类型
- **Operator guidance 操作指南**
 - Protection equipments 保护设备
 - Environmental warnings 环境警告
 - Safety indications 安全指示
- 特殊物料配料和位置需要确认
 - Toxic Material 有毒物料
 - Explosion-proof rooms 防爆房间
- 和电子秤集成
- **Real-time update for Inventory Control 库存控制的实时更新**



称重 & 分配 - WD

Product: Product S Component: Microcrystalline Cellulose

Order: Product Code: Component Code: Log Comment:

Operator: Standard Quantity: kg Required Qty: kg

Module Type: Dispensing Module: Tolerance: kg

Vessel Type: Scale: Scale Precision: Help:

Weighing Panel

Source: Use the Receiving Container as the Dispensing Container?

Source Container	Dispensing Display	Destination Container	Status
Tare Wt: <input type="text" value="10.0000"/> kg	11.8800 kg	Tare Wt: <input type="text" value="5.0000"/> ...	Operator Trained:
Net Wt: <input type="text" value="24.8000"/> kg		Net Wt: <input type="text" value="11.8800"/> ...	Module Ready:
Gross Wt: <input type="text" value="34.8000"/> kg		Gross Wt: <input type="text" value="16.8800"/> ...	Module Conditions:
Remaining: <input type="text" value="11.7000"/> kg	11.7000 kg	11.5830 kg	Scale Calibrated:

11.8800 kg || -0.1800 kg

0.0000 kg 11.7000 kg 13.1274 kg

Dispense Properties and Scale Control

Source Container: Lot: Container: Available: kg Allocated: kg

History

Reset Scale

Set Tare

Reset Tare

Complete

Exit WD

Press 'Complete' to finish the dispensing operation.

设备跟踪 - ET

- 减少手动设备操作记录
 - 使用状况, 维修, 清洁, 校验, 状态, 事件记录
 - 其他数据
- 跟踪设备使用情况
 - 收集正在使用设备实时数据
- 确认正在使用设备的状态
 - 清洁, 校验, 消毒, 验证
- 简单明了呈现设备历史
- workflows 的管理



设备跟踪 - ET

Portal Documents Training **Equipment** Recipe Authoring Materials Orders Reports

Custom Views New Equipment Equipment Classes Deleted Equipment Requests Work Orders Search Material History Legend

Custom Views

- Equipment Class
- Code
- CPM
- My Work Orders
- By Floor

SP_Room

- SP_R101
 - Equipment
 - Events
 - Production
 - L3
 - Other Cleaning
 - L2
 - 2008-01-15 18:03:03
 - 2008-01-15 18:02:10
 - 2008-01-15 18:01:05
 - L1
 - 3xL3
 - Maintenance
- SP_R102
 - Equipment
 - Events
 - L2
 - Maintenance
 - Production
 - Other Cleaning
 - L3
 - 3xL3
 - L1
 - 2007-09-14 13:26:01
 - 2007-08-06 13:08:03
 - SP_R103
 - SP_R201
 - SP_R202

Day Week Month Year

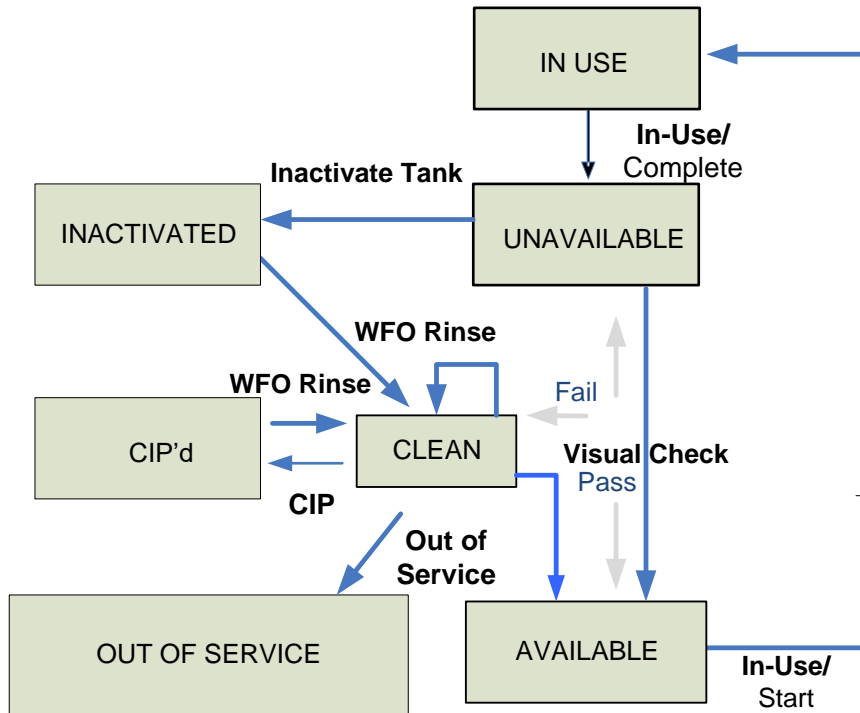
August, 2007

Sun	Mon	Tue	Wed	Thu	Fri	Sat
29	30	31	Aug 1	2 SP_R103 L1 2007-08-02	3 SP_R101 L1 2007-08-03	4
5	6 SP_R203 L2 2007-08-06	7 SP_R202 L1 2007-08-07 SP_R203 L1 2007-08-07	8 SP_R102 L1 2007-08-08 more items	9 SP_R102 L2 2007-08-09 SP_R202 L2 2007-08-09	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25

设备管理

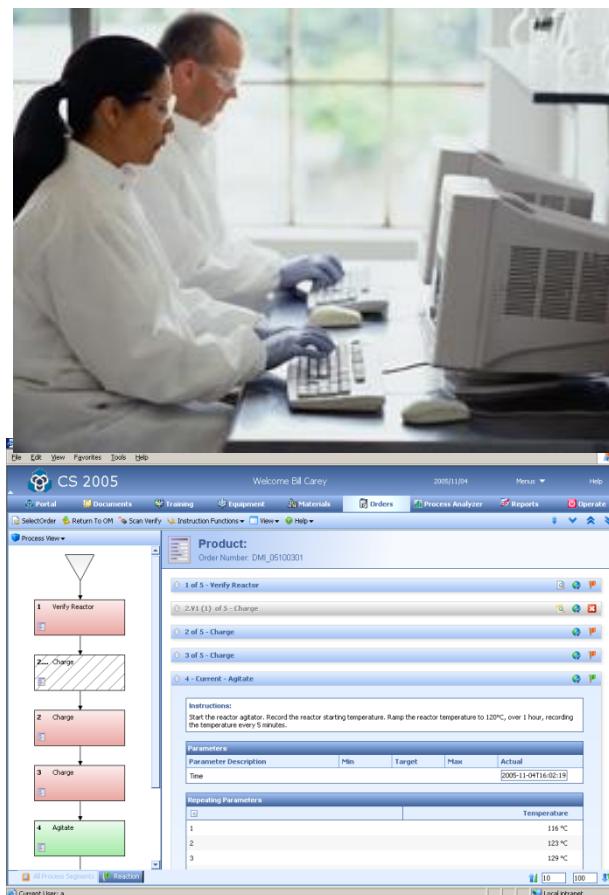
特色

- 可以看到全厂设备的状态
- 广泛的已组态设备状态模型
- 灵活的事件定义-可以包括 workflow
- 灵活的事件触发- 内部和外部触发均可基于设备类和远程模型，易于复制
- 比较简单添加特殊用户的方案



电子 workflows - EWI

- 根据生产的步骤程序化控制
- 确保正在使用正确的SOP
- 确认设备和物料的状态
- 确认操作员的资质
- 生产不可修改的生产批记录
- 完全符合审计和跟踪的生产数据
- 回放和仿真功能



电子工作流程

SelectOrder Return To OM Scan Verify Instruction Functions View Reassign Help

Product: IBPN_FG_200
Order Number: FG-042008d

2 - Current - Verify that the Tablet Press Changeover is Complete

Instructions:
Scan the barcode label or type the barcode value of the tablet press that will be used. Upon execution of this work instruction, verification will be performed in Equipment Tracking (ET) to verify that the equipment has been properly changeover from the prior product and that it is currently in a clean, ready to use state.

Parameters	
Parameter Description	Actual
Equipment Barcode	<input type="text"/>

Signatures:
Operator (Required)

3 of 9 - Scan container to charge

4 of 9 - Select the Packaging Method

5 of 9 - Scan Packaging Material

6 of 9 - Set up Complete

7 of 9 - In-process Weight Checks

All Process Segments Prep

EWI电子 workflows - 当前的步骤

The screenshot displays a web-based workflow interface for equipment verification. The browser address bar shows the URL: `http://dmics2005demo/wf/default.aspx?orderGUID=ACB6904E-28C9-4625-85C3-37089B88FE71`. The page title is "OP_EQUIP_VERIFICATION:1 - Equipment Verification".

Order Information:
Order Number: 20080825-9
Product Code: B_UN240
Product Description: Blended Uranyl Nitrate

Workflow Diagram (Left):
A flowchart showing the process steps:
1. START
2. T1: Identify Equipment (highlighted)
3. T2: Equipment Check Acceptable
4. T3: Equipment Check Unacceptable
5. T5: End (represented by a triangle)

Manual Work Instruction - Current (Right):
Unique ID: 1-1-1-2-1 (1)
Status: Current
Start Time: 2008-08-25T17:50:03

Identify the Blender to use for this procedure.
The system will perform a Lockout status verification.

Signatures:
Operator Required

Parameters:

Description	Actual Value
Select Equipment	23V001

Navigation buttons: Previous, Play, Next

Task Details:

- T2 - 'WI_EQUIP_IDENTIFY:1/BSTATUS' = '\$phase_state:Complete' AND 'WI_EQUIP_IDENTIFY:1/WI_STA...
- T3 - 'WI_EQUIP_IDENTIFY:1/BSTATUS' = '\$phase_state:Complete' AND 'WI_EQUIP_IDENTIFY:1/WI_STA...

Execution and History buttons are visible at the bottom of the workflow area.

EWI – 回放功能

The screenshot displays a web browser window with the URL `http://dmics2005demo/wf/default.aspx?orderGUID=ACB6904E-28C9-4625-85C3-37089B88FE71`. The page title is "MR_PDCF_BLENDED - Blending". The interface includes a navigation bar with "Return to OM", "Workflows", "Go To Current Step", "View", "History", "Stop Auto Refresh", "Session", "Legend", "Settings", and "Help".

The main content area is divided into two panels. The left panel shows a process flow diagram with a "START" box, a transition "T1", a "Blending" box, and another transition "T2". The "Blending" box is highlighted with a red glow. The right panel displays a "MANUAL WORK INSTRUCTION - Complete" for "Identify Material".

The instruction details include:

- Unique ID: 1-1-2-5-0-2 (1)
- Status: Complete
- Start Time: 2008-08-25T18:00:29
- End Time: 2008-08-25T18:01:55

The instruction text reads: "Identify the IUN240, Uranyl Nitrate by scanning the barcode on the container. 50 kg total is needed. 0 kg has been charged so far." It also lists the operator as "Operator - bcarey (Bill Carey) - 2008-08-25T18:01:55".

Below the instruction is a "Parameters" table:

Description	Actual Value	Signatures or Date Executed
Scan inventory barcode:	-I120AD2525335\$	Operator - bcarey (Bill Carey) - 2008-08-25T18:...

At the bottom of the interface is a playback control bar with a filmstrip showing five frames: "WI_VACUUM_START:1", "WI_VACUUM_CHECK:1", "WI_MATL_IDENTIFY:1" (highlighted in red), "WI_MATL_CHARGE:1", and "WI_SAMPLE_TAKE:1". Each frame has a duration of "00:00:02". Navigation buttons for back, forward, and search are also present.

EWI – 电子批记录

The screenshot displays the EWI software interface. The main window shows a 'Batch Report' for 'Compliance Suite'. The report includes the following sections:

Batch Header Information

Order Number:	08-0206j	Quantity:	1000.0000 L	Version:	49
Product:	(132453) Tris-HCL 0.1M pH 7.2				
WD Start:	06-Feb-2008 17:07:51	EWI Start:	06-Feb-2008 17:01:13	EWI End:	06-Feb-2008 17:26:27
Order Signoff:	06-Feb-2008 17:32				

Comments

Bill of Material	Date	Operator
Empty: empty	20-2-6-8 5: NaN:6	sa (SA Administrator)
OnNextSource: empty	20-2-6-8 5: NaN:5	sa (SA Administrator)
OnNextSource: empty	20-2-6-8 5: NaN:1	sa (SA Administrator)
OnNextSource: empty	20-2-6-8 5: NaN:1	sa (SA Administrator)
Empty: empty	20-2-6-8 5: NaN:1	sa (SA Administrator)

Instructions

Instructions [FORCED]	Date	Operator
6 (6:0) Instr_InstructionTerminationStep continue	06-Feb-2008 17:21:36	sa (SA Administrator)
10 (10:0) WI_Sample_DPC:1 force navigation	06-Feb-2008 17:17:06	sa (SA Administrator)
15 (15:0) WI_Area_Dispen:1 forced	06-Feb-2008 17:25:54	sa (SA Administrator)

Bill of Materials

Standard Dispense

Component:	(08-876) Tris Base					
Target Quantity:	121.0000 gr	Lower / Upper:	118.58 / 123.42 gr	Actual Quantity:	120.0 gr	
Dispense Container	Source Lot	Quantity	Expiry Date	Dispense Location	Date Performed	Operator
1	2008013 (Containers: Nr. 3)	120.0 gr	07-Jun-2009 07:16:58	Dispensing Module 1	06-Feb-2008 17:07:51	sa (SA Administrator)

Compliance Suite 08-0206j Page 1 of 6

The interface also features a sidebar with 'Recent Documents' and 'Self-Certification' sections. The 'Recent Documents' list includes:

- 08-0206j_02062008173238
- 08-0205d_02052008212951

The 'Self-Certification' section lists various QA1007 documents with dates ranging from 2009-01-03 to 2009-01-02.

安全和审计 - SA

- **Users, profiles and access management**
- **Interfaces with domain management Microsoft Windows™ Active Directory**
- **Provides a full audit trail history**
- **Uses encryption and check sum data protection**
- **Ensure compliance with 21 CFR Part 11**



培训和发展 - TD

- **Maintains training requirements**
- **Integrates training certifications real-time with production**
- **Training reports and department views**
- **Ability to self-certify**
- **Linked to DCA for document training use before approved document promotion to effective status occurs**
 - Create a rule for effective status: When XX% operators trained in SOP123, it is promoted to effective status.



工业4.0项目概念设计

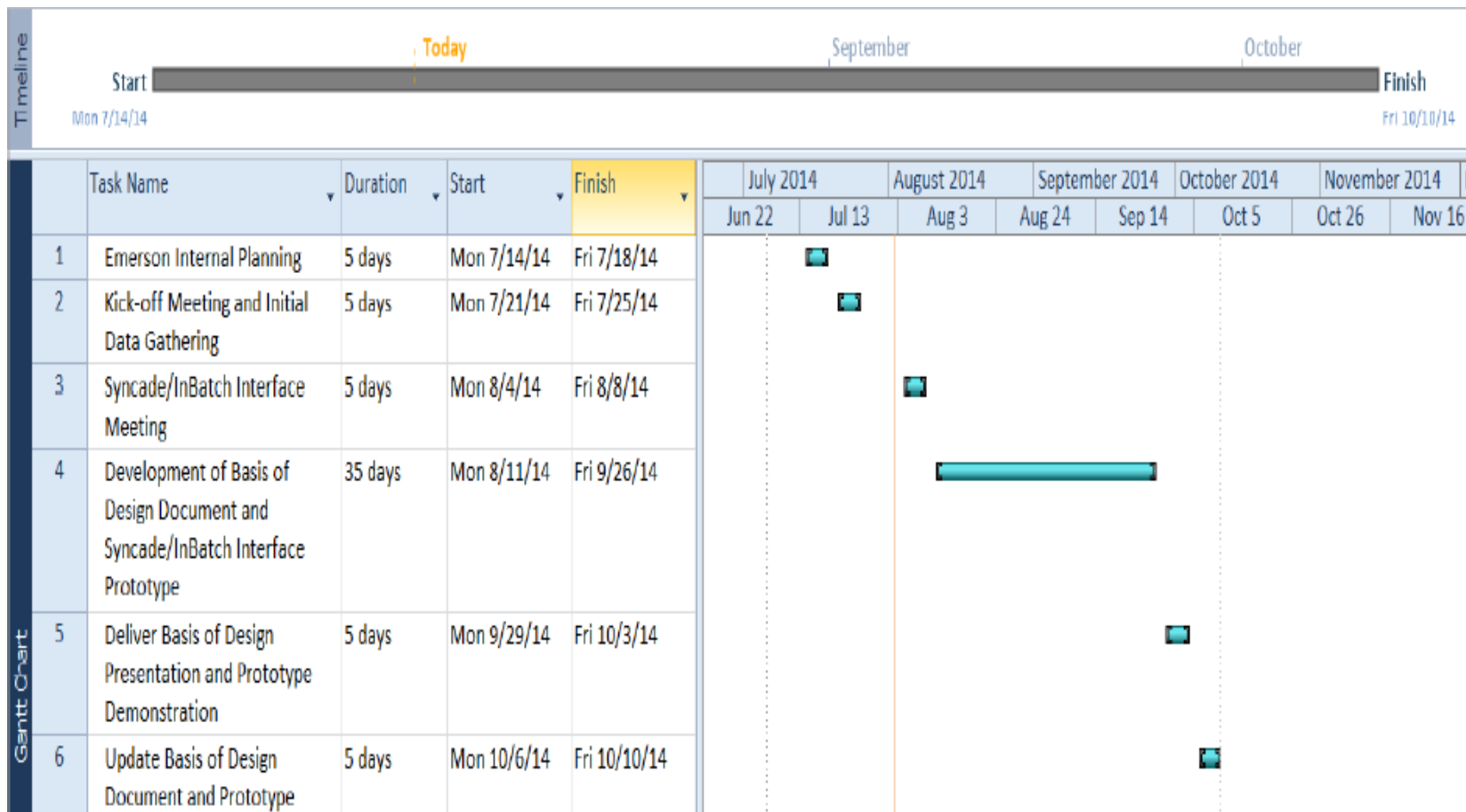
概念设计工作范围

- 了解**PAS**和**Syncade**之间的功能划分范围
- 定义每个接口的要求
- **MES**原则的制定
- 项目执行的预估-详细设计，执行，测试和发货
- 通过现场的多次交流确定**MES**的标准

概念设计的输出资料

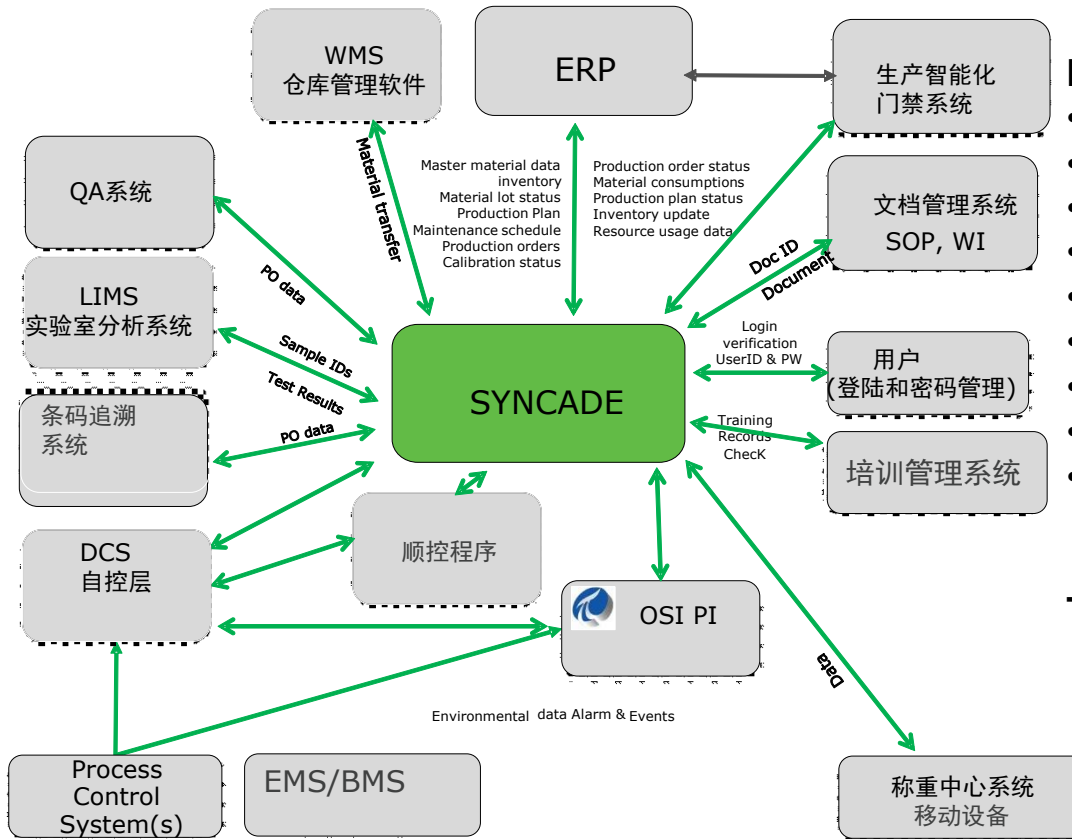
- URS
- 操作观点的申明 (with S95 breakdown w/other systems)
- 系统架构 – hardware & software (including interfaces defined on next slide)
- High Level Guideline Documents supporting User Requirements:
 - DCA(Integration with Docspace)
 - Equipment Management(Integration with SAP PM)
 - Material Management/W&D(Integration with WMS and SAP)
 - Order Management/Recipes(Integration with SAP)
 - Interfaces – see next slide (does not include PLM or Operational Intelligence)
 - Training Management(Integration with Compliancewire)
 - Reports & Dashboard - Batch End Reporting and Review by Exception process
- Prototype – Syncade/DCS interface
- Estimate for Project execution

项目的概念设计进度表



案例分享

案例分享 – 系统分析图



Interface Prototype and Guidelines for:

- Syncade Integration to Automation Layer

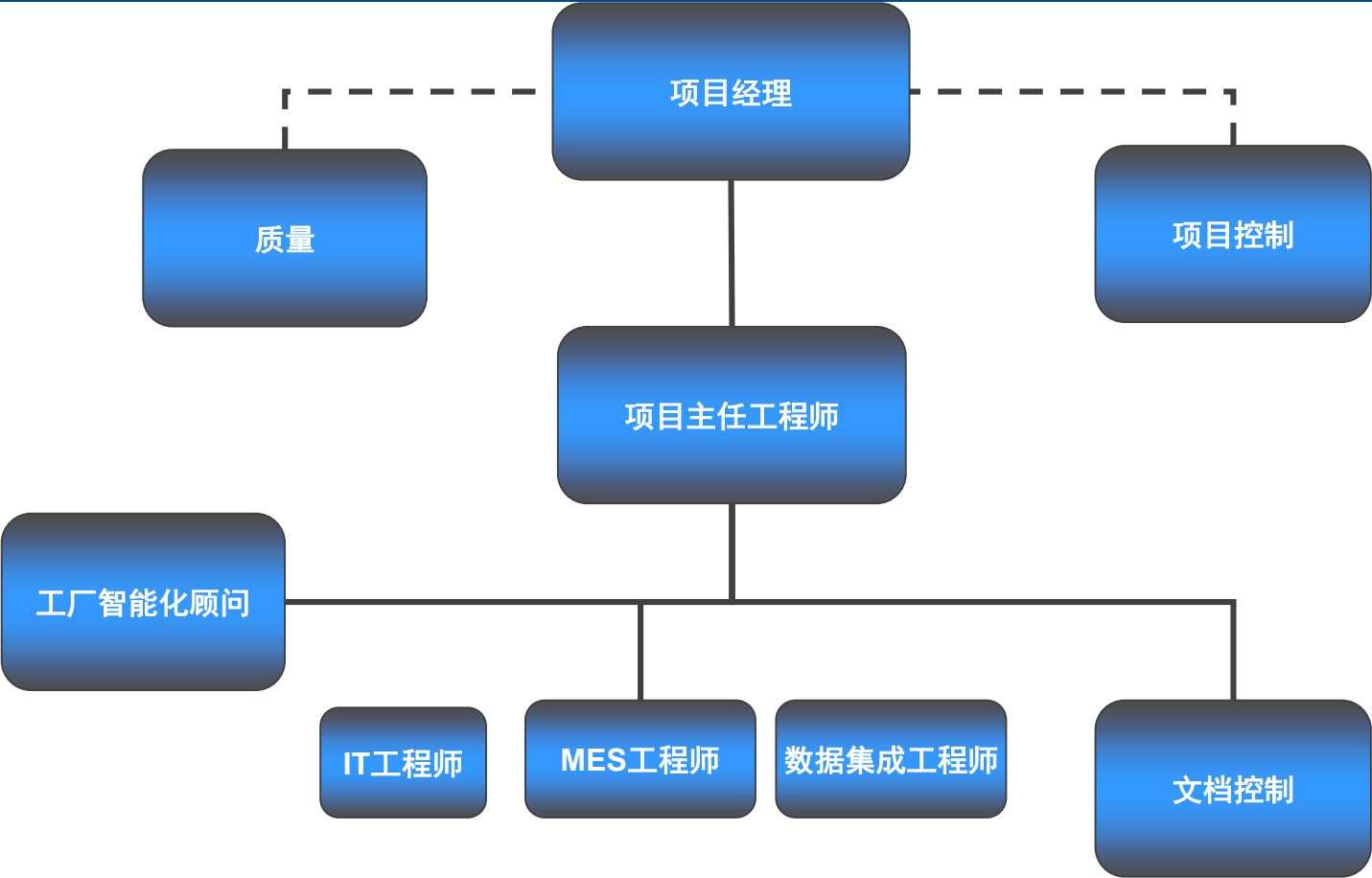
High level Guidelines for Interfaces to:

- SAP
- WMS 仓库管理系统 Swisslog
- eLIMS Sample Management
- Compliancewire Training
- Docspace Document Management
- OSI Pi Historian
- Loftware Labeling system
- Serialization Site Repository 爱创
- SAP PM CMMS Maintenance

TBD:

- TrackWise
- Scheduler

典型的项目组架构



Syncade用户

Genentech
A Member of the Roche Group

Roche

gsk
GlaxoSmithKline

Lilly

 **Bristol-Myers Squibb**

Lonza

Amway

PMR&S

biogen idec

RepliGen

COOK[®]
PHARMICA

ucb

fhi360

PhilipMorrisUSA
an Altria Company

HAN/DOK
HANDOK
PHARMACEUTICALS
CO., LTD.

Vopak

 **Savannah River Nuclear Solutions, LLC**
A Fluor Daniel Partnership

élan

isolagen
Changing the Face of Time

Pfizer

Shire

CIMA LABS[™]
a Cephalon company

tengion[®]

sanofi pasteur
The vaccines business of sanofi-aventis Group

MENTOR

Recip

Nestlé

Johnson & Johnson

kaneka
KANEKA CORPORATION

PharmaTEC
制 药 业

国际制药客户



中国的制药客户



Lonza Engineering Ltd



石药集团



海正药业



Thanks
