

基于数字化工厂的医疗 器械行业智造解决方案

Camstar MES solution for medical device
digital manufacturing.



Agenda



我们对医疗器械数字化工厂建设的理解

Camstar MES及其在医疗器械行业案例介绍

医疗器械行业套件产品定位及功能概览

Q & A

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企业提高竞争力概述

提高竞争力

质量保证
能力

产品研发
能力

成本控制
能力

供应商管
理能力

订单交付
能力

客户服务
能力

精益管理思想结合数字化信息系统工具的应用，建立相应的信息链闭环及其持续改善路径

1 质量

- 质量体系 and 合规 (FDA, CFDA, ISO 13485)
- 设计生产过程记录 (DHF, DMR, DHR, eBR)
- 质量流程 (CAPA, NC, 客诉)

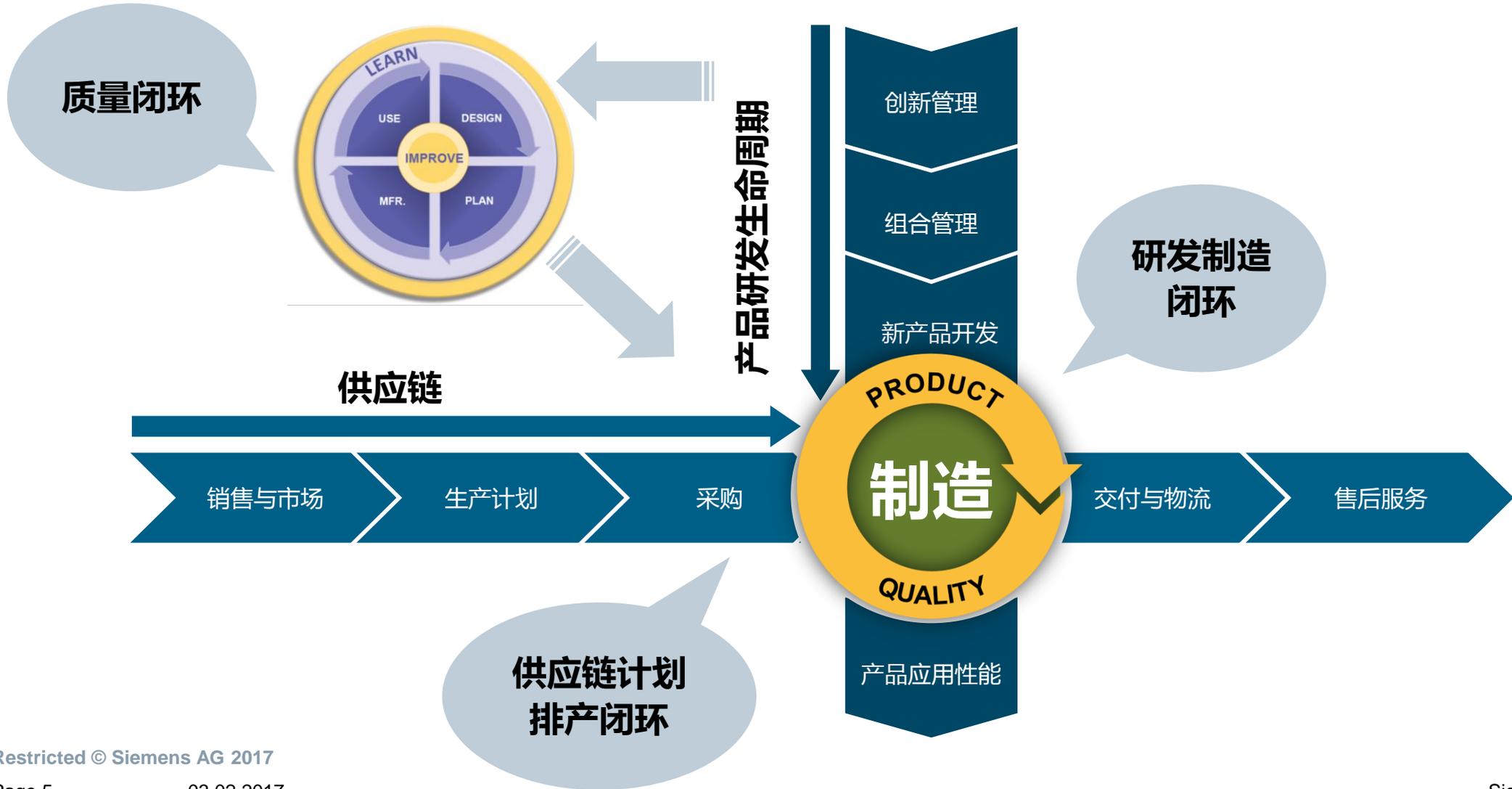
2 成本

- 低成本合规 (如无纸化、自动化等)
- 风险成本-减少客诉和质量事件
- 精益制造管理

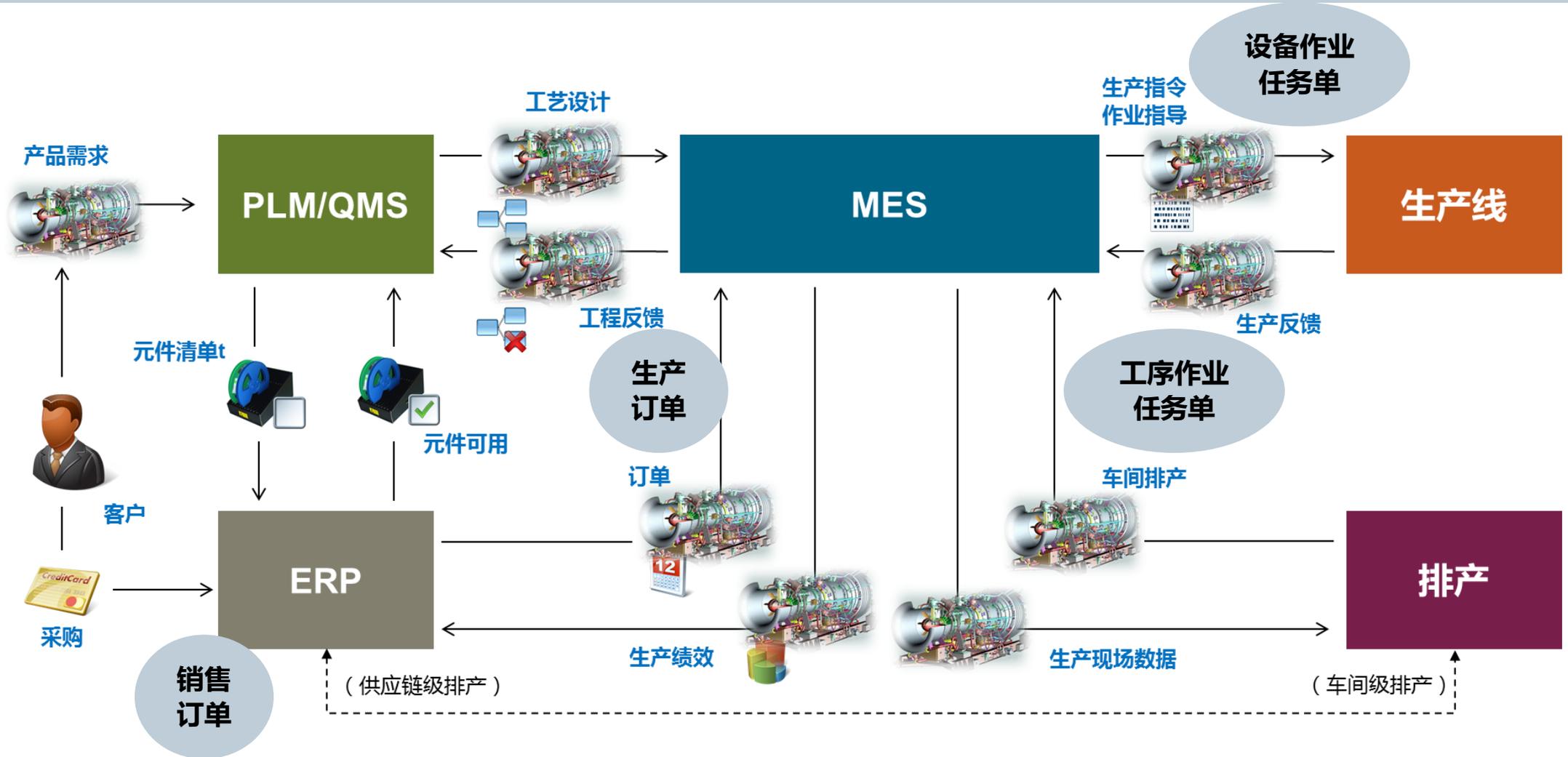
3 交付

- 定制化需求和设计变更效率
- 多品种小批量生产方式

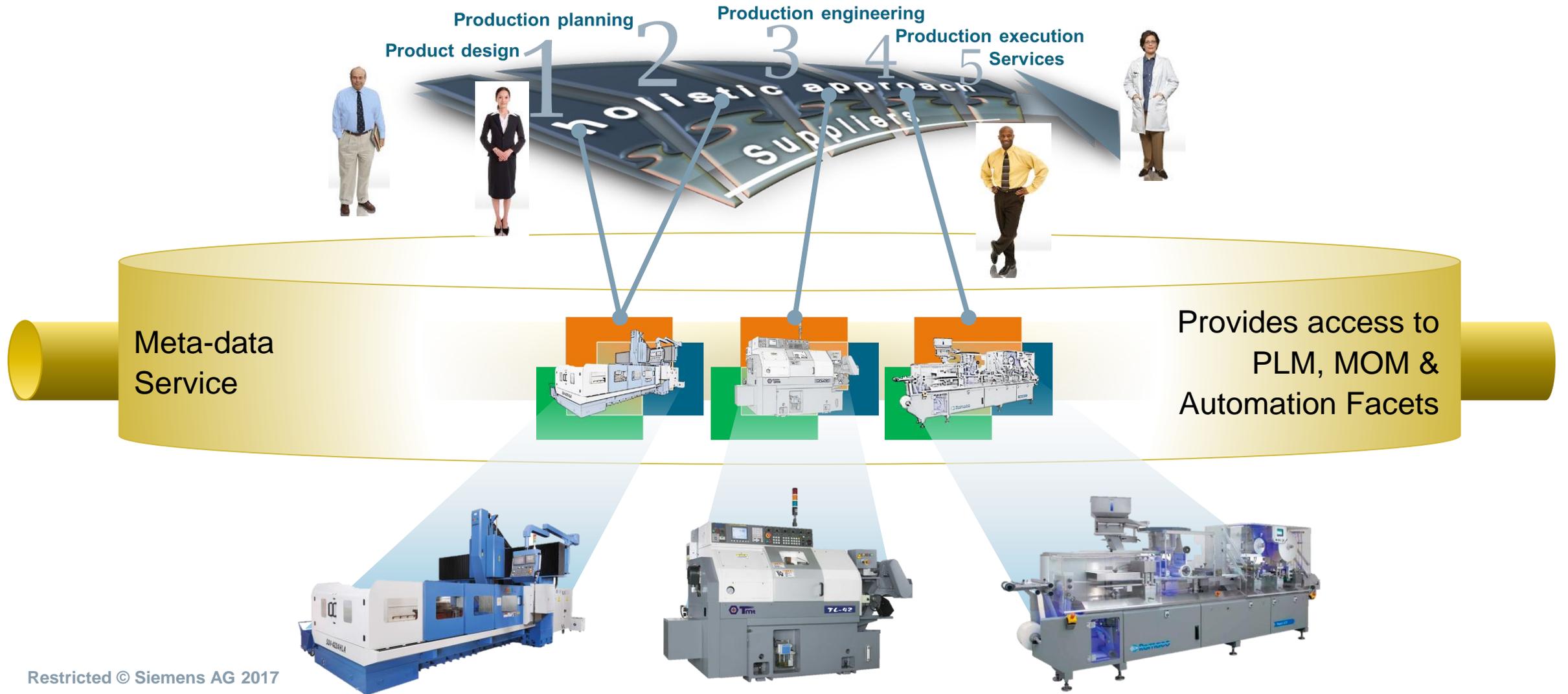
从不同的维度和信息闭环看待MES系统的应用



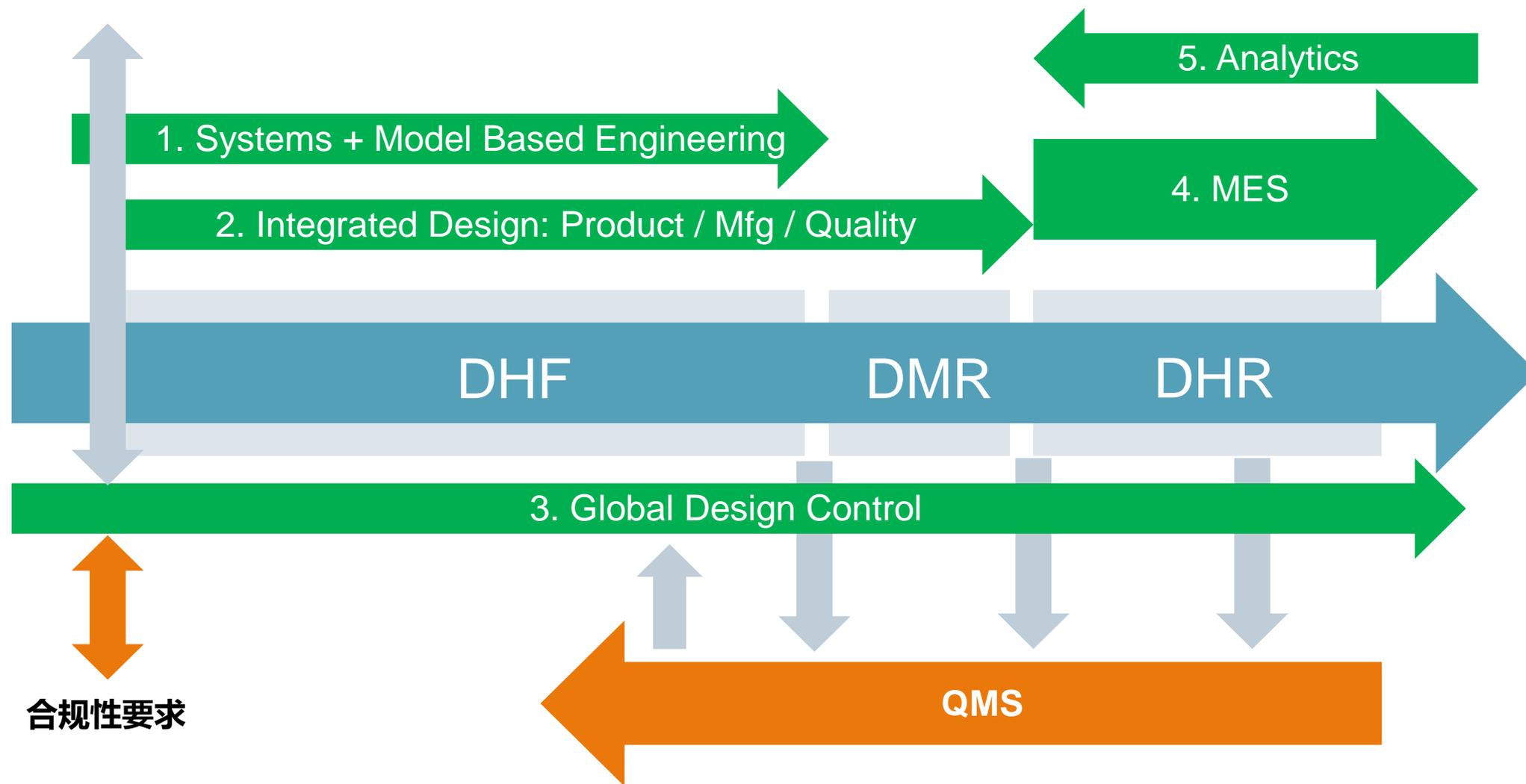
从不同的维度和信息闭环看待MES系统的应用 – 示例



从不同的维度和信息闭环看待MES系统的应用 – 连接人和设备



业务蓝图 – 研发、制造和质量闭环的紧密集成



制造运营系统能力体系建设示例

业务应用	系统能力建设
产品定义及工艺定义	主数据管理，配方管理，设计图纸及标签管理
产品设别与追溯	产品序列号/批号定义、产品追踪与追溯
生产计划与排产	生产计划、详细排产
物料管理与追踪	仓库管理、线边仓管理、物流自动化控制
现场作业执行	制造执行、自动化与控制
数据采集	工艺过程数据采集、质检数据采集、实验数据采集
设备维护	预防维护、维护执行、设备校正、备品备件
合规性审查与放行	过程记录/批次记录审查、不合格处置、记录归档
统计分析及智能分析	绩效监控、风险分析、高级产品数据分析、OEE、预警
质量系统/ QA	PLM、变更管理、质量事件管理、文档管理
质量实验执行	实验数据管理(LIMS)、实验流程与执行、科学数据管理
制造外协	供应商协同、外部制造集成与管控

建设路径示例



Agenda



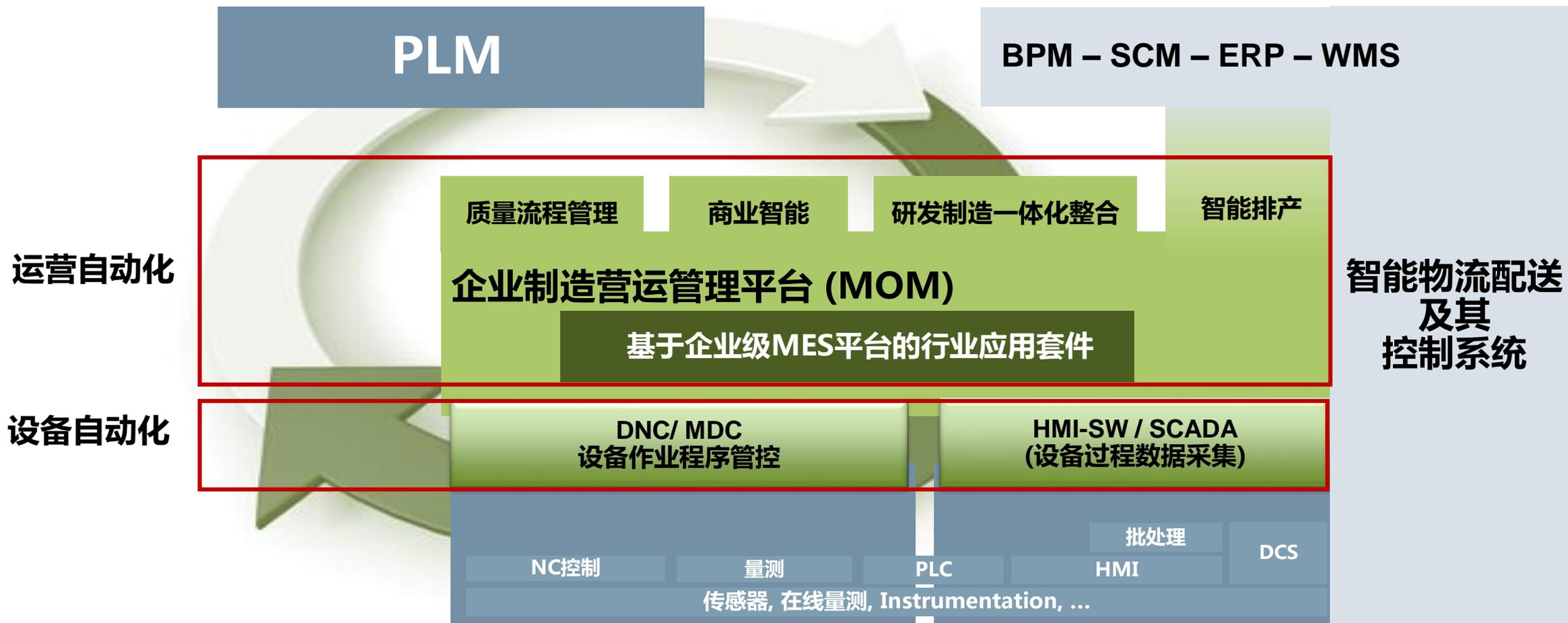
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企业制造运营管理平台的定位



医疗设备及医疗器械行业典型客户 (全球120+工厂实施)



标杆客户实施效果反馈

Final Release (减少DHR生产记录终检)

 75%

 100%

In-process Review (消除生产记录过程检查)

100%

Labor Productivity (提高作业效率)

 6%

 8%

WIP Reduction (降低WIP库存)

 12%

 22%

NCR Reduction (减少NCR)

 25%

 41%

CAPA Reduction (减少CAPA)

 54%

Mfg Complaint Reduction (减少客诉)

 58%

OEE Improvement (提升OEE)

 12%

 35%

FPY Improvement (提升一次通过率)

 1%

 3.6%

 17%

Paper Administration (纸张存档管理)

85%

Compliance Exposure (减少合规问题(召回))

 67%

 90%

制造过程类型

组装和测试

机加/装配/自动化 生产线

其他

电子组装



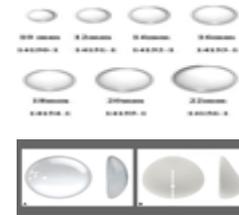
离散制造/组装和测试



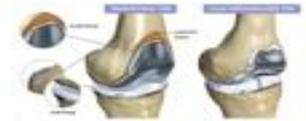
机加/研磨/作业工序



连续和批量(Batch)



个体定制化, 数字化, etc.,



生产过程物料追踪追溯单位

Unit

Unit/Lot

Lot/Batch

Batch/Lot

Unit/Lot/Batch

制造过程类型

组装和测试

机加/装配/自动化 生产线

其他

电子组装



离散制造/组装和测试



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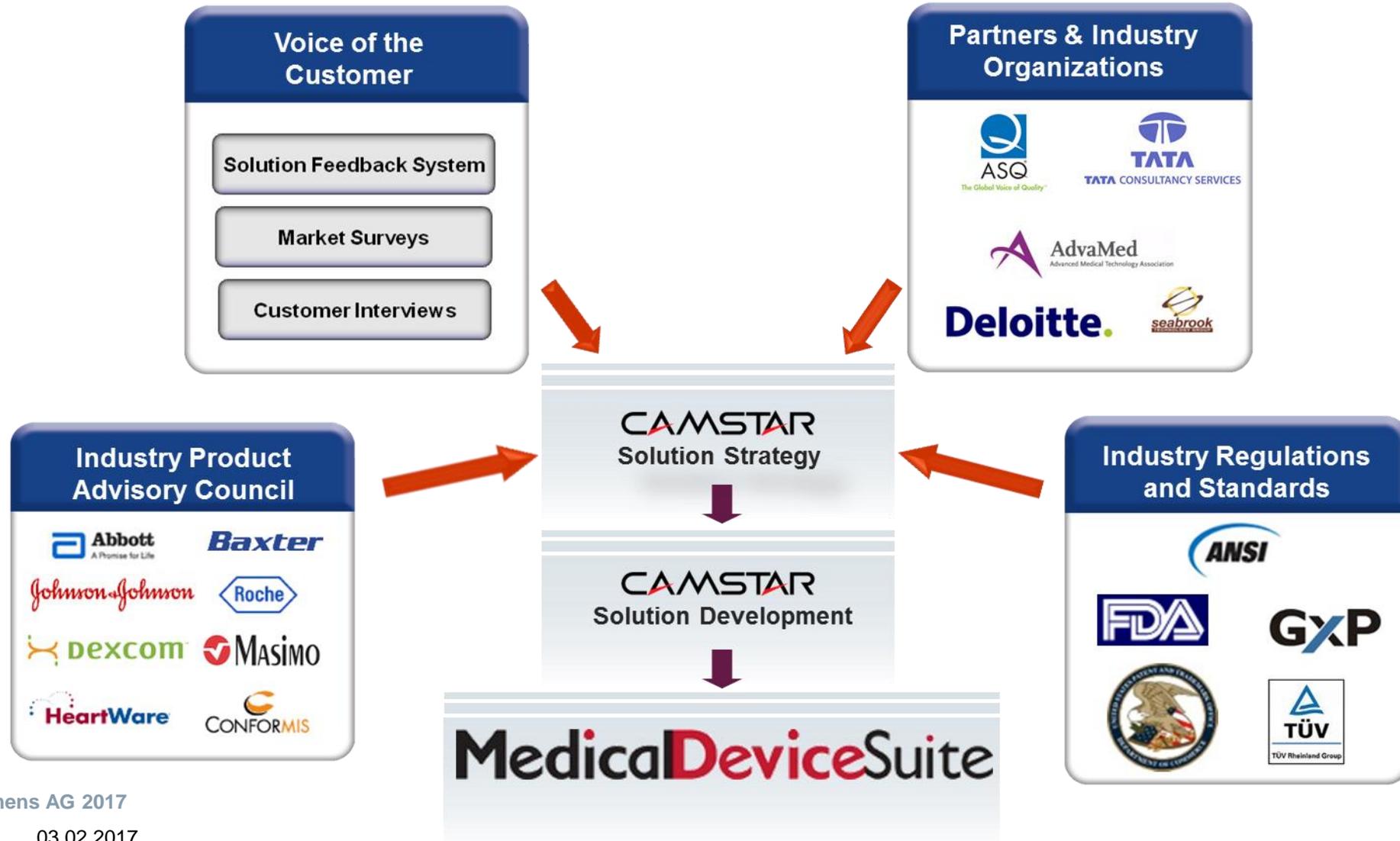


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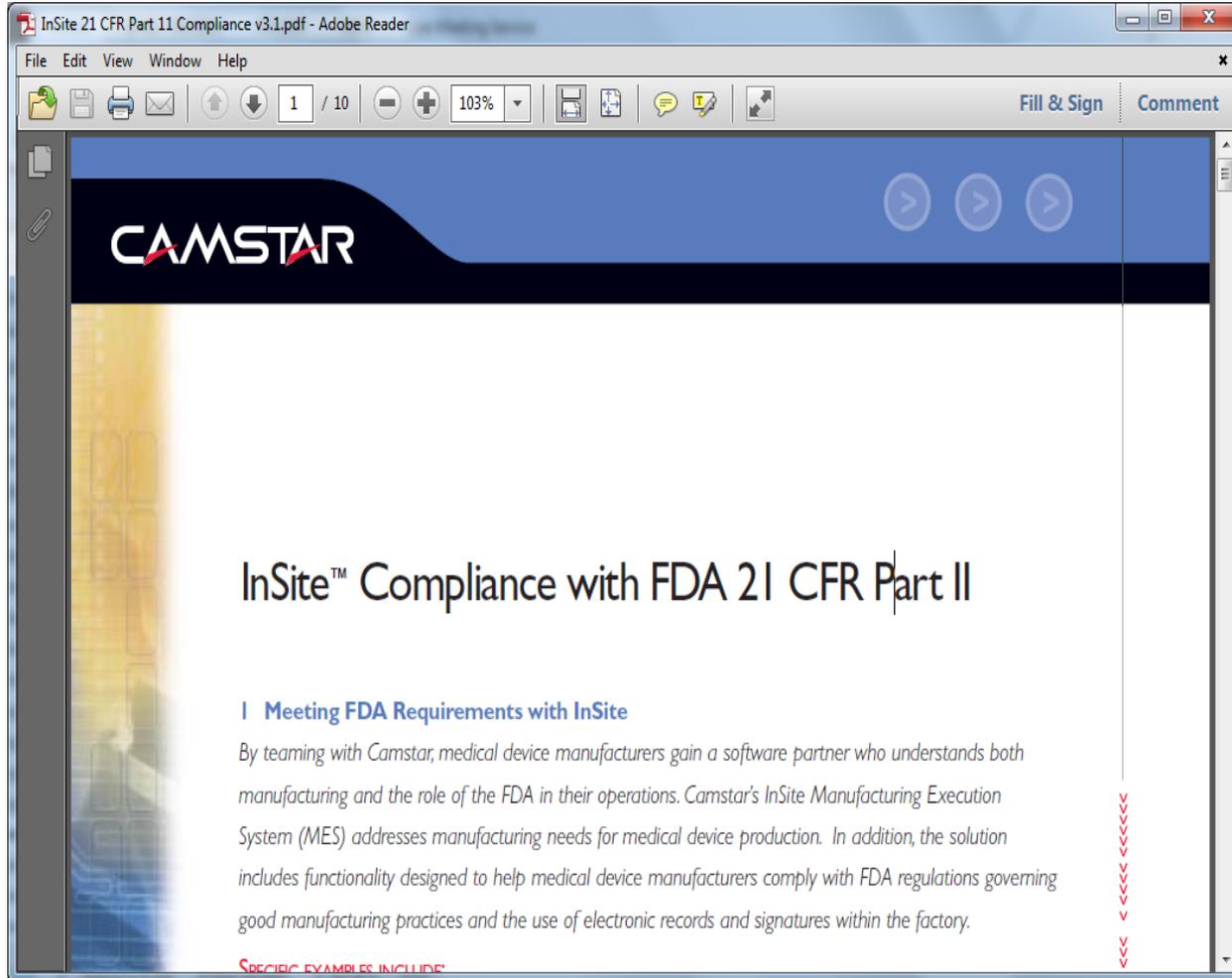
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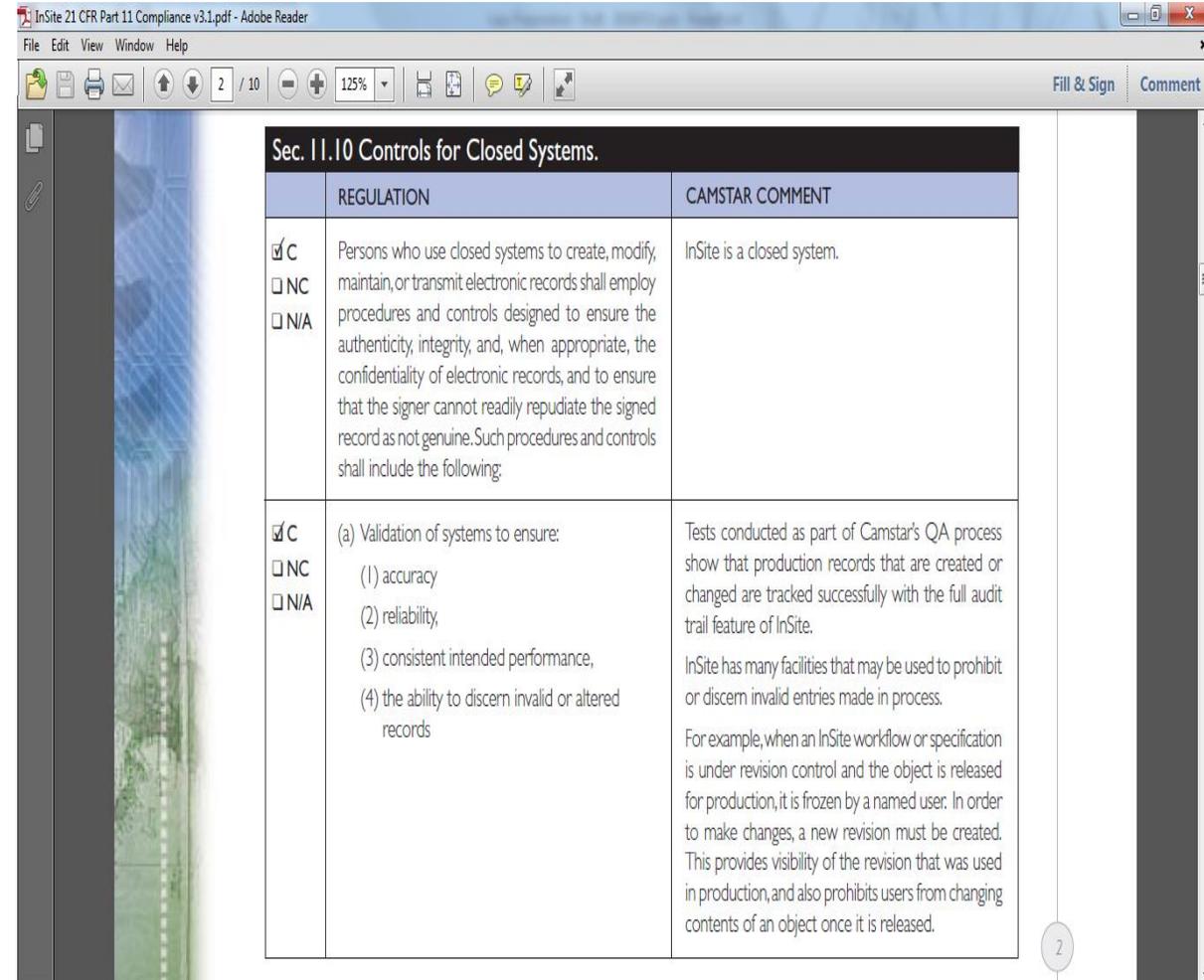
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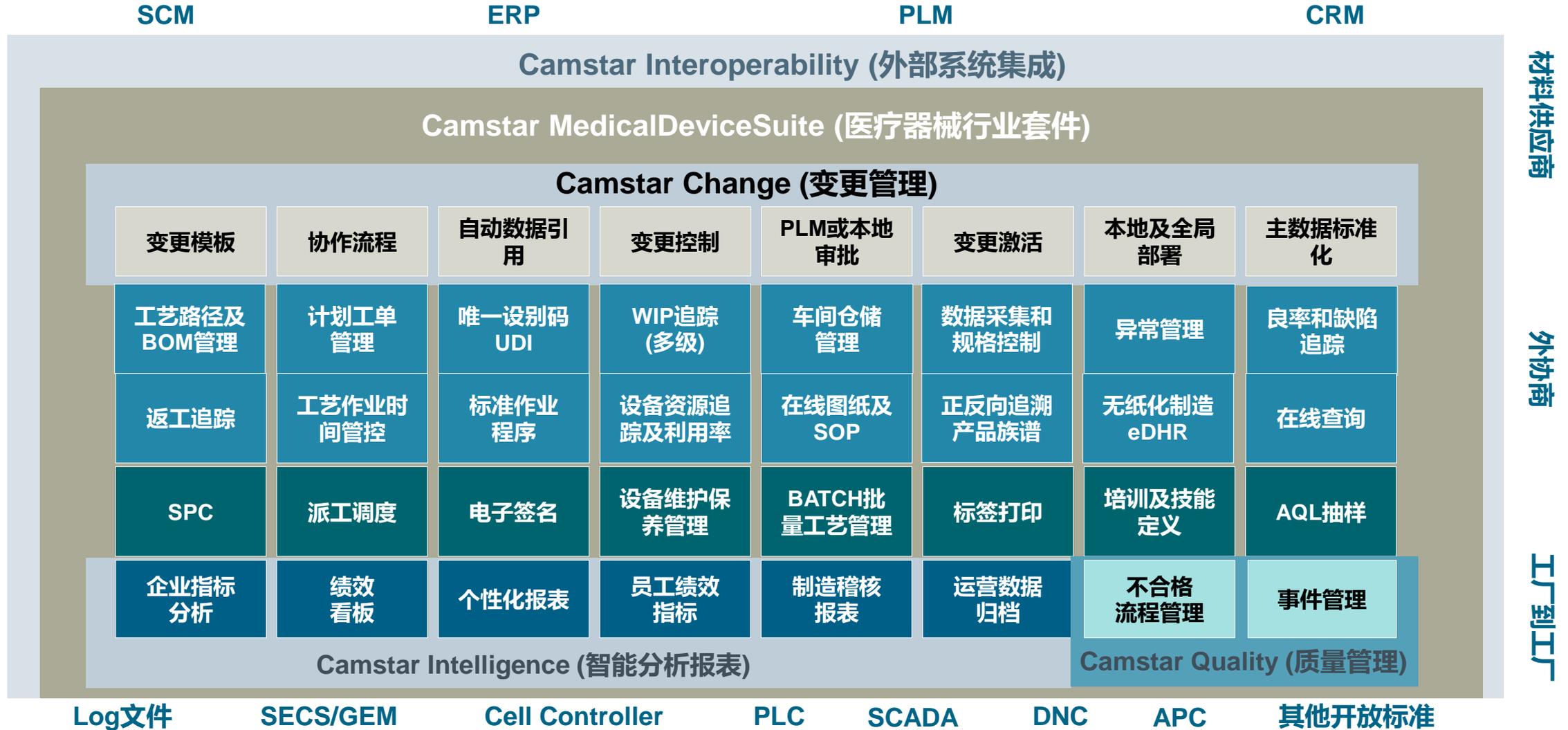
关于 FDA 21 CFR Part II 合规性的说明



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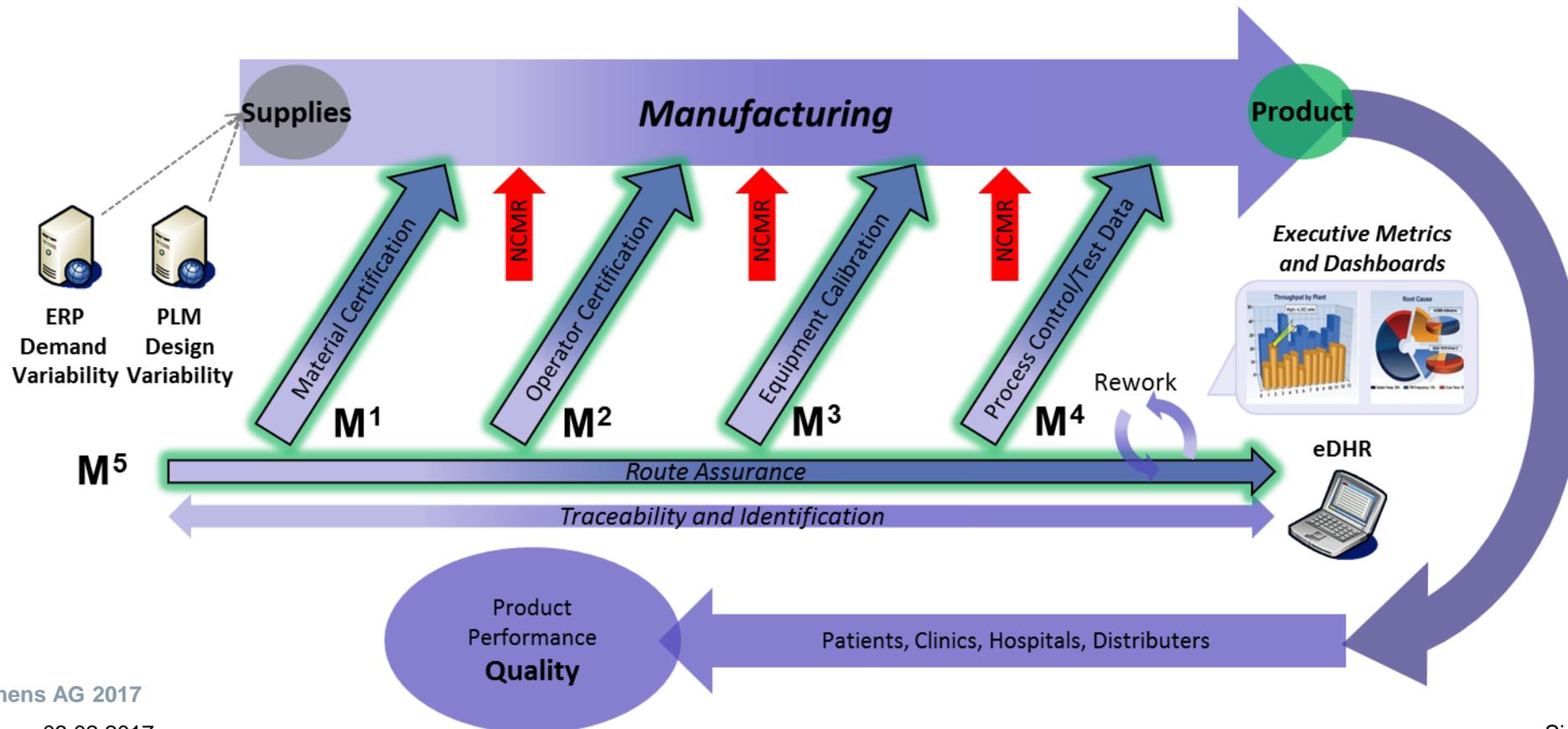


基于企业级MES平台的医疗器械行业套件



eDHR 概述

- M¹: Material** = Define, Manage and Enforce Right Materials to be used at the Right operation, Right Quantities
- M²: Man** = Define, Manage and Enforce Right Operator is working at the Right Operation with Right Skill Sets
- M³: Machine** = Define, Manage and Enforce Right Equipment to be used at Right Steps with Right Status
- M⁴: Measure** = Define, Manage Inspection Plans, Data Collection Plans and Enforce that Right Data is collected
- M⁵: Method** = Define, Manage and Enforce Mfg & Inspection Routers with Alternate Paths



eDHR 示例

Reference	Product CategoryFunctionality Deployed.....											Location		
		Order Mgmt +	WIP Mgmt +	Dispatch Mgmt +	Maint. Enforce +	Trg Enforce +	Re-Work Loop +	Label Prntng +	E-Proc's +	E-Sigs +	NCM Mgmt +	E-Data Collect +		= eDHR / eBR	
3M Northridge	Drug Delivery													✓	Global (CA HQ)
3M Unitek	Orthodontic Products													✓	Global (CA HQ)
Abbott Nutrition	Nutritional													✓	OH
Abbott Vascular	Class III implantables													✓	Global (CA HQ)
Biotronik	Class III implantables													✓	Global (German HQ)
Boston Scientific	Class III implantables													✓	Global (MA HQ)
CaridianBCT	Blood Collection Technology													✓	Global (CO HQ)
Carl Zeiss Meditek	Vision Systems													✓	CA
CibaVision	Contact Lens													✓	Global (NJ HQ)
DexCom	Diabetes Monitors													✓	Global (TX HQ)
Fresenius Medical Care	Class III Dialysis Filters													✓	Global (MA HQ)
HTI (Hutchinson Tech)	Oxygen Monitors													✓	Global (MN HQ)
J&J Biosense Webster	Diagnostics													✓	Global (CA HQ)
J&J Cordis	Class III implantables													✓	Global (NJ HQ)
J&J Ethicon	Class III implantables													✓	Global (NJ HQ)
J&J LifeScan	Diabetes Care													✓	Global (NJ HQ)
J&J Mentor Corp	Class III implantables													✓	Global (TX HQ)
Life Technologies	Biologics													✓	CA
NP Medical	Med Dev													✓	Global (MA HQ)
Pacific Biosciences	Biologics													✓	CA
Roche Diagnostics	Diabetes test strips													✓	Global (IN HQ)
Terumo CVS	Med Dev													✓	Global (MI HQ)
Zoll Medical	Class III external devices													✓	Global (MA HQ)

The screenshot displays the CAMSTAR software interface for managing product and process data. The main window shows a 'Workflow Diagram' with a sequence of steps: Mount, Sew, Die Attach, Wire Bond, Monitor, Encapsulate, Trim, Test, Pack, and FG. The steps are connected by arrows, indicating a sequential flow. A 'Monitor' step is connected to 'Die Attach' and 'Wire Bond'. A 'Test' step is connected to 'Trim' and 'Pack'. A 'Pack' step is connected to 'FG'. A 'Wire Bond' step is connected to 'Encapsulate'. A 'Die Attach' step is connected to 'Sew'. A 'Sew' step is connected to 'Mount'. A 'Mount' step is connected to 'FG'. A 'Test' step has a red dashed circle around it, indicating it is the current step. The interface includes a top navigation bar with 'Container', 'Event', 'Resource', 'Search', 'Pages', 'Reports', and 'Modeling'. The left sidebar shows a list of objects and instances, including 'Workflow', 'HH Simple Flow ROR: 1', 'One Step ROR: 1', 'ROUTE1 ROR: 1', 'ROUTE2 ROR: 1', 'ROUTE3 ROR: 1', 'Standard Flow ROR: 1', 'Std Flow AP ROR: 1', 'VG_Assembly ROR: 1', and 'VG_Main ROR: 1'. The right sidebar shows 'Specs' and 'Workflows' sections. The bottom status bar shows the time '12:29 PM' and the date 'Wednesday, January 22, 2014'.

现场作业执行

The screenshot shows the CAMSTAR Shop Floor Viewer interface. On the left, a 'Main' window displays a table of work orders. A red arrow points from a 'Technical File Query' callout to the 'EProcedure' window on the right. The 'EProcedure' window shows a task list and a detailed view of 'Step 2' with technical drawings and a 'Pass/Fail' status.

Annotations:

- 故障记录在线查询 (Online query of fault records)
- 工序间作业信息传递 (Workshop-to-workshop information transfer)
- 过程追溯信息在线查询 (Online query of process traceability information)
- 当前工序作业任务清单 (Current workshop task list)
- 当前作业任务状态明细 (Detailed status of current task)
- 制造资源明细 (Manufacturing resource details)
- 技术文件查询 (Technical file query)
- Shop Floor Viewer

Container	Qty	Qty2	Spec
RA00032	1000	0	R_WireBo... 1

Step	Status	Count
Step 1	Passed	Count 1 (Min 1)
Step 2	Not Executed	Count 0 (Min 1)
Step 3	Not Executed	Count 0 (Min 1)
Step 4	Not Executed	Count 0 (Min 1)

现场透明化示例



过程数据采集和管控

Customer: BAX01-03
Product: 2M91617 (1)*[COLLEAGUE SINGLE CHANNE...]
Operation: BAX OPN 100
Qty: 1[ea]
Mfg Order: BAX01

BAX ACCURACY TASKS
F069930004 Colleague Accuracy Test Phase

Task 3 of 5 CHANNEL B

01 Passed ✓
START TEST
Count: 1 (Min 1)

02 Passed ✓
CHANNEL A
Count: 1 (Min 1)

03 Not Executed
CHANNEL B
Count: 0 (Min 1)

04 Not Executed
CHANNEL C
Count: 0 (Min 1)

05 Not Executed
END TEST
Count: 0 (Min 1)

Instructions:
10mL/hr for 1 hour

Workstation:

Beaker Number	BeakerWt	BeakerwithWaterWt
BH344	34.1	44.2

(?BeakerwithWaterWt - ?BeakerWt) = **Volume Collected**

10.448
9.550

[+ Show additional fields](#)

Req Sample Count:

[+ Attachments](#)



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