

Towards a Smart Factory with MES MES 系统 成就智慧工厂

- Vogel Seminar Chongqing China April 2016
- 中国 重庆 弗戈制药论坛 2016年4月



MES as a Navigation System to make your Factory Smart

MES 正如导航系统
成就您的智慧工厂

Guiding through
your business processes

智能引导 您的生产



目录


1 Company Werum 德国维隆公司

2 What is an MES MES是什么样的系统

3 Smart Factory in Pharma with MES MES成就制药业的智慧工厂

4 How to run a project smart 如何实施MES项目

5 Summary 总结



Werum is regarded as No 1 Pharma MES supplier
17 out of Top 30 pharma companies
800+ PAS-X installation

德国维隆是制药业 MES 第一品牌
占据全球最大30家制药公司中17席
多达800多个PAS-X成功案例

- Market-leading Pharma MES made in Germany
- 500 employees dedicated for Pharma MES
- Founded 1969

来自德国的制药业MES引领者
500名雇员专注制药MES
成立于1969年

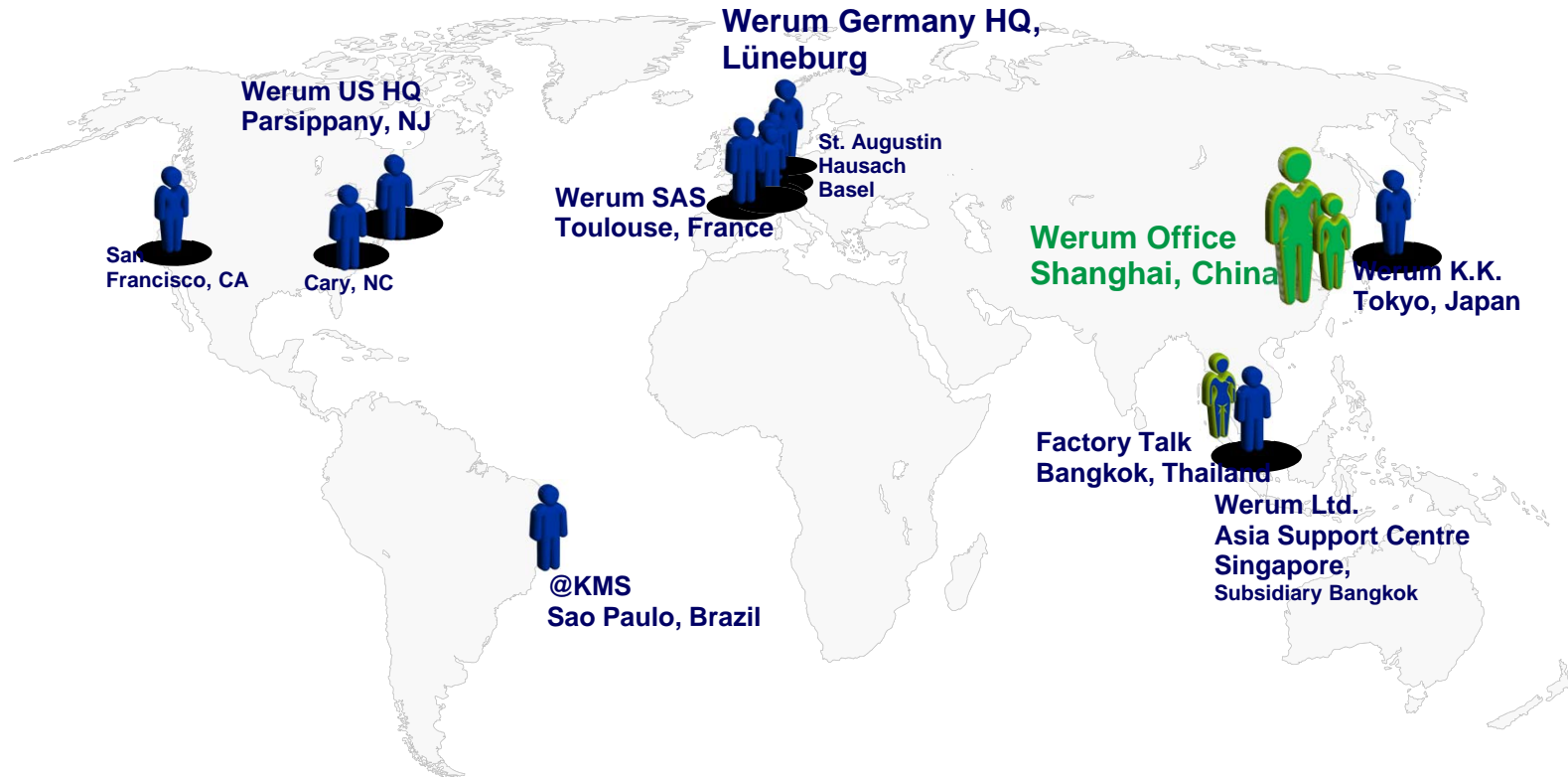
The Largest Pharma MES user community

全球最大的制药业 MES用户群体

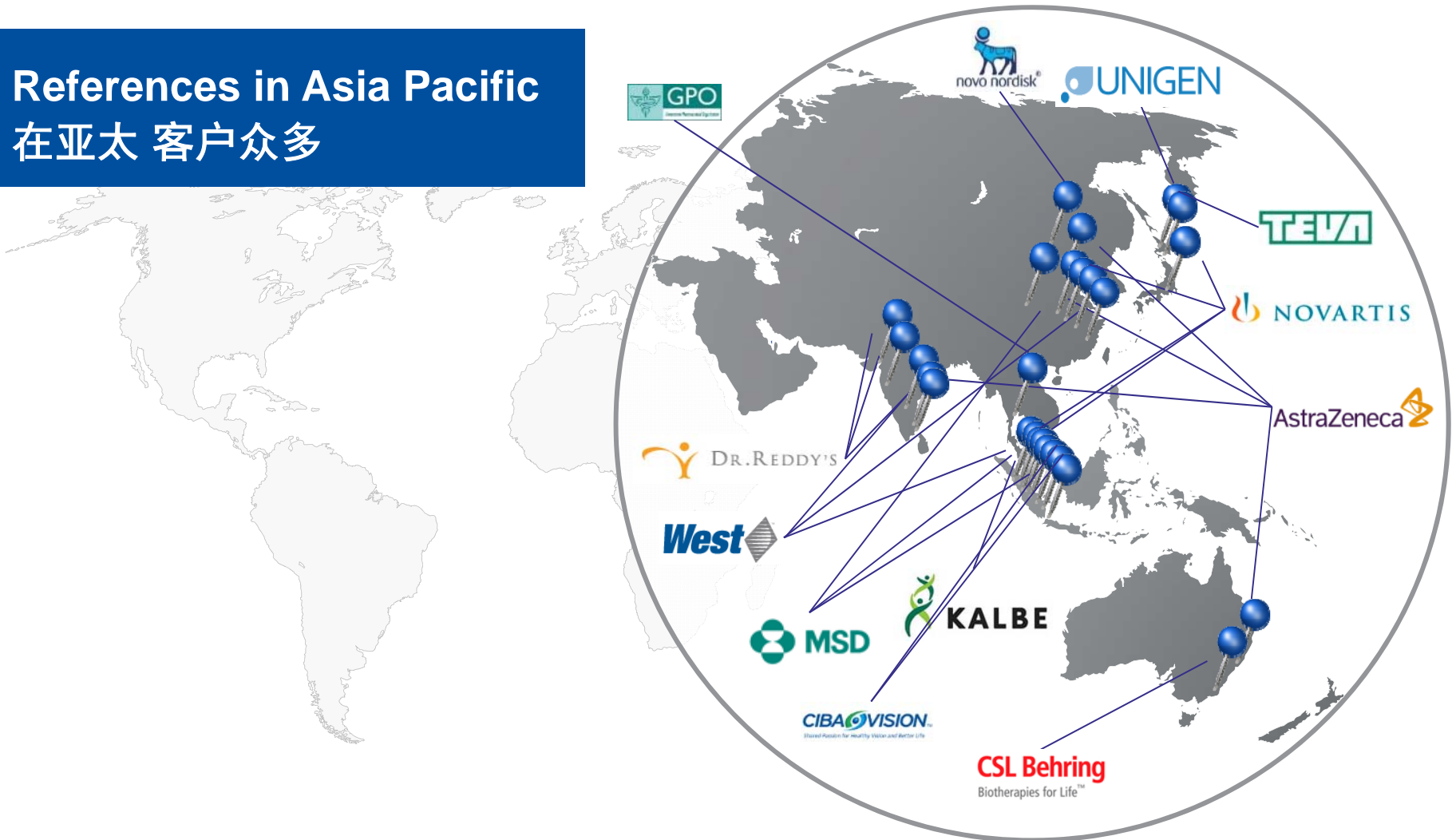


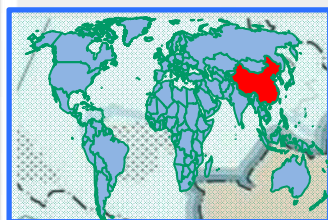
Werum Global Footprint Local presence

全球足迹，来到中国



References in Asia Pacific
在亚太 客户众多





Werum Customers in China
中国 在用客户



What we can do for Pharma manufacturers

我们能为制药公司做什么

**We help Pharma manufacturers
to improve their production performance
and compliance.**

合规，提升生产性能

- Improve process / product quality
提高工艺性能 / 提高产品质量
- Monitor and boost manufacturing performance
监控并帮助生产绩效的提高
- Produce less deviations but more yield
减少偏差提高产量
- Reduce time to market
缩短上市时间



- Meet compliance requirements
合规
- Eliminate paper in the factory
无纸化生产

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Focused Scope on Pharma, but all Pharma 专注制药，覆盖制药全部细分领域

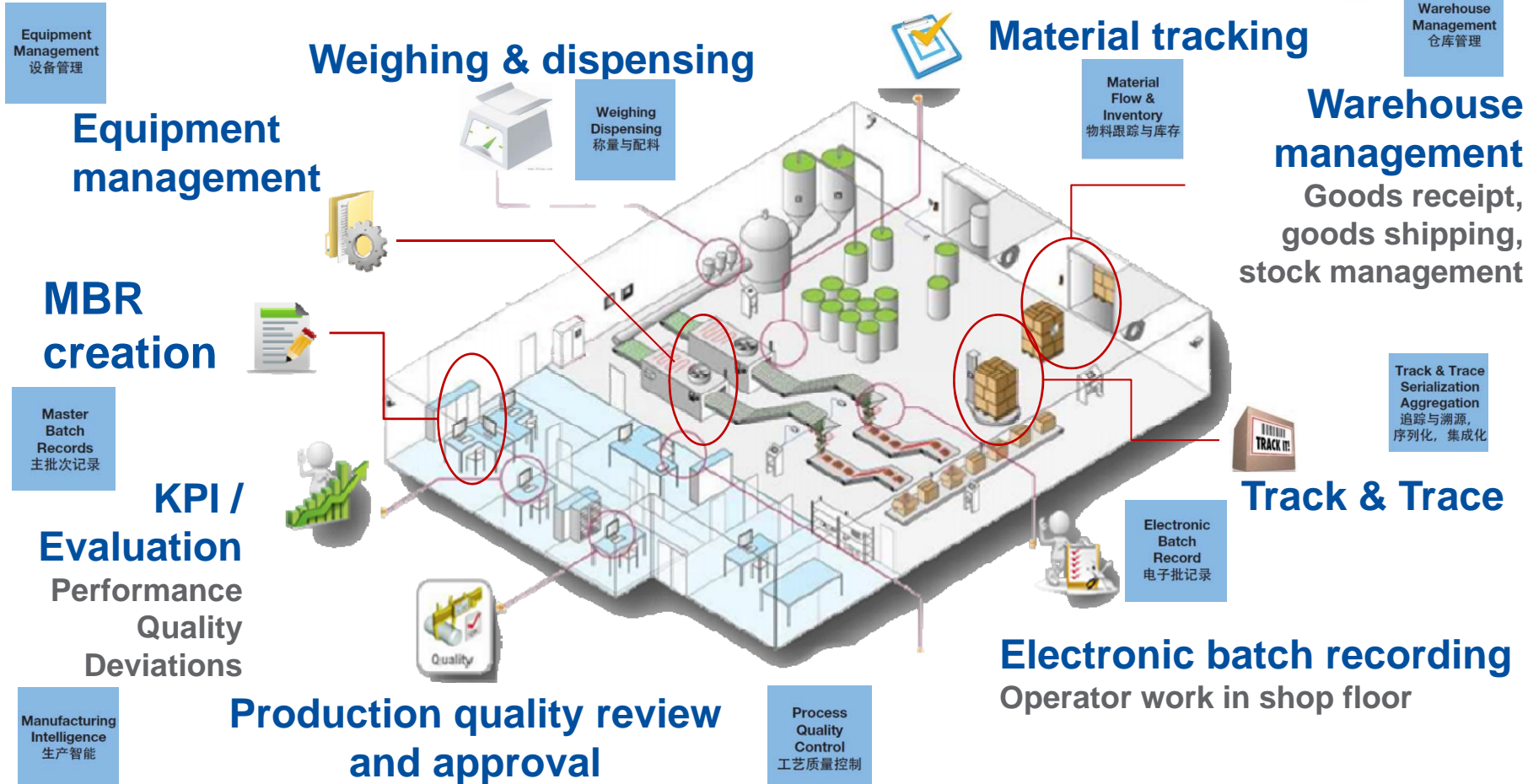
PAS X IT SOLUTIONS FOR REGULATED INDUSTRIES



PAS-X 涵盖全生命周期各阶段和所有行业的各细分领域



MES Functional Overview 在制药厂, MES的功能一览



Supporting Electronic GMP Workflows 电子化 GMP workflow

Define, control and document all pharmaceutical activities

对整个制药生产的工艺制定, 工艺控制, 并记录保存

Master Batch Record (MBR) 主批报

- Bill of Material
- Process Definition
- Work Instructions
- Version

1

Electronic Batch Record (EBR) 电子批记录

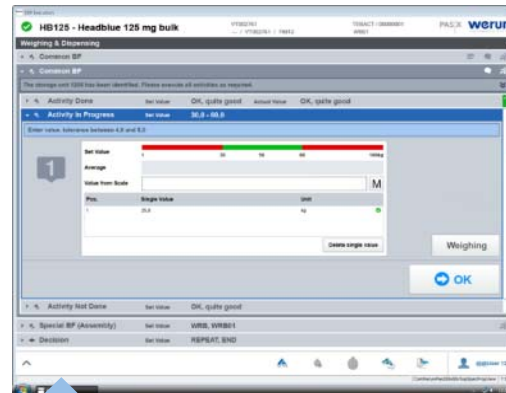
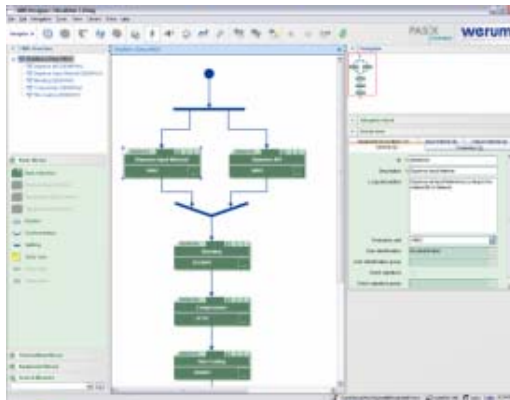
- Order Number
- Batch Number
- Exact Work Center Routing
- Right Sequence & Right First Time

2

Completed Batch Record (BR) 批报

- Actual Values
- Exception Summary
- Review by Exception
- Signatures

3



MO report PB002 - Headblue 250mg
Status/Report version Circulad01

Batch size 10kg
Batch no. SH09002725
Order no. PBM0352

BO no. MX1 Sub-batch 1

Item	Proc.	Material no.	Material name	Material type	Target quantity	Actual quantity	Take-out type	Target container
0000-1	1	NOCOSM	Sodium Hyaluronid	Rawmat	0.7 kg	0 kg	Weighing	MOX1-10
0000-1	1	TALCUSM	Talcum	Rawmat	2.1 kg	0 kg	Weighing	MOX1-10
0000-1	1	NOCDOSM	None	Rawmat	2.2 kg	0 kg	Weighing	MOX1-10

Item	Proc.	Material no.	Material name	Material type	Target quantity	Actual quantity	Take-out type	Target container
0000-1	1	NOCOSM	Sodium Hyaluronid	Rawmat	0.7 kg	0 kg	Weighing	MOX1-10
0000-1	1	TALCUSM	Talcum	Rawmat	2.1 kg	0 kg	Weighing	MOX1-10
0000-1	1	NOCDOSM	None	Rawmat	2.2 kg	0 kg	Weighing	MOX1-10

Container ID	Material name	Target quantity	Actual quantity	Used for	Target BO
MOX1-10	Headblue filling	10 kg	0 kg	Back material	

Item	Production unit	Production unit ID	Comment
1	Blending station 1	BLND001	

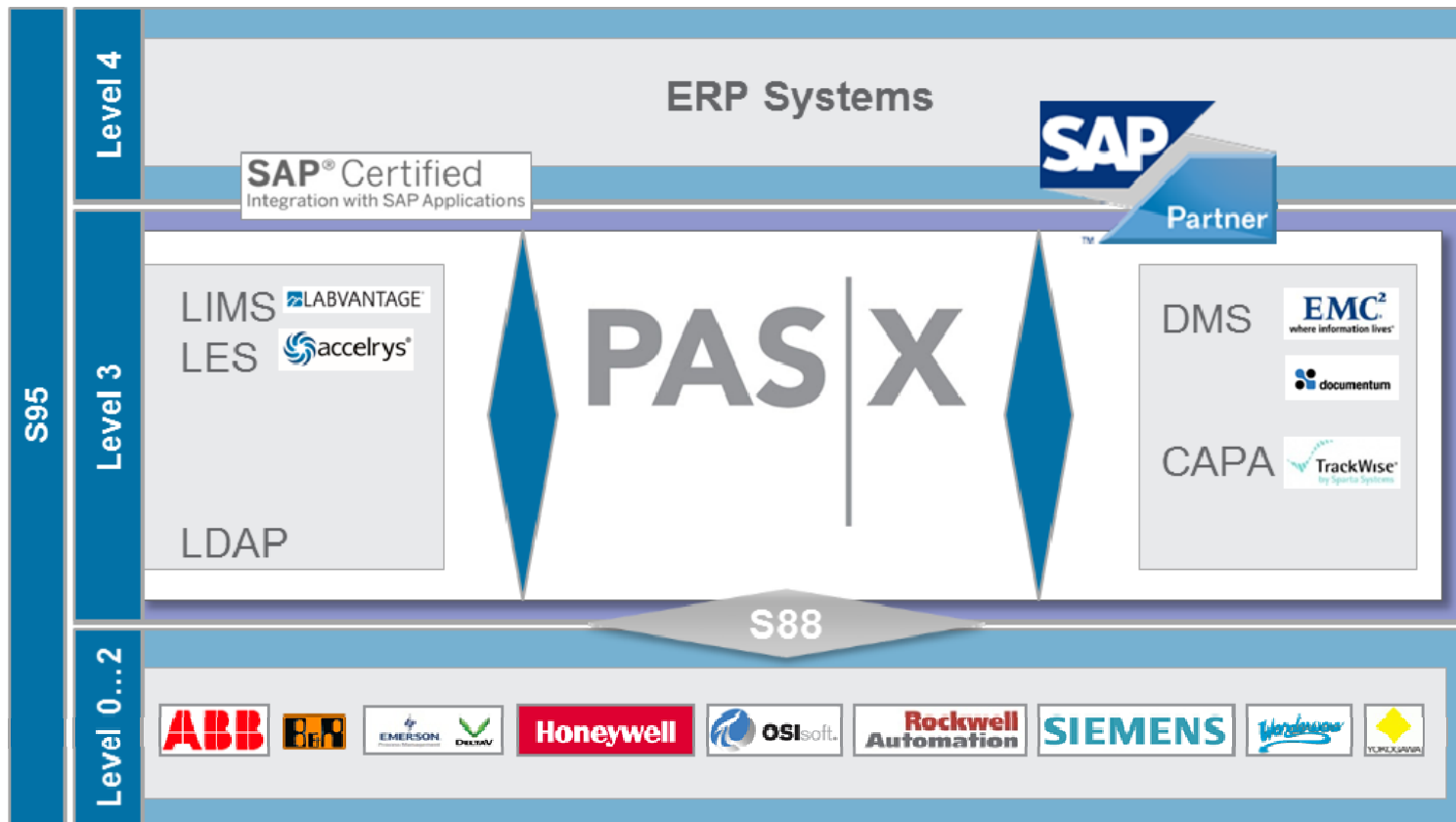
Item	Technical function	Set value	Actual value	Date	Signature
(1)	IPC time	2:00 (1:30 - 3:30) min	1:57 min	2015/2008 (E.G.)	

Order & EBR creation (ERP & MES)
生产订单与电子批记录的创建

EBR review and release (MES & Operator)
电子批记录审查和放行

Integration is a must for Smart Factory

对于智能工厂，系统集成是必须的





Video of MES Highlights

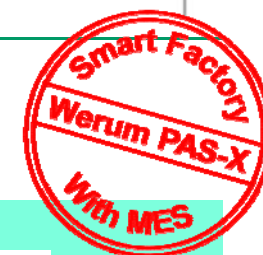


The collage features several key elements:

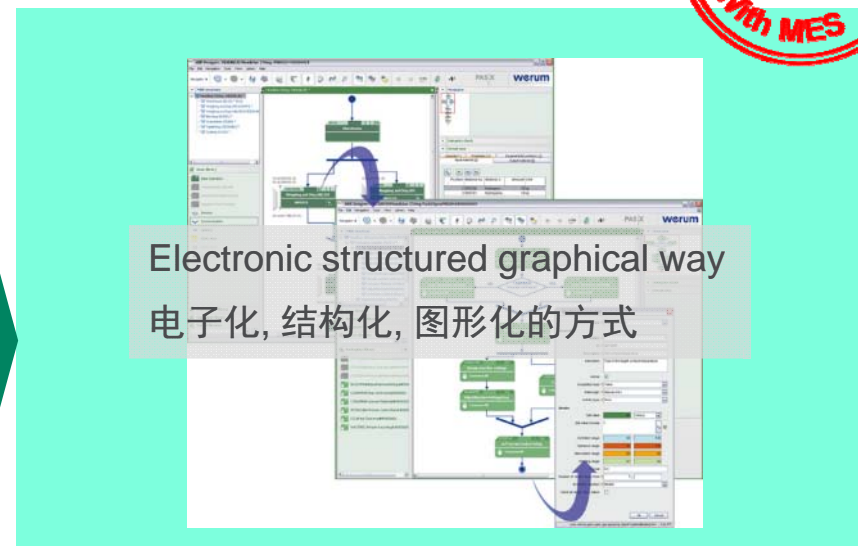
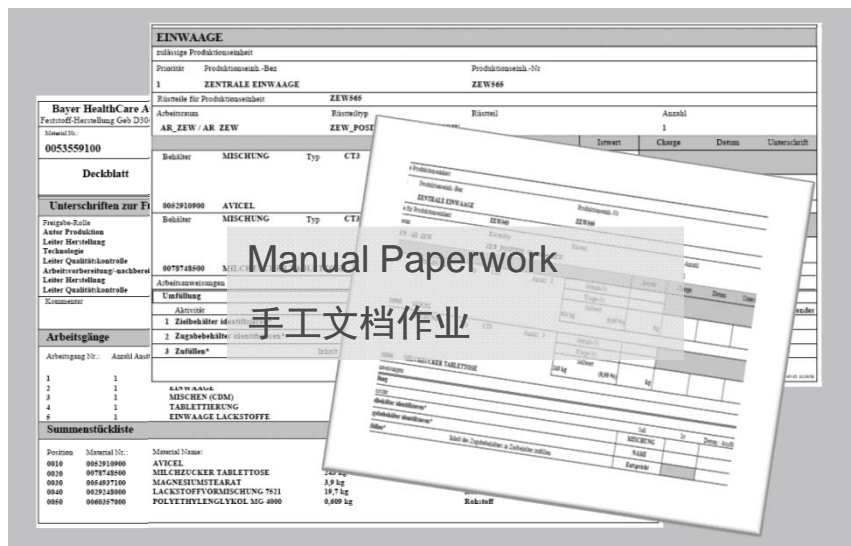
- Process Flow:** A diagram showing a sequence from 'Weighing' (WB01) to 'Compression' (TABLET01).
- Hardware:** A laptop, a tablet, a handheld scanner, and a PDA device.
- Software Interfaces:** A production floor control panel, a detailed exception overview table, and a bar chart titled 'Exception Overview'.
- Barcode:** A standard 1D barcode with numbers 1-8 below it.
- Production:** A photograph of a worker in a lab coat handling materials in a large industrial vessel.

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MBR Creation 主批报的创建



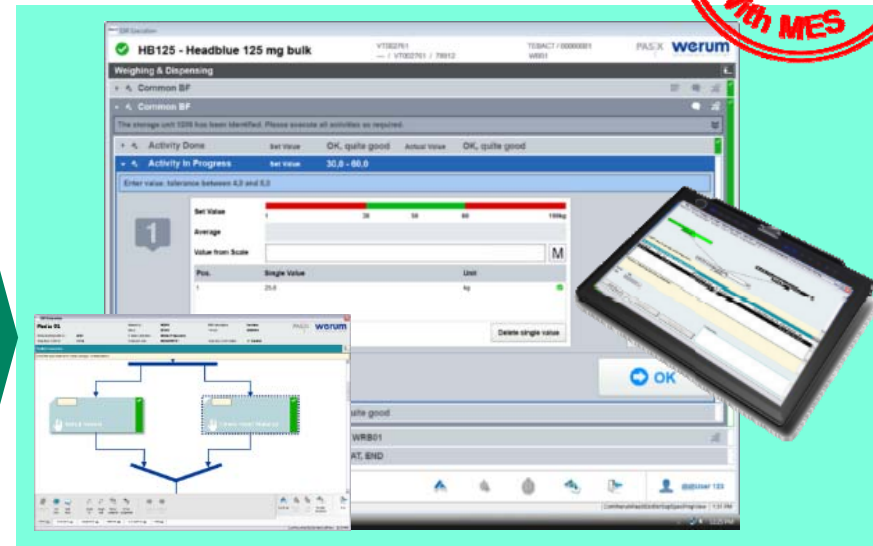
- Usage of text edit to create MBR-doc
使用纸质文档编辑主批报
- Usage of predefined text parts is optional
或者使用预定义格式的文档段落
- Structuring of information by discipline
依靠条理性来组织信息结构
- The sequence of steps must not reflect reality
操作步骤很难真实反映出来
- Release workflows with paperwork
纸质文件审批 workflow

- Electronic structured graphical way to define, represent, instruct manufacturing process
电子化, 结构化, 图形化的方式来定义, 呈现和引导生产流程
- MBR creation based on pre defined templates with best practice results
基于最佳实践经验证的预定义好的模板进行主批报的创建
- Changes are easy to manage 容易进行变更管理
- Integrated approval workflows 一体化的审批 workflow



Electronic Batch Recording 电子批记录执行

Bayer HealthCare AG Fertstoff-Fertstellung Gdb D104305		Herstellvorschrift		Ausgabe Nr.: 1	Grültig ab:
Material No: 0053559100	Material Name SCHENTABL U KERNE UNLACK	Chargegröße 780,9 (760,4-800,4) kg	Variante: BB1	Status	Im Entwurf
Abhängig Da: 4	Abhängig Beschreibung TABLETTIERUNG			Seite 5 von 32	
Abnahme		Stk	Gr	Datum / Ausfallscode	
16 Tablettenmaschine einrichten*	-Schnelldiamant: 17 x 7 mm -Wälzungsrad: 10 mm -Tablettenmaschengewicht: 678,8 mg -Rundlaufzeit: 31 - 50 s -Stanzdicke: 5,2 - 6,0 mm -Zerfall: >= 10 mm -Erstliche maximale Presskraft: 39000 N	Entspricht			
17 Vorgabe Maschinenleistung*		8900 Stk/h	Stk/h		
18 Tabletten anpassen*		Entspricht			
19 Codierung oben überprüfen*		MD			
20 Codierung unten überprüfen*		BLANKO			
21 Form und Farbe der Tablette*		ablang / weiss			
22 Gebinde vorbereiten	Tablettenabzeichen zusammen mit der Abfüllung mit LDPE-Folien, Materialnummer 210812 zusammen, Parameter der Schiene dokumentieren.				
23 Regelliste zuordnen	Regelliste für Zahnengräder beschreiben und als Zustandsdokument dem Fertigungsprozess zuordnen.	Entspricht			
24 Tablettenabgewichte bestimmen	Prüfung statistisch durchführen, Ergebnisse in der Regelliste dokumentieren.	Entspricht			
25 Maximale Presskraft dokumentieren		>= 39000 N	N		
26 Maschinenleistung dokumentieren		8900 / 2000 - 8900 / Stk/h	Stk/h		
27 Vollständigkeitkontrolle	Vollständigkeit und korrekter Sitz der Falzhülse bzw. Oberenstopfplatte und Sicherungsschleife	Entspricht			
28 Ende der Tablettierung					
29 Geogewicht Verlust		>= 0,00 kg	kg		
30 Zusatzdokumente weiterleiten	Anzahl Seiten dokumentieren	>= 0 St	St		

- Fill entries in a paper form without guidance
手工填写, 没有引导
- Control of entries by 4-eyes-principle
依赖四眼规则
- Manual calculation sometimes
有时还需要手工进行计算
- Late detection of entry errors and GMP non compliance
难以及时发现填写中的错误信息, 合规总是处处有挑战

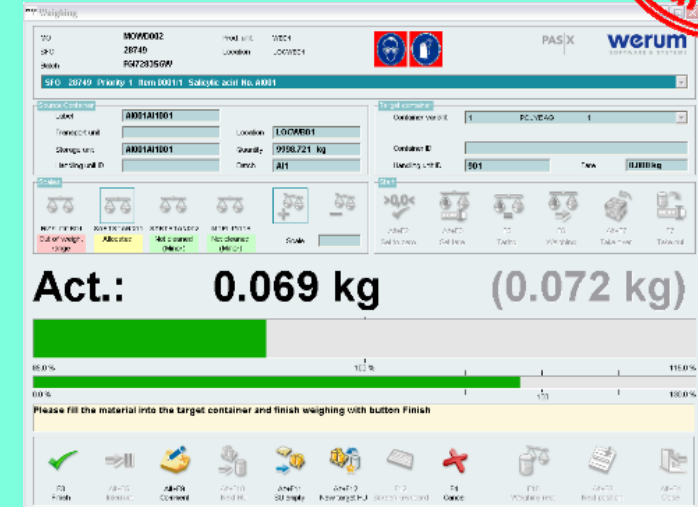
- System guides operation through the process like a navigation system
系统像导航系统一样引导操作
- Data directly from automation
数据直接来自自动化系统或设备
- Reduction of entry errors (high Right First Time rate)
减少输入时的错误 (高首次即正确率)
- Enforcement of GMP compliance
强制合规



Integrated Scale Devices for Material Management

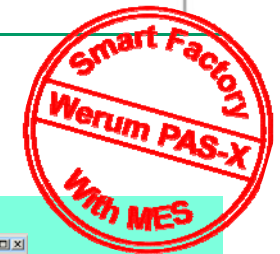
集成称量设备实现一体化物料管理

Bayer HealthCare AG Fasstoff-Herstellung Goh D104/305		Herstellvorschrift	Ausgabe Nr.: 2 Variante: RR1	Gültig ab:
005		Status: Im Entwurf		Seite 5 von 32
16		In		Datum / Auslieferer
17		Sech		
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
Zusatzdokumente weitergeleitet		Auszahl Setze dokumentieren	=> 0,00 kg	kg
			=> 0 St	St

- Verify correct material & scales according manufacturing record
根据生产中的记录确认物料和设备是否正确
- Weigh correct amount
按照规定逐步称量出物料和数据
- Check record for allowed tolerances
检查称量值是否在允许的误差区间
- Attach label to bag & 2nd copy to the record
对容器和文件记录分别贴标签
- Update ERP inventory 更新ERP库存管理数据

- Scan material barcode 扫码
- Select scale 选秤
- Weigh correct amount with system support
系统辅助直接获得所需物料和数据
- MES prints label & updates ERP
系统打印标签并实现ERP数据更新



Equipment 设备管理

Start Time	Start Date	Activity / Load Description	Program Number	Performed By	Cycle Number	Stop Time	Stop Date	Cycle Completed Successfully Pass / Fail	Cycle Approved By Initial / Date	Checked By Initial / Date
09:27	13/04/10	Air detection Function TEST	100	SSG	4468	10:18	13/04/10	PASS	SMH	SMH
10:38	13/04/10	LEAK RATE		SSG	4469	11:02	13/04/10	PASS	SMH	SMH
14:05	13/04/10			SSG	4470	15:20	13/04/10	PASS	SMH	SMH
17:46	13/04/10			SSG	4471	18:10	13/04/10	PASS	SMH	SMH
05:09	15/04/10	Warm up	02	DFD	4473	06:11	15/04/10	PASS	TFL	TFL
11:29	15/04/10	OB-140-CA-1003 Max Load Reduct Parameters Funct01	99	SON	4474	14:56	15/04/10	PASS	SON	SON

- Manual Entries
 - Manual Calculations
 - Manual Checks
 - Info not available centrally

手工填写日志
 手工计算
 手工检查
 时找数据非统一管理



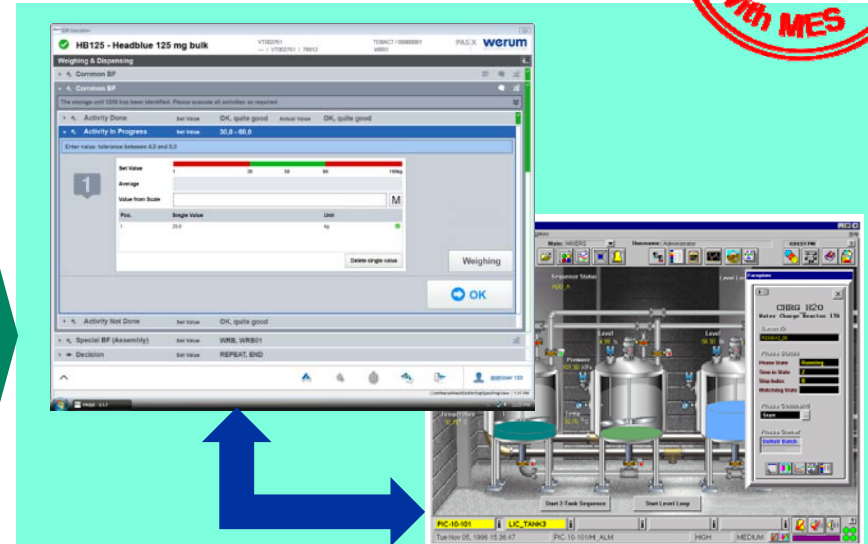
Equipment ID	Description	State diagram	Current state	Usable	Priority
AL660	Level 1 Autoclave No.1				
	Air Detector Test	Air Test OK	Yes	4	
	Allocation	Not Allocated	Yes	1	
	Bowse Deck Test	Bowse Deck OK	Yes	2	
	Comment	Comment	Yes	9	
	Leak Rate Test	Leak Rate OK	Yes	3	
	Quarterly_Clean	Quarterly Clean OK	Yes	6	
	Quarterly_Clean	Quarterly Clean OK	Yes	7	

- Check Logbook
检查设备使用日志
- Verify daily checks have been performed
确认设备检查记录完整
- Perform calculations 计算
- Determine the current state of equipment
确定设备状态可用

- Scan equipment barcode
扫描设备条码
- Check status on screen
直接在屏幕上检查设备状态

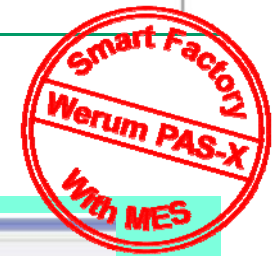


Integration with Automation Systems 自动化系统集成

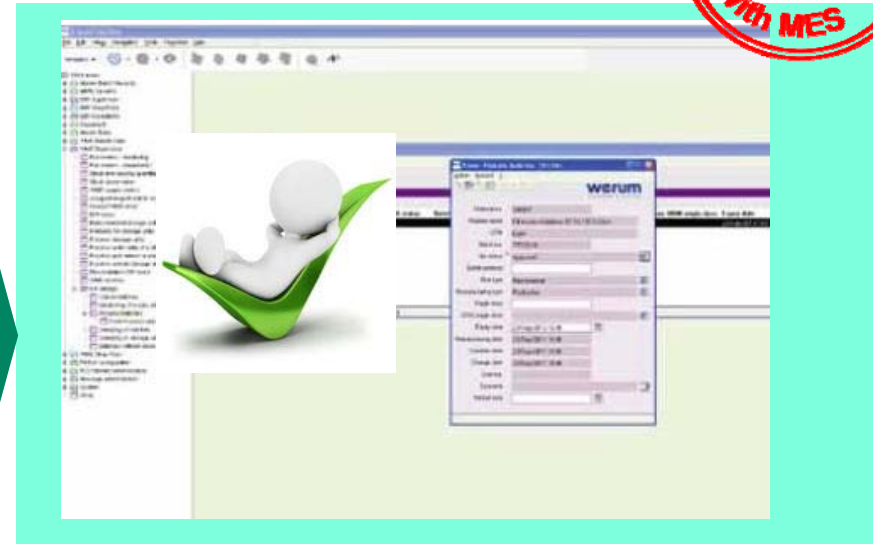
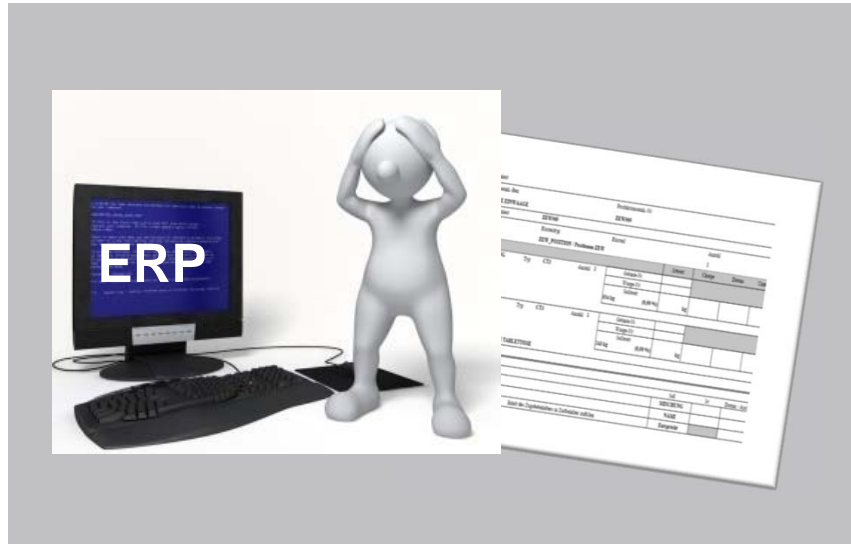


- Paper record instructs **technician** to perform action on control system
依靠文件指示**操作人员**在控制系统实施操作
- **Technician** logs onto control system & performs action
操作人员**在**控制系统实施操作并填写日志
- **Technician** records **manually** value in paper record
操作人员**手工**记录数值信息
- **Technician** checks result within range per record
操作人员**按照**文件要求检查数值是否满足范围要求

- **MES automatically** instructs the Control System to perform the task
MES系统自动指示控制系统完整相应任务
- **Control System** accepts set points starts procedures
控制系统接收记录启动程序的开始点
- Results are sent by **Control System**
控制系统自行发送结果数据
- **MES checks** against the range
MES根据设定范围自行检查数据



ERP Reporting 对接 ERP



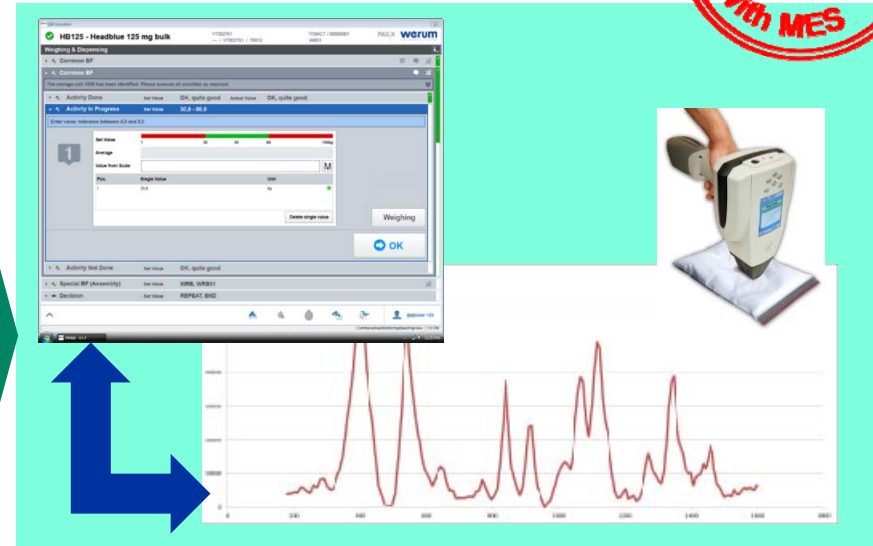
- Select correct material
选择物料
- Manually input of data in ERP system
输入数据
- Report manually on BR the reporting to ERP
批记录报告数据填给ERP

- Technician scans material barcode 扫码
- MES automatically checks status and updates ERP with material number, batch number and quantity and records the user and date

MES 自动检查物料信息并与 ERP交互数据
(物料编号, 批次编号, 数量, 使用人及使用时间记录)



Integration with LIMS 对接 LIMS



- Paper record instructs to log sample
依照文档指示填写取样记录
- Manually log sample in LIMS – print label
在LIMS填写取样记录- 并打印标签
- Take sample & insert label into paper record
取样, 标签入文档
- Confirm sample in LIMS 在LIMS确认样品
- Sample sent to lab 样品送实验室分析
- Quality test 质量测试报告
- Await result & enter in paper record 出结果后填写文档记录

- MES notifies LIMS of sample event
MES 通知 LIMS 取样
- LIMS creates sample & tells sample ID to MES
LIMS 生成样本并将样本ID发送给MES
- MES prints label MES打印标签
- Technician sends sample to labs 样本送实验室
- Samples tested & results automatically send to MES
样本完成分析测试, 结果自动传给 MES

MES Data for Process Stability & Performance

数据用于工艺性能和稳定性提升



- Lots of Paper – No Data 大量纸张, 而非数据
 - Is it correct? 它正确吗?
 - Is it complete? 它完整吗?
 - Is it secure? 它安全吗?
 - Do you gain knowledge from it? 你能获取你真正要的吗?

■ Turn MES data into knowledge
MES 将数据直接转化成所需的认知

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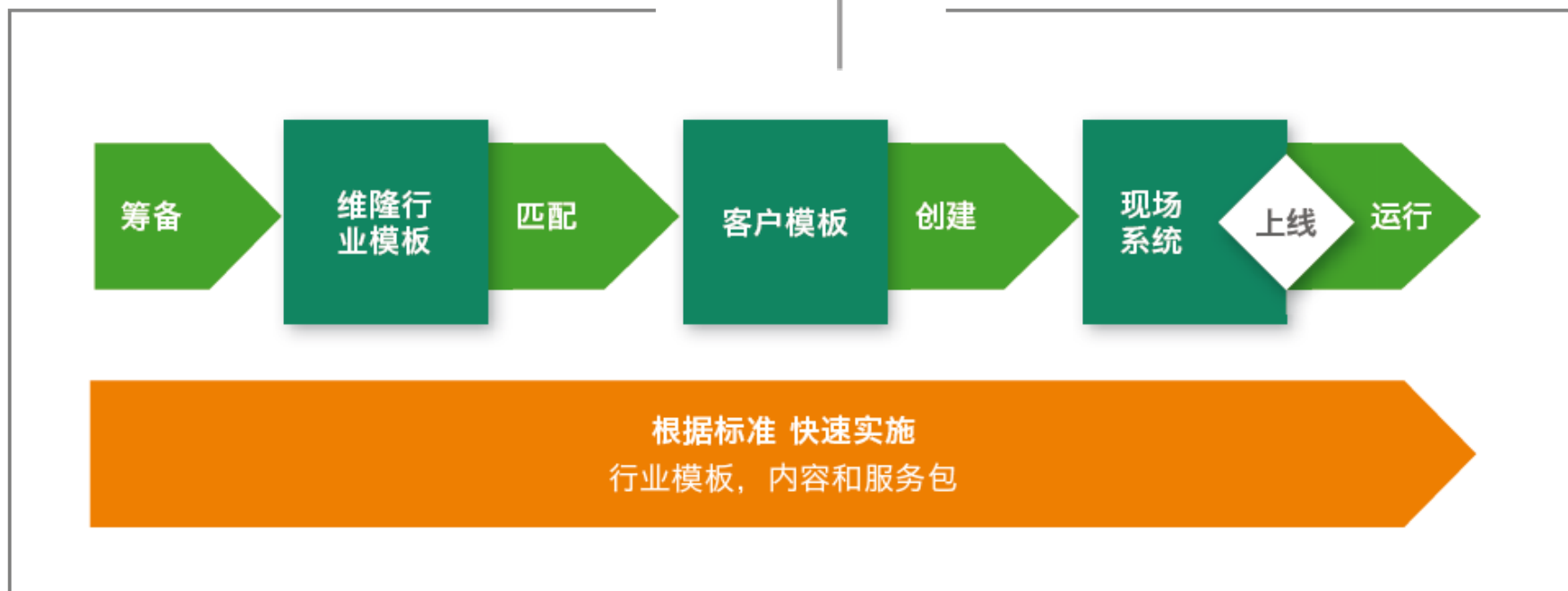
Werum's unique implementation methodology:

快速实施：Werum独有

Ready – Fit – Build – Run

筹备 – 匹配 – 创建 – 运行

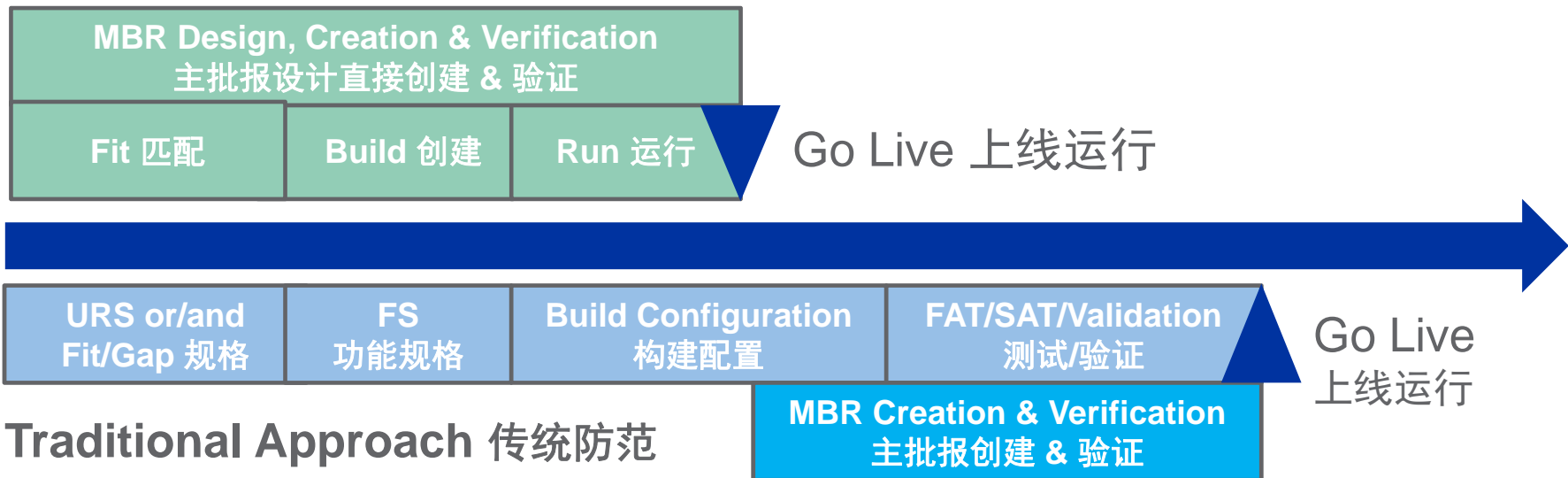
PAS | X IMPLEMENTATION METHODOLOGY



Product based Implementation Approach 基于产品的实施方法
PAS-X Software, Services & Content MES软件, 服务, 模板

Faster Implementation & Reduced Risk
不仅是快速实施，更是风险降低

PAS-X Approach 实施方法

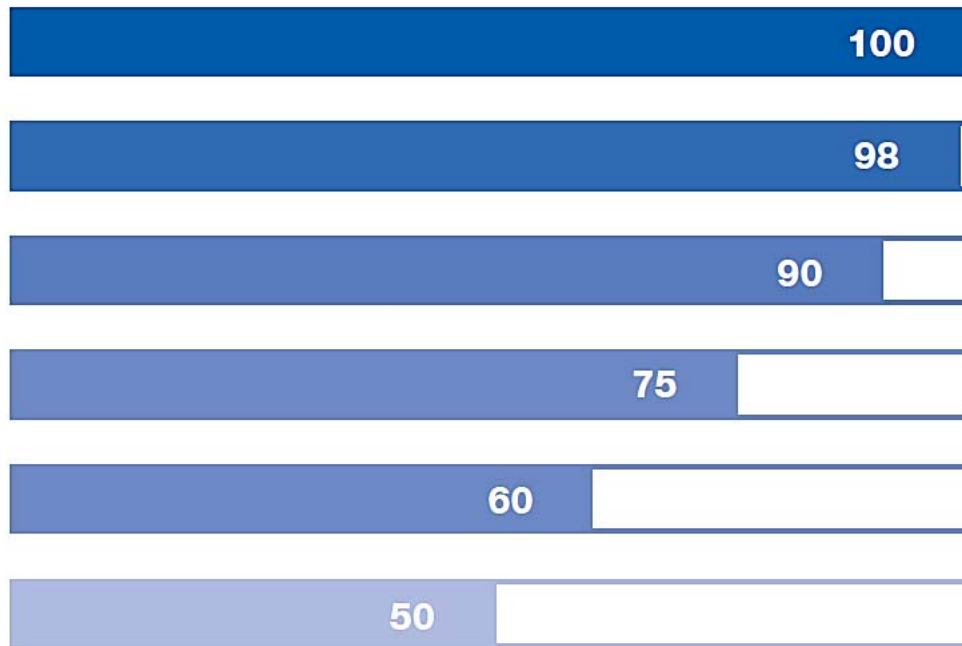


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Benefits with MES: Customer Figures

受益: 来自用户的数据



纸张管理得以减少

提高了“首次即正确”率

快速生成批记录

审查时间得以加快

交货周期得以缩短

工艺流程分析得以改进

Customer experience from Bayer, Novartis, Janssen, MSD 这些都是用户的使用经验

J&J: Reduction of Review Time form 45 days to 10 days, 强生: 审查时间从45天缩短至10天
93% of 19000 technical BR in 2014 with auto release 2014年19000个技术批报自动放行

Bio Factory of the Future

未来生物制药工厂



- Stainless steel bioreactors
不锈钢生物反应器
- Clean & Steam in place (CIP/SIP)
在线清洗和蒸汽灭菌
- Extensive preventive maintenance and working parts
大量活动部件和预防性维护
- Large footprint 占地大
- Batch loss in the event of a contamination
一旦污染, 批废料大

- Gamma-irradiated plastic bags
伽玛射线照射过的塑料容器
- No need for CIP/SIP
无须在线清洗或蒸汽灭菌
- Savings in utility costs
建设成本降低
- Only few working parts
只有少量活动部件
- Smaller, more flexible footprint
占地小, 更具灵活性
- Disposal of bag in the event of a contamination
污染发生时, 抛弃式处理

Amgen: Factory of the Future using PAS-X 安进新加坡工厂采用

- Reduce Costs / Increase Efficiency 降低成本 提高效率
 - Reduce Mistakes (Data Collection and Monitoring) 减少错误 (数据采集监控)
 - Prevention of Production Errors 防止生产中的错误
 - Early Problem Intervention 及早介入问题
 - “Right First Time” Production 生产中“首次即正确”
 - Shorter Throughput Time 减少吞吐时间
 - Less Waste and Rework 减少浪费和重复工作
 - Near-Real Time Quality Review by Exception 接近实时的进行偏差审查
 - Greater Visibility of Production Status 生产可视化
 - Greater Visibility of Eqpt Availability & Status 设备及状况可视化

Smart Factory with the Current PAS-X Version

成就智慧工厂 PAS-X当前版本

Data Integrity 数据完整性
CPV 持续工艺验证
Quality Metrics 质量度量
E-Inspections 在线检查

Operational Excellence 卓越运营

Compliance 合规

Smart Factory 智慧工厂

Review by Exception 异常审查

Right First Time 首次即正确

Paperless 无纸化



1990

Today

Werum's Unique Value Proposition

德国维隆 独特价值



你的工厂里仍需
用纸的唯一地方。

PAS | X

