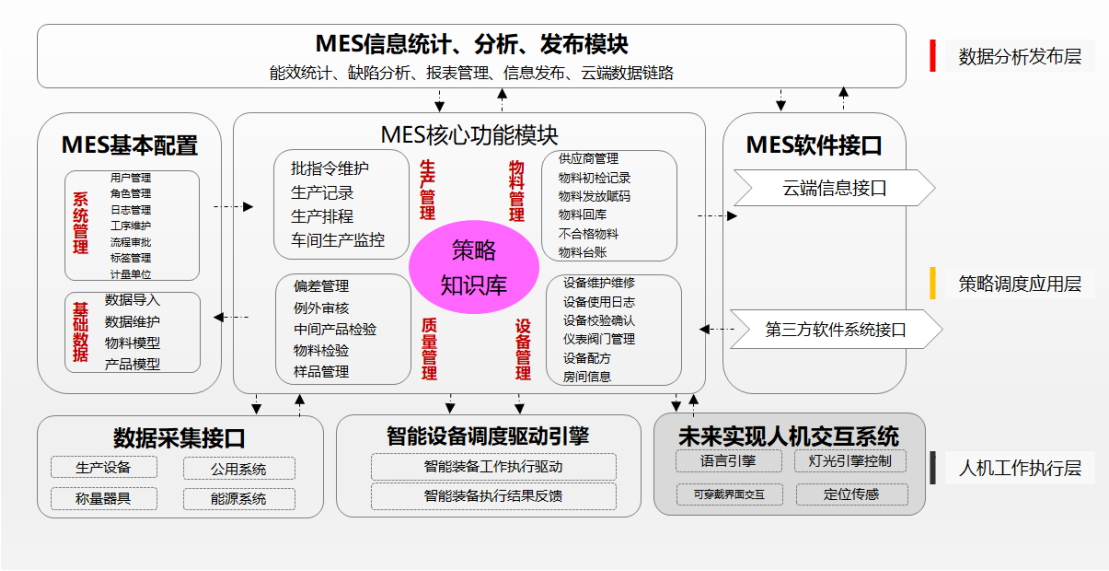
一、 Manufacturing license execution system (MES)

System introduction:

Based on isa-88 / 95 standard, CGMP regulations and electronic batch record, the personnel, equipment, materials, environment and procedures of pharmaceutical production are organically combined to realize the standardization, electronization and visualization of the whole production process, ensure the reliability and integrity of production data, effectively reduce quality risk, improve efficiency and enhance the competitiveness of pharmaceutical enterprises. As the core system of pharmaceutical enterprise informatization, MES system plays the role of Core Bridge in business informatization integration, and is responsible for connecting various business systems. Manufacturing execution system (MES) focuses on the management of the whole production process. It can connect the production resources, warehouse, production, quality control, middle and high-level management leaders and relevant departments to form a unified business supervision platform, and realize the functions of enterprise organization, personnel, plan, assets, product formula, production and processing, quality inspection, deviation investigation and recording Record and report the whole process control and strict standardized management. It can save a lot of production costs and ensure the clean production environment.

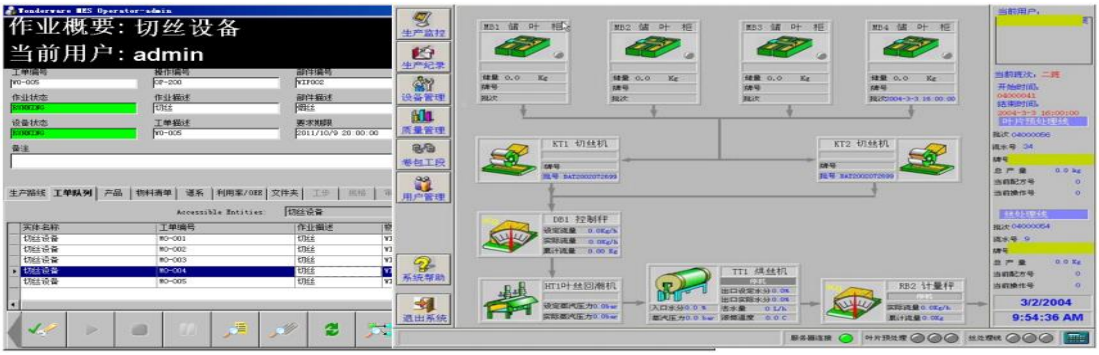
System architecture:



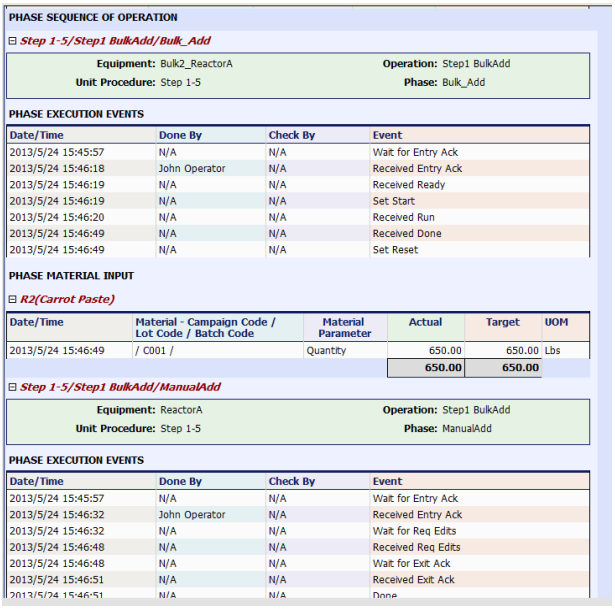
Functional features:

Structured, electronic and visual production process in accordance with CGMP regulations: the system is highly flexible and extensible, and can support multiple production lines and products through configuration according to process flow and SOP; during the execution of batch instructions, the system

strictly controls the process, prevents material errors, ensures the effectiveness of equipment, and checks the conformity of data in real time to ensure the whole production process Compliance; the system provides graphical and visual means to audit and analyze electronic batch records to improve management efficiency.



Perfect electronic batch record management system: through the real-time automatic collection or manual entry of process parameters, environmental indicators, related operations and other information in the process of production execution, quality inspection and material flow, the whole production process is recorded in the system, which can produce readable and suitable information for GMP and FDA Check, review, and copy accurate and complete records in electronic form.



PHASE SEQUENCE OF OPERATION

Step 1-5/Step1 BulkAdd/Bulk_Add

Equipment: Bulk2_ReactorA Operation: Step1 BulkAdd
Unit Procedure: Step 1-5 Phase: Bulk_Add

PHASE EXECUTION EVENTS

Date/Time	Done By	Check By	Event
2013/5/24 15:45:57	N/A	N/A	Wait for Entry Ack
2013/5/24 15:46:18	John Operator	N/A	Received Entry Ack
2013/5/24 15:46:19	N/A	N/A	Received Ready
2013/5/24 15:46:19	N/A	N/A	Set Start
2013/5/24 15:46:20	N/A	N/A	Received Run
2013/5/24 15:46:49	N/A	N/A	Received Done
2013/5/24 15:46:49	N/A	N/A	Set Reset

PHASE MATERIAL INPUT

R2(Carrot Paste)

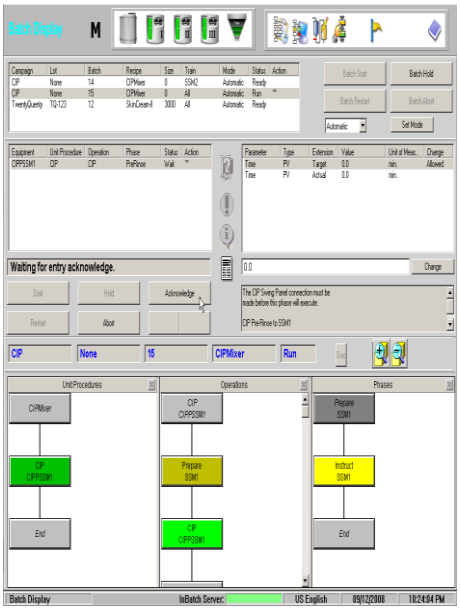
Date/Time	Material - Campaign Code / Lot Code / Batch Code	Material Parameter	Actual	Target	UOM
2013/5/24 15:46:49	/ C001 /	Quantity	650.00	650.00	Lbs
			650.00	650.00	

Step 1-5/Step1 BulkAdd/ManualAdd

Equipment: ReactorA Operation: Step1 BulkAdd
Unit Procedure: Step 1-5 Phase: ManualAdd

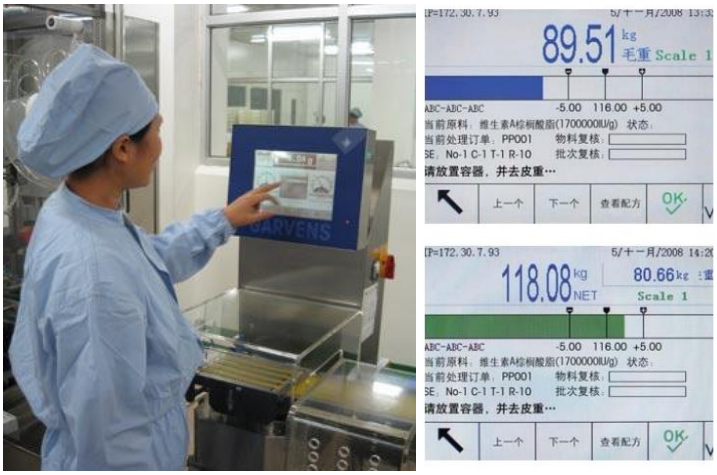
PHASE EXECUTION EVENTS

Date/Time	Done By	Check By	Event
2013/5/24 15:45:57	N/A	N/A	Wait for Entry Ack
2013/5/24 15:46:32	John Operator	N/A	Received Entry Ack
2013/5/24 15:46:32	N/A	N/A	Wait for Req Edits
2013/5/24 15:46:48	N/A	N/A	Received Req Edits
2013/5/24 15:46:48	N/A	N/A	Wait for Exit Ack
2013/5/24 15:46:51	N/A	N/A	Received Exit Ack
2013/5/24 15:46:51	N/A	N/A	Done



Integrated weighing equipment to achieve integrated material weighing management: by scanning the material label to determine the correctness of the material, automatically calculate the material demand, obtain weighing data, print weighing label, generate weighing report, ensure that the weighing process meets the production requirements. The system supports net weight

weighing, cumulative weighing, peeling weighing and other methods.



Product advantages:

- Perfect product functions, good versatility, flexibility and scalability, suitable for the production management of preparations, APIs, medical devices and other products.
- Provide rich data analysis methods, support data comparative analysis between batches, and generate annual review data
- Realize the integration with SCADA, LIMS, ERP and other systems
- Support secondary development, fully meet the personalized needs of users

Abundant data analysis means help to find problems and improve process: the system provides detailed data and trend analysis of single batch of most sites and multiple batches of the same data point, and automatically calculates the maximum value, minimum value, average value, variance, range, etc.